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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, 2020

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 each exchange on which registered
Common Stock, $0.0001 par value per share	OCUL	The Nasdaq Global 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 1, 2020, there were 71,391,376 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, seek regulatory approval for and commercialize DEXTENZA for additional indications, including for the treatment of ocular itching associated with allergic conjunctivitis, and our other product candidates based on our proprietary bioresorbable hydrogel technology platform;
- our ability to manufacture DEXTENZA, ReSure Sealant® and our product candidates in compliance with current Good Manufacturing Practices, or cGMP;
- our ability to 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, including the submission of a supplemental new drug application for the approval of the treatment of ocular itching associated with allergic conjunctivitis as an additional indication, and 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 our 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 1 clinical trial of OTX-TIC for the reduction of intraocular pressure in patients with primary open-angle glaucoma or ocular hypertension, our Phase 1 clinical trial of OTX-TKI for the treatment of wet age-related macular degeneration, or wet AMD, and our Phase 2 clinical trial of OTX-CSI for the chronic treatment of dry eye disease;
- 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 and maintain reimbursement for our products;
- our estimates regarding the market opportunity for DEXTENZA, ReSure Sealant and our other product candidates;
- the preclinical and clinical development of our product candidate for the short-term treatment of the signs and symptoms of dry eye disease and our intravitreal implant with protein-based or small molecule drugs, including tyrosine kinase inhibitors, for the treatment of wet AMD, diabetic macular edema, or DME, and retinal vein occlusion, or RVO;

- 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, DME and RVO;

- our license agreement and collaboration with AffaMed Therapeutics Limited under which we are collaborating on the commercialization of DEXTENZA and our product candidate OTX-TIC in mainland China and certain other Asian jurisdictions;

- 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;

- uncertainty regarding the extent to which the COVID-19 pandemic and related response measures will adversely affect our business, results of operations and financial condition; 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 that could cause actual results or events to differ materially from the forward-looking statements that we make. Additional discussion of these and other risks, uncertainties and factors may be found under the heading “Risk Factors” in Part II, Item 1A in this Quarterly Report on Form 10-Q. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations, 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. The forward-looking statements included in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q. We do not assume, and we expressly disclaim, any obligation or undertaking 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, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 70,642	$ 54,437
Accounts receivable, net	7,779	2,548
Inventory	1,154	954
Prepaid expenses and other current assets	2,328	2,231
Total current assets	81,903	60,170
Property and equipment, net	8,490	10,151
Restricted cash	1,764	1,764
Operating lease assets	6,062	6,655
Total assets	$ 98,219	$ 78,740
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 3,238	$ 3,268
Accrued expenses and other current liabilities	12,165	7,635
Operating lease liabilities	1,297	1,126
Notes payable, net of discount, current	6,206	—
Total current liabilities	22,906	12,029
Operating lease liabilities, net of current portion	7,909	8,905
Derivative liability	28,764	12,124
Notes payable, net of discount	18,964	25,007
2026 convertible notes, net	23,802	24,305
Total liabilities	102,345	82,370
Commitments and contingencies (Note 13)		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 5,000,000 shares authorized and no shares issued or outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, $0.0001 par value; 100,000,000 shares authorized and 63,070,980 and 50,333,559 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	6	5
Additional paid-in capital	449,507	379,980
Accumulated deficit	(453,639)	(383,615)
Total stockholders' deficit	(4,126)	(3,630)
Total liabilities and stockholders' equity (deficit)	$ 98,219	$ 78,740

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,	
	2020	2019	2020	2019
Revenue:				
Product revenue, net	$ 5,876	$ 829	$ 10,054	$ 1,971
Total revenue, net	5,876	829	10,054	1,971
Costs and operating expenses:				
Cost of product revenue	450	806	1,403	1,486
Research and development	6,951	10,235	21,070	30,966
Selling and marketing	6,520	6,777	19,803	17,349
General and administrative	5,961	6,155	16,282	16,571
Total costs and operating expenses	19,882	23,973	58,558	66,372
Loss from operations	(14,006)	(23,144)	(48,504)	(64,401)
Other income (expense):				
Interest income	6	308	162	1,016
Interest expense	(1,715)	(1,651)	(5,042)	(4,296)
Change in fair value of derivative liability	3,771	5,717	(16,640)	7,334
Other income (expense), net	—	(8)	—	(8)
Total other income (expense), net	2,062	4,366	(21,520)	4,046
Net loss and comprehensive loss	$ (11,944)	$ (18,778)	$ (70,024)	$ (60,355)
Net loss per share, basic	$ (0.19)	$ (0.40)	$ (1.22)	$ (1.37)
Weighted average common shares outstanding, basic	62,992,558	46,944,536	57,440,885	44,052,470
Net loss per share, diluted	$ (0.21)	$ (0.45)	$ (1.22)	$ (1.37)
Weighted average common shares outstanding, diluted	68,761,790	52,713,768	57,440,885	44,052,470

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,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (70,024)	$ (60,355)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	5,427	6,806
Non-cash interest expense	3,279	2,469
Change in fair value of derivative liability	16,640	(7,334)
Depreciation and amortization expense	2,106	1,856
(Gain)/loss on disposal of property and equipment	—	7
Changes in operating assets and liabilities:		
Accounts receivable	(5,231)	(913)
Prepaid expenses and other current assets	(97)	(500)
Inventory	(200)	(678)
Operating lease assets	593	552
Accounts payable	113	32
Accrued expenses	911	543
Operating lease liabilities	(825)	(596)
Net cash used in operating activities	(47,308)	(58,111)
Cash flows from investing activities:		
Purchases of property and equipment	(588)	(1,637)
Net cash used in investing activities	(588)	(1,637)
Cash flows from financing activities:		
Proceeds from issuance of 2026 convertible notes, net of issuance costs	—	37,275
Proceeds from exercise of stock options	1,044	34
Proceeds from issuance of common stock pursuant to employee stock purchase plan	350	294
Proceeds from the Paycheck Protection Program Loan	3,201	—
Repayment of the Paycheck Protection Program Loan	(3,201)	—
Proceeds from issuance of common stock upon public offering, net	62,707	28,647
Net cash provided by financing activities	64,101	66,250
Net increase in cash, cash equivalents and restricted cash	16,205	6,502
Cash, cash equivalents and restricted cash at beginning of period	56,201	60,676
Cash, cash equivalents and restricted cash at end of period	$ 72,406	$ 67,178
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	$ 71	$ 464
Derivative liability in connection with issuance of 2026 convertible notes	$ —	$ 16,434

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

Ocular Therapeutix, Inc.

Consolidated Statements of Stockholders' Equity (Deficit)
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Par Value			
Balances at December 31, 2019	50,333,559	$ 5	$ 379,980	$ (383,615)	$ (3,630)
Issuance of common stock upon exercise of stock options	46,321	—	128	—	128
Issuance of common stock upon public offering, net of issuance costs	2,657,823	—	12,690	—	12,690
Stock-based compensation expense	—	—	1,665	—	1,665
Net loss	—	—	—	(21,512)	(21,512)
Balances at March 31, 2020	53,037,703	$ 5	$ 394,463	$ (405,127)	$ (10,659)
Issuance of common stock upon exercise of stock options	75,862	—	378	—	378
Issuance of common stock in connection with employee stock purchase plan	104,579	—	350	—	350
Issuance of common stock upon public offering, net of issuance costs	9,735,649	1	50,016	—	50,017
Stock-based compensation expense	—	—	1,826	—	1,826
Net loss	—	—	—	(36,568)	(36,568)
Balances at June 30, 2020	62,953,793	$ 6	$ 447,033	$ (441,695)	$ 5,344
Issuance of common stock upon exercise of stock options	117,187	—	538	—	538
Stock-based compensation expense	—	—	1,936	—	1,936
Net loss	—	—	—	(11,944)	(11,944)
Balances at September 30, 2020	63,070,980	$ 6	$ 449,507	$ (453,639)	$ (4,126)

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

Ocular Therapeutix, Inc.

Consolidated Statements of Stockholders' Equity
(In thousands, except share data)
(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.

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, building the initial sales and marketing infrastructure for the commercialization of the Company's approved products and product candidates and launching its initial product.

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, 2020, the Company's lead product, DEXTENZA® (dexamethasone insert) 0.4mg, and its hydrogel ophthalmic wound sealant, ReSure Sealant®, have been approved by the U.S. Food and Drug Administration (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.

The Company has incurred recurring losses and negative cash flows from operations since inception, including a net loss of $70,024 for the nine months ended September 30, 2020. As of September 30, 2020, the Company had an accumulated deficit of $453,639.

As of November 5, 2020, the issuance date of this Quarterly Report on Form 10-Q, the Company believes that its existing cash and cash equivalents of $70,642, as of September 30, 2020, along with proceeds of $75,675 from the sale of the Company's common stock, net of underwriting discounts and commissions but before deducting offering expenses, in October 2020 (Note 15), will enable the Company to fund its planned operating expenses, debt service obligations and capital expenditure requirements for at least the next twelve months. This estimate is based on the Company's currently forecasted operating plan which includes estimates of anticipated cash inflows from DEXTENZA and ReSure Sealant product sales and cash outflows from operating expenses. These estimates are subject to various assumptions including those related to the severity and duration of the COVID-19 pandemic, the revenues and expenses associated with the commercialization of DEXTENZA, the pace of the Company's research and clinical development programs, and other aspects of the Company's business.

The future viability of the Company is dependent on its ability to generate product sales, raise capital or reduce spending to finance its operations. The Company expects to seek additional funds through equity offerings, debt financings, government or other third-party funding, collaborations, strategic alliances, licensing arrangements, royalty agreements, and marketing and distribution arrangements. If the Company is unable to obtain 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 ability to raise capital and 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, 2019 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of September 30, 2020 and for the three and nine months ended September 30, 2020 and 2019 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, 2019 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, 2020 and results of operations and cash flows for the three and nine months ended September 30, 2020 and 2019 have been made. The results of operations for the three and nine months ended September 30, 2020 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2020.

Risks and Uncertainties

The Company is monitoring the potential impact of COVID-19, if any, on the carrying value of certain assets. To date, the Company has not experienced material business disruption, nor has it incurred impairment of any assets as a result of COVID-19. The extent to which these events may impact the Company's business will depend on future developments, which are highly uncertain and cannot be predicted at this time. The duration and intensity of the COVID-19 pandemic and any resulting disruption to the Company's operations is uncertain, and the Company will continue to assess the impact of COVID-19 on its financial position.

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 and the disclosure of contingent assets and liabilities at the date of the consolidated 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. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, and those of its customers, vendors, suppliers, and collaboration partners, will depend on future developments that are highly uncertain, subject to change and difficult to predict, including new information that may emerge concerning COVID-19, the actions taken to

contain it or treat its impact and the economic impact on local, regional, national and international customers and markets. The Company has made estimates of the impact of COVID-19 within its financial statements, and there may be changes to those estimates in future periods. Actual results may differ from these 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, 2020 and December 31, 2019, were carried at fair value determined according to the fair value hierarchy described above (Note 3). The Company's derivative liability at September 30, 2020 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 9) 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 6) and this is carried, net of derivative liability, at its amortized cost of $23,802 at September 30, 2020. The estimated fair value of the 2026 Convertible Notes was $55,941 at September 30, 2020. 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. The Company recognizes revenue in accordance with Accounting Standards Codification 606 – *Revenue from Contracts with Customers* ("Topic 606"). 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 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 the Company's 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 rebates, 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, 2020, as well as a reduction to accounts 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 in certain circumstances that has been purchased from the Company 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 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-usable 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 accounts 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 accrued expenses and other current liabilities on the consolidated balance sheets.

Concentration of Credit Risk and of Significant Suppliers and Customers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company has all cash and cash equivalents balances at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on a small number of third-party manufacturers to supply products for research and development activities in its preclinical and clinical programs and for sales of its products. The Company's development programs as well as revenue from future sales of its product sales could be adversely affected by a significant interruption in the supply of any of the components of these products.

For the three and nine months ended September 30, 2020, three individual customers accounted for 39%, 38% and 10% and three individual customers accounted for 40%, 30%, and 12%, respectively, of the Company's total revenue. At September 30, 2020, three individual customers accounted for 44%, 35% and 11% of the Company's total accounts receivable. No other customer accounted for more than 10% of total revenue or accounts receivable at September 30, 2020.

For the three and nine months ended September 30, 2019, two individual customers accounted for 13% and 10%, and one individual customer accounted for 18%, respectively, of the Company's total revenue. At December 31, 2019, three individual customers accounted for 39%, 18% and 11% of the Company's total accounts receivable. No other customer accounted for more than 10% of total accounts receivable for the year ended December 31, 2019.

Inventory

The Company values its inventories at the lower of cost or estimated net realizable value.

Inventory consisted of the following:

	September 30, 2020	December 31, 2019
Raw materials	$ 333	$ 217
Work-in-process	75	148
Finished goods	746	589
	$ 1,154	$ 954

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 at September 30, 2020 and December 31, 2019, on its consolidated balance sheet. The Company held restricted cash as security deposits for the lease of its manufacturing space and corporate headquarters.

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, 2020	September 30, 2019	December 31, 2019
Cash and cash equivalents	$ 70,642	$ 65,414	$ 54,437
Restricted cash	1,764	1,764	1,764
Total cash, cash equivalents and restricted cash as shown on the statements of cash flows	$ 72,406	$ 67,178	$ 56,201

Net Loss Per Share

The Company follows the two-class method when computing net loss per share. 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 the Company's 2026 Convertible Notes and the exercise of 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 and 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 August 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-13, *Disclosure Framework - Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). This standard modifies certain disclosure requirements on fair value measurements. This standard became effective for the Company on January 1, 2020 and did not have a material impact on the Company's disclosures.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606 ("ASU 2018-18"). ASU 2018-18 makes targeted improvements to GAAP for collaborative arrangements, including (i) clarification that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account, (ii) adding unit-of-account guidance in Topic 808, Collaborative Arrangements, to align with the guidance in Topic 606 and (iii) a requirement that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. This

guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within that fiscal year. This standard became effective for the Company on January 1, 2020 and the adoption of ASU 2018-18 did not have a material impact on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued amendments to accounting guidance that simplify the accounting for income taxes, as part of its initiative to reduce complexity in the accounting standards. The amendments eliminate certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The amendments also clarify and simplify other aspects of the accounting for income taxes. The Company early adopted the amendments as of January 1, 2020, on a prospective basis. The amendments did not have a significant impact on the Company's consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. In November 2018, the FASB issued ASU No. 2018-19, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses*, which narrowed the scope and changed the effective date for non-public entities for ASU 2016-13. The FASB subsequently issued supplemental guidance within ASU No. 2019-05, *Financial Instruments—Credit Losses (Topic 326): Targeted Transition Relief* ("ASU 2019-05"). ASU 2019-05 provides an option to irrevocably elect the fair value option for certain financial assets previously measured at amortized cost basis. For public entities that are Securities and Exchange Commission filers, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. For all other entities, ASU 2016-13 is effective for annual periods beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. This standard will be effective for the Company on January 1, 2023. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40)*. This standard amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and improves and amends the related earnings per share guidance for both Subtopics. The amendments in the ASU are effective for public business entities that meet the definition of an SEC filer, excluding entities eligible to be smaller reporting companies as defined by the SEC, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. The FASB also specified that an entity should adopt the guidance as of the beginning of its fiscal year and is not permitted to adopt the guidance in an interim period. The Company is assessing the impact of ASU 2020-06 on its consolidated financial statements.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's financial assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2020 and December 31, 2019 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of September 30, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ —	$ 66,369	$ —	$ 66,369
Liability:				
Derivative liability (Note 5)	—	—	28,764	28,764
Total	$ —	$ 66,369	$ 28,764	$ 95,133

	Fair Value Measurements as of December 31, 2019 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ —	$ 45,156	$ —	$ 45,156
Liability:				
Derivative liability (Note 5)	—	—	12,124	12,124
Total	$ —	$ 45,156	$ 12,124	$ 57,280

4. Accrued Expenses

Accrued expenses as of September 30, 2020 and December 31, 2019 consisted of the following:

	September 30, 2020	December 31, 2019
Accrued payroll and related expenses	$ 5,395	$ 5,042
Accrued professional fees	701	1,011
Accrued research and development expenses	845	849
Accrued interest payable on 2026 convertible notes	3,619	—
Accrued other	1,605	733
	$ 12,165	$ 7,635

5. Derivative Liability

The 2026 Convertible Notes (Note 6) contained an embedded conversion option that met the criteria to be bifurcated and accounted for separately (the "Derivative Liability") from the 2026 Convertible Notes. 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, 2020 include the Company's stock price on the valuation date ($7.61 on September 30, 2020), the expected annual volatility of the Company's stock (100%) and the bond yield (13.0%), 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, 2020
Balance at December 31, 2019	$ 12,124
Change in fair value	16,640
Balance at September 30, 2020	$ 28,764

6. 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 14.8% through September 30, 2020.

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 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) 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 5, 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, 2020 is as follows:

	September 30, 2020
2026 Convertible Notes	$ 37,500
Less: unamortized discount	(13,698)
	$ 23,802

7. 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, 2020 or 2019. The Company has provided a valuation allowance for the full amount of its net deferred tax assets because, at September 30, 2020 and December 31, 2019, 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, 2020 or December 31, 2019. As of September 30, 2020 and December 31, 2019, 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.

8. 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 vascular endothelial growth factor ("VEGF")-targeting compounds for the treatment of retinal diseases. The Collaboration Agreement does not cover the development of any product candidates 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 ("Regeneron 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 Regeneron Licensed Product. Such efforts shall include initiating the dosing phase of a subsequent clinical trial within specified time periods following the completion of the first-in-human clinical trial or the initiation of preclinical toxicology studies, subject to certain extensions.

Under the terms of the Collaboration Agreement, Regeneron has agreed to pay the Company $10,000 upon the exercise of the Option. If Regeneron elects to exercise the Option, the Company is also eligible to receive up to $145,000 per Regeneron Licensed Product upon the achievement of specified development and regulatory milestones, $100,000 per Regeneron Licensed Product upon first commercial sale of such Regeneron Licensed Product and up to $50,000 based on the achievement of specified sales milestones for all Regeneron 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 Regeneron 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.

On May 8, 2020, the Company entered into an amendment (the "Amendment") to the Collaboration Agreement. Pursuant to the Amendment, the Company and Regeneron have adopted a new work plan to transition joint efforts under the Collaboration Agreement to the research and development of an extended-delivery formulation of aflibercept to be delivered to the suprachoroidal space. Regeneron has agreed to pay personnel and material costs of the Company for specified preclinical development activities in connection with the revised work plan, as well as certain other costs. In addition, the Amendment provides for the modification of the terms of the Option previously granted to Regeneron under the Collaboration Agreement. As amended, the Option is exclusive for twenty-four months following May 8, 2020. Through September 30, 2020, the Option has not been exercised, and no payments have been made.

As of September 30, 2020, the Company has recorded $480 related to work performed for preclinical development activities in connection with the revised work plan which the Company has recorded as a reduction of research and development expense as this research is not an output of the Company's ordinary business activities.

9. 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, 2020.

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.

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 its covenants under the Credit Agreement. 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, 2020	December 31, 2019
Borrowings outstanding	$ 25,000	$ 25,000
Accrued exit fee	310	180
Unamortized discount	(140)	(173)
	25,170	25,007
Less: current portion	(6,206)	—
Long-term notes payable	$ 18,964	$ 25,007

As of September 30, 2020, 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
2020 (October 1 through December 31)	$ —	$ 624	$ 624
2021	8,333	2,094	10,427
2022	8,333	1,270	9,603
2023	8,334	1,320	9,654
	$ 25,000	$ 5,308	$ 30,308

Interest paid amounted to $1,769 and $1,850 for the nine months ended September 30, 2020 and 2019, respectively.

On April 22, 2020, in accordance with the Credit Agreement, the Company obtained consent from MidCap Financial Trust permitting the Company to secure a loan under the Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Stability Act. The Company received loan proceeds of $3,201 (the "PPP Loan") on April 23, 2020 pursuant to this program. However, based on updated guidance related to this program, the Company repaid the PPP Loan in full on May 5, 2020.

10. Common Stock

In May 2020, the Company entered into an underwriting agreement with Jefferies LLC ("Jefferies") and Piper Sandler & Co. ("the Underwriters"), in connection with an underwritten public offering of 8,181,819 shares of the Company's common stock. Under the terms of this underwriting agreement, the Company also granted the Underwriters an option to purchase up to an additional 1,227,272 shares of common stock at the public offering price, less the underwriting discounts and commissions. The Underwriters subsequently exercised this option to purchase such option shares in full. The public offering price of the shares in this offering was $5.50 per share, and the Underwriters purchased all of the shares from the Company at a price of $5.17 per share. After deducting underwriting discounts and commissions and offering expenses, the Company received net proceeds from the offering of $48,327.

On April 5, 2019, the Company entered into an Open Market Sales Agreement℠ (the "2019 Sales Agreement") with 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, 2020, the Company sold none and 2,984,381 shares of common stock under the 2019 Sales Agreement, resulting in net proceeds of approximately $0 and $14,358 after commissions and expenses. Through September 30, 2020, the Company sold 10,321,840 shares of common stock under the 2019 Sales Agreement, resulting in net proceeds of approximately $46,984 after underwriting discounts and commissions and offering expenses.

11. Net Loss Per Share

Basic and diluted net loss per share was calculated as follows for the three and nine months ended September 30, 2020 and 2019.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Numerator:				
Net loss	$ (11,944)	$ (18,778)	$ (70,024)	$ (60,355)
Denominator:				
Weighted average common shares outstanding, basic	62,992,558	46,944,536	57,440,885	44,052,470
Net loss per share basic	$ (0.19)	$ (0.40)	$ (1.22)	$ (1.37)

For the nine months ended September 30, 2020 and 2019 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, 2020 and 2019:

	Three Months Ended September 30,	
	2020	2019
Net loss attributable to common stockholders, basic	$ (11,944)	$ (18,778)
Interest expense on 2026 Convertible Notes	1,069	998
Change in fair value of derivative liability	(3,771)	(5,717)
Net loss attributable to common stockholders, diluted	$ (14,646)	$ (23,497)
Weighted average common shares outstanding, basic	62,992,558	46,944,536
Shares issuable upon conversion of 2026 Convertible Notes, as if converted	5,769,232	5,769,232
Weighted average common shares outstanding, diluted	68,761,790	52,713,768
Net loss per share attributable to common stockholders, diluted	$ (0.21)	(0.45)

The Company excluded the following common stock equivalents, outstanding as of September 30, 2020 and 2019, from the computation of diluted net loss per share for the three and nine months ended September 30, 2020 and 2019 because they had an anti-dilutive impact.

	As of September 30,	
	2020	2019
Options to purchase common stock	8,970,789	7,621,722
Warrants for the purchase of common stock	18,939	18,939
	8,989,728	7,640,661

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, 2020 and 2019 because they had an anti-dilutive impact.

12. 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, 2020, 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, 2020, the Company granted options to purchase 104,000 and 1,920,950 shares of common stock, respectively, at a weighted exercise price of $8.28 and $4.88 per share, respectively. As of September 30, 2020, 1,005,768 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, 2020, 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, 2020, none and 104,579 shares of common stock were issued under the ESPP. As of September 30, 2020, 580,790 shares remained available for issuance under the ESPP.

Inducement Stock Option Awards

The Company has a 2019 Inducement Stock Incentive Plan (the "Inducement Plan"), which became effective and was approved by the Board of Directors of the Company on October 29, 2019. Awards under the Inducement 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 Inducement Plan. Each person who is granted an Award under the Inducement Plan is deemed a "Participant." The Inducement 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 Inducement Plan is 500,000. As of September 30, 2020, 446,000 shares of common stock remained available for issuance under the Inducement Plan.

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,	
	2020	2019	2020	2019
Research and development	$ 383	$ 543	$ 1,120	$ 1,756
Selling and marketing	441	260	1,245	718
General and administrative	1,112	2,366	3,062	4,332
	$ 1,936	$ 3,169	$ 5,427	$ 6,806

As of September 30, 2020, the Company had an aggregate of $10,974 of unrecognized stock-based compensation cost, which is expected to be recognized over a weighted average period of 2.4 years.

As of September 30, 2020, there were 16,227 outstanding unvested service-based stock options held by non-employees for the purchase of common stock.

13. Commitments and Contingencies

Intellectual Property Licenses

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

On September 13, 2018, the Company entered into a second amended and restated license agreement (the "Second Amended Agreement") with Incept. The Second Amended Agreement amends and restates in full the Company's prior amended and restated Incept License to expand the scope of the Company's intellectual property license and modify future intellectual property ownership and other rights thereunder. From 2014 through September 30, 2020, royalties paid under this agreement related to product sales were $481 and have been charged to cost of product revenue.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners, and other parties with respect to certain matters including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and senior management team that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of September 30, 2020.

Purchase Commitments

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

Manufacturing Commitments

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

Collaboration Agreement

On October 10, 2016, the Company entered into the Collaboration Agreement with Regeneron, which the parties amended in May 2020 (Note 8). If the Option to enter into an exclusive worldwide license is exercised, Regeneron will conduct further preclinical development and an initial clinical trial under a collaboration plan. The Company is obligated to reimburse Regeneron for certain development costs incurred by Regeneron under the collaboration plan during the period through the completion of the initial clinical trial, subject to a cap of $25,000, which cap may be increased by up to $5,000 under certain circumstances; the timing of such payments are not known. If Regeneron elects to proceed with further development following the completion of the collaboration plan, it will be solely responsible for conducting and funding further development and commercialization of product candidates. If the Option is exercised, Regeneron is required to use commercially reasonable efforts to research, develop and commercialize at least one Regeneron 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.

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 First Circuit held an oral argument on the appeal on February 4, 2020. The First Circuit issued its decision on April 9, 2020, affirming the District Court's dismissal of the class action. The plaintiffs did not seek review of the First Circuit's decision prior to the deadline for filing a petition for a writ of certiorari in the United States Supreme Court.

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, certain current board members, certain former board members, 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 October 20, 2020, the parties filed a joint stipulation and proposed order voluntarily dismissing the action without prejudice.

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 October 16, 2020, the parties filed a joint stipulation and proposed order voluntarily dismissing the action without prejudice.

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. On October 26, 2020, the parties filed a joint stipulation and proposed order voluntarily dismissing the action without prejudice. The court signed the proposed order on October 28, 2020.

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

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.

14. 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. Jonathan M. Sparks, Ph.D., a partner at McCarter & English, also served in the capacity as the Company's in-house counsel from October 2017 through August 31, 2020. The Company incurred fees for legal services rendered by McCarter of $115 and $209 and $630 and $672 for the three and nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020 and December 31, 2019, there was $88 and $107, respectively, recorded in accounts payable and $0 and $242, respectively, recorded in accrued expenses for McCarter.

15. Subsequent Events

On October 5, 2020, the Company issued to an employee a non-statutory stock option to purchase an aggregate of 350,000 shares of the Company's common stock at an exercise price of $8.42 per share. Subject to the employee'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 under the Company's Inducement Plan, as an inducement material to the employee's acceptance of an offer of employment with the Company in accordance with Nasdaq Listing Rule 5635(c)(4). As of November 1, 2020, 96,000 shares of common stock remained available for issuance under the Inducement Plan.

On October 13, 2020, the Company entered into an underwriting agreement with the Underwriters, in connection with an underwritten public offering of 7,180,000 shares of the Company's common stock. Under the terms of this underwriting agreement, the Company also granted the Underwriters an option to purchase up to an additional 1,077,000 shares of common stock at the public offering price, less the underwriting discounts and commissions. The Underwriters subsequently exercised this option to purchase such option shares in full. The public offering price of the shares in this offering was $9.75 per share, and the Underwriters purchased all of the shares from the Company at a price of $9.165 per share. After deducting underwriting discounts and commissions but before deducting offering expenses, the Company received net proceeds from the offering of $75,675.

On October 29, 2020, the Company entered into a license agreement (the "License Agreement") with AffaMed Therapeutics Limited ("AffaMed") for the development and commercialization of the Company's DEXTENZA product regarding ocular inflammation and pain following cataract surgery and allergic conjunctivitis (collectively, the "DEXTENZA Field") and for the Company's OTX-TIC product candidate (collectively with DEXTENZA, the "AffaMed Licensed Products") regarding open-angle glaucoma and ocular hypertension (collectively, the "TIC Field" and, with the DEXTENZA Field, each a "Field"), in each case in mainland China, Taiwan, Hong Kong, Macau, South Korea, and the countries of the Association of Southeast Asian Nations (collectively, the "Territories"). The Company retains development and commercialization rights for the AffaMed Licensed Products in the rest of the world.

Under the terms of the License Agreement, the Company is entitled to upfront payments totaling $12,000. The Company is also eligible to receive up to an additional $91,000 in aggregate, inclusive of a low-seven-figure clinical support payment, upon the achievement of certain development and commercial milestones. The Company is also entitled to receive tiered, escalating royalties on the net sales of the AffaMed Licensed Products ranging from a low-teen to low-twenties percentage. Royalties under the License Agreement are payable on an AffaMed Licensed Product-by-AffaMed Licensed Product and jurisdiction-by-jurisdiction basis and are subject to potential reductions in specified circumstances, subject to a specified floor.

Pursuant to the terms of the License Agreement, the Company is generally responsible for expenses related to the development of the AffaMed Licensed Products in the applicable Fields in the Territories, provided that AffaMed (i) reimburse the Company a low-teen percentage of expenses incurred in connection with certain clinical trials conducted by the Company and designed to support marketing approval of the AffaMed Licensed Product by the FDA or the European Medicines Agency ("Global Studies"); (ii) is solely responsible for expenses incurred in connection with territory-specific clinical trials that it conducts in furtherance of the development plan agreed between the parties in the applicable Fields in the Territories ("Local Studies"); and (iii) reimburse the Company in full for expenses incurred in connection with obtaining and maintaining regulatory approvals of the AffaMed Licensed Products in the applicable Fields in the Territories. In the event AffaMed declines to participate in a Global Study or to conduct a Local Study in any jurisdiction in which the Company determines to conduct such a study, the Company is relieved of its obligation to provide AffaMed clinical data from such study, other than safety data, unless AffaMed subsequently reimburses the Company in the amounts described above plus a prespecified premium.

The License Agreement expires upon the expiration of the last royalty term for the last AffaMed Licensed Product in any applicable Field in the Territories and each party has certain termination rights. The Company is in the process of assessing the accounting for this agreement.

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 12, 2020. 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 in our product candidates.

We currently incorporate therapeutic agents that have previously received regulatory approval from the U.S. Food and Drug Administration, or FDA, 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. Currently, our primary commercial product is DEXTENZA® (dexamethasone ophthalmic insert) 0.4mg for intracanalicular use for the treatment of ocular inflammation and pain following ophthalmic surgery.

Our core pipeline assets include four development programs. We are currently evaluating two of these programs in Phase 1 clinical trials: OTX-TKI, an intravitreal implant injected by fine-gauge needle of a hydrogel, anti-angiogenic formulation of axitinib a tyrosine kinase inhibitor, or TKI, for the treatment of wet age-related macular degeneration, or wet AMD, and OTX-TIC, an intracameral travoprost implant for the reduction of elevated intraocular pressure, or IOP, in patients with primary open-angle glaucoma or ocular hypertension. We are currently evaluating one program, OTX-CSI (intracanalicular cyclosporine insert) for the chronic treatment of dry eye disease, in a Phase 2 clinical trial. We expect to file a Phase 2-enabling investigational new drug application, or IND, in the fourth quarter of 2020 to evaluate the fourth program, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, in a Phase 2 clinical trial.

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 large molecule vascular endothelial growth factor, or VEGF, inhibitor, aflibercept, currently marketed under the brand name Eylea. On May 8, 2020, we entered into an amendment to our existing collaboration agreement with Regeneron.
Pursuant to this amendment, we and Regeneron have adopted a new workplan to transition joint efforts under the existing collaboration agreement to the research and development of an extended-delivery formulation of aflibercept to be delivered to the suprachoroidal space. Regeneron has agreed to pay for our personnel and material costs for specified preclinical development activities in connection with the revised workplan, as well as costs of certain specialty equipment.

In May 2019, we announced the results of the Phase 3 clinical trial of our product candidate OTX-TP (intracanalicular travoprost insert) for the reduction of IOP, in patients with glaucoma and ocular hypertension. In October 2019, we announced that we had met with the FDA who determined that the results did not achieve clinical meaningfulness for OTX-TP. As a result, we announced that we did not intend to advance OTX-TP without a partner.

In November 2018, the FDA approved our new drug application, or NDA, for DEXTENZA® 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. DEXTENZA is a local programmed-release, drug-eluting, preservative-free intracanalicular insert that is placed into the canaliculus through a natural opening called the punctum located in the portion of the lower eyelid near the nose. 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 enrolled a 96-subject, pivotal Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis and reported topline results in April 2020. We intend to file a sNDA in the fourth quarter of 2020 with the FDA for an indication expansion of allergic conjunctivitis.

In addition to our ongoing drug product development, we also currently market ReSure® Sealant, a hydrogel ophthalmic wound sealant approved by the FDA as a device to seal corneal incisions following cataract surgery. We are also assessing the potential use of our hydrogel platform technology in other areas of the body.

Business Update Regarding COVID-19

The pandemic caused by an outbreak of a new strain of coronavirus, or the COVID-19 pandemic, that is affecting the U.S. and global economy and financial markets and the related responses of government, businesses and individuals are also impacting our employees, patients, communities and business operations. The implementation of travel bans and restrictions, quarantines, shelter-in-place/stay-at-home and social distancing orders and shutdowns, for example, affected our business in the third quarter of 2020. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition and those of our customers, vendors, suppliers, and collaboration partners will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. Management continues to actively monitor this situation and the possible effects on our financial condition, liquidity, operations, suppliers, industry, and workforce. In the paragraphs that follow, we have described impacts of the COVID-19 pandemic on our clinical development programs. For additional information on risks posed by the COVID-19 pandemic, please see "Part II, Item 1A — Risk Factors — Risks Related to the COVID-19 Pandemic," included elsewhere in this Quarterly Report on Form 10-Q.

Retinal Disease Programs

We are engaged in the development of formulations of our hydrogel administered via intravitreal injection to address large markets for diseases and conditions of the back of the eye with significant growth potential. The global market for retinal disease was approximately $13 billion in 2019 and was estimated to grow at approximately 11% per year over the next five years according to Market Scope with the U.S. market representing $6.8 billion. Our initial development efforts have been focused on the use of our extended-delivery hydrogel in combination with anti-angiogenic drugs, such as TKIs or protein-based anti-VEGF drugs, for the treatment of retinal diseases such as wet AMD, diabetic macular edema, or DME, and retinal vein occlusion, or RVO. Our initial goal for these programs is to provide extended delivery over a four to six-month period thereby reducing the frequency of the current monthly or bi-monthly immediate release intravitreal anti-VEGF injection regimen for wet AMD and other retinal diseases.

OTX-TKI (axitinib intravitreal implant)

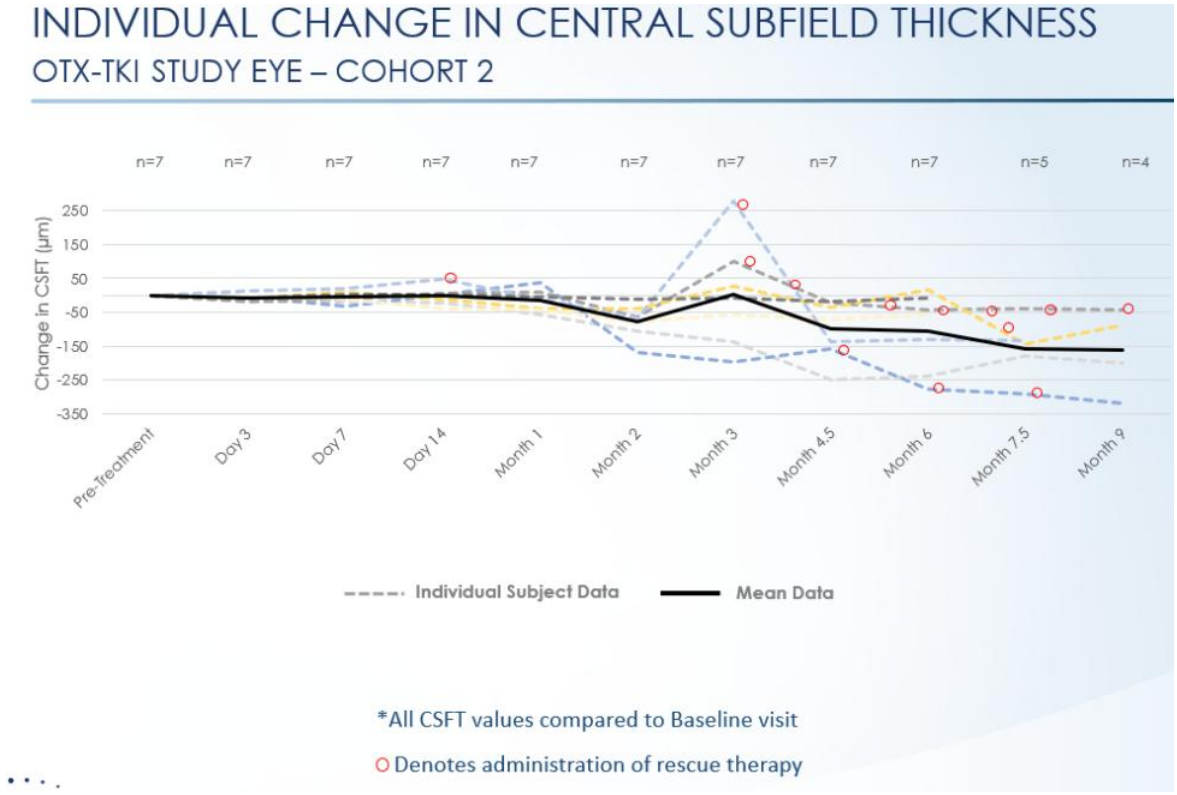
OTX-TKI is a preformed, bioresorbable hydrogel fiber incorporating a small molecule TKI with anti-angiogenic properties delivered by intravitreal injection. TKIs have shown promise in the treatment of wet AMD. In May 2017, we reported data from preclinical studies evaluating the biological activity, 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, dose escalation study designed to evaluate the safety, durability and tolerability of OTX-TKI. We also plan to evaluate biological activity by measuring retinal thickness using spectral domain optical coherence tomography, or OCT, and following visual acuity over time. Two cohorts were enrolled: a lower dose cohort of 200 µg with six subjects and a higher dose cohort of 400 µg with seven subjects. In July 2020, we reported that the data collection and other administrative activities of a clinical trial site had been adversely impacted by the effects of the COVID-19 pandemic, resulting in incomplete data available to us prior to that time. We recently enrolled a third cohort of twelve subjects, split between parallel arms of six subjects each. Subjects in the first arm of the third cohort will receive a dose of 600 µg, and subjects in the second arm will receive a 400 µg dose combined with an anti-VEGF induction injection.

In October 2020, interim data from this Phase 1 clinical trial of OTX-TKI was presented at the Euretina 2020 Virtual conference. This interim data continues to provide support that OTX-TKI:

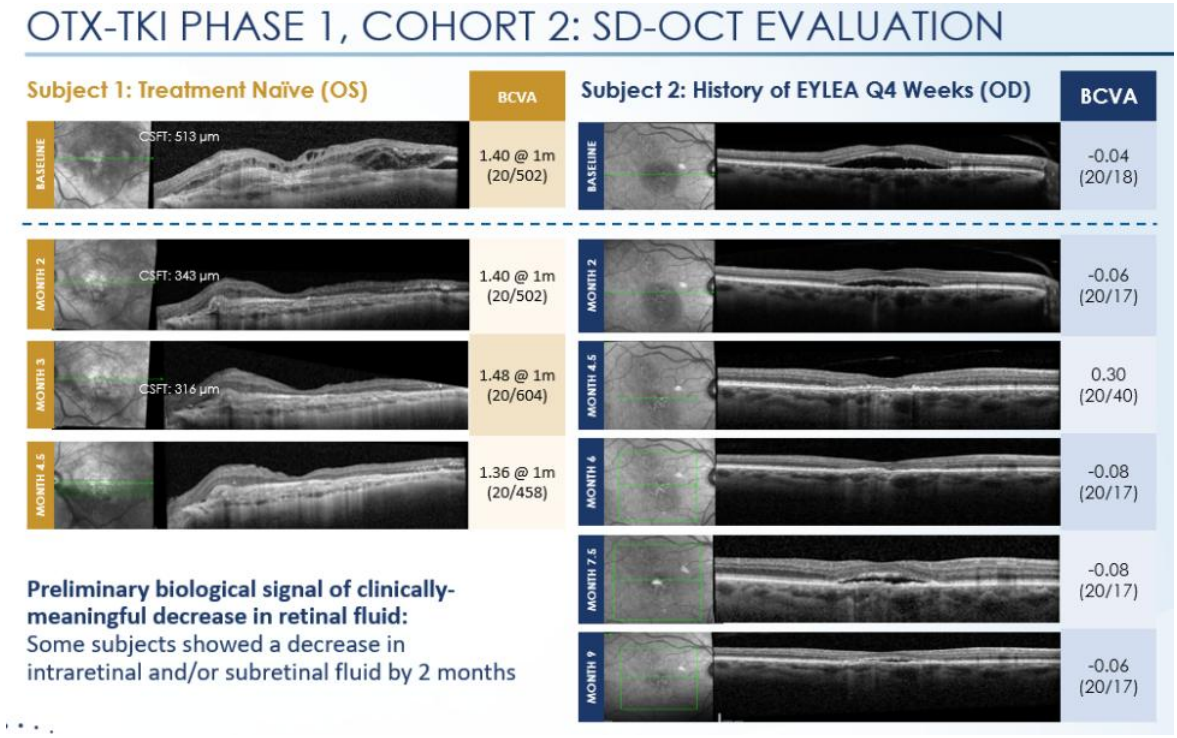
- Was generally well-tolerated and observed to have a favorable safety profile;
- Showed a decrease in intraretinal or subretinal fluid in some subjects by two months;
- Demonstrated durability of therapy, as shown by a clinically meaningful reduction in intraretinal and/or subretinal fluid, as indicated by a decrease in the central subfoveal thickness measured by OCT for up nine months in one patient treated in the second (400 µg dose) cohort;
- Exhibits a dose response, as evidenced by the observation of a greater clinical response in the second (400 µg dose) cohort compared with the first (200 µg dose) cohort; and
- Was observed to show limited to no movement, at a level which was not clinically noticeable to subjects.

We plan to present a clinical update at the American Academy of Ophthalmology conference in November 2020, file an IND application by the end of 2020 to initiate clinical development of OTX-TKI in the United States for patients with wet AMD, DME, and RVO, and initiate a Phase 2 clinical trial in Australia in mid-2021.

Individual Change in Central Subfield Thickness Values: Cohort 2



Cohort 2: Standard OCT Evaluation, Subjects 1 and 2



OTX-AFS (aflibercept suprachoroidal injection) in Collaboration with Regeneron

In October 2016, we entered into a strategic collaboration, option and license agreement with Regeneron for the development and potential commercialization of products using our extended-delivery hydrogel formulation 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. We and Regeneron amended this agreement in May 2020 to, among other things, transition joint efforts under the collaboration to the research and development of an extended-delivery formulation of aflibercept to be delivered to the suprachoroidal space. We refer to the collaboration, option and license agreement, as amended to date, as the Collaboration Agreement.

Under the terms of the Collaboration 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 Regeneron 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 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. Regeneron has agreed to pay our personnel and material costs of ours for specified preclinical development activities in connection with the revised workplan, as well as costs of certain specialty equipment.

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 Regeneron 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. If Regeneron elects to exercise the Option, we are also eligible to receive up to $145 million per Regeneron Licensed Product upon the achievement of specified development and regulatory milestones, including successful results from the first-in-human clinical trial; $100 million per Regeneron Licensed Product upon first commercial sale of such Regeneron Licensed Product; and up to $50 million based on the achievement of specified sales milestones for all Regeneron 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 Regeneron Licensed Products.

As amended, the Option is exclusive for twenty-four months following May 8, 2020. The field of the potential license remains limited to Regeneron Licensed Products delivered by local administration to or around the eye for diagnostic, therapeutic, or prophylactic purposes relating to ophthalmic diseases or conditions.

The Collaboration Agreement will automatically terminate upon the failure of Regeneron to conduct or complete certain preclinical activities within specified timeframes or provide required notices regarding such certain preclinical activities to us, in each case subject to specified exceptions, unless Regeneron exercises its Option, the matter has been referred to the joint research committee, or the parties have otherwise agreed in writing. The Agreement will also terminate if Regeneron has not exercised its Option prior to the expiration of the Option Period. If Regeneron has timely exercised its Option, the Collaboration Agreement will expire on a Regeneron Licensed Product-by-Regeneron 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 a Regeneron Licensed Product in such country. We have agreed to grant Regeneron a fully paid-up, non-exclusive license to continue to develop and commercialize the Regeneron Licensed Products following expiration. The Collaboration Agreement is terminable by Regeneron at its convenience, for any or all of the Regeneron Licensed Products, upon 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.

Glaucoma Programs

The global market for glaucoma was estimated by Market Scope at $4.8 billion in 2019 with the U.S. market representing $1.9 billion. The primary goal of glaucoma treatment is to slow the progression of this chronic disease by reducing IOP 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 IOP for several months with a single implant.

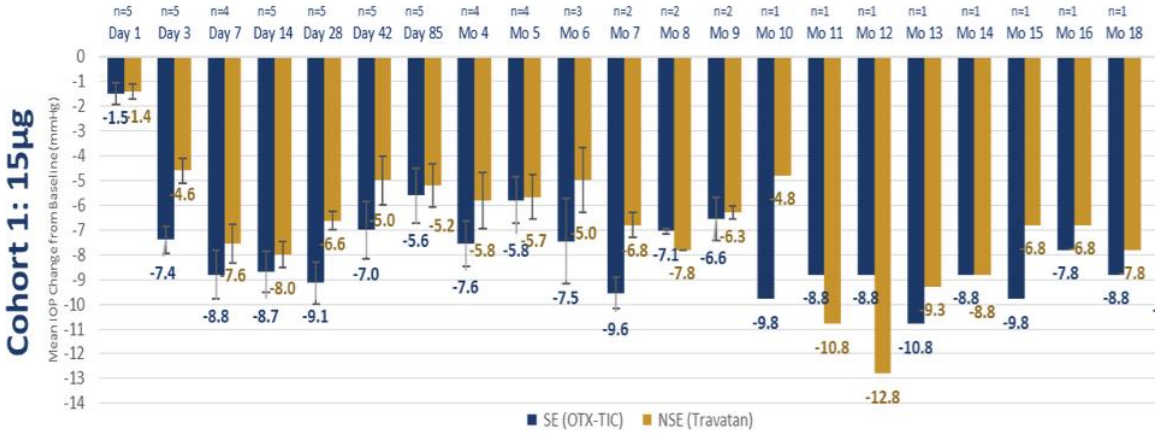
OTX-TIC (travoprost intracameral implant)

OTX-TIC is our product candidate for glaucoma and ocular hypertension patients in need of a significant reduction in IOP. 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 IND for our U.S. Phase 1 trial became effective in the first quarter of 2018, and we dosed the first patient in May 2018. The study is a multi-center, open-label, dose escalation, proof of concept study to evaluate the safety, biological activity, durability and tolerability of OTX-TIC compared to topical travoprost (eye drops) 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

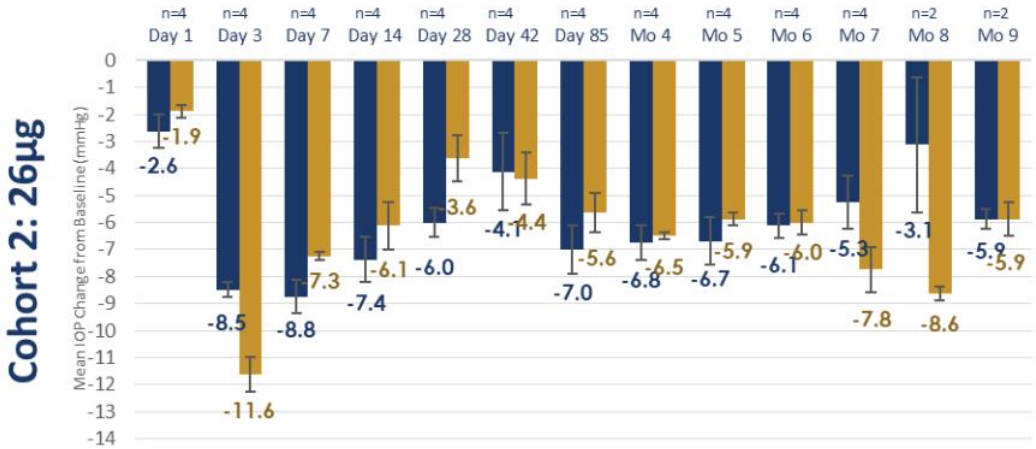
to achieve IOP lowering for up to thirteen months at a level at least as good as the current standard of care topical eye drop that was placed in each subject's non-study eye. In addition, the hydrogel carrier, as designed, biodegraded in approximately five to seven months. There were no clinically meaningful 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.

At the Glaucoma 360 meeting in February of 2020, we presented results from the first two of four patient cohorts in the Phase 1 clinical trial. Data from the first two fully enrolled cohorts (cohort 1 = 5 subjects, cohort 2 = 4 subjects) shows a clinically meaningful reduction from baseline in mean IOP values at the 8 a.m. timepoint in patients treated with a single insertion of OTX-TIC throughout the six-month study period. The data also shows that the mean IOP values at the 8 a.m. timepoint remained decreased from the baseline values beyond the study period and, in one patient, for up to twenty-one months at the time of assessment. The implant was observed to consistently bioresorb in five to seven months and showed little to no movement. Importantly, endothelial cell counts and pachymetry assessments indicate no clinically meaningful changes from baseline have occurred.

Cohort 1: Mean IOP Change from Baseline at 8:00 a.m.



Cohort 2: Mean IOP Change from Baseline at 8:00 a.m.



We have completed the first two cohorts, have fully enrolled the third cohort to assess the impact of a faster degrading implant with the same therapeutic dose as administered in cohort one and are enrolling a fourth cohort to assess an additional formulation with a smaller implant of OTX-TIC. Enrollment in our fourth cohort has recently slowed due to COVID-19, and we now expect to provide topline data for the third and fourth cohorts in the first quarter of 2021. We expect to commence a Phase 2 clinical trial in the middle of 2021.

OTX-TP (intracanalicular travoprost insert)

Our product candidate OTX-TP is an intracanalicular insert that delivers a preservative-free formulation of the drug travoprost for the reduction of 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 a.m., 10 a.m., and 4 p.m.) 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 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, and these differences were statistically significant (p value < 0.05) for eight of the nine time points. 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.

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 3 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 IOP 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. Based on the feedback following these discussions with the FDA, we do not intend to initiate a second Phase 3 clinical trial at this time without the assistance of a collaborative partner. We believe that if we were to find a partner for our OTX-TP program, we or such partner could decide to conduct additional Phase 2 clinical trials to address feedback from the FDA prior to another Phase 3 clinical trial. Given the potential use of OTX-TP as a chronic therapy, however, we have continued our open-label, one-year safety extension study, which we have now begun to close out, to generate six-month and one-year safety data for a limited number of subjects to support a potential product registration in the future.

Ocular Surface Diseases

We are engaged in the development of formulations of our hydrogel administered via intracanalicular inserts to address large markets for diseases and conditions of the surface of the eye. Our initial development efforts are focused on the use of our extended-delivery hydrogel in combination with well-known and well-understood corticosteroids for the treatment of dry eye disease, allergic conjunctivitis and inflammation and pain associated with post ophthalmic surgery.

Dry Eye Disease

The global market for dry ocular surface disease, which we refer to as dry eye disease, was estimated by Market Scope at $5.1 billion in 2019 with the U.S. market representing $2.1 billion. We have two programs in development: OTX-CSI, designed as a chronic treatment of dry eye disease, and OTX-DED, designed as a short-term treatment to address the signs and symptoms of dry eye disease.

OTX-CSI (cyclosporine intracanalicular insert)

OTX-CSI incorporates the FDA-approved immunomodulator cyclosporine as an active pharmaceutical ingredient into a hydrogel, drug-eluting, preservative-free intracanalicular insert. The product candidate is designed for patients suffering from moderate to severe dry eye and to be administered by a physician as a bioresorbable intracanalicular insert. There are approximately 8.6 million patients diagnosed with moderate to severe dry eye disease in the United States, according to the Market Scope 2019 Dry Eye Products Market Report, or the Market Scope Report. OTX-CSI is designed to release cyclosporine to the ocular surface for approximately three months to increase tear production for the treatment of dry eye disease. We filed an IND for OTX-CSI in the United States in December 2019 and initiated a Phase 1 clinical trial in the first quarter of 2020. The Phase 1 clinical trial was a U.S.-based, open-label, single-center trial that included five subjects (ten eyes) who were followed for approximately four months. The study was designed to evaluate the safety, tolerability and durability of OTX-CSI and assess the biological activity by measuring signs and symptoms of dry eye disease over this time period.

On October 8, 2020, we announced that we had received topline data from our Phase 1 clinical trial evaluating OTX-CSI in the chronic treatment of dry eye disease. All subjects completed the 16-week study period with no drop-outs. There were no serious adverse effects reported. The inserts were observed to be well-tolerated, and there were no adverse events of stinging, irritation, blurred vision or tearing reported or observed.

Tear production as measured by the Schirmer's test improved from mean values of 4.2 mm at baseline to 8.2 mm at Week 12. One of five subjects (20%) had a greater than 10mm increase from baseline in Schirmer's score at Week 12. Subjects saw an improvement in signs of dry eye disease as measured by corneal total fluorescein staining (a mean value of 6.7 at baseline, improved to a mean value of 2.7 at Week 12, on a scale of 0 to 15). Further, subjects saw an improvement in symptoms of dry eye disease as measured by the VAS eye dryness severity score (a mean value of 51 at baseline, improved to a mean value of 33 at Week 12, on a scale of 0 to 100) and the VAS dry eye frequency score (a mean value of 51 at baseline, improved to a mean value of 31 at Week 12, on a scale of 0 to 100). The onset of action of OTX-CSI was seen as early as two weeks for both signs and symptoms of dry eye disease and was observed to continue over the 16 week study period.

In September 2020, we dosed the first patients in a Phase 2 clinical trial designed to assess the safety, tolerability and durability and to evaluate the efficacy of OTX-CSI in the chronic treatment of dry eye disease. The Phase 2 clinical trial is a U.S.-based, randomized, double-masked, multi-center trial evaluating two different formulations of OTX-CSI with vehicle insert in approximately 105 subjects who are to be followed for a period of 16 weeks. Endpoints include tear production as measured by the Schirmer's test; signs of dry eye disease as measured by corneal fluorescein staining; and symptoms of dry eye disease as measured by the visual analog scale, or VAS, eye dryness severity score and the VAS dry eye frequency score. We anticipate receiving topline data from this Phase 2 clinical trial in the first half of 2022.

OTX-DED (dexamethasone intracanalicular insert)

OTX-DED incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient into a hydrogel, drug-eluting, preservative-free intracanalicular insert. While OTX-DED incorporates the same active drug as DEXTENZA, it includes a lower dose of the drug that is delivered via a smaller insert. There are approximately 8.6 million patients diagnosed with episodic dry eye disease in the United States, according to the Market Scope Report. OTX-DED is designed to release dexamethasone over a period of two to three weeks for the short-term treatment of the signs and symptoms of dry eye disease. To utilize the strong safety profile of DEXTENZA, we intend to file a Phase 2-enabling IND by the end of the year 2020 and, if successful, we plan to initiate a Phase 2 trial in the first quarter of 2021. We believe that this formulation will address several of the current limitations of existing dry eye disease treatments: the

slow onset of action, through the occlusion of the punctum; the burning/stinging upon application; the toxicity associated with preservatives; and the potential for abuse of topical steroids.

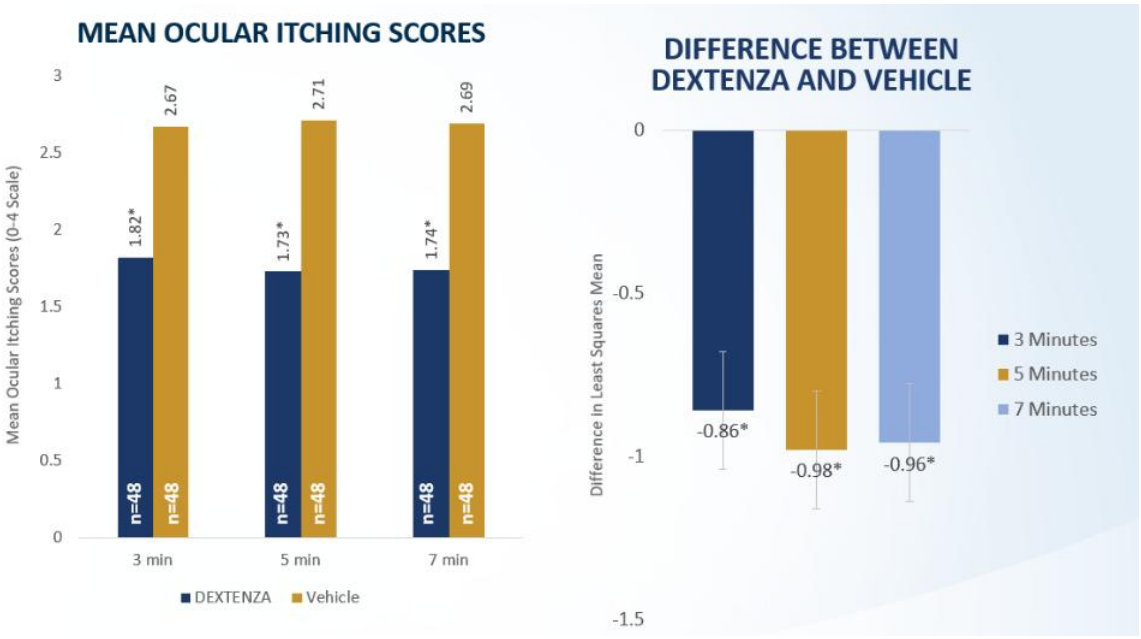
DEXTENZA for the Treatment of Ocular Itching Associated with Allergic Conjunctivitis

It is estimated that up to 10 million people in the United States seek medical attention for the inflammatory response associated with allergic conjunctivitis caused by both seasonal and perennial allergens. We believe that allergic conjunctivitis represents a discrete and significant potential market for DEXTENZA beyond its current use in the surgical setting. DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient into a hydrogel, drug-eluting, preservative-free intracanalicular insert. We are developing DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis as a hands-free, abuse-deterrent therapy administered in the office setting as a bioresorbable, intracanalicular insert, designed to release the corticosteroid dexamethasone to the ocular surface for up to 30 days.

In the third quarter of 2019, we began dosing patients in a 96-subject, pivotal Phase 3 clinical trial evaluating DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis. This Phase 3 clinical trial was a U.S.-based, multi-center, 1:1 randomized, double-masked, placebo-controlled trial that was fully enrolled, and was designed to test the safety and efficacy of DEXTENZA (dexamethasone ophthalmic insert) 0.4 mg versus a placebo vehicle punctum plug using Ora, Inc.'s modified Conjunctival Allergen Challenge (Ora-Cac®), or CAC, Model. The trial was 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 for this trial was ocular itching (subject-reported 5-point scale (0 to 4)) on day 8 at 3 minutes, 5 minutes and 7 minutes post-challenge and included subjects with seasonal and perennial allergens.

In April 2020, we reported topline results of this Phase 3 clinical trial. DEXTENZA-treated subjects demonstrated a statistically significant (p-value < 0.0001) difference in mean ocular itching scores, compared to vehicle-treated subjects, at all three pre-specified time points (see the figure below). An assessment of the secondary endpoint of ocular itching at all other visits (day 7, day 8 (morning), day 8 (afternoon at 10 minutes following exposure), day 14, and day 15 (morning and afternoon)) also showed that DEXTENZA-treated subjects reported lower itching scores than vehicle-treated subjects at 3 minutes, 5 minutes, 7 minutes and 10 minutes post-exposure to the allergen challenge (p-value <0.05 for all 21 time points except day 7 at 3 minutes).

Primary Efficacy Endpoint Ocular Mean Itching Scores at Day 8 (PM)



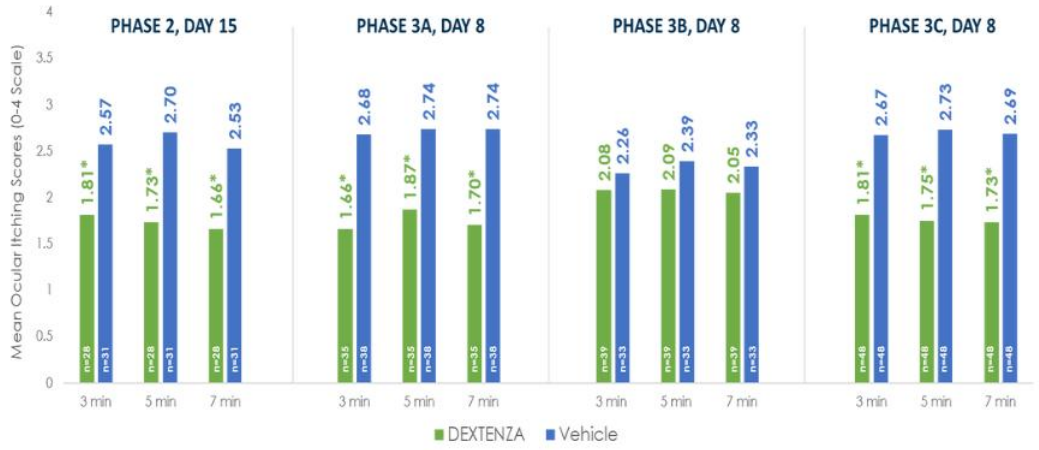
*Statistically significant; P≤0.0001; Least Squared Means; Population: ITT = MCMC; Bars represent Standard Error

In the trial, DEXTENZA was observed to have a favorable safety profile and be well-tolerated with no serious adverse events observed. No subjects required rescue medication and no subjects experienced elevated IOP. There were 8 ocular treatment emergent adverse events in this trial (2 in the DEXTENZA group and 6 in the vehicle group).

These data are generally consistent with our observations in our prior Phase 2 and Phase 3a clinical trials using a similar repeat CAC model as reflected in the two figures below. For all analyses we have conducted, the subject is the unit of analysis. For the Phase 2 clinical trial, the data shown is for the prespecified primary endpoint of ocular itching at day 15 using the Intent-to-Treat (ITT) population with last observation carried forward (LOCF) as the method of imputation. For the Phase 3 trials, the data shown is for the prespecified primary endpoint of ocular itching at day 8 using the ITT population and imputing missing data using the Markov chain Monte Carlo (MCMC) multiple imputation method. The two figures below reflect the Phase 3 data using the MCMC method with different bases for imputation. In the first figure, the basis for imputation for the MCMC method is at the individual eye level. In the second figure, the basis for imputation for the MCMC method is at the subject level (average of the two eyes). Both methods may be appropriate and, in this case, yield similar conclusions. In certain data we have previously disclosed, we have presented analyses using the MCMC method with the individual eye as the basis for imputation. However, the statistical analysis plan for each of the three Phase 3 trials specifies that the basis for imputation for the MCMC method should be the subject level. Multiple other methods of imputation were also performed in some of the Phase 3 studies including LOCF, baseline observation carried forward (BOCF), worse case observation (WCO), and observation only with no imputation with similar clinical conclusions.

Primary Efficacy Endpoint – Eye Level Imputation

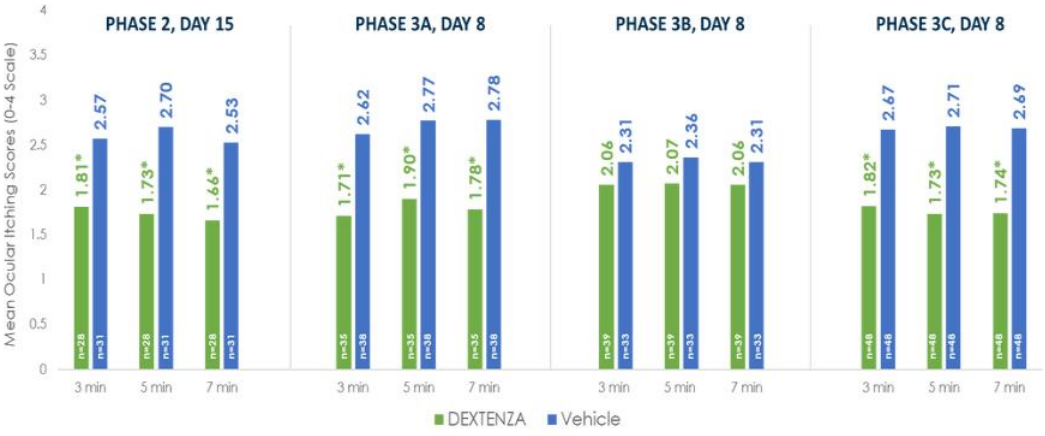
Mean Ocular Itching Scores Across All Studies



* Statistically Significant; P≤0.0025; Population: ITT + LOCF (Phase 2) & ITT + MCMC (Phase 3)

Primary Efficacy Endpoint – Subject Level Imputation

Mean Ocular Itching Scores Across All Studies



* Statistically Significant; P≤0.0025; Population: ITT + LOCF (Phase 2) & ITT + MCMC (Phase 3)

We plan to file an sNDA in the fourth quarter of 2020 for DEXTENZA to include the treatment of ocular itching associated with allergic conjunctivitis as an additional approved indication. If we are able to file our sNDA as planned, we would expect a target action date under the Prescription Drug User Fee Act, commonly known as PDUFA, in approximately October 2021. We believe that the totality of the efficacy and safety data across the Phase 2 trial and the three Phase 3 trials (n = 323 subjects), as well as the safety data associated with the prior approval of DEXTENZA for the treatment of inflammation and pain following ophthalmic surgery, represent a strong data package in support of the sNDA.

DEXTENZA ® (dexamethasone ophthalmic insert)

DEXTENZA incorporates the FDA-approved corticosteroid dexamethasone as an active pharmaceutical ingredient into a hydrogel, preservative-free 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 for post-surgical ocular inflammation and pain, we have built our own highly targeted, key account manager, or KAM, sales force that focuses on the ambulatory surgical centers, or ASCs, responsible for the largest volumes of cataract surgery. Our field team consists of approximately 30 KAMs and eight field reimbursement managers. DEXTENZA is available through a network of specialty distributors. Our initial commercial efforts are focused on the approximately 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 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 more reliable reimbursement process.

To date, three of seven Medicare Administrative Contractors, or MACs, have established physician fee schedules for procedure code 0356T for the administration of drug-eluting intracanalicular inserts, including DEXTENZA, effective July 1, 2020: Novitas Solutions, Inc., or Novitas; First Coast Service Options, Inc., or First Coast; and National Government Services, Inc., or NGS. The professional fee for CPT code 0356T is now eligible for physician payment for each insertion, in accordance with the applicable MAC's fee schedule. Novitas covers Medicare patients in New Mexico, Texas, Colorado, Oklahoma, Arkansas, Louisiana, Mississippi, New Jersey, Pennsylvania, Delaware, Virginia and the District of Columbia. First Coast covers Medicare patients in Florida, Puerto Rico, and the U.S. Virgin Islands. NGS covers Medicare patients in Illinois, Minnesota, Wisconsin, New York, Massachusetts, Connecticut, New Hampshire, Maine, Rhode Island, and Vermont. Combined, Novitas, First Coast and NGS cover approximately 50% of all Medicare beneficiaries. Three of the remaining four MACs have retired their non-coverage policies for CPT code 0356T, and we believe that these MACs may publish fee schedules and/or provide payment for 0356T in the near future.

On September 10, 2020, we announced that we had dosed the first pediatric patients in a Phase 3 clinical trial evaluating DEXTENZA for the treatment of post-surgical ocular inflammation and pain in children following cataract surgery. The Phase 3 clinical trial is a U.S.-based, randomized, multicenter clinical trial in which we intend to enroll approximately 60 subjects. The clinical trial is designed to evaluate the safety and biological activity of DEXTENZA compared to an active control, prednisolone acetate suspension eye drops, for the treatment of inflammation and pain following ocular surgery for pediatric cataract in children between zero and three years of age. The primary endpoint is the absence of pain at day eight post-treatment as measured by a FLACC (Face, Legs, Activity, Cry, Consolability) score of zero . This planned clinical trial is a post-approval requirement of the FDA in accordance with the Pediatric Research Equity Act of 2003, in connection with the FDA's prior approval of DEXTENZA for the treatment of inflammation and pain following ophthalmic surgery in adults.

On November 4, 2020, we announced that our application for the creation of a Category I Current Procedural Terminology, or CPT, procedure code, presented at the October 2020 meeting of the American Medical Association CPT Editorial Panel, or the Panel, had been granted. Category I CPT codes normally have a standardized Medicare physician fee schedule. As a result, they can improve coverage and payment across all payers for procedures performed in both the ASC and physician office settings. The Panel has agreed to create a permanent Category I CPT procedure code, effective January 1, 2022, to replace the Category III CPT code (0356T) currently available for the administration of drug-eluting intracanalicular inserts including DEXTENZA.

Additionally, we have received proposals for, and plan to support, several investigator-initiated trials evaluating DEXTENZA in different clinical situations. To date, third-party clinical investigators have initiated over 20 trials to

study the use of DEXTENZA in cataract surgery and other potential indications. Two of the trials have completed enrollment, the remaining trials are actively enrolling and treated patients are being followed.

ReSure® Sealant

We commercially launched this product in the United States in 2014. ReSure Sealant is a device 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 the 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.

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. In December 2019, we submitted the protocol for the agreed upon retrospective study and the prospective study outline, as required per the terms of the warning letter. We received feedback from the FDA in February 2020, and we responded to the FDA in March 2020. In May 2020, the protocol was approved by the FDA.

On September 8, 2020, we reported that we received a close-out letter from the FDA dated September 2, 2020, regarding the October 2018 warning letter. If we complete the proposed retrospective study in accordance with our agreement with the FDA, we believe that the FDA will deem our obligations to conduct post-approval studies related to ReSure Sealant to have been satisfied. 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.

While ReSure Sealant remains commercially available in the United States, there is no sales support currently provided to the product. We have received only limited revenues from ReSure Sealant to date and anticipate only limited sales for 2020.

AffaMed License Agreement

On October 29, 2020, we entered into a license agreement, or the License Agreement, with AffaMed Therapeutics Limited, or AffaMed, for the development and commercialization of DEXTENZA product regarding ocular inflammation and pain following cataract surgery and allergic conjunctivitis, or collectively, the DEXTENZA Field, and for OTX-TIC, or collectively with DEXTENZA, the AffaMed Licensed Products, regarding open-angle glaucoma and ocular hypertension, or collectively, the TIC Field and, with the DEXTENZA Field, each a Field, in each case in

mainland China, Taiwan, Hong Kong, Macau, South Korea, and the countries of the Association of Southeast Asian Nations, or collectively, the Territories. We retain development and commercialization rights for the AffaMed Licensed Products in the rest of the world.

Under the License Agreement, we granted AffaMed (i) a non-exclusive, royalty-free, non-sublicensable license under certain of our intellectual property rights and know-how to use the AffaMed Licensed Products in connection with specified activities in accordance with a development plan agreed between the parties and (ii) an exclusive, royalty-bearing, sublicensable, non-transferable (subject to specified exceptions), license under certain of our intellectual property rights and know-how to commercialize the AffaMed Licensed Products in the applicable Field in the Territories. We have further agreed not to, and to cause its affiliates or agents not to, develop or commercialize in the Territories (i) the AffaMed Licensed Products outside of the applicable Fields and (ii) any other product containing the same active pharmaceutical ingredients as the AffaMed Licensed Products and administered into the anterior chamber of the eye, in each case without AffaMed's prior written consent. AffaMed has agreed not to, and to cause its affiliates or agents not to, engage in the development, manufacture, or commercialization of any competing product in the Territories.

Under the terms of the License Agreement, we are entitled to upfront payments totaling $12 million. We are also eligible to receive up to an additional $91 million in aggregate, inclusive of a low-seven-figure clinical support payment, upon the achievement of certain development and commercial milestones. There can be no guarantee, however, that any of these milestones will be achieved. We are also entitled to receive tiered, escalating royalties on the net sales of the AffaMed Licensed Products ranging from a low-teen to low-twenties percentage. Royalties under the License Agreement are payable on an AffaMed Licensed Product-by-AffaMed Licensed Product and jurisdiction-by-jurisdiction basis and are subject to potential reductions in specified circumstances, subject to a specified floor.

Pursuant to the terms of the License Agreement, we are generally responsible for expenses related to the development of the AffaMed Licensed Products in the applicable Fields in the Territories, provided that AffaMed (i) reimburse us a low-teen percentage of expenses incurred in connection with certain clinical trials conducted by us and designed to support marketing approval of the AffaMed Licensed Product by FDA or the European Medicines Agency, or the Global Studies; (ii) is solely responsible for expenses incurred in connection with territory-specific clinical trials that it conducts in furtherance of the development plan agreed between the parties in the applicable Fields in the Territories, or the Local Studies; and (iii) reimburse us in full for expenses incurred in connection with obtaining and maintaining regulatory approvals of the AffaMed Licensed Products in the applicable Fields in the Territories. In the event AffaMed declines to participate in a Global Study or to conduct a Local Study in any jurisdiction in which we determine to conduct such a study, we are relieved of our obligation to provide AffaMed clinical data from such study, other than safety data, unless AffaMed subsequently reimburses us in the amounts described above plus a prespecified premium.

AffaMed is further obligated, at its sole cost and expense, to use commercially reasonable efforts to commercialize the AffaMed Licensed Products in the applicable Fields in the Territories. The License Agreement contemplates that the parties negotiate and enter into a future agreement requiring us to use commercially reasonable efforts to manufacture and supply finished drug products in sufficient quantity for clinical development and commercialization of the AffaMed Licensed Products in the applicable Fields in the Territories.

In accordance with its terms, the License Agreement expires upon the expiration of the last royalty term for the last AffaMed Licensed Product in any applicable Field in the Territories. Either party may, subject to specified cure periods, terminate the License Agreement in the event of the other party's uncured breach. Either party may also terminate the License Agreement under specified circumstances relating to the other party's insolvency. During an established period following a change of control of us or our entry into a global licensing agreement that includes the Territories with a third party, we have the option to terminate the License Agreement, subject to a specified notice period and the repayment of any costs and expenses incurred by AffaMed in connection with the License Agreement, including upfront and milestone payments AffaMed has previously paid to us, at a prespecified premium. AffaMed has the right to terminate the License Agreement at any time following the completion of a Phase 3 clinical trial to evaluate OTX-TIC.

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 currently have a number of preclinical programs that we are exploring for further development.

We are also assessing the potential use of our hydrogel platform technology in other areas of the body and have studied 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. 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 local 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 the treatment of ocular itching associated with allergic conjunctivitis, OTX-CSI and OTX-DED for dry eye disease, OTX-TIC for glaucoma and ocular hypertension, and OTX-TKI for wet AMD. Since inception, we have incurred significant operating losses. Our net loss was $11.9 million and $18.8 million and $70.0 million and $60.4 million for the three and nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $453.6 million.

Our total costs and operating expenses were $19.9 million and $58.6 million for the three and nine months ended September 30, 2020, respectively, including $2.6 million and $7.4 million in non-cash stock-based compensation expense and depreciation expense, respectively. Our operating expenses have grown as we continue to support the commercial launch of DEXTENZA following its entry into the market in July 2019; continue to pursue the clinical development of OTX-TKI, OTX-TIC, OTX-CSI, OTX-DED, OTX-AFS and DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis; 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 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 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 $35.1 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 Sales 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 2020, we sold 326,558 shares of common stock under the 2019 Sales Agreement, resulting in net proceeds of approximately $1.7 million after commissions and expenses. From inception to November 1, 2020, we have sold 10,321,840 shares of common stock under the 2019 Sales Agreement, resulting in net proceeds of approximately $47.0 million after underwriting discounts and commissions and offering 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.

In May 2020, we entered into an underwriting agreement with Jefferies and Piper Sandler & Co., or the Underwriters, for an underwritten public offering of 8,181,819 shares of our common stock. Under the terms of this underwriting agreement, we also granted the Underwriters an option to purchase up to an additional 1,227,272 shares of our common stock at the public offering price, less the underwriting discounts and commissions. The Underwriters subsequently exercised this option to purchase the optional shares in full. The public offering price of the shares sold in this offering was $5.50 per share, and the Underwriters purchased all of the shares from us at a price of $5.17 per share. After deducting underwriting discounts and commissions and offering expenses, we received net proceeds from the offering of approximately $48.3 million.

In October 2020, we entered into an underwriting agreement with the Underwriters, for an underwritten public offering of 7,180,000 shares of our common stock, or the October 2020 Offering. Under the terms of this underwriting agreement, we also granted the Underwriters an option to purchase up to an additional 1,077,000 shares of our common stock at the public offering price, less the underwriting discounts and commissions. The Underwriters subsequently exercised this option to purchase the optional shares in full. The public offering price of the shares sold in this offering was $9.75 per share, and the Underwriters purchased all of the shares from us at a price of $9.165 per share. After deducting underwriting discounts and commissions, but before deducting offering expenses, we received net proceeds from the offering of approximately $75.7 million.

We primarily derive our product revenues from the sale of DEXTENZA in the United States to a network of specialty distributors, who then resell DEXTENZA to ASCs and hospital outpatient departments, or HOPDs. In addition to distribution agreements with specialty distributors, we enter into arrangements with government payers that provide for government-mandated rebates and chargebacks with respect to the purchase of DEXTENZA. We have previously reported in-market unit sales figures—unit sales from specialty distributors to ASCs and HOPDs—for July, August and September 2020 of 2,221, 2,920 and 4,812 units, respectively. We estimate over 4,000 units were sold to ASCs and HOPDs in-market in October 2020.

We believe that our existing cash and cash equivalents of $70.6 million as of September 30, 2020, together with the proceeds from the October 2020 Offering of $75.2 million, net of underwriting discounts and commissions and estimated offering expenses, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements into 2023. This estimate is based on our currently forecasted operating plan which includes estimates of anticipated cash inflows from DEXTENZA and ReSure Sealant product sales and cash outflows from operating expenses. These estimates are subject to various assumptions including those related to the severity and duration of the COVID-19 pandemic, the revenues and expenses associated with the commercialization of DEXTENZA, the pace of our research and clinical development programs, and other aspects of our business. We have based our estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect and would therefore need to raise additional capital to support our ongoing operations or adjust our plans accordingly. See "—Liquidity and Capital Resources."

Financial Operations Overview

Revenue

From our inception through September 30, 2020, 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. 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 2020. 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.

For the three and nine months ended September 30, 2020, three individual customers accounted for 39%, 38% and 10% and three individual customers accounted for 40%, 30%, and 12%, respectively, of our total revenue. At September 30, 2020, three individual customers accounted for 44%, 35% and 11% of our total accounts receivable. No other customer accounted for more than 10% of total revenue or accounts receivable at September 30, 2020.

For the three and nine months ended September 30, 2019, two individual customers accounted for 13% and 10% and one individual customer accounted for 18%, respectively, of our total revenue. At December 31, 2019, three individual customers accounted for 39%, 18% and 11% of our total accounts receivable. No other customer accounted for more than 10% of total accounts receivable for the year ended December 31, 2019.

The COVID-19 pandemic did have an impact on our financial results for the three month period ended September 30, 2020; the implementation of travel bans and restrictions, quarantines, shelter-in-place/stay-at-home and social distancing orders and shutdowns, for example, adversely affected our business. The reduction in elective cataract surgeries since mid-March 2020 has had an adverse impact on product revenues from DEXTENZA and ReSure Sealant. Although we saw signs of a rebound in cataract surgeries during the third quarter of 2020, we believe the number of procedures currently being performed continues to be below the level performed prior to the COVID-19 pandemic. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition and those of our customers, vendors, suppliers, and collaboration partners will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets.

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, including 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 of our products by the FDA or other regulatory agencies; 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 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 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, 2020 and 2019, we incurred limited marketing expenses in connection with ReSure Sealant, which we began commercializing in 2014, and increased selling and marketing expenses in connection with the commercial launch and ongoing sales of DEXTENZA. 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, legal and administrative functions. General and administrative expenses also include insurance, 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 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. Interest income consists primarily of interest income earned on cash and cash equivalents. In the three and nine months ended September 30, 2020 and 2019, 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 the 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 period until the embedded derivative is settled. The changes in fair value are non-cash adjustments, 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. 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 12, 2020 and the notes to the financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. There have been no significant changes to our critical accounting policies since the beginning of this fiscal year.

Results of Operations

Comparison of the Three Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended September 30, 2020 and 2019:

	Three Months Ended September 30,		Increase (Decrease)
	2020	2019	
	(in thousands)		
Revenue:			
Product revenue, net	$ 5,876	$ 829	$ 5,047
Total revenue, net	5,876	829	5,047
Costs and operating expenses:			
Cost of product revenue	450	806	(356)
Research and development	6,951	10,235	(3,284)
Selling and marketing	6,520	6,777	(257)
General and administrative	5,961	6,155	(194)
Total costs and operating expenses	19,882	23,973	(4,091)
Loss from operations	(14,006)	(23,144)	9,138
Other income (expense):			
Interest income	6	308	(302)
Interest expense	(1,715)	(1,651)	(64)
Change in fair value of derivative liability	3,771	5,717	(1,946)
Other income (expense), net	—	(8)	8
Total other income (expense), net	2,062	4,366	(2,304)
Net loss	$ (11,944)	$ (18,778)	$ 6,834

Revenue

We generated $5.9 million of revenue during the three months ended September 30, 2020 from sales of our products, of which $5.4 million was attributable to sales of DEXTENZA and $0.5 million was attributable to sales of ReSure Sealant. We generated $0.5 million and $0.3 million of revenue during the three months ended September 30, 2019 from sales of our DEXTENZA and ReSure Sealant product, respectively. We began to recognize product revenue from DEXTENZA during the second quarter of 2019 with the first commercial shipments to customers in June 2019. We believe the growth in revenue for DEXTENZA was due primarily to increased market acceptance and continued increases in elective surgical volumes during the period.

Research and Development Expenses

	Three Months Ended September 30,		Increase
	2020	2019	(Decrease)
	(in thousands)		
Direct research and development expenses by program:			
ReSure Sealant	$ 49	$ 57	$ (8)
DEXTENZA for post-surgical ocular inflammation and pain	262	274	(12)
DEXTENZA for ocular itching associated with allergic conjunctivitis	195	576	(381)
OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease	61	—	61
OTX-TP for glaucoma and ocular hypertension	140	252	(112)
OTX-TIC for glaucoma and ocular hypertension	255	181	74
OTX-TKI for wet AMD	303	246	57
OTX-CSI for chronic treatment of dry eye disease	364	—	364
Preclinical programs	119	421	(302)
Unallocated expenses:			
Personnel costs	2,777	5,305	(2,528)
All other costs	2,426	2,923	(497)
Total research and development expenses.	$ 6,951	$ 10,235	$ (3,284)

Research and development expenses were $7.0 million for the three months ended September 30, 2020, compared to $10.2 million for the three months ended September 30, 2019. Research and development costs decreased by $3.3 million primarily due to a decrease of $2.5 million in unallocated personnel costs and $0.5 million in unallocated all other costs and a net decrease of $0.3 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, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-CSI for the chronic treatment of dry eye disease, and our other preclinical programs.

For the three months ended September 30, 2020, we incurred $1.7 million in direct research and development expenses for our programmed-release drug delivery product candidates, including $0.2 million for DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis, $0.3 million for DEXTENZA for the treatment of post-surgical inflammation and pain, and $0.1 million for OTX-TP. 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. Unallocated research and development expense decreased $3.0 million for the three months ended September 30, 2020, compared to the three months ended September 30, 2019, due primarily to a decrease in personnel costs of $2.5 million and all other costs of $0.5 million as a result of the organizational restructuring that took place in November 2019. It is possible that the COVID-19 pandemic and response efforts could delay our clinical development programs and plans and increase our associated costs.

Selling and Marketing Expenses

	Three Months Ended September 30,		Increase
	2020	2019	(Decrease)
	(in thousands)		
Personnel related (including stock-based compensation)	$ 4,487	$ 3,607	$ 880
Professional fees	1,768	2,345	(577)
Facility related and other	265	825	(560)
Total selling and marketing expenses	$ 6,520	$ 6,777	$ (257)

Selling and marketing expenses were $6.5 million for the three months ended September 30, 2020, compared to $6.8 million for the three months ended September 30, 2019. The decrease of $0.3 million was primarily due to a

decrease of $0.6 million in professional fees including consulting, trade shows, marketing material and conferences and $0.6 million in facility related and other costs partially offset by an increase of $0.9 million in personnel costs, including stock-based compensation.

We expect our selling and marketing expenses to increase in the remainder of 2020 and beyond as we continue to support the commercial launch of DEXTENZA.

General and Administrative Expenses

	Three Months Ended September 30,		Increase (Decrease)
	2020	2019	
	(in thousands)		
Personnel related (including stock-based compensation)	$ 2,675	$ 3,790	$ (1,115)
Professional fees	2,116	1,587	529
Facility related and other	1,170	778	392
Total general and administrative expenses	$ 5,961	$ 6,155	$ (194)

General and administrative expenses were $6.0 million for the three months ended September 30, 2020, compared to $6.2 million for the three months ended September 30, 2019. The decrease of $0.2 million was primarily due to a decrease of $1.1 million in personnel costs, including stock-based compensation partially offset by an increase in professional fees of $0.5 million and facility related costs of $0.4 million.

Other Income (Expense), Net

Other income, net was $2.1 million for the three months ended September 30, 2020, compared to other income, net of $4.4 million for the three months ended September 30, 2019. The change of $2.3 million was due to the change in fair value of the derivative liability associated with the 2026 Convertible Notes of $1.9 million. The change in fair value of the derivative liability was a gain in the amount of $3.8 million during the three months ended September 30, 2020 due to changes in the underlying assumptions of the derivative liability, primarily related to an increase in our common stock price. 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 to 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.

Comparison of the Nine Months Ended September 30, 2020 and 2019

The following table summarizes our results of operations for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30,		Increase (Decrease)
	2020	2019	
	(in thousands)		
Revenue:			
Product revenue, net	$ 10,054	$ 1,971	$ 8,083
Total revenue, net	10,054	1,971	8,083
Costs and operating expenses:			
Cost of product revenue	1,403	1,486	(83)
Research and development	21,070	30,966	(9,896)
Selling and marketing	19,803	17,349	2,454
General and administrative	16,282	16,571	(289)
Total costs and operating expenses	58,558	66,372	(7,814)
Loss from operations	(48,504)	(64,401)	15,897
Other income (expense):			
Interest income	162	1,016	(854)
Interest expense	(5,042)	(4,296)	(746)
Change in fair value of derivative liability	(16,640)	7,334	(23,974)
Other income (expense), net	—	(8)	8
Total other income (expense), net	(21,520)	4,046	(25,566)
Net loss	$ (70,024)	$ (60,355)	$ (9,669)

Revenue

We generated $10.1 million of revenue during the nine months ended September 30, 2020 from sales of our products, of which $8.8 million was attributable to sales of DEXTENZA and $1.2 million was attributable to sales of ReSure Sealant. We generated $0.6 million and $1.4 million of revenue during the nine months ended September 30, 2019 from sales of our DEXTENZA and ReSure Sealant product, respectively. We began to recognize product revenue from DEXTENZA during the second quarter of 2019 with the first commercial shipments to customers in June 2019. We believe the growth in revenue for DEXTENZA was due primarily to increased market acceptance during 2020.

Research and Development Expenses

	Nine Months Ended September 30,		Increase (Decrease)
	2020	2019	
	(in thousands)		
Direct research and development expenses by program:			
ReSure Sealant	$ 92	$ 130	$ (38)
DEXTENZA for post-surgical ocular inflammation and pain	758	789	(31)
DEXTENZA for ocular itching associated with allergic conjunctivitis	2,291	691	1,600
OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease	61	—	61
OTX-TP for glaucoma and ocular hypertension	507	1,410	(903)
OTX-TIC for glaucoma and ocular hypertension	676	480	196
OTX-TKI for wet AMD	829	424	405
OTX-CSI for chronic treatment of dry eye disease	601	—	601
Preclinical activities	198	1,552	(1,354)
Unallocated expenses:			
Personnel costs	8,541	15,392	(6,851)
All other costs	6,516	10,098	(3,582)
Total research and development expenses	$ 21,070	$ 30,966	$ (9,896)

Research and development expenses were $21.1 million for the nine months ended September 30, 2020, compared to $31.0 million for the nine months ended September 30, 2019. Research and development costs decreased by $9.9 million primarily as a result of a decrease of $6.9 million in unallocated personnel costs and $3.6 million in unallocated all other costs, partially offset by a net increase of $0.6 million in costs incurred in connection with the clinical development of our DEXTENZA product candidate for the treatment of post-surgical ocular inflammation and pain, our DEXTENZA product candidate for the treatment of ocular itching associated with allergic conjunctivitis, our OTX-TP product candidate for the treatment of glaucoma and ocular hypertension, OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease, OTX-TIC for glaucoma and ocular hypertension, OTX-TKI for wet AMD and OTX-CSI for the chronic treatment of dry eye disease and other preclinical activities.

For the nine months ended September 30, 2020, we incurred $5.9 million in direct research and development expenses for our programmed-release drug delivery product candidates, including $0.8 million for our DEXTENZA product for the treatment of post-surgical ocular inflammation and pain, $2.3 million for our DEXTENZA product for the treatment of ocular itching associated with allergic conjunctivitis and $0.5 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, 2019, we incurred $5.3 million in direct research and development expenses for our programmed-release drug delivery product candidates, 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. Unallocated research and development expense decreased $10.4 million for the nine months ended September 30, 2020, compared to the nine months ended September 30, 2019, due primarily to a decrease in personnel costs of $6.9 million and all other costs of $3.6 million as a result of the organizational restructuring that took place in November 2019.

Selling and Marketing Expenses

	Nine Months Ended September 30,		Increase
	2020	2019	(Decrease)
	(in thousands)		
Personnel related (including stock-based compensation)	$ 12,582	$ 8,542	$ 4,040
Professional fees	4,993	6,729	(1,736)
Facility related and other	2,228	2,078	150
Total selling and marketing expenses	$ 19,803	$ 17,349	$ 2,454

Selling and marketing expenses were $19.8 million for the nine months ended September 30, 2020, compared to $17.3 million for the nine months ended September 30, 2019. The increase of $2.5 million was primarily due to increases of $4.0 million in personnel related costs, including stock-based compensation, and $0.1 million in facility-related costs, partially offset by decrease of $1.7 million in professional fees including consulting, trade shows and conferences.

General and Administrative Expenses

	Nine Months Ended September 30,		Increase
	2020	2019	(Decrease)
	(in thousands)		
Personnel related (including stock-based compensation)	$ 7,466	$ 8,474	$ (1,008)
Professional fees	5,618	6,174	(556)
Facility related and other	3,198	1,923	1,275
Total general and administrative expenses	$ 16,282	$ 16,571	$ (289)

General and administrative expenses were $16.3 million for the nine months ended September 30, 2020, compared to $16.6 million for the nine months ended September 30, 2019. The decrease of $0.3 million was primarily due to a decrease of $1.0 million in personnel related costs, including stock-based compensation and professional fees of $0.6 million, partially offset by an increase of $1.3 million in facility-related and other costs.

Other Income (Expense), Net

Other expense, net was $21.6 million for the nine months ended September 30, 2020, compared to other income, net of $4.0 million for the nine months ended September 30, 2019. The change of $25.6 million was due primarily to the change in fair value of the derivative liability associated with the 2026 Convertible Notes of $24.0 million, an increase in interest expense of $0.8 million associated with the Credit Facility and the 2026 Convertible Notes, partially offset by decrease in interest income earned of $0.8 million on current cash balances.

Change in Fair Value of Derivative Liability

The change in fair value of the derivative liability was a loss in the amount of $16.6 million during the nine months ended September 30, 2020 due to changes in the underlying assumptions of the derivative liability, primarily related to an increase 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. The change in fair value of derivative liability during the nine months ended September 30, 2019 was a gain of $7.3 million.

Liquidity and Capital Resources

Since inception, we have incurred significant operating losses. Our net losses were $70.0 million and $60.4 million for the nine months ended September 30, 2020 and 2019, respectively, and $86.4 million and $60.0 million for the years ended December 31, 2019 and 2018, respectively. As of September 30, 2020, we had an accumulated deficit of $453.6 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 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 the treatment of ocular itching associated with allergic conjunctivitis, OTX-TKI for wet AMD, OTX-TIC for glaucoma and ocular hypertension, and OTX-CSI and OTX-DED for dry eye disease. While it is difficult to predict the extent or duration of the impact of the global COVID-19 pandemic on future financial results, we anticipate current guidelines and recommendations from the global health authorities, including the delay of elective surgeries, will impact revenue in the fourth quarter of 2020 and beyond.

Through September 30, 2020, 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 completed our October 2020 Offering at a public offering price of $9.75 per share. The October 2020 Offering consisted of 8,257,000 shares of common stock sold by us, including those shares sold in connection with the exercise by the Underwriters of their option to purchase additional shares. We received net proceeds from this offering of approximately $75.7 million, after deducting underwriting discounts and commissions but before deducting offering expenses.

In May 2020, we completed a follow-on offering of our common stock at a public offering price of $5.50 per share. The offering consisted of 9,409,091 shares of common stock sold by us, including those shares sold in connection with the exercise by the Underwriters of their option to purchase additional shares. We received net proceeds from the follow-on offering of approximately $48.3 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 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.

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. 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. From inception through November 1, 2020, we have sold 10,321,840 shares of common stock under the 2019 Sales Agreement, resulting in net proceeds of approximately $47.0 million after underwriting discounts and commissions and other offering expenses.

On April 22, 2020, in accordance with our Credit Agreement, we obtained consent from MidCap Financial Trust permitting us to secure a loan under the Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Stability Act. We received loan proceeds of approximately $3.2 million, which we refer to as the PPP Loan, on April 23, 2020 pursuant to this program. However, based on updated guidance related to this program, we repaid the PPP Loan in full on May 5, 2020.

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 $25.0 million which cap may be increased by up to $5.0 million under certain circumstances.

As of September 30, 2020, we had cash and cash equivalents of $70.6 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 $3.6 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. We believe that our existing cash and cash equivalents of $70.6 million as of September 30, 2020, together with the net proceeds from the October 2020 Offering, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements into 2023. This estimate is based on our currently forecasted operating plan which includes estimates of anticipated cash inflows from DEXTENZA and ReSure Sealant product sales and cash outflows from operating expenses. These estimates are subject to various assumptions including those related to the severity and duration of the COVID-19 pandemic, the revenues and expenses associated with the commercialization of DEXTENZA, variable expense reductions, the pace of our research and clinical development programs, and other aspects of our business. We have based our estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect and would therefore need to raise additional capital to support our ongoing operations or adjust our plans accordingly.

Cash Flows

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

	Nine Months Ended September 30,	
	2020	2019
Cash used in operating activities	$ (47,308)	$ (58,111)
Cash used in investing activities	(588)	(1,637)
Cash provided by financing activities	64,101	66,250
Net increase in cash and cash equivalents	$ 16,205	$ 6,502

Operating activities. Net cash used in operating activities was $47.3 million for the nine months ended September 30, 2020, primarily resulting from our net loss of $70.0 million and changes in our operating assets and liabilities of $4.8 million, offset by $27.5 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 were partially offset by contributions from our revenues during the applicable period. Our net non-cash charges during the nine months ended September 30, 2020 consisted primarily of $10.8 million of stock-based compensation expense, depreciation expense and other non-cash expenses and the change in fair value of the derivative liability of $16.6 million. Net cash used by changes in our operating assets and liabilities during the nine months ended September 30, 2020 consisted primarily of increases in accrued expenses, accounts receivable, and inventories as we continue to commercialize DEXTENZA.

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 were partially offset by any contributions from our revenues during the applicable period. 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 we continue to commercialize DEXTENZA.

Investing activities. Net cash used in investing activities for the nine months ended September 30, 2020 and 2019 totaled $0.6 million and $1.6 million, respectively. For the nine months ended September 30, 2020, net cash used in investing activities is due to $0.5 million of purchases of property and equipment, which consisted primarily of laboratory equipment. 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.

Financing activities. Net cash provided by financing activities for the nine months ended September 30, 2020 was $64.1 million and for the nine months ended September 30, 2019 was $66.3 million. Net cash provided by financing activities for the nine months ended September 30, 2020 consisted primarily of $48.6 million in proceeds from our May 2020 follow-on offering of our common stock, net of underwriting discounts and commissions and other offering expenses, $14.4 million in proceeds from our 2019 Sales Agreement, net of underwriting discounts and commissions and other offering expenses, $1.0 million in proceeds from the exercise of stock options and $0.4 million in proceeds from the issuance of common stock pursuant to the employee stock purchase plan. 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.

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 to continue to support the DEXTENZA sales and marketing efforts and to support 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 ongoing clinical trials of our product candidates OTX-TKI, OTX-TIC, and OTX-CSI;
- initiate planned Phase 2 clinical trials for our product candidates OTX-TKI, OTX-TIC, and OTX-DED;
- 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;
- conduct research and development activities on, and seek regulatory approvals for, DEXTENZA and OTX-TIC in certain Asian countries pursuant to our license agreement and collaboration with AffaMed Therapeutics Limited, or AffaMed;
- 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 front-of-the-eye and back-of-the-eye programs 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 existing facilities 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. 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 completed the restructuring and recorded the restructuring charges in the fourth quarter of 2019. We incurred total restructuring costs of approximately $0.6 million, which includes severance, benefits and related costs, all of which were paid during the three months ending December 31, 2019. 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.

We believe that our existing cash and cash equivalents of $70.6 million as of September 30, 2020, together with the $75.7 million of net proceeds from the October 2020 Offering after deducting underwriting discounts and commissions but before deducting offering expenses, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements into 2023. This estimate is based on our currently forecasted operating plan which includes estimates of anticipated cash inflows from DEXTENZA and ReSure Sealant product sales and cash outflows from operating expenses. These estimates are subject to various assumptions including those related to the severity and duration of the COVID-19 pandemic, the revenues and expenses associated with the commercialization of DEXTENZA, variable expense reductions, the pace of our research and clinical development programs, and other aspects of our business. We have based our estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect and would therefore need to raise additional capital to support our ongoing operations or adjust our plans accordingly.

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 our planned and ongoing clinical trials of our extended-delivery drug delivery product candidates, in particular DEXTENZA for additional indications, OTX-TIC for glaucoma and ocular hypertension, OTX-TKI for wet AMD, OTX-CSI for the chronic treatment of dry eye disease, and OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease;
- 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 as potential option exercise fees, development, regulatory and sales milestone payments and royalty payments and the amounts we are obligated to pay to Regeneron as reimbursement if it chooses to exercise its option to advance a product candidate under our collaboration agreement;
- the amounts we are entitled to receive, if any, from AffaMed as reimbursements for clinical trial expenditures, development, regulatory, and sales milestone payments, and royalty payments under our license agreement with AffaMed;

- 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 Regeneron's reimbursement of certain preclinical expenses incurred by us under our collaboration agreement and for our potential receipt of option exercise, development, regulatory and sales milestone payments and royalty payments and our license agreement with AffaMed provides for AffaMed's reimbursement of certain clinical expenses incurred by us in connection with our collaboration and for our potential receipt of development, royalty, and sales milestone payments as well as royalty 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. In addition, the COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could adversely impact our ability to raise additional funds through equity or debt financings. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Since our inception in 2006, we have not recorded any U.S. federal or state income tax benefits for the net losses we have incurred in each year or our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2019, we had federal net operating loss carryforwards of $274.3 million, which begin to expire in 2024, and state net operating loss carryforwards of $219.4 million, which begin to expire in 2024. As of December 31, 2019, we also had federal research and development tax credit carryforwards of $8.2 million and state research and development tax credit carryforwards $4.3 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, 2020 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	$ 13,450	$ 2,491	$ 5,075	$ 3,156	$ 2,728
Purchase commitments	6,548	3,218	$ 3,265	$ 65	$ —
Debt obligations including interest	30,307	8,517	18,797	2,993	—
2026 Convertible Notes	53,475	—	—	—	53,475
Total	$ 103,780	$ 14,226	$ 27,137	$ 6,214	$ 56,203

In the table above, we set forth our enforceable and legally binding obligations and future commitments at September 30, 2020, 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, 2020. 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 at 15 Crosby Drive in Bedford, Massachusetts. 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 Agreement 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 to increase the aggregate principle amount 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 Original Agreement, that we entered into with Incept in January 2012. We amended and restated the Original Agreement most recently in September 2018. Under the amended and restated agreement, or the Incept 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 products, devices, materials, or components thereof, or the In-Licensed Products, including or covered by Original IP (as defined in the Incept License Agreement), excluding the Shape-Changing IP (as defined in the Incept License Agreement), in the Ophthalmic Field of Use (as defined in the Incept 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 In-Licensed Products including or covered by Original IP, excluding the Shape-Changing IP, in the Additional Field of Use (as defined in the Incept 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 In-

Licensed Products including or covered by Incept IP (as defined in the Incept 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 In-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 May 8, 2020, we entered into an amendment (the "Amendment") to the Collaboration Agreement. Pursuant to the Amendment, we and Regeneron have adopted a new workplan to transition joint efforts under the Collaboration Agreement to the research and development of an extended-delivery formulation of aflibercept to be delivered to the suprachoroidal space. Regeneron has agreed to pay our personnel and material costs for specified preclinical development activities in connection with the revised workplan, as well as certain other costs. In addition, the Amendment provides for the modification of the terms of the Option previously granted to Regeneron under the Collaboration Agreement.

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.

On October 29, 2020, we entered into the License Agreement with AffaMed. Pursuant to the terms of the License Agreement, we are generally responsible for expenses related to the development of the AffaMed Licensed Products in the applicable Fields in the Territories, provided that AffaMed (i) reimburse us a low-teen percentage of expenses incurred in connection with Global Studies; (ii) is solely responsible for expenses incurred in connection with Local Studies; and (iii) reimburse us in full for expenses incurred in connection with obtaining and maintaining regulatory approvals of the AffaMed Licensed Products in the applicable Fields in the Territories. In the event AffaMed declines to participate in a Global Study or to conduct a Local Study in any jurisdiction in which we determine to conduct such a study, we are relieved of our obligation to provide AffaMed clinical data from such study, other than safety data, unless AffaMed subsequently reimburses us in the amounts described above plus a prespecified premium.

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, 2020, we had cash and cash equivalents of $70.6 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, 2020. 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, 2020, 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, 2020 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 First Circuit held an oral argument on the appeal on February 4, 2020. The First Circuit issued its decision on April 9, 2020, affirming the District Court's dismissal of the class action. The plaintiffs did not seek review of the First Circuit's decision prior to the deadline for filing a petition for a writ of certiorari in the United States Supreme Court.

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, certain current board members, certain former board members, 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 October 20, 2020, the parties filed a joint stipulation and proposed order voluntarily dismissing the action without prejudice.

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 October 16, 2020, the parties filed a joint stipulation and proposed order voluntarily dismissing the action without prejudice.

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. On October 26, 2020, the parties filed a joint stipulation and proposed order voluntarily dismissing the action without prejudice. The court signed the proposed order on October 28, 2020.

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

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 the Coronavirus Pandemic

The coronavirus (COVID-19) pandemic has disrupted, and is expected to continue to adversely affect, our operations, including our ability to generate revenue from sales of DEXTENZA or ReSure Sealant. In the future, it may have other adverse effects on our business and operations, including potentially delaying one or more of our clinical trials. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business, operations and ability to raise capital.

The COVID-19 coronavirus pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, strict travel restrictions, heightened border scrutiny, and other measures. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the pandemic and its effects on our business and operations are uncertain.

We believe the COVID-19 pandemic has adversely affected, and we expect it to continue to adversely affect, the progress of our commercialization of DEXTENZA and our ability to generate revenue from sales of DEXTENZA, as a result of many factors, including:

- a decrease in patients attending routine ophthalmology appointments or undergoing elective surgical procedures, including cataract surgery;
- diversion of healthcare resources away from elective surgical procedures, including cataract surgery, to focus on pandemic concerns;
- potential interruptions in global shipping affecting the transport of raw materials used in the manufacture of our product, drug product, patient samples and related literature; and
- the impact of further limitations on travel that could interrupt key commercialization activities, such as travel by our key account managers, which could adversely impact the progress of our commercialization of DEXTENZA.

The COVID-19 pandemic also has the potential to delay or otherwise adversely affect our clinical development activities, including our ability to recruit or retain patients in our ongoing clinical trials, as a result of many factors, including:

- diversion of healthcare resources away from the conduct of our clinical trials to focus on pandemic concerns, including the availability of necessary materials, the attention of physicians serving as our clinical trial investigators, access to hospitals serving as our clinical trial sites, and availability of hospital staff supporting the conduct of our clinical trials;
- the inability or reluctance of patients enrolled in our clinical trials to visit clinical trial sites if patients are affected by the virus or are fearful of traveling to our clinical trial sites because of the outbreak;
- potential interruptions in global shipping affecting the transport of clinical trial materials, such as investigational drug product, patient samples, and raw materials used in the manufacture of our product candidates; medical and laboratory supplies used in our clinical trials or preclinical studies; or animals that are used for preclinical testing, and other supplies used in our clinical trials and preclinical studies;
- the impact of personnel shortages, further limitations on travel, or other operational challenges that could interrupt key clinical trial activities, such as clinical trial site initiations and monitoring and reporting activities, travel by our employees, contract research organizations, or CROs, or patients to clinical trial sites, or the ability of employees at our manufacturing facility to report to work, any of which could delay or adversely impact the conduct or progress of our clinical trials or limit the amount of clinical data we will be able to report; and
- any future interruption of, or delays in receiving, supplies of clinical trial material from our manufacturing facility due to stay-at-home orders, production slowdowns or stoppages, or disruptions in delivery systems.

Any negative impact that the COVID-19 pandemic has on recruiting or retaining patients in our clinical trials, the ability to provide materials for our product candidates, the operations of our clinical trials, or the regulatory review process could cause additional delays with respect to product development activities, which could materially and adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, affect our ability to raise additional capital, and have a material adverse effect on our financial results. For example, we have seen a slight slowdown in our enrollment in the fourth cohort of our Phase 1 clinical trial evaluating OTX-TIC due to COVID-19. We believe enrollment will increase as ophthalmology offices resume operations for non-emergent patients. We now expect to provide topline data for the third and fourth cohorts of this clinical trial in the first quarter of 2021. However, if enrollment delays continue for a prolonged period, the completion of our Phase 1 clinical trial could be further delayed.

Additionally, in May 2020, we disclosed the receipt of interim data regarding our ongoing Phase 1 clinical trial of OTX-TKI for the potential treatment of wet AMD and other retinal diseases. The Phase 1 clinical trial is a multi-center, open-label, dose-escalation study in Australia designed to evaluate the safety, biological activity, durability and tolerability of OTX-TKI. At that time, two cohorts had been enrolled, a lower dose cohort of 200 µg and a higher dose cohort of 400 µg. We disclosed that, as of May 13, 2020, the first two patients in the second (400 µg) cohort had shown

a clinically meaningful reduction in intraretinal and/or subretinal fluid out to six months with a single implant. In July 2020, we reported that the data collection and other administrative activities of the clinical trial site in Australia where these two patients were being treated had been adversely impacted by the effects of the COVID-19 pandemic. Specifically, the clinical trial site reported to us that one of these two patients showing a clinically meaningful reduction in intraretinal and/or subretinal fluid had been treated with anti-VEGF medication at a site visit at month 4.5 (in mid-March 2020) and at month 6 (in early May 2020). The administration of this anti-VEGF medication at the month 4.5 visit and at the month 6 visit was not entered into the clinical trial database until after a subsequent visit at month 7.5 in mid-June 2020. As a result, this information was not available to or known by us in connection with our prior disclosures.

The COVID-19 pandemic continues to rapidly evolve and its ultimate scope, duration and effects are unknown. The extent of the impact of the disruptions to our business, preclinical studies and clinical trials, commercialization activities and revenue as a result of the outbreak will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

The pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could adversely impact our ability to raise additional funds through public offerings or private placements and may also impact the volatility of our stock price and trading in our stock. Moreover, it is possible the pandemic will significantly impact economies worldwide, which could result in adverse effects on our business and operations. We cannot be certain what the overall impact of the COVID-19 pandemic will be on our business and it has the potential to adversely affect our business, financial condition, results of operations, and prospects.

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 $60.0 million for the year ended December 31, 2018, $86.4 million for the year ended December 31, 2019, and $70.0 million for the nine months ended September 30, 2020. As of September 30, 2020, we had an accumulated deficit of $453.6 million. Through September 30, 2020, 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, 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 ongoing clinical trials of our product candidates OTX-TKI, OTX-TIC and OTX-CSI;
- initiate planned Phase 2 clinical trials for our product candidates OTX-TKI, OTX-TIC, and OTX-DED;
- 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;

- conduct research and development activities on, and seek regulatory approvals for, DEXTENZA and OTX-TIC in certain Asian countries pursuant to our license agreement and collaboration with AffaMed Therapeutics Limited, or AffaMed;
- 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 front-of-the-eye and back-of-the-eye programs 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 existing facilities 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.

Prior to our commercial launch of DEXTENZA in July 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, including DEXTENZA for additional indications;
- obtaining marketing approval for these product candidates;
- 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. However, the successful commercialization of DEXTENZA in the United States is subject to many risks. The COVID-19 pandemic has substantially reduced the number of elective ophthalmic surgeries performed since mid-March 2020. Although we saw signs of a rebound in cataract surgeries during the third quarter of 2020, we believe the number of procedures currently being performed continues to be below the level performed prior to the COVID-19 pandemic. DEXTENZA is our first significant product launch, and we may not be able to commercialize DEXTENZA successfully. 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 we have. We do not anticipate revenue from sales of DEXTENZA for the treatment of ocular inflammation and pain following ophthalmic surgery 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 our commercialization efforts and may never generate revenue that is sufficient 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 including ocular itching associated with allergic conjunctivitis, 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, 2020, we had cash and cash equivalents of $70.6 million, outstanding debt of $25.0 million, net of unamortized discount and $37.5 million aggregate principal amount of senior subordinated convertible notes plus accrued interest of $3.6 million. We believe that our existing cash and cash equivalents of $70.6 million as of September 30, 2020, together with the net proceeds from the October 2020 sale of our common stock discussed in Note 15 of our consolidated financial statements of approximately $75.7 million, after deducting underwriting discounts and commissions but before deducting offering expenses, will enable us to fund our planned operating expenses, debt service obligations and capital expenditure requirements into 2023. This estimate is based on our currently forecasted operating plan which includes estimates of anticipated cash inflows from DEXTENZA and ReSure Sealant product sales and cash outflows from operating expenses. These estimates are subject to various assumptions including those related to the severity and duration of the COVID-19 pandemic, the revenues and expenses associated with the commercialization of

DEXTENZA, variable expense reductions, the pace of our research and clinical development programs, and other aspects of our business. We have based our estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect and would therefore need to raise additional capital to support our ongoing operations or adjust our plans accordingly. 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 our planned and ongoing clinical trials of our extended-delivery drug delivery product candidates, in particular DEXTENZA for additional indications, OTX-TIC for glaucoma and ocular hypertension, OTX-TKI for wet AMD, OTX-CSI for the chronic treatment of dry eye disease, and OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease;
- 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 as potential option exercise fees, development, regulatory and sales milestone payments and royalty payments and the amounts we are obligated to pay to Regeneron as reimbursement if it chooses to exercise its option to advance a product candidate under our collaboration agreement;
- the amounts we are entitled to receive, if any, from AffaMed as reimbursements for clinical trial expenditures, development, regulatory, and sales milestone payments, and royalty payments under our license agreement with AffaMed;
- 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 our Annual Report on Form 10-K.

Our audited consolidated financial statements for the period ended December 31, 2019 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 Regeneron's reimbursement of certain preclinical expenses incurred by us under our collaboration agreement and for the potential receipt of option exercise, development, regulatory and sales milestone and royalty payments and our license agreement with AffaMed provides for AffaMed's reimbursement of certain clinical expenses incurred by us in connection with our collaboration and for our potential receipt of development, royalty, and sales milestone payments as well as 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. The COVID-19 pandemic has already caused significant disruptions in the financial markets, and may continue to cause such disruptions, which could adversely impact our ability to raise additional funds through equity or debt financings.

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 have $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 additional 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.

The elimination of LIBOR could adversely affect our business, results of operations or financial condition.

In July 2017, the head of the United Kingdom Financial Conduct Authority announced plans to phase out the use of LIBOR by the end of 2021. Although the impact is uncertain at this time, the elimination of LIBOR could have an adverse impact on our business, results of operations, or financial condition. We may incur significant expenses to amend our LIBOR-indexed loans and other applicable financial or contractual obligations, including our Credit Facility, to a new reference rate, which may differ significantly from LIBOR. Accordingly, the use of an alternative rate could result in increased costs, including increased interest expense on our credit facilities, and increased borrowing and hedging costs in the future. At this time, no consensus exists as to what rate or rates may become acceptable alternatives to LIBOR and we are unable to predict the effect of any such alternatives on our business, results of operations or financial condition.

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. We commercially launched DEXTENZA on July 1, 2019 and, to date, have not generated significant 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 its 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. 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, OTX-TKI for wet AMD, OTX-CSI for the chronic treatment of dry eye disease, and OTX-DED for the short-term treatment of the signs and symptoms of dry eye disease. 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. 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 and AffaMed;
- 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 collaborations with Regeneron and AffaMed, 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. Post-hoc analyses that we performed on the results of our two 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.

Even if we obtain favorable clinical trial results in an additional Phase 3 clinical trial of DEXTENZA for allergic conjunctivitis, such as our third Phase 3 clinical trial, 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. For example, in April 2020, we announced the topline results from our third Phase 3 clinical trial assessing ocular itching associated with allergic conjunctivitis in which DEXTENZA achieved its primary endpoint as treated subjects demonstrated a statistically significant (p-value < 0.0001) difference in mean ocular itching scores compared to vehicle-treated subjects at all three pre-specified time points compared with placebo-treated subjects. We believe that this efficacy data, considered in totality with a favorable safety profile and the data from the prior Phase 2, Phase 3a and Phase 3b clinical trials, provides the basis for a submission of a supplemental new drug application, or sNDA, for DEXTENZA to include the treatment of ocular itching associated with allergic conjunctivitis as an additional approved indication. However, the FDA may not agree with our view of the clinical meaningfulness of the data. We understand that the FDA has in the past considered, for trials similar to ours, clinical meaningfulness to be a 0.5 unit difference at all relevant time points and at least a 1.0 unit difference at a majority of time points assessed. DEXTENZA did not achieve these measures in the third Phase 3 clinical trial. Achievement of such differences is also affected by the statistical methodology we utilize to review the clinical trial data. As previously disclosed, in our first Phase 3 clinical trial for the treatment of ocular itching associated with allergic conjunctivitis, DEXTENZA achieved a 0.5 unit difference at all relevant time points and at least a 1.0 unit difference at a majority of time points assessed using the Markov chain Monte Carlo, or MCMC, method where the basis for imputation was at the individual eye level. However, using the MCMC method specified in the applicable statistical analysis plan—where the basis for imputation is at the subject level (average of the two eyes)—DEXTENZA did not achieve all of these

measures. If the FDA were to require that a product candidate achieve these measures of clinical meaningfulness, approval of our sNDA could be delayed or prevented.

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 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 our first 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 were 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 IOP 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 often conducted our initial and earlier stage clinical trials for our product candidates, including our intracanalicular insert product candidates, outside the United States. We are currently conducting a Phase 1 clinical trial for our product candidate OTX-TKI for the treatment of wet AMD in Australia, and we plan to initiate a Phase 2 clinical trial for OTX-TKI in Australia in mid-2021. We generally plan to conduct our later stage and pivotal clinical trials of our 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, but we were unable to start dosing patients until 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;
- actual or threatened public health emergencies or outbreaks of disease (including, for example, the COVID-19 pandemic);
- 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 Phase 3 clinical trial of OTX-TP exceeded its target enrollment of 550 patients at approximately 49 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, 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).

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 local programmed-release hydrogel-based 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. Our collaboration with Regeneron focuses on the development and potential commercialization of products to be delivered to the suprachoroidal space 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. For example, as part of our restructuring plan announced in November 2019, we 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 inflammation and pain 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 prioritization of these programs, at the expense of others, during our restructuring may have delayed programs such as OTX-CSI and OTX-DED that we are now seeking to develop. Although we believe such prioritization was the best use of our resources at the time, we may not have been correct. Further, 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. For example, between March 2015 and May 2018, we received several Form 483s from the FDA containing inspectional observations relating to inadequate procedures for documenting follow-up information pertinent to the investigation of complaints and for evaluation of complaints for adverse event reporting; process controls, analytical testing and physical security procedures related to manufacture of our drug product for stability and commercial production purposes; and procedures for manufacturing processes and analytical testing related to the manufacture of drug product for commercial production. In each of July 2016 and July 2017, we also received a Complete Response Letter, or CRL, from the FDA regarding our NDA for DEXTENZA pertaining to, among other things, the deficiencies in manufacturing processes, controls, and analytical testing identified during pre-NDA approval inspections of our manufacturing facility documented on Form 483s. 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 $27.5 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 our supply of the 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 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 focuses on ambulatory surgical centers responsible for the largest volumes of cataract surgery. Previously, 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 also intend to 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, distribution or other marketing arrangements, including our collaboration with Regeneron, 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 lack of adequate number 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 as a device 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. 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. 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. Separately, a CPT procedure code has been established to facilitate reimbursement for physicians for the procedure of inserting DEXTENZA into the canaliculus. 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 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. We and Regeneron amended this agreement in May 2020 to, among other things, transition joint efforts under the collaboration to the research and development of an extended-delivery formulation of aflibercept to be delivered to the suprachoroidal space. We refer to the collaboration, option and license agreement, as amended to date, as the Collaboration Agreement.

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 it. We did not receive any upfront payment under the Collaboration Agreement. Regeneron has agreed to pay personnel and material costs for specified preclinical development activities under the collaboration, and 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. As amended, the option is now exclusive until May 8, 2022, twenty-four months from the effective date of the amendment. 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 intravitreal implant product candidates developed pursuant to the Collaboration Agreement 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 collaborations with Regeneron and AffaMed, 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 collaborations with Regeneron and AffaMed pose, 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 have conducted 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 was 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 on third parties, such as CROs, to conduct clinical trials of certain of our product candidates, including DEXTENZA for the treatment of ocular itching associated with allergic conjunctivitis, and we may continue to do so. 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. For example, in May 2020, we disclosed the receipt of interim data regarding our ongoing Phase 1 clinical trial of OTX-TKI for the potential treatment of wet AMD and other retinal diseases. In July 2020, however, we received further, and partially contradictory, information from the clinical trial site where certain patients were being treated. As the clinical trial site had not entered certain data concerning these patients into the clinical trial database in a timely manner, complete information was not available to or known by us at the time of our prior disclosures. 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 a significant portion of the patent rights and 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 decided to proceed with the administrative proceeding related to one of the patents while declining to do so for the other. In June 2020, the PTAB, after an *inter partes* review, determined that we had proven by a preponderance of the evidence that all claims of such patent at issue held by such third party were invalid; the third party has appealed this decision. We continue to believe that DEXTENZA does not infringe the claims of the remaining patent and that, if and to the extent it were asserted against DEXTENZA, such patent would be subject to a claim of invalidity. We have become aware that the USPTO has recently allowed a patent application filed by this third party related to intracanalicular inserts containing dexamethasone. If, upon issuance of this patent application as a patent, it were asserted against DEXTENZA or other of our product candidates, we believe such patent 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 a significant portion of our patent rights and 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 CRLs from the FDA. 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, including certain jurisdictions covered by our AffaMed collaboration, 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. Following protracted negotiations, the United Kingdom left the European Union on January 31, 2020. Under the withdrawal agreement, there is a transitional period until December 31, 2020 (extendable up to two years). Discussions between the United Kingdom and the European Union have so far mainly focused on finalizing withdrawal issues and transition agreements but have been extremely difficult to date. To date, only an outline of a trade agreement has been reached. Much remains open but the Prime Minister has indicated that the United Kingdom will not seek to extend the transitional period beyond the end of 2020. If no trade agreement has been reached before the end of the transitional period, there may be significant market and economic disruption. The Prime Minister has also indicated that the UK will not accept high regulatory alignment with the EU.

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. In December 2019, we submitted the protocol for the agreed-upon retrospective study and the prospective study outline, as required per the terms of the

warning letter. We received feedback from the FDA in February 2020 and responded to the FDA in March 2020. In May 2020, the FDA approved the protocol. Subsequently, we received a close-out letter from the FDA dated September 2, 2020.

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.

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. On April 27, 2020, the United States Supreme Court reversed this decision.

In addition, 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. The Trump Administration recently represented to the United States Court of Appeals considering this judgment that it does not oppose the lower court's ruling. On July 10, 2019, the United States Court of Appeals for the Fifth Circuit heard oral argument in this case. On December 18, 2019, that court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. The United States Supreme Court has scheduled oral arguments for this case for November 10, 2020.

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 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 2020 contained further drug price control measures that could be enacted 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 would 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. For example, on December 23, 2019, the Trump Administration published a proposed rulemaking that, if finalized, would allow states or certain other non-federal government entities to submit importation program proposals to FDA for review and approval. Applicants would be required to demonstrate their importation plans pose no additional risk to public health and safety and will result in significant cost savings for consumers. At the same time, FDA issued draft guidance that would allow manufacturers to import their own FDA-approved drugs that are authorized for sale in other countries (multi-market approved products).

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.

As we expand our operations outside of the United States, such as we have begun to do with our collaboration with AffaMed, 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.

Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition.

Recent changes in tax law may adversely affect our business or 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, contained 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, or NOLs, to 80% of current year taxable income and elimination of NOL carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely), the imposition of 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), the allowance of immediate deductions for certain new investments instead of deductions for depreciation expense over time, and the modification or repeal many business deductions and credits.

As part of Congress' response to the COVID-19 pandemic, the Families First Coronavirus Response Act, or FFCR Act, was enacted on March 18, 2020, and the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, was enacted on March 27, 2020. Both contain numerous tax provisions. In particular, the CARES Act retroactively and temporarily (for taxable years beginning before January 1, 2021) suspends application of the 80%-of-income limitation on the use of NOLs, which was enacted as part of the 2017 Tax Act. It also provides that NOLs arising in any taxable year beginning after December 31, 2017, and before January 1, 2021 are generally eligible to be carried back up to five years. The CARES Act also temporarily (for taxable years beginning in 2019 or 2020) relaxes the limitation of the tax deductibility for net interest expense by increasing the limitation from 30 to 50% of adjusted taxable income.

Regulatory guidance under the 2017 Tax Act, the FFCR Act and the CARES Act is and continues to be forthcoming, and such guidance could ultimately increase or lessen impact of these laws on our business and financial condition. It is also likely that Congress will enact additional legislation in connection with the COVID-19 pandemic,

some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to the 2017 Tax Act, the FFCR Act or the CARES Act.

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

As of December 31, 2019, we had federal and state NOL carryforwards of $274.3 million, of which $126.2 million begin to expire in 2024 . We also have state NOL carryforwards of $219.4 million, which begin to expire in 2024. As of December 31, 2019, we also had federal research and development tax credit carryforwards of $8.2 million and state research and development tax credit carryforwards $4.3 million, which begin to expire in 2026 and 2025, respectively. These NOL and tax credit carryforwards could expire unused and be unavailable to offset our future income tax liabilities. As described above under the heading "*Changes in tax laws or in their implementation or interpretation may adversely affect our business and financial condition*," the 2017 Tax Act, as amended by the CARES Act, includes changes to U.S. federal tax rates and the rules governing NOL carryforwards that may significantly impact our ability to utilize our NOLs to offset taxable income in the future. Nor is it clear how various states will respond to the 2017 Tax Act, the FFCR Act or the CARES Act. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

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 inflammation and pain 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 completed the restructuring and recorded 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 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, Massachusetts to accommodate our growth. We are evaluating expanding our manufacturing operations into 15 Crosby Drive, Bedford, Massachusetts while maintaining our existing operations located at 36 Crosby Drive, Bedford, Massachusetts. 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 was appealed to the United States Court of Appeals for

the First Circuit, and the First Circuit affirmed the dismissal in April 2020. The plaintiffs did not seek review of the First Circuit's decision prior to the deadline for filing a petition for a writ of certiorari in the United States Supreme Court.

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 on October 20, 2020, the parties filed a joint stipulation and proposed order voluntarily dismissing the action without prejudice. 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 and on October 16, 2020, the parties filed a joint stipulation and proposed order voluntarily dismissing the action without prejudice. 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 and on October 26, 2020, the parties filed a joint stipulation and proposed order voluntarily dismissing the action without prejudice. The court signed this proposed order on October 28, 2020. 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, political and social, 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 a "smaller reporting company" and the reduced disclosure requirements applicable to such companies may make our common stock less attractive to investors.

We are 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. 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;
- reduced disclosure obligations regarding executive compensation;
- 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 expect to continue to take advantage of some or all of the available exemptions until we cease to be a smaller reporting company.

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.

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 since January 1, 2020, when we ceased to be an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, 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.

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. On January 1, 2020, we became subject to the requirement to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm because we were no longer an emerging growth company. Although the SEC provided smaller reporting companies relief from this requirement in March 2020, to maintain compliance with Section 404, we will continue to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will 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 neither we nor, if required, our independent registered public accounting firm will 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 or our independent registered public accounting firm 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

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

Purchase of Equity Securities

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

Item 5. Other Items.

On November 2, 2020, our board of directors appointed Patricia Kitchen to the role of Chief Operating Officer, effective immediately.

Ms. Kitchen, 42, previously served as our Chief Operations Officer, a role she was appointed to on June 28, 2019. Ms. Kitchen previously served as Head of Technical Services for the United States and Rest of World of Mundipharma International Limited, a pharmaceutical company, from April 2016 to June 2019. Prior to joining Mundipharma International Limited, she served as Director of Technical and Scientific Affairs of Teva Pharmaceuticals Ltd., a pharmaceutical company specializing in generic medicines, from 2014 to April 2016. Ms. Kitchen received a B.S. in Biology and a B.A. in Secondary Education from Arizona State University.

Ms. Kitchen has no family relationships with any of our directors, executive officers or persons nominated or chosen by us to become a director or executive officer. Ms. Kitchen does not have any direct or indirect interest in any related person transactions required to be disclosed pursuant to Item 404(a) of Regulation S-K.

In connection with her new role as Chief Operating Officer, Ms. Kitchen will no longer serve as our Chief Operations Officer. Ms. Kitchen remains party to her existing employment agreement, a copy of which has been filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q for the three months ended March 31, 2020, filed with the Securities and Exchange Commission, or SEC, on May 8, 2020, and to our standard form of indemnification agreement, a copy of which has been filed as Exhibit 10.12 to our Registration Statement on Form S-1 (File No. 333-196932) filed with the SEC on June 20, 2014. Pursuant to the terms of her indemnification agreement, we may be required, among other things, to indemnify Ms. Kitchen for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by her in any action or proceeding arising out of her service as one of our officers.

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*	License Agreement, by and between the Registrant and AffaMed Therapeutics Limited, dated October 29, 2020.					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	Inline XBRL Instance Document (the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document)					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Database					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
104	The cover page from this Quarterly Report on Form 10-Q, formatted in Inline XBRL and contained in Exhibit 101					X

* Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

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 5, 2020

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

Exhibit 10.1

EXECUTION VERSION
CONFIDENTIAL

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

LICENSE AGREEMENT

BY AND BETWEEN

OCULAR THERAPEUTIX, INC.

AND

AFFAMED THERAPEUTICS LIMITED

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LIST OF EXHIBITS

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (this "Agreement") is made and entered into as of October 29, 2020, ("Effective Date") between Ocular Therapeutix, Inc., a corporation organized and existing under the laws of Delaware with a principal place of business at 24 Crosby Drive Bedford, MA 01730 ("Ocular"), and AffaMed Therapeutics Limited a Corporation duly organized and existing under the laws of Hong Kong, with a principal place of business at Room 3306-3307, Two Exchange Square, 8 Connaught, Hong Kong ("Licensee").

Ocular and Licensee may be referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, Ocular is the owner of, or otherwise controls, the Ocular Technology in the Territory (each as defined below);

WHEREAS, Ocular has expertise in the development of biopharmaceutical products and desires to further Develop and Manufacture the Licensed Products to enable Licensee's Commercialization thereof (each as defined below);

WHEREAS, Licensee has commercial capabilities in the Territory, and is interested in obtaining an exclusive license to Develop and Commercialize the Licensed Products in the Territory; and

WHEREAS, the Parties desire to collaborate to Develop and Commercialize the Licensed Products in the Territory;

NOW THEREFORE, the Parties agree as follows:

ARTICLE I

DEFINITIONS

Section 1.01 "AC" means allergic conjunctivitis.

Section 1.02 "Accounting Standards" means, United States Generally Accepted Accounting Principles or International Financial Reporting Standards, as applicable, in each case, consistently applied.

Section 1.03 "Affiliate" means, with respect to an entity, any corporation or other business entity controlled by, controlling, or under common control with such entity, with "control" meaning (a) direct or indirect beneficial ownership of at least fifty percent (50%) of the voting stock of, or at least a fifty percent (50%) interest in the income of, the applicable entity (or such lesser percentage that is the maximum allowed to be owned by a foreign entity in a particular jurisdiction and is sufficient to grant the holder of such voting stock or interest the

power to direct the management and policies of such entity) or (b) possession, directly or indirectly, of the power to direct the management and policies of an entity, whether through ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise. Notwithstanding the foregoing, CBC Group and its portfolio companies shall not be deemed Affiliates of Licensee.

Section 1.04 "API" means active pharmaceutical ingredient.

Section 1.05 "Arising IP" means any invention (whether patentable or not) conceived, reduced to practice, authored, created or developed (a) solely by or on behalf of a Party or any of its Affiliates or (b) jointly by or on behalf of the Parties or any of their Affiliates in the course of its activities under this Agreement during the Term ("Joint Arising IP").

Section 1.06 "Arising Patent Rights" means Patent Rights claiming Arising IP.

Section 1.07 "Arising Product IP" means any Arising IP that specifically relates to any Licensed Product, including any method of use therefor and is not generally applicable to compounds and products. Arising Product IP includes the Licensee Product Data.

Section 1.08 "Arising Product Patent Rights" means Patent Rights claiming Arising Product IP.

Section 1.09 "Business Day" means a day other than (a) a Saturday or a Sunday or (b) a day on which banking institutions in Boston, Massachusetts, or in Beijing, China are authorized or required by Law to remain closed.

Section 1.10 "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

Section 1.11 "Calendar Year" means the respective periods of twelve (12) months commencing on January 1 and ending on December 31.

Section 1.12 "Change in Control" means, as to a Party, the (i) consolidation or merger of such Party with or into any person or entity as a result of which the beneficial owners of the outstanding voting securities or other ownership interests of such Party immediately prior to such transaction have beneficial ownership of fifty percent (50%) or less of the outstanding voting securities or other ownership interests of such surviving person or entity immediately following such transaction, or (ii) sale, transfer or other disposition of all or substantially all of the assets of such Party related to this Agreement, or (iii) acquisition by any person or entity, or group of persons or entities acting in concert, of beneficial ownership of fifty percent (50%) percent or more of the outstanding voting securities or other ownership interests of such Party or the power, directly or indirectly, to elect a majority of the members of such Party's board of directors or similar governing body, or (iv) acquisition by any person or entity, or group of persons or entities acting in concert, of the power to direct the management or policies of such Party.

Section 1.13 "Clinical Trial" means any clinical study involving the administration of a product to a human subject for the purpose of evaluating the safety, efficacy, performance or other characteristic of such product.

Section 1.14 "Commercialization" or "Commercialize" means, with respect to a pharmaceutical product, any and all activities directed to the marketing, promotion, importation, distribution, pricing, Reimbursement Approval, offering for sale, or sale of such pharmaceutical product, and interacting with Regulatory Authorities regarding the foregoing. Commercialization shall exclude Manufacturing.

Section 1.15 "Commercially Reasonable Efforts" means, with respect to the performing Party under this Agreement, the carrying out of obligations of such Party in a diligent, expeditious and sustained manner with efforts and resources that are consistent with the efforts and resources typically used by biopharmaceutical companies of similar size and resources as such Party in the exercise of its commercially reasonable business practices with respect to the Development, Manufacture or Commercialization of products (as applicable) that are wholly owned by such biopharmaceutical companies and having market potential, profit potential and strategic value and of a stage in Development or product life comparable to that of Licensed Product(s), including reasonably necessary personnel, based on conditions then prevailing and taking into account issues of safety and efficacy, product profile, difficulty in Developing such Licensed Product, competitiveness of alternative Third Party products in the marketplace, the patent or other proprietary position of such Licensed Product, the regulatory structure involved and the potential profitability of such Licensed Product, as applicable.

Section 1.16 "Competing Product" means: (a) for DEXTENZA, any product that is directly competitive with DEXTENZA, including any biopharmaceutical product intended for the same indications in the Field as DEXTENZA; and (b) for OTX-TIC, any product that is administered as a intracameral insert, is intended for the same indication in the Field as OTX-TIC, is directed to the same biological target as OTX-TIC and has the same mechanism of action as OTX-TIC.

Section 1.17 "Confidential Information" means, subject to Section 12.02(a)-(d), Know-How and any technical, scientific, trade, research, manufacturing, business, financial, marketing, product, supplier, intellectual property or other information that may be disclosed by one Party or any of its Affiliates to the other Party or any of its Affiliates, regardless of whether such information is specifically designated as confidential and regardless of whether such information is in written, oral, electronic, or other form. Notwithstanding the foregoing, subject to Section 12.02(a)-(d), all information that (a) was disclosed prior to the Effective Date by or on behalf of either Party or any of its Affiliates under, and subject to, the Mutual Confidentiality and Non-Disclosure Agreement between the Parties with an effective date of [**] ("Confidentiality Agreement") and (b) is "Confidential Information" as defined in the Confidentiality Agreement, shall be deemed "Confidential Information" hereunder.

Section 1.18 "Controlled" means, subject to Section 2.06 and Section 16.02, with respect to a Party, any Know-How, Patent Right, Regulatory Documents or other intellectual property right, that such Party or any of its Affiliates has the ability (other than pursuant to a

license granted to such Party under this Agreement) to grant to the other Party a license or sublicense to, or other right with respect to, such Know-How, Patent Right, Regulatory Documents or other intellectual property right without violating the terms of any pre-existing agreement with any Third Party.

Section 1.19 "Cover", "Covering" or "Covered" means, with respect to a product, composition, technology, process or method and a Patent Right, that, in the absence of ownership of, or a license granted under, a claim in such Patent Right, the manufacture, use, offer for sale, sale or importation of such product or composition or the practice of such technology, process or method would infringe such claim (or, in the case of a claim of a pending patent application, would infringe such claim if it were to issue as a claim of an issued patent).

Section 1.20 "Development" means formulation, pre-clinical and clinical development activities, including (i) Clinical Trials of such pharmaceutical compound or product and (ii) preparation, submission, review, and development of data or information for the purpose of submission to a Regulatory Authority to obtain authorization to conduct clinical trials or obtain Regulatory Approval of such pharmaceutical product. Development shall include Clinical Trials initiated following receipt of Regulatory Approval, but shall exclude Manufacturing and Commercialization.

Section 1.21 "Development Plan" means the plan setting out activities to be undertaken in Developing the Licensed Products in the Field in the Territory, together with estimated timelines for such activities, including the proposed clinical trials, registry studies and regulatory plans, as well as outlining the key elements involved in obtaining Regulatory Approval of the Licensed Products in the Field in the Territory, as may be amended from time to time in accordance with Section 4.01, which plan shall include in reasonable detail (a) Development activities reasonably anticipated to be undertaken by the Ocular Entities with respect to the Licensed Products in the Field in the Territory, (b) Development activities required to be undertaken by the Licensee Entities, (c) the endpoints for all clinical trials contemplated by such plan, and (d) regulatory activities and interactions anticipated to be conducted by the Ocular Entities in support of Regulatory Approval of the Licensed Products in the Field in the Territory, including planned Regulatory Filings to be submitted in connection with such approvals.

Section 1.22 "DEXTENZA" means an ophthalmic insert containing 0.4 mg of dexamethasone for intracanalicular use in the treatment of ocular inflammation and pain following ophthalmic surgery and the treatment of allergic conjunctivitis.

Section 1.23 "Dollars" or "$" means the legal tender of the United States.

Section 1.24 "Drug Approval Application" means a New Drug Application as defined in the FD&C Act, or an equivalent application filed with any Regulatory Authority in any country other than the United States.

Section 1.25 "Existing In-License Agreement" means the [**] Agreement between [**] and Ocular dated [**].

Section 1.26 "FDA" means the U.S. Food and Drug Administration or any successor agency thereto.

Section 1.27 "FD&C Act" means the U.S. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time.

Section 1.28 "Field" means, (a) with respect to DEXTENZA, post-operative / cataract surgery and allergic conjunctivitis; and (b) with respect to OTX-TIC, open angle glaucoma and ocular hypertension.

Section 1.29 "First Commercial Sale" means, with respect to a product in a Jurisdiction, the first sale for end use or consumption of such product in such Jurisdiction in an arms' length transaction to a Third Party following receipt of applicable Regulatory Approval of such product in such Jurisdiction. Sales for test marketing or clinical trial purposes shall not constitute a First Commercial Sale.

Section 1.30 "Functional Sublicensee" means a Third Party distributor or distribution service provider in any Jurisdiction in the Territory that (a) is not a Sublicensee and (b) makes any upfront, royalty, or other payments (other than or in addition to payments for supply of Licensee Products) to Licensee or any of its Affiliates or Sublicensees with respect to any Licensee Product or performs material Commercialization activities beyond the mere distribution of Licensed Products.

Section 1.31 "Generic Product" means, as to a Licensed Product, any pharmaceutical product that (a) contains the same active pharmaceutical ingredient as such Licensed Product; (b) is sold by a Third Party that is not a licensee or Sublicensee of Licensee or any of its Affiliates and that has not otherwise been authorized by Licensee or any of its Affiliates, under a Regulatory Approval granted by a Regulatory Authority to such Third Party pursuant to an abbreviated Regulatory Approval process that is based upon or relies upon the Regulatory Approval granted by such Regulatory Authority for the Licensed Product; and (c) is lawfully substitutable for the Licensed Product.

Section 1.32 "Global Brand Strategy" means the global brand strategy that determines, among other aspects, product positioning, market access strategies, messaging strategies, trademark layout and logos, all as determined by Ocular for Licensed Products and updated from time to time and provided to Licensee.

Section 1.33 "Global Medical Affairs Strategy" means the global Medical Affairs strategy for Licensed Products, as determined by Ocular and updated from time to time and provided to Licensee.

Section 1.34 "Global Study" means any clinical trial for any Licensed Product that (a) is conducted, in whole or in part, by any Ocular Entity and (b) is designed to be sufficient to support Regulatory Approval by the FDA or the EMA, at a minimum.

Section 1.35 "Good Clinical Practices" or "GCP" means the then-current good clinical practice standards, practices, and procedures promulgated or endorsed by any applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time to time.

Section 1.36 "Good Laboratory Practices" or "GLP" means the then-current good laboratory practice standards, practices, and procedures promulgated or endorsed by any applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time to time.

Section 1.37 "Good Manufacturing Practices" or "GMP" means the then-current good manufacturing practice standards, practices, and procedures promulgated or endorsed by any applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time to time.

Section 1.38 "Good Pharmacovigilance Practices" or "GVP" means the then-current good pharmacovigilance practice standards, practices, and procedures promulgated or endorsed by any applicable Regulatory Authority as set forth in the guidelines imposed by such Regulatory Authority, as may be updated from time to time.

Section 1.39 "Governmental Authority" means any federal, national, multinational, state, provincial, country, city or local government or any court, arbitrational tribunal, administrative agency or commission or government authority acting under the authority of any federal, national, multinational, state, provincial, country, city or local government.

Section 1.40 "IND" means an Investigational New Drug application for submission to the FDA or any equivalent counterpart application in any country other than the United States (including, e.g., a clinical trial application in Mainland China), including all supplements and amendments thereto.

Section 1.41 "Indication" means the intended use of a product for the treatment, control, mitigation, prevention or cure of a distinct recognized human disease or condition, or of a manifestation of a recognized human disease or condition, or for the relief of symptoms associated with a recognized human disease or condition.

Section 1.42 "Initial Development Outline" means the initial outline of the development strategy for the Licensed Product in the Territory attached hereto as Exhibit B.

Section 1.43 "In-License Agreement" means any agreement between Ocular or any of its Affiliates, on the one hand, and one or more Third Parties, on the other hand, entered into prior to or after the Effective Date pursuant to which Ocular acquires Control of any Know-How or Patent Right that Covers the Development, Manufacture or Commercialization of any Licensed Product in the Field in the Territory, that Licensee has accepted as an In-License Agreement under Section 2.06, including the Existing In-License Agreement.

Section 1.44 "Joint Global Study" means a Global Study which includes clinical sites in the Territory and is designed to be sufficient to support Regulatory Approval in Greater China, for which Licensee elects to participate pursuant to Section 4.01(c) and is responsible for paying a portion of costs as set forth in Section 4.02(b).

Section 1.45 "Jurisdiction" means each of the following: Mainland China, Taiwan, Hong Kong, Macau ("collectively, "Greater China"), South Korea, Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand and Vietnam.

Section 1.46 "Know-How" means inventions (whether patentable or not), discoveries, trade secrets, technology, information, Regulatory Documents, formulae, practices, methods, knowledge, know-how, processes, procedures, experience, results and test data (including physical, chemical, biological, toxicological, pharmacological, clinical, veterinary, analytical and quality control data), dosage regimens, control assays, product specifications, manufacturing, and marketing, pricing, distribution cost and sales data and descriptions; but excluding Patent Rights.

Section 1.47 "Law" means any law, statute, rule, regulation, order, judgment, standard or ordinance of any Governmental Authority.

Section 1.48 "Licensed Product" means each of (a) DEXTENZA in the form of dexamethasone formulated in an intracanalicular insert, and (b) OTX-TIC in the form of a sustained release travoprost intracameral insert. For clarity, any other Ocular products are not Licensed Products.

Section 1.49 "Licensee Entity" means, as applicable, (a) Licensee, (b) any of Licensee's Affiliates or (c) any Sublicensee or Subcontractor of Licensee with respect to any Licensed Product.

Section 1.50 "Licensee Know-How" means all Know-How that is: (a) Controlled as of the Effective Date or during the Term by Licensee or any of its Affiliates; and (b) necessary for the Development, Manufacture or Commercialization of any Licensed Product; and (c) incorporated or generated by Licensee in the Development or Commercialization of the Licensed Product; but excluding all Arising Product IP assigned by Licensee to Ocular pursuant to Section 9.01(c).

Section 1.51 "Licensee Patent Rights" means all Patent Rights that: (a) are Controlled as of the Effective Date or during the Term by Licensee or any of its Affiliates; and (b) Cover any Licensed Product or their respective Development, Manufacture or Commercialization; and (c) are incorporated or generated by Licensee in the Development or Commercialization of the Licensed Product; but excluding Arising Product Patent Rights assigned to Licensee pursuant to Section 9.01(c).

Section 1.52 "Licensee Sole Arising Patent Rights" means Patent Rights claiming Arising Product IP conceived, reduced to practice, authored, created or developed solely by or on behalf of Licensee or any of its Affiliates.

Section 1.53 "Licensee Technology" means Licensee Know-How and Licensee Patent Rights.

Section 1.54 "Local Study" means any Territory-specific registrational studies that are conducted by a Licensee Entity or, to the extent set forth in Section 4.01(b), by an Ocular Entity, in the Territory with respect to the Licensed Product; but excluding all Global Studies.

Section 1.55 "Mainland China" means China excluding Taiwan, Hong Kong and Macau.

Section 1.56 "Manufacture" or "Manufacturing" means, as applicable, all activities associated with the production, manufacture, process of formulating, processing, filling, finishing, packaging, labeling, shipping, importing or storage of pharmaceutical compounds or materials, including process development, process validation, stability testing, manufacturing scale-up, pre-clinical, clinical and commercial manufacture and analytical development, product characterization, quality assurance and quality control development, testing and release.

Section 1.57 "Medical Affairs" means matters relating to information services; publication, scientific and medical affairs; advisory and collaborative activities with opinion leaders and professional societies including medical education, symposia and other medical programs and communications; but excluding other Development activities.

Section 1.58 "NDA" means a New Drug Application (as more fully described in 21 C.F.R. 314.50 et seq. or its successor regulation) and all amendments and supplements thereto filed with the FDA, or any equivalent filing in a country or jurisdiction other than the United States.

Section 1.59 "Net Sales" means the amount received for the sale of a particular Licensed Product to a Third Party (other than a Licensee Entity) by Licensee or any of its Affiliates, Sublicensees or Functional Sublicensees for consideration, reduced by the following amounts to the extent such items are customary under industry practices and to the extent such amounts are included in the gross sales price, all as calculated in accordance with Accounting Standards, consistently applied:

(a) discounts (including trade, quantity and cash discounts) actually allowed, cash and non-cash coupons, retroactive price reductions, and charge-back payments and rebates granted to any Third Party (including to governmental authorities, purchasers, reimbursers, customers, distributors, wholesalers, and group purchasing and managed care organizations or entities (and other similar entities and institutions));

(b) credits or allowances, if any, on account of price adjustments, recalls, claims, damaged goods, rejections or returns of items previously sold (including Licensed Product returned in connection with recalls or withdrawals) and amounts written off by reason of uncollectible debt; provided that, if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it is paid;

(c) rebates (or their equivalent), chargebacks and retroactive price adjustments and any other similar allowances granted by a Licensee Entity (including to governmental authorities, purchasers, reimbursers, customers, distributors, wholesalers, and group purchasing and managed care organizations and entities (and other equivalent entities and institutions)) which effectively reduce the selling price or gross sales of the Licensed Product;

(d) insurance, customs charges, freight, postage, shipping, handling, and other transportation costs incurred by a Licensee Entity in shipping Licensed Product to a Third Party; and

(e) to the extent separately stated on purchase orders, invoices or other documents of sale, any sales or use tax, value added tax, goods and services tax, or similar tax, levied directly on the sale of a Licensed Product, that are paid to the taxing authority by or on behalf of a Licensee Entity, but excluding any taxes paid on the income from such sales.

If non-monetary consideration is received by a Licensee Entity for any Licensed Product in the relevant Jurisdiction, Net Sales will be calculated based on the average price charged for such Licensed Product, as applicable, during the preceding royalty period, or in the absence of such sales, the fair market value of the Licensed Product, as applicable, as determined by the Parties in good faith. Notwithstanding the foregoing, Net Sales shall not be imputed to transfers of Licensed Products, as applicable, for use in clinical trials, non-clinical development activities or other development activities with respect to Licensed Products by or on behalf of the Parties, for bona fide charitable purposes or for compassionate use or for Licensed Product samples, if no monetary consideration is received for such transfers.

Section 1.60 "NMPA" means the National Medical Product Administration of China (formerly known as the China Food and Drug Administration), including its divisions and the Center for Drug Evaluation, and local counterparts thereto, and any successor agency or authority thereto having substantially the same function.

Section 1.61 "Ocular Entity" means, as applicable, (a) Ocular, (b) any of Ocular's Affiliates or (c) any direct or indirect licensee, sublicensee or contractor of Ocular with respect to any Licensed Product.

Section 1.62 "Ocular Know-How" means all Know-How that is both (a) Controlled as of the Effective Date or during the Term by Ocular or any of its Affiliates and (b) necessary or reasonably useful for the Development, Manufacture or Commercialization of any Licensed Product in the Field in the Territory.

Section 1.63 "Ocular Patent Rights" means all Patent Rights that both (a) are Controlled as of the Effective Date or during the Term by Ocular or any of its Affiliates in the Territory, and (b) Cover any Licensed Product, or its Development, Manufacture or Commercialization, in the Field in the Territory. Ocular Patent Rights as of the Effective Date include those listed in Exhibit A.

Section 1.64 "Ocular Regulatory Documents" means Regulatory Documents Controlled by Ocular or any of its Affiliates as of the Effective Date or at any time during the Term that relate to a Licensed Product.

Section 1.65 "Ocular Technology" means Ocular Know-How and Ocular Patent Rights, including Arising IP assigned to Ocular by Licensee pursuant to Section 9.01(c).

Section 1.66 "OTX-TIC" means a bioresorbable intracameral implant containing micronized travoprost that is injected into the anterior chamber of the eye for the treatment of glaucoma.

Section 1.67 "Patent Rights" means (a) all patents and patent applications (including provisional applications) in any country or jurisdiction, and (b) any substitutions, divisions, continuations, continuations-in-part, reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like.

Section 1.68 "Phase 1 Clinical Trial" means a Clinical Trial, or the relevant portion of such trial, of a product in patients in or for any Jurisdiction that would satisfy the requirements of applicable Laws for such Jurisdiction in which such Clinical Trial is conducted, such as 21 C.F.R. § 312.21(a), relating to Clinical Trials conducted in the United States, or any successor regulation thereto or foreign equivalents.

Section 1.69 "Phase 2 Clinical Trial" means a Clinical Trial, or the relevant portion of such trial, conducted in patients with a product in or for any Jurisdiction that would satisfy the requirements of applicable Laws of the country in which such Clinical Trial is conducted, such as 21 C.F.R. § 312.21(b), relating to Clinical Trials conducted in the United States, or any successor regulation thereto or foreign equivalents.

Section 1.70 "Phase 3 Clinical Trial" means a Clinical Trial, or the relevant portion of such trial, in or for any Jurisdiction that would satisfy the requirements of applicable Laws of the country in which such Clinical Trial is conducted, such as 21 C.F.R. § 312.21(c), relating to Clinical Trials conducted in the United States, or any successor regulation thereto or foreign equivalents.

Section 1.71 "POAG and OHT" means primary open angle glaucoma and ocular hypertension.

Section 1.72 "POPI" means post-operative pain and inflammation.

Section 1.73 "Product Materials" means tangible Licensed Products.

Section 1.74 "Regulatory Approval" means, with respect to a particular regulatory jurisdiction, any approval, product or establishment license, registration or authorization of any Governmental Authority (other than any Reimbursement Approval) necessary for the commercial sale of a pharmaceutical product in such regulatory jurisdiction.

Section 1.75 "Regulatory Authority" means, in a particular country or jurisdiction, any applicable Governmental Authority involved in granting Regulatory Approval in such country or jurisdiction, including (a) in the United States, the FDA and any other applicable Governmental Authority in the United States having jurisdiction over pharmaceutical products, (b) in the European Union, the European Medicines Agency ("EMA"), (c) in Mainland China, the NMPA and (d) any other applicable Governmental Authority in the Territory having jurisdiction over pharmaceutical products.

Section 1.76 "Regulatory Documents" means all (a) applications (including all INDs and Drug Approval Applications), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, advertising and promotion documents, adverse event files and complaint files; and (c) preclinical, clinical and other data results, analyses, publications, and reports contained or referred to in any of the foregoing; in each case ((a), (b) and (c)) relating to a Licensed Product. For the avoidance of doubt, Regulatory Documents include Regulatory Approvals and Regulatory Filings.

Section 1.77 "Regulatory Exclusivity" means, with respect to any Jurisdiction, an additional market protection, other than patent protection, granted by a Regulatory Authority in such Jurisdiction which confers an exclusive Commercialization period during which Licensee Entities have the exclusive right to market and sell the Licensed Product in such Jurisdiction through a regulatory exclusivity right (e.g., new drug entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity, or any applicable data exclusivity).

Section 1.78 "Regulatory Filings" means all applications, filings, dossiers and the like submitted to a Regulatory Authority for the purpose of Developing, Manufacturing or Commercializing a product, including obtaining Regulatory Approval from that Regulatory Authority. Regulatory Filings include all INDs, Drug Approval Applications and other Regulatory Approval and Reimbursement Approval applications.

Section 1.79 "Reimbursement Approval" means an approval, agreement, determination, or other decision by any applicable Regulatory Authority or other Governmental Authority that establishes prices at which a pharmaceutical product may be priced, or will be reimbursed by the Regulatory Authorities or other applicable Governmental Authorities, in a particular country or jurisdiction.

Section 1.80 "Safety Data Exchange Agreement" means that agreement between the Parties regarding receipt, investigation and reporting of product complaints, adverse events, product recalls, and any other information related to the safety of the Licensed Products as set forth in Section 10.03.

Section 1.81 "Secondary Packaging" means grouped or display packaging of the Licensed Products for use in sales of multiple Licensed Product units, as distinguished from the primary packaging of Licensed Products units provided by Ocular to Licensee under the Supply Agreement.

Section 1.82 "Serialization" means a combination of systems and procedures that records the history of the chain of custody of the Finished Drug Product from Licensee Entity to the point the Finished Drug Product is dispensed.

Section 1.83 "Subcontractor" means a Third Party contractor engaged by a Party or its Affiliates to conduct certain activities of such Party under this Agreement on a fee-for-service basis, including (a) contract research organizations, (b) contract manufacturers, and (c) distributors and distribution service providers.

Section 1.84 "Sublicensee" means any Third Party to whom Licensee or any of its Affiliates or any Sublicensee grants a license or sublicense of Licensee's rights under Section 2.01(a)(ii), excluding all Subcontractors.

Section 1.85 "Supply Price" means: (a) for clinical supply, Ocular's cost of goods for the applicable Licensed Products; and (b) for commercial supply, [**] percent ([**]%) of Ocular's cost of goods for the applicable Licensed Products, provided that, in the case of commercial supply, the Supply Price shall not exceed (i) in the case of DEXTENZA, the greater of [**] percent ([**]%) of the Net Sales for DEXTENZA or Ocular's cost of goods therefor and (ii) in the case of OTX-TIC, the greater of [**] percent ([**]%) of the Net Sales for OTX-TIC or Ocular's cost of goods therefor.

Section 1.86 "Tax" means any present or future taxes, levies, imposts, duties, tariffs, charges, assessments or fees of any nature imposed by a Governmental Authority in the exercise of its taxing power (including interest, penalties and additions thereto), including value-added tax or any similar tax (including but not limited to sales, use, or goods and services tax) ("VAT") and withholding tax.

Section 1.87 "Territory" means any Jurisdiction, or, collectively, all Jurisdictions, as the context requires.

Section 1.88 "Third Party" means any person or entity other than the Parties and their respective Affiliates.

Section 1.89 "Trade Control Laws" shall refer to U.S. laws which prohibit or limit export, distribution or sales of goods from the United States and their re-export from other countries into certain countries, referred to as Sanctioned Countries. More specifically and for purpose of performing the Agreement, Trade Control Laws shall refer to the U.S. Export Administration Regulations and the economic sanctions, rules and regulations implemented under statutory authority or President's Executive Orders and administered by the U.S. Treasury Department's OFAC.

Section 1.90 "Trademark" means any trademark, trade name, service mark, service name, brand, domain name, trade dress, logo, slogan or other indicia of origin or ownership, including the goodwill and activities associated with each of the foregoing.

Section 1.91 "U.S." or "United States" means the United States of America, including its districts, territories and possessions.

Section 1.92 "Valid Claim" means (a) an issued and unexpired claim of any Patent Right that has not been rejected, revoked or held unenforceable, unpatentable or invalid by a decision of a court or other Governmental Authority of competent jurisdiction, which is not appealable or has not been appealed within the time allowed for appeal, and which has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue, re-examination or disclaimer or otherwise or (b) a claim of a pending patent application that is being actively prosecuted and that remains pending not later than [**] following the filing of the earliest patent application from which such claim derives priority and that has not been cancelled, withdrawn from consideration, abandoned, disclaimed, finally rejected or expired without the possibility of appeal or refiling.

Section 1.93 "Wholly Owned Subsidiary" means any Affiliate who is a subsidiary of a Party and one hundred percent (100%) of whose capital stock is at the applicable time owned by such Party and/or one or more Wholly Owned Subsidiaries of such Party.

Section 1.94

Additional Defined Terms	Section
AAA	Section 15.01
Achieved Milestone	Section 8.02(a)
Arising IP	Section 9.01(c)
Acquired Party	Section 16.02
Acquirer	Section 16.02
Agreement	Preamble
Alliance Manager	Section 3.09
Annual Net Sales	Section 8.04
Arbitration Request	Section 15.01(a)
Bankrupt Party	Section 14.03(a)
Breaching Party	Section 14.02
Breach Notice	Section 14.02
CMC	Section 2.04(a)
CRO	Section 3.01(c)
Committee	Section 3.01(b)
Confidentiality Agreement	Section 1.17
Current Ocular Information	Section 2.04(b)
Deductible VAT	Section 8.10(b)(i)
Distributor	Section 3.01(c)

Additional Defined Terms	Section
Effective Date	Preamble
EMA	Section 1.75
Event of Bankruptcy	Section 14.03(a)
Executive Officer	Section 3.05
Existing Acquirer Affiliates	Section 16.02
FCPA	Section 11.05(b)(i)
Government Official	Section 11.05(a)(A)
Greater China	Section 1.45
ICH	Section 10.02
[**]	Section 1.25
Indemnified Party	Section 13.03
Indemnifying Party	Section 13.03
Infringement Activity	Section 9.03
In-Market Release	Section 5.02(a)
JC	Section 3.01(a)
Joint Arising IP	Section 1.05
Licensee	Preamble
Licensee Directed Challenge Defense	Section 9.03(d)
Licensee Indemnitees	Section 13.01
Licensee Product Data	Section 2.05(a)
Losses	Section 13.01
Marketing Materials	Exhibit C, Section 1.03(a)
Non-Breaching Party	Section 14.02
Ocular	Preamble
Ocular Indemnitees	Section 13.02
Ocular Product Data	Section 2.04(b)
Ocular Prosecuted Patent Rights	Section 9.02(b)
Ocular Trademarks	Exhibit C, Section 2.01(a)
Ocular Web Presence	Exhibit C, Section 2.01(b)
Ocular Works	Exhibit C, Section 2.02(c)
Other Covered Party	Section 11.05(a)(B)
Other Party	Section 14.03(a)
Party or Parties	Preamble
Public Statement	Section 12.04
Qualifying Generic Competition	Section 8.05(a)
Recipient	Section 12.02
Regulatory Budget	Section 4.02(a)
Representatives	Section 12.01
Royalty Term	Section 8.04(b)
Rules	Section 15.01
Severed Clause	Section 17.03

Additional Defined Terms	Section
Supply Agreement	Section 7.01
Term	Section 14.01
Third Party Challenge	Section 9.03(c)
TTM Period	Section 8.03
VAT	Section 1.86

Section 1.95 Interpretation. (a) Whenever any provision of this Agreement uses the word “including,” “include,” “includes,” or “e.g.,” such word shall be deemed to mean “including without limitation” and “including but not limited to”; (b) “herein,” “hereby,” “hereunder,” “hereof” and other equivalent words shall refer to this Agreement in its entirety and not solely to the particular portion of this Agreement in which any such word is used; (c) a capitalized term not defined herein but reflecting a different part of speech from that of a capitalized term which is defined herein shall be interpreted in a correlative manner; (d) wherever used herein, any pronoun or pronouns shall be deemed to include both the singular and plural and to cover all genders; (e) the recitals set forth at the start of this Agreement, along with the schedules and the exhibits to this Agreement, and the terms and conditions incorporated in such recitals and schedules and exhibits, shall be deemed integral parts of this Agreement and all references in this Agreement to this Agreement shall encompass such recitals and schedules and exhibits and the terms and conditions incorporated in such recitals and schedules and exhibits; provided that, in the event of any conflict between the terms and conditions of the body of this Agreement and any terms and conditions set forth in the recitals, schedules or exhibits, the terms of the body of this Agreement shall control; (f) in the event of any conflict between the terms and conditions of this Agreement and any terms and conditions that may be set forth on any order, invoice, verbal agreement or otherwise, the terms and conditions of this Agreement shall govern; (g) this Agreement shall be construed as if both Parties drafted it jointly, and shall not be construed against either Party as principal drafter; (h) unless otherwise provided, all references to Sections, Articles and Schedules in this Agreement are to Sections, Articles and Schedules of and to this Agreement; (i) any reference to any Law shall mean such Law as in effect as of the relevant time, including all rules and regulations thereunder and any successor Law in effect as of the relevant time, and including the then-current amendments thereto; (j) wherever used, the word “shall” and the word “will” are each understood to be imperative or mandatory in nature and are interchangeable with one another; (k) references to a particular person or entity include such person’s or entity’s successors and assigns to the extent not prohibited by this Agreement; (l) references to Ocular’s knowledge shall be taken to refer to the knowledge of Ocular’s senior management team as of the Effective Date; (m) the captions and table of contents used herein are inserted for convenience of reference only and shall not be construed to create obligations, benefits or limitations; and (n) the word “or” shall be inclusive and not exclusive (i.e., “and/or”);.

ARTICLE II

LICENSES; EXCLUSIVITY

Section 2.01 Grant of Licenses.

(a) Subject to the terms and conditions of this Agreement, Ocular hereby grants to Licensee (i) a non-exclusive, royalty-free, non-sublicensable license under the Ocular Technology to use Licensed Products for activities required of Licensee under the Development Plan; and (ii) an exclusive (including as to Ocular and its Affiliates), royalty-bearing, sublicensable (solely in accordance with Section 2.02), non-transferable (except in accordance with Section 16.01) license under the Ocular Technology to use, sell, offer for sale, import, have imported, Commercialize and have Commercialized Licensed Products in the Field in the Territory in accordance with this Agreement. Ocular shall not, either by itself or through any of its Affiliates (excluding products of Ocular's Acquirers and Existing Acquirer Affiliates that were not Ocular products prior to the applicable Ocular Change in Control), (sub)licensees or contractors, Develop or Commercialize any Licensed Product outside the Field in the Territory, or Develop or Commercialize any product containing the same API (either alone or in combination with any other ingredient) and administered into the anterior chamber of the eye in the Territory, without first obtaining Licensee's prior written consent and granting Licensee the first right to do so.

(b) Subject to the terms and conditions of this Agreement, Licensee hereby grants to Ocular (i) an exclusive (including as to Licensee and its Affiliates), royalty-free, fully-paid-up, transferable, sublicensable, perpetual, irrevocable license under the Licensee Technology and its interest in the Joint Arising IP to Develop, Manufacture and Commercialize the Licensed Products outside the Territory; and (ii) from and after any early termination of this Agreement, an exclusive (including with regard to Licensee and its Affiliates), royalty-free, fully-paid-up, transferable, sublicensable, perpetual, irrevocable license under the Licensee Technology and its interest in the Joint Arising IP to Develop, Manufacture and Commercialize the Licensed Products in the Territory.

Section 2.02 Rights to Sublicense or Subcontract. Licensee may not sublicense to any Third Party any of the rights granted to Licensee by Ocular under Section 2.01(a) except with Ocular's prior written consent, provided that, upon Ocular's receipt of [**] consent in accordance with the Existing In-License Agreement, and subject to (i) compliance with and performance of any further actions required under Section 2.2 of the Existing In-License Agreement; and (ii) Licensee's compliance with Section 2.06, including with respect to the Existing In-License Agreement, or as otherwise directed by [**], Licensee may grant sublicenses to its Affiliates (after written notice to Ocular) under the license granted by Ocular to Licensee in Section 2.01(a)(ii). Notwithstanding the foregoing, in the event that Ocular is unable to obtain [**] consent in accordance with the foregoing sentence for Licensee's grant of a sublicense of any of the rights granted to Licensee by Ocular under Section 2.01(a) to its Affiliate, Ocular shall upon Licensee's written request grant a sublicense of the applicable rights directly to such Affiliate in accordance with the Existing In-License Agreement and this Agreement, provided that, for clarity, any

sublicense to a Third Party who is not Licensee's Affiliate shall remain subject to Ocular's prior written consent. Licensee shall have the right to engage Subcontractors for its activities under this Agreement. Licensee shall ensure that all Licensee Entities comply with all applicable provisions of this Agreement and shall remain responsible for the acts or omissions of all Licensee Entities with respect to this Agreement as if such acts or omissions were taken by Licensee hereunder.

Section 2.03 No Other Rights and Retained Rights. Nothing in this Agreement shall be interpreted to grant a Party any rights under any Patent Rights or Know-How Controlled by the other Party that are not expressly granted herein, whether by implication, estoppel or otherwise, and, notwithstanding the foregoing provisions of Section 2.01, neither Party grants any right or license in this Agreement to the other Party under Patent Rights or Know-How Controlled by the first Party with respect to APIs or drug products other than the Licensed Product. Any rights not expressly granted to a Party by the other Party under this Agreement are hereby retained by such other Party.

Section 2.04 Knowledge Transfer.

(a) Within [**] after the Effective Date, the Parties shall mutually agree on a technology transfer plan pursuant to which Ocular will make available to Licensee all material information then Controlled by the Ocular Entities and reasonably necessary or reasonably useful for Licensee's Development or Commercialization of the Licensed Products in the Field in the Territory. Provided that such technology transfer plan is completed and agreed within the foregoing [**], Ocular shall make available to Licensee the agreed information within [**] after the conclusion of such initial [**] period. Notwithstanding the foregoing, the foregoing information made available to Licensee shall not include any chemistry, manufacturing, and controls ("CMC") information unless otherwise agreed by the Parties in connection with regulatory activities mutually agreed by the Parties to be undertaken by Licensee pursuant to Section 5.01(d).

(b) Throughout the Term, on a periodic basis, Ocular shall make available to Licensee (i) Current Ocular Information (as assessed periodically), to the extent not previously provided to Licensee; and (ii) copies of certain Ocular Regulatory Documents, clinical and preclinical data, safety and pharmacovigilance data, in each case that are Controlled by Ocular (collectively, the "Ocular Product Data") to the extent such Ocular Product Data is necessary or reasonably useful for any Licensee Entity to Develop or Commercialize any Licensed Product in the Field in the Territory in accordance with this Agreement. Notwithstanding the foregoing, the foregoing information made available to Licensee shall not include any CMC information unless otherwise agreed by the Parties in connection with regulatory activities mutually agreed by the Parties to be undertaken by Licensee pursuant to pursuant to Section 5.01(d). Each information transfer under this Section 2.04(b) shall include such information Controlled by the Ocular Entities and necessary or reasonably useful for (a) subject to the foregoing limitation as to CMC information, Licensee's permitted or obligated Development activities as reasonably contemplated by this Agreement and the then-current Development Plan; and (b) Licensee's

regulatory (solely to the extent mutually agreed pursuant to Section 5.01(d)) and Commercialization activities as reasonably contemplated by this Agreement, taking into consideration the stage of the collaboration and different Development stages of DEXTENZA and OTX-TIC ("Current Ocular Information").

(c) Any knowledge transfer by Ocular pursuant to this Section 2.04 shall be at no additional cost to Licensee, except that Licensee shall reimburse Ocular for any reasonable out-of-pocket costs directly incurred by Ocular with respect to such transfer within [**] of its receipt of an invoice from Ocular for such costs. All direct costs and ongoing support beyond those set forth in this Section 2.04 shall be charged to Licensee at the then-applicable industry rate.

Section 2.05 Product Data and Regulatory Documents.

(a) Throughout the Term, to the extent applicable (for example, if generated in the course of a Licensee Entity's designated and permitted activities under the Development Plan or in the course of a Licensee Entity's permitted Commercialization of the Licensed Products in the Field in the Territory), on a periodic basis not less than [**] or more frequently as requested by Ocular, Licensee shall make available to Ocular all Licensee clinical and preclinical data, efficacy, safety and pharmacovigilance data in each case that are Controlled by Licensee or any of its Affiliates (collectively, the "Licensee Product Data") to the extent such Licensee Product Data is necessary or reasonably useful for any Ocular Entity to (i) Develop any Ocular product, including any Licensed Product; or (ii) Commercialize any Licensed Product outside the Territory, in each case ((i) and (ii)) in accordance with this Agreement. In accordance with Section 15.03, Licensee shall provide Licensee Product Data to Ocular in English. Upon Ocular's request, Licensee shall provide Licensee Product Data to an independent translator designated by Ocular for localized translation at Ocular's cost and expense. Ocular shall reimburse Licensee for any reasonable out-of-pocket costs incurred by Licensee in fulfilling its obligations under this Section 2.05(a).

Section 2.06 In-License Agreements.

(a) Subject to Section 16.02, in the event that Ocular or any of its Affiliates enters into an agreement with a Third Party after the Effective Date that Ocular determines is necessary or reasonably useful for the Development or Commercialization of any Licensed Product in the Field in the Territory, then Ocular will promptly provide Licensee with notice and a copy of the applicable Third Party agreement. Within [**] following receipt of such notice, Licensee will decide, in its sole discretion, whether to accept the applicable Third Party agreement as an In-License Agreement, and provide notice of such decision to Ocular. If Licensee accepts such In-License Agreement, Licensee shall pay royalties for sales of the Licensed Product by any Licensee Entity in the Territory in accordance with such In-License Agreement and the *pro rata* share of any other license consideration (such as upfront license fees and milestone payments) associated with such In-License Agreement to the extent that such consideration is attributed or allocated by the operation of the terms of such In-License Agreement to any Licensee Entity's activities in the Field in the Territory under this Agreement. In the event that

Licensee declines to accept such Third Party agreement as an In-License Agreement, then (i) such Third Party agreement shall not be deemed to be an "In-License Agreement" hereunder and (ii) any rights granted to Ocular under such Third Party agreement will not be deemed to be "Controlled" by Ocular or licensed to Licensee under this Agreement. In the event that Licensee accepts such Third Party agreement as an In-License Agreement, such Third Party agreement will thereafter be included within the definition of "In-License Agreement," and any rights granted to Ocular under such In-License Agreement will be deemed to be "Controlled" by Ocular and sublicensed to Licensee pursuant to the terms of this Agreement.

(b) Subject to Section 16.02, Licensee acknowledges and agrees that certain of the rights, licenses and sublicenses granted by Ocular to Licensee in this Agreement (including any sublicense rights) are subject to the terms of each In-License Agreement and the rights granted to the Third Party counterparties thereunder, the scope of the licenses granted to Ocular or any applicable Affiliate thereunder and the rights retained by such Third Party counterparties and any other Third Parties (including Governmental Authorities) set forth therein. Licensee shall, and shall ensure that each Licensee Entity shall, perform and take such actions to allow Ocular and its Affiliates to comply with their obligations under each In-License Agreement, to the extent applicable to Licensee's rights or obligations under this Agreement. Without limiting the foregoing, Licensee hereby agrees to be bound by all applicable terms and conditions of the Existing In-License Agreement. Without limiting the foregoing, each Licensee Entity shall prepare and deliver to Ocular, or assist Ocular in preparing, any additional reports required under any In-License Agreement, in each case reasonably sufficiently in advance to enable Ocular and its Affiliates to comply with their obligations thereunder. Each Licensee Entity shall comply with all provisions of each In-License Agreement that are applicable to such Licensee Entity's exercise of rights or performance of obligations under this Agreement. To the extent there is a conflict between the terms of any In-License Agreement and any rights granted to, or obligations imposed upon, Licensee hereunder, the terms of the applicable In-License Agreement(s) shall control. Any breach by any Licensee Entity of any provision of any In-License Agreement applicable to any of them pursuant to this Section 2.06 shall be deemed a material breach of this Agreement. Notwithstanding the foregoing, Licensee shall not have any payment obligation under any Existing In-License Agreement resulting from Licensee's practice of the sublicense granted to Licensee under Section 2.01(a) in accordance with this Agreement, and Ocular shall be solely responsible for fulfilling such payment obligations. During the Term, Ocular shall not terminate any In-License Agreement, or amend or waive compliance under any In-License Agreement in a manner that would adversely affect Licensee's right under such sublicense.

Section 2.07 Exclusivity.

(a) During the Term, neither Licensee nor any of its Affiliates shall, itself or with or through any Third Party, without the prior written consent of Ocular, engage in Development, Manufacture or Commercialization of any Competing Product in the Territory.

(b) Licensee acknowledges and agrees that the exclusivity obligations set forth in this Section 2.07, including the duration and scope thereof, are intended, in part, to protect

the Parties' trade secrets and other Confidential Information. In the event that any arbitrator or court determines that the duration or scope of any such provision is unreasonable and that any such provision is to that extent unenforceable, Licensee agrees that such provision shall remain in full force and effect for the greatest time period and to the greatest scope that would not render it unenforceable. The Parties intend that the provisions of this Section 2.07 shall be deemed to be a series of separate covenants, one for each and every product, Indication and Jurisdiction where such provision is intended to be effective.

(c) If, during the term of the exclusivity covenant in Section 2.07(a), Licensee or any of its Affiliates acquires or becomes an Affiliate of a Third Party (whether by way of a purchase of assets, merger, consolidation, Change in Control or otherwise) that is, at such time, Developing, Manufacturing or Commercializing a Competing Product in a manner that, if performed by Licensee or any of its Affiliates, would violate Section 2.07(a), then Licensee or its applicable Affiliate will, no later than [**] following the closing date of the relevant acquisition or other event, unless otherwise agreed by Ocular, notify Ocular in writing that Licensee or such Affiliate will:

(i) Divest, whether by license, divestiture of assets or otherwise, its interest in such Competing Product in the Territory to a Third Party, to the extent necessary to be in compliance with Section 2.07(a), provided that Licensee or its applicable Affiliate may retain an economic interest through such a license, divestiture of assets or other transaction as long as Licensee does not retain any other material rights as to such Competing Product in the Territory beyond a passive economic interest; or

(ii) terminate the Development, Manufacture and Commercialization of such Competing Product in the Territory, to the extent necessary to be in compliance with Section 2.07(a).

If Licensee or any of its Affiliates notifies Ocular in writing that it or its relevant Affiliate intends to divest such Competing Product as provided in Section 2.07(c)(i), or terminate the Development, Manufacture and Commercialization of the Competing Product in the Territory as provided in Section 2.07(c)(ii), then Licensee or its relevant Affiliate will effect such divestiture or termination within [**] after the date of the relevant acquisition or other event, subject to compliance with applicable Law, and will confirm to Ocular in writing when such divestiture or termination has been completed. Licensee will keep Ocular reasonably informed of its and its Affiliates' efforts and progress in effecting such divestiture or termination until it is completed. Until such divestiture or termination occurs, Licensee shall keep its and its Affiliates' activities with respect to such Competing Product separate from their activities with respect to the Licensed Products and shall continue to fully perform all of their obligations hereunder with respect to Licensed Products, including their applicable diligence obligations with respect to the Development and Commercialization of Licensed Products hereunder.

Section 2.08 Exports and Resale. Each Licensee Entity will use Commercially Reasonable Efforts to monitor and prevent exports or resale of Licensed Products from inside the Territory for Development or Commercialization outside of the Territory using methods commonly used

in the industry for such purpose, and shall promptly inform Ocular of any such actual or suspected exports from the Territory, and the actions taken to prevent such exports. If Licensee or any of its Affiliates or, to Licensee's or any of its Affiliates' knowledge, any other Licensee Entity receives a request or order to Develop, Manufacture or Commercialize any Licensed Product outside of the Territory, Licensee shall immediately notify Ocular thereof, shall not accept such request or order, and shall direct the relevant individual or entity to Ocular. Each Ocular Entity will use Commercially Reasonable Efforts to monitor and prevent exports or resale of Licensed Products from outside the Territory for Development or Commercialization in the Territory using methods commonly used in the industry for such purpose, and shall promptly inform Licensee of any such actual or suspected exports into the Territory, and the actions taken to prevent such exports. If Ocular or any of its Affiliates or, to Ocular's or any of its Affiliates' knowledge, any other Ocular Entity receives a request or order to Develop, Manufacture or Commercialize any Licensed Product in the Field in the Territory, Ocular shall immediately notify Licensee thereof, shall not accept such request or order, and shall direct the relevant individual or entity to Licensee.

ARTICLE III

GOVERNANCE

Section 3.01 General.

(a) The Parties shall establish a Joint Committee ("JC") to oversee and coordinate: (i) the Development of the Licensed Products in the Field in the Territory and (ii) the Commercialization of the Licensed Products in the Field in the Territory. The JC shall have decision-making authority with respect to the matters within its purview to the extent expressly provided herein, provided that after the completion of the activities in the Joint Development Plan, the JC shall only oversee and coordinate the Commercialization of the Licensed Products in the Field in the Territory.

(b) From time to time, the JC may establish one or more subcommittees or working groups to oversee particular projects or activities, as it deems necessary or advisable (each, a "Committee"). Each Committee shall consist of such number of members as the JC determines is appropriate from time to time. Such members shall be individuals with expertise and responsibilities in the relevant areas. Each Committee shall discuss matters within the scope of such Committee's oversight and shall report the outcome of the discussions of such Committee to the JC promptly after each meeting. Following the receipt of the report from such Committee, the JC shall make any required decisions regarding matters set forth in such report.

(c) JC Responsibilities. Within [**] following the Effective Date, the Parties shall establish the JC.

The JC shall oversee and coordinate the following Development Activities:

(i) review and approve the Development Plan and any proposed updates or amendments to the Development Plan, and propose revisions to the Development Plan in accordance with Section 4.01;

(ii) review and approve the Regulatory Budget and any proposed updates or amendments to the Regulatory Budget;

(iii) determine with respect to each Global Study and on an Indication-by-Indication basis whether to include clinical sites in the Territory in such Global Study and whether such Global Study shall be a Joint Global Study (but subject to Section 4.01(c));

(iv) discuss the clinical sites in the Territory, if any, to be included in each Local Study;

(v) approve the protocols for each Local Study and Joint Global Study;

(vi) determine the clinical sites in the Territory to be included in each Joint Global Study;

(vii) for each Joint Global Study, coordinate the operations of the Ocular Entities and Licensee Entities with respect to such Joint Global Study;

(viii) determine the contract research organizations (each, a "CRO") in the Territory to be used for each Joint Global Study;

(ix) discuss the Ocular Entities' regulatory strategy for the Licensed Products in the Territory based on the then-current Development Plan;

(x) provide a forum to share information with respect to the Development of the Licensed Products in the Field, including updates on progress and status of Local Studies and Joint Global Studies in the Territory and updates regarding interactions with Regulatory Authorities;

(xi) subject to Section 12.05, review and approve publications and publications plans as to the Development and Commercialization of Licensed Products in the Territory;

(xii) review and approve the Licensee Entities' In-Market Release plans and Secondary Packaging as described in Section 5.02;

(xiii) discuss Third Party wholesalers or distributors (each, a "Distributor") to be engaged by Licensee to market, distribute and sell each Licensed Product in the Territory;

(xiv) discuss material updates with respect to Manufacturing Activities, including current and projected availability of Product Materials;

(xv) oversee, review, coordinate and provide strategic guidance on the Development of the Licensed Products in the Field in the Territory; and

(xvi) perform such other duties as are specifically assigned to the JC under this Agreement.

Beginning at least [**] prior to the anticipated filing of the first Drug Approval Application for a Licensed Product in the Territory, the JC shall oversee and coordinate the following Commercialization Activities:

(i) discuss Licensee's proposed Commercialization activities;

(ii) ensure that the Licensee Entities' Medical Affairs strategy for the Licensed Products in the Territory is in line with Ocular's Global Medical Affairs Strategy;

(iii) discuss safety data exchange and pharmacovigilance matters relating to the Licensed Products in the Field in the Territory in accordance with the Safety Data Exchange Agreement;

(iv) discuss the Licensee Entities' pricing strategy for the Licensed Products in the Territory;

(v) discuss Licensee Entities' forecasted sales numbers for the next [**];

(vi) review and discuss any promotional or other materials for a Licensed Product proposed to be used by Licensee in the Territory in accordance with Section 6.02;

(vii) discuss each Party's plans and strategies with respect to such Party's presence at international congresses and conventions, relationships with key opinion leaders and other medical educational activities; and

(viii) perform such other duties as are specifically assigned to the JC under this Agreement.

Section 3.02 Membership. The JC shall be composed of an equal number of representatives from each of Ocular and Licensee, each of which representatives shall be of the seniority and experience appropriate for service on the JC in light of the functions, responsibilities and authority of the JC and the status of activities within the scope of the authority and responsibility of the JC. Any representative from either Party may represent such Party on the JC. Each Party may replace any of its representatives on the JC at any time with written notice to the other Party; provided that such replacement meets the standard described in the preceding

sentence. Each Party's representatives and any replacement of a representative shall be bound by obligations of confidentiality and non-use applicable to the other Party's Confidential Information that are at least as stringent as those set forth in ARTICLE XII. Each Party may invite a reasonable number of its or its Affiliate's employees as required or useful to discuss the applicable agenda items. The JC shall appoint a chairperson from among its members, with the first chairperson of being a representative of Ocular. Each chairperson (whether initially appointed or any successor therefor) shall serve a term of one (1) year, at which time, the JC shall select a successor chairperson who is a representative of the Party other than the Party represented by the outgoing chairperson (e.g., the second chairperson of the JC shall be a representative of Licensee, the third chairperson of each of the JC shall be a representative of Ocular, etc.). Within [**] following each JC meeting, the chairperson shall circulate to all JC members a draft of the minutes of such meeting. The JC shall then approve, by mutual agreement, such minutes within [**] following circulation. No chairperson of the JC shall have any greater authority than any other member of the JC.

Section 3.03 Meetings.

(a) The JC shall hold an initial meeting within [**] after its formation or as otherwise agreed by the Parties. Thereafter, unless the Parties otherwise agree, the JC will meet in person or by video or teleconference at least [**]. Unless otherwise agreed in writing by the Parties, any in-person meetings will be held at a mutually agreed location, and the JC shall make reasonable efforts to meet in person at least [**] to the extent reasonably practicable in light of travel, entertainment and business restrictions in light of the COVID-19 pandemic in existence as of the Effective Date and any applicable governmental responses thereto. Each Party shall be responsible for all of its own personnel and travel costs and expenses relating to participation in JC meetings.

(b) Ocular may upon reasonable notice include relevant representatives of Ocular licensees of the Licensed Product outside the Territory to attend any JC meeting as non-voting guest; provided that such additional representatives shall be bound by obligations of confidentiality and non-use applicable to the other Party's Confidential Information that are at least as stringent as those set forth in ARTICLE XII.

Section 3.04 JC Decision Making. All decisions of the JC shall be made by unanimous vote, with each Party's representatives collectively having one (1) vote, and shall be set forth in minutes approved by both Parties. If the JC is unable to reach agreement on any matter within [**] after the matter is referred to it or first considered by it, such matter shall be referred to the Executive Officers for resolution in accordance with Section 3.05.

Section 3.05 Executive Officers; Disputes. Unless otherwise set forth in this Agreement, in the event of a dispute arising under this Agreement between the Parties, the Parties shall refer such dispute to the chief executive officer of each Party or such individual's designee (each such individual, such Party's "Executive Officer"), who shall attempt in good faith to resolve such dispute. Each Party shall promptly notify the other Party of its initial, or any change in its, Executive Officer.

Section 3.06 Final Decision-Making Authority. If the Parties are unable to resolve a given dispute within the purview of the JC within [**] after referring such dispute to the Executive Officers pursuant to Section 3.05, then, subject to Section 3.07, Ocular's Executive Officer shall have the deciding vote. Any decision made by Ocular's Executive Officer in accordance with this Section 3.06 shall be deemed to be a decision of the JC.

Section 3.07 Limitations on Decision-Making.

(a) Ocular shall not have the deciding vote on, and the JC shall have no decision-making authority regarding, any of the following matters:

(i) the imposition of any requirements on Licensee to undertake obligations beyond those for which it is responsible, or to forgo any of its rights, under this Agreement;

(ii) the imposition of any requirements that Licensee takes or declines to take any action that would result in a violation of any Law or any agreement with any Third Party or the infringement of intellectual property rights of any Third Party;

(iii) the unilateral imposition on Licensee of obligations under the Development Plan, or the unilateral decision to add, delay or terminate any Local Trial, or the unilateral decision to deny the addition of any Local Trial proposed by Licensee so long as the proposed Local Trial is not reasonably expected to negatively and materially affect the Licensed Product outside the Territory;

(iv) the resolution of any dispute involving the breach or alleged breach of this Agreement;

(v) any decision that is expressly stated to require the mutual agreement (or similar language) of the JC or the Parties or the approval of the other Party (but not "approval" of the JC);

(vi) any matter described in Section 3.01(c) to the extent such matter is solely described as a matter to be discussed by the JC without any expressly stated JC approval right;

(vii) any matters that would excuse Ocular from any of its obligations under this Agreement; or

(viii) modifying the terms of this Agreement or taking any action to expand or narrow the responsibilities of the JC.

(b) In no event may Ocular unilaterally determine that it has fulfilled any obligations hereunder or that Licensee has breached any obligations hereunder.

(c) In no event may Ocular unilaterally determine that the events required for the payment of milestone payments have occurred.

(d) For clarity, approval by the JC shall not be understood to mean approval by a Party.

Section 3.08 Scope of Governance. Notwithstanding the creation of each of the JC, each Party shall retain the rights, powers and discretion granted to it under this Agreement, and the JC shall not be delegated or vested with rights, powers or discretion unless such delegation or vesting is expressly provided herein, or the Parties expressly so agree in writing. It is understood and agreed that issues to be formally decided by the JC are only those specific issues that are expressly provided in this Agreement to be decided by the JC. For clarity, the JC shall not have any rights, powers or discretion to decide any matter not relating to the Development, Manufacturing or Commercialization of the Licensed Product in the Field and the Territory.

Section 3.09 Alliance Managers. Each of the Parties shall appoint a single individual to manage Development, Manufacturing and Commercialization obligations between the Parties under this Agreement (each, an "Alliance Manager"). The role of the Alliance Manager is to act as a single point of contact between the Parties to ensure a successful relationship under this Agreement. The Alliance Managers may attend any JC and Committee meetings. Each Alliance Manager shall be a non-voting participant in the JC and such Committee meetings, unless s/he is also appointed a member of the JC; provided, however, that an Alliance Manager may bring any matter to the attention of the JC if such Alliance Manager reasonably believes that such matter warrants such attention. Each Party may change its designated Alliance Manager at any time upon written notice to the other Party. Any Alliance Manager may designate a substitute to temporarily perform the functions of that Alliance Manager by written notice to the other Party. Each Party's Alliance Manager and any substitute for an Alliance Manager shall be bound by obligations of confidentiality and non-use applicable to the other Party's Confidential Information that are at least as stringent as those set forth in ARTICLE XII. Each Alliance Manager will also: (a) plan and coordinate cooperative efforts and internal and external communications; and (b) facilitate the governance activities hereunder and the fulfillment of action items resulting from JC meetings.

ARTICLE IV

DEVELOPMENT

Section 4.01 Development in the Field in the Territory.

(a) The Initial Development Outline is attached to this Agreement as Exhibit B and as soon as reasonably practicable after the Effective Date or within [**], Ocular shall finalize the Development Plan and present it to the JC for approval. The Development Plan shall be prepared based on and in accordance with the Initial Development Outline. The Development of Licensed Products in the Field in the Territory shall be governed by the Development Plan, and, except as set forth in this Section 4.01 or as otherwise agreed by the Parties in accordance with

Section 5.01(d), the Licensee Entities shall solely perform those Development activities allocated to Licensee under and in accordance with the Development Plan. Each Development Plan shall provide for each Local Study or Joint Global Study to be conducted in the Territory and shall at least contain the Development activities set forth in the Initial Development Outline. Each Development Plan shall reflect Licensee's participation in the Joint Global Studies and Local Studies, if any. The JC shall periodically review and update the Development Plan. Each Party may submit to the JC from time to time proposed amendments to the Development Plan. The JC shall review and may approve such proposed amendments or any other proposed amendments that the JC may consider from time to time in its discretion and, upon any such approval by the JC, the Development Plan shall be amended accordingly.

(b) Each Joint Global Study conducted in the Territory shall be conducted by or on behalf of Ocular or Licensee in accordance with the Development Plan and the study protocol approved by the JC. Each Local Study conducted in the Territory shall be conducted by or on behalf of Licensee in accordance with the Development Plan and the study protocol approved by the JC, provided, however, that Ocular may conduct Global Studies or Local Studies in the Territory without Licensee's consent in the event that Licensee determines not to participate in such Global Studies or not to conduct such Local Studies (including pursuant to Section 4.01(c)). Subject to any activities expressly allocated to Licensee under the Development Plan, Ocular shall be responsible for implementation activities in the Territory as to each Joint Global Study as determined by the JC. Each Joint Global Study shall be designed to enroll sufficient human subjects in the Territory to support the Regulatory Approval in Greater China. Licensee shall be responsible for paying certain costs of activities with respect to each Joint Global Study and certain Local Studies in the Territory in accordance with Section 4.02(b).

(c) Licensee shall use Commercially Reasonable Efforts to execute and to perform, or cause to be performed, the activities assigned to it in the Development Plan. Subject to Section 4.02(b), Licensee shall have the sole discretion to determine whether to participate in each Global Study or to conduct a Local Study by itself.

(d) To the extent supported by clinical results, unless otherwise agreed by the Parties, subject to Section 4.05, Ocular shall file for, and endeavor to obtain, or cause to be obtained, Regulatory Approval for the Licensed Products in each Jurisdiction in the Territory, including by providing all necessary resources required to seek and maintain Regulatory Approval for the Licensed Products in each Jurisdiction in the Territory.

(e) If applicable, Licensee shall use Commercially Reasonable Efforts to obtain, or cause to be obtained Reimbursement Approval, for the Licensed Products in each Jurisdiction in the Territory, including by providing all necessary resources required to seek and maintain Reimbursement Approval for the Licensed Products in each Jurisdiction in the Territory.

Section 4.02 Development Costs.

(a) Except as expressly provided in this Agreement or the Development Plan, (i) Ocular's reasonable costs and expenses of seeking and maintaining Regulatory Approvals for

the Licensed Products in each Jurisdiction of the Territory shall be reimbursed by Licensee to Ocular in accordance with a plan and budget to be prepared by Ocular and approved in advance by mutual agreement of the JC ("Regulatory Budget") (for clarity, Ocular shall not have the deciding vote regarding such Regulatory Budget); and (ii) each Party shall otherwise bear its own costs incurred in the performance of its obligations under this ARTICLE IV. In the event that the Parties are unable to agree on the costs set forth in the Regulatory Budget, the Parties agree to select an independent third party with appropriate commercial and regulatory experience to determine the reasonableness of such costs.

(b) Notwithstanding anything to the contrary in Section 4.02(a), (A) for any Joint Global Study, Licensee shall bear [**] percent [**]% of the out-of-pocket global Development costs incurred for such Joint Global Study in accordance with a plan and budget presented to Licensee at the time Licensee elects to participate in such Joint Global Study; and (B) for any Local Study performed by Licensee in accordance with Section 4.01(c), Licensee shall bear all costs incurred by Licensee Entities and all out-of-pocket costs incurred by Ocular and its Affiliates. In the event that, pursuant to Licensee's election under Section 4.01(c), (i) Licensee both determines not to participate in a Joint Global Study and does not elect to conduct a Local Study reasonably designed to support regulatory approval for the same Jurisdiction(s) in the Territory with respect to the same Licensed Product as the proposed Joint Global Study; and (ii) Ocular subsequently determines to conduct either a Global Study or a Local Study reasonably designed to support regulatory approval for such Jurisdictions in the Territory with respect to such Licensed Product, then Licensee may elect, prior to Ocular conducting such Global Study or a Local Study, to bear the applicable costs set forth in this Section 4.02(b) as if such Global Study were a Joint Global Study or as if such Local Study were conducted by Licensee, as applicable. In the event that Licensee does not elect to bear such costs in accordance with the prior sentence of this Section 4.02(b), notwithstanding anything to the contrary, Ocular shall have no obligation to provide any data (other than safety data) arising from such Global Study or Local Study to Licensee, including pursuant to Ocular's obligations with respect to Ocular Product Data under Section 2.04(b), unless Licensee pays to Ocular the applicable costs set forth in this Section 4.02(b) plus [**] percent ([**]%) thereof. Except as set forth above, Licensee shall not be required to bear the costs of Global Studies.

(c) Within [**] following the end of each Calendar Quarter, Ocular shall invoice Licensee for the amounts set forth in Section 4.02(a) and Section 4.02(b). Licensee shall pay all amounts payable under such invoice within [**] after the end of each Calendar Quarter.

Section 4.03 Development Reports. At least [**] in advance of the first meeting of the JC in each Calendar Year, (a) Licensee shall provide Ocular with a written report that summarizes the status of items to be performed by the Licensee Entities under the Development Plan in the year prior to such meeting of the JC, and at least [**] in advance of each other meeting of the JC in such Calendar Year, Licensee shall provide Ocular with a written report that updates the previous annual report or update provided to Ocular; and (b) Ocular shall provide Licensee with a written report that summarizes the Development of the Licensed Products in the Field in the Territory performed by the Ocular Entities in the year prior to such meeting of the JC, and at least

[**] in advance of each other meeting of the JC in such Calendar Year, Ocular shall provide Licensee with a written report that updates the previous annual report or update provided to Licensee. The Ocular reports described in this Section 4.03 shall include the status of Regulatory Filings for Licensed Products in the Field in the Territory. The reports to be submitted by Licensee under this Section 4.03 shall include any information that is reasonably necessary or useful for the Development or Commercialization of Licensed Products by Ocular Entities outside of the Territory.

Section 4.04 Records. The Licensee Entities shall maintain written or electronic records in sufficient detail, in a good scientific manner (in accordance with all applicable GLP, GMP, GVP and GCP promulgated or endorsed by any applicable Regulatory Authority in the Territory, or as otherwise specified in the Development Plan) and appropriate for regulatory and patent purposes, which are complete and accurate in all material respects and reflect all Development work assigned to and performed by the Licensee Entities under the Development Plan and results achieved. Ocular shall have the right, upon reasonable advance notice, and no more than [**], to inspect and copy all such records. Ocular shall have the right to use and reference all data and results generated by or on behalf of Licensee, its Affiliates or (sub)licensees in the course of Development of the Licensed Product, and Licensee hereby grants Ocular the right to reference any and all Regulatory Filings and Regulatory Approvals Controlled by Licensee for the Licensed Product solely for Ocular to exercise its rights and fulfill its obligations under this Agreement and to exercise its retained rights outside the Territory.

Section 4.05 Development and Commercialization in South Korea. Although South Korea is a Jurisdiction in the Territory, Licensee acknowledges and agrees that Ocular does not anticipate beginning to modify its manufacturing capabilities to meet South Korean Regulatory Approval requirements until [**]. Therefore, notwithstanding anything to the contrary, including Section 4.01(d), Section 5.01(a) and Section 7.01, (i) Ocular shall have no obligations with respect to the Development (including Regulatory Approvals) of any Licensed Product in South Korea until the completion of such manufacturing capability modifications; and (ii) Ocular's subsequent Manufacturing obligations under this Agreement and the Supply Agreement shall be dependent upon Ocular's completion of any such Development (including Regulatory Approvals) occurring after the completion of such manufacturing capability modifications.

ARTICLE V

REGULATORY

Section 5.01 Regulatory Filings.

(a) Subject to Section 4.01(a) and Section 4.05, Ocular shall have the responsibility to, prepare, obtain, and maintain all Regulatory Filings, Licensed Product labeling and Regulatory Approvals, and to conduct communications with the Regulatory Authorities in the Territory, for the Development of Licensed Products in the Field in the Territory undertaken by Ocular and the for the Commercialization of Licensed Products in the Field in the Territory undertaken by Licensee. Licensee shall be responsible for Ocular's documented out-of-pocket

expenses incurred in connection with the foregoing. Ocular shall provide Licensee with an opportunity to review and comment on all such Regulatory Filings in the Territory and consider Licensee's comments in good faith, provided, however, that Ocular shall be entitled to redact CMC information and such other information as it considers sensitive to its business. For clarity, Licensee shall be solely responsible for all costs and expenses related to the Parties' participation in any such communications.

(b) All Regulatory Filings for Local Studies and Global Studies of Licensed Products in the Field in the Territory and corresponding applications for Regulatory Exclusivity shall be filed in the name of and shall be owned by Ocular. All Regulatory Filings and Regulatory Approvals in the Field in the Territory shall be at Licensee's sole expense.

(c) Within [**] following the end of each Calendar Quarter, Ocular shall invoice Licensee for the amounts set forth in Section 5.01(a) Licensee shall pay all amounts payable under such invoice within [**] after the end of each Calendar Quarter.

(d) The Parties may mutually agree that Licensee shall be the owner of certain Regulatory Filings or Regulatory Approvals for the Licensed Products in the Territory, in which case Ocular shall assign such ownership to Licensee subject to the Parties' agreement on terms for Licensee's conduct of such regulatory activities, including restrictions designed for the protection of CMC information and such other information as Ocular considers sensitive to its business.

Section 5.02 In-Market Release; Secondary Packaging. As may be further detailed in the Supply Agreement:

(a) Subject to this Section 5.02(a), Licensee shall be responsible for all activities related to the release of the Licensed Products in each Jurisdiction in the Territory, and shall conduct all such activities required under applicable Laws in connection with the marketing, promotion and sale of the Licensed Products by the Licensee Entities in each Jurisdiction in the Territory, including labelling requirements ("In-Market Release"). Licensee's plan for In-Market Release shall be subject to review and approval by the JC. The Licensee Entities shall perform all In-Market Release activities (i) in compliance in all material respects with applicable Laws and (ii) in a manner that could not reasonably be expected to have a material adverse effect on the Development, Manufacture or Commercialization of the Licensed Product outside of the Territory.

(b) Licensee shall be responsible for all activities related to Secondary Packaging of the Licensed Products in each Jurisdiction in the Territory. The design and specification of all Secondary Packaging shall be subject to review and approval by the JC. The Licensee Entities shall design, manufacture, store and sell Licensed Products within such Secondary Packaging (i) in compliance in all material respects with applicable Laws and (ii) in a manner that could not reasonably be expected to have a material adverse effect on the Development, Manufacture or Commercialization of the Licensed Product outside of the Territory.

ARTICLE VI

COMMERCIALIZATION

Section 6.01 General. Under the oversight of the JC, Licensee (itself or through any of the Licensee Entities) shall have the sole right to Commercialize (including booking sales, establishing pricing and engaging in related interactions with Governmental Authorities in order to obtain listing on the central or provincial reimbursement list, warehousing, commercial distribution, order processing, invoicing and collection) the Licensed Products in the Field in the Territory at its sole expense. Licensee shall keep the JC reasonably informed on its plans for the Commercialization of the Licensed Products in the Field in the Territory. Licensee shall additionally promptly respond through the JC in reasonable detail to any follow-up questions or requests for additional information from Ocular with respect to its plans for the Commercialization of the Licensed Products in the Field in the Territory.

Section 6.02 Promotional Materials. Licensee shall ensure that all promotional materials for the Licensed Products in the Territory are consistent with the approved labeling for such Licensed Products and that such promotional materials comply in all respects with Law. Licensee shall share the promotional materials used in the Territory by any Licensee Entity in connection with the Licensed Products in the Territory with the JC on a regular basis, and the JC shall have the right to review and comment on (but for clarity shall not have the right to approve), which comments shall be considered in good faith by the Licensee Entities, any of the Licensee Entities' promotional materials prior to their use in the Territory.

Section 6.03 Commercialization Reports. At least [**] prior to each meeting of the JC, for any meeting of the JC following the First Commercial Sale of any Licensed Product in the Field in the Territory, Licensee shall provide the JC with (a) a written report that summarizes Commercialization and Medical Affairs activities performed during the prior [**] period with respect to each Licensed Product in each Jurisdiction in the Territory, (b) detailed sales reports for each month of the prior [**] period of each Licensed Product in each Jurisdiction in the Territory, and (c) [**] sales forecasts for each Licensed Product in each Jurisdiction in the Territory for the next [**]. Licensee shall provide an update of such report at each JC meeting.

Section 6.04 Commercialization Efforts. At its sole cost and expense, Licensee shall use Commercially Reasonable Efforts to Commercialize Licensed Products in each Jurisdiction in the Territory.

Section 6.05 Standards of Conduct. The Licensee Entities shall perform all Commercialization activities with respect to Licensed Products in the Field in the Territory (a) in a professional and ethical business manner, and (b) in compliance in all material respects with applicable Laws. Licensee shall ensure that the Medical Affairs strategy that each applicable Licensee Entity pursues for the Licensed Products in the Territory is in line with the Global Medical Affairs Strategy provided to Licensee reasonably in advance.

Section 6.06 Trademarks; Use of Names. The Parties shall cooperate to choose a Trademark for use in the Territory, which may vary by Jurisdiction if agreed to by the Parties, and any such Trademark shall be owned by Ocular and subject to the terms of the trademark license set forth in Exhibit C. Without limiting the terms of such trademark license or Section 5.02(b), each unique use of such Trademark on Secondary Packaging shall be subject to the prior approval of the JC by consensus. Except as expressly provided herein, or except as otherwise required by applicable Law or agreed by the Parties in advance in writing, neither Party shall have any right to use the other Party's or the other Party's Affiliates', and Licensee shall not have any right to use any Ocular Entity's, corporate names or logos in connection with any Commercialization of any Licensed Product. At either Party's option, each Licensed Product in the Territory shall be co-branded with the Ocular name and Ocular-designated corporate trademark, in a manner to be reasonably agreed by the Parties, which may include entering into a trademark license agreement in form and substance reasonably acceptable to Ocular.

ARTICLE VII

MANUFACTURE AND SUPPLY

Section 7.01 Supply. The Parties will negotiate in good faith and enter into a supply agreement for clinical and commercial supply of Product Materials and a related quality agreement (collectively, the "Supply Agreement"), and such Supply Agreement shall be entered into at least [**] prior to the anticipated date of receipt of the first Regulatory Approval for the first Licensed Product in the Territory, or at such later date as may be mutually agreed in writing. The Supply Agreement will be consistent with the terms set forth in this Section 7.01. Subject to Section 4.05, from and after the execution of the Supply Agreement, and subject to the terms of the Supply Agreement, Ocular will use Commercially Reasonable Efforts, either itself or through Third Parties, to Manufacture and supply to Licensee Product Materials in quantities that are reasonably sufficient for the conduct of Development or Commercialization, as applicable, of Licensed Products in the Field in the Territory by the Licensee Entities. For any Product Materials supplied by Ocular to Licensee pursuant to this Section 7.01 in the Field in the Territory, Licensee shall pay to Ocular the Supply Price for such Product Materials, payable within [**] after receipt of an invoice therefor after the acceptance of the Product Materials. For clarity, nothing (including the exclusivity of the license granted Licensee under Section 2.01(a)) will prevent Ocular from manufacturing or having manufactured all or any portion of the Licensed Products in the Territory to supply Licensee's use in the Territory or for Ocular's use outside the Territory, and the Supply Agreement will contain customary provisions regarding acceptance, rejection, product release and warranty, inspection, supply failure remedy and backup supply, forecasting and ordering.

Section 7.02 Serialization. Licensee shall ensure that any distribution of Licensed Products by or on behalf of the Licensee Entities complies with any Serialization requirements required by applicable Law or reasonably requested by Ocular. As between the Parties, Licensee

shall be responsible, at its cost and expense, with respect to any traceability issues or counterfeiting limitations required by applicable Laws or reasonably requested by Ocular with respect to the Commercialization of Licensed Products in the Territory.

Section 7.03 Ocular Supply Chain Security Requirements. Licensee commits to refrain from selling Licensed Product to unauthorized Third Parties or end users under Trade Control Laws such as any military and law enforcement parties of Sanctioned Countries, including but not limited to military hospitals. Licensee shall perform this Agreement in the Territory in compliance with Trade Control Laws as defined herein and within the limits set forth by any applicable OFAC Authorization. Licensee shall ensure that any Licensee Entity shall comply with Trade Control Laws and the scope of any applicable OFAC Authorization. Licensee shall ensure that this duty to comply with such Trade Control Laws and the prohibitions or restrictions it involves will be reflected in the Supply Agreement. Licensee shall perform its contractual obligations in conformity with any restrictions which may be set forth by any applicable OFAC Authorization and the Trade Control Laws. Such OFAC Authorization or Trade Control Laws may restrict the selling of Licensed Products to specific Third Parties as mentioned therein. Licensee shall comply with such restrictions imposed by the OFAC Authorization to the extent they apply to Third Parties to which it sells Licensed Products pursuant to this Agreement. While storing, handling or distributing the Licensed Product, Licensee Entities shall make all reasonable efforts to comply with Ocular supply chain security requirements, in order in particular to verify the security and integrity of the Licensed Products through all points of the supply chain. Licensee shall also ensure that any Subcontractors used by Licensee in the distribution of the Licensed Products are duly informed of such requirements and shall require that such Subcontractors comply with these requirements. Licensee expressly agrees it will not do anything under this Agreement or the Supply Agreement which could cause Ocular to be in breach of Trade Control Laws. In the event that any Licensee Entity violates any Trade Control Law or the terms or conditions set by the OFAC Authorization to any Sanctioned Countries (or in the case of a Licensee Entity, the Licensee Entity commits such violation and Licensee fails to terminate its agreement with the Licensee Entity upon becoming aware of such violation), or breaches any provision in this Section 7.03, Ocular shall have the right to unilaterally terminate this Agreement pursuant to Section 14.02, except that the cure and dispute resolution period set forth therein shall not apply.

ARTICLE VIII

PAYMENTS

Section 8.01 Upfront Payment. Within [**] after the Effective Date, Licensee shall pay Ocular the one-time, non-refundable, non-creditable upfront payments set forth below, by wire transfer.

DEXTENZA for POPI	DEXTENZA for AC	OTX-TIC for POAG and OHT
[**]	[**]	[**]

DEXTENZA for POPI	DEXTENZA for AC	OTX-TIC for POAG and OHT
	Total upfront payment:	$12,000,000

Section 8.02 Clinical Development Milestone and Clinical Development Support Payments.

(a) Licensee shall make the non-refundable, non-creditable milestone payments to Ocular set forth in the table below no later than [**] after the date on which Licensee receives an invoice from Ocular for each payment, and Ocular shall only have the right to issue such invoice after the achievement of such milestone event (if achieved by Ocular) or receiving written notification from Licensee that such milestone event has been achieved (if achieved by Licensee). Licensee shall notify Ocular within [**] after the achievement of such milestone event. The milestone payments set forth in the below table shall be payable only once under this Agreement, upon the first achievement of such milestone event, and Licensee's total payment obligation under this Section 8.02(a) shall not exceed [**] dollars ($[**]). Notwithstanding the foregoing, if Licensee has not paid to Ocular a milestone payment for a particular Licensed Product/Indication combination set forth below, and a milestone event set forth in a subsequent row for such Licensed Product/Indication combination occurs ("Achieved Milestone"), then, upon the occurrence of such later milestone event, Licensee shall additionally pay to Ocular the prior milestone payment in conjunction with payment for the Achieved Milestone.

DEXTENZA for POPI		DEXTENZA for AC		OTX-TIC for POAG and OHT	
Milestone Event	Payment Amount	Milestone Event	Payment Amount	Milestone Event	Payment Amount
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]
[**]	[**]	[**]	[**]	[**]	[**]

(b) Licensee shall make a non-refundable, non-creditable payment to Ocular in respect of support for the Phase 2 Clinical Trial of OTX-TIC for POAG and OHT of $[**] not later than [**] following enrollment of the first patient in such Phase 2 Clinical Trial.

Section 8.03 Commercial Milestone Payments. Licensee shall pay to Ocular the following non-refundable and non-creditable amounts upon the first achievement of aggregate Net Sales of all Licensed Products in the Territory exceeding the minimum annual Net Sales thresholds set forth below for the trailing twelve (12) month period (starting on the first of each month) ("TTM Period"). Licensee shall notify Ocular of the achievement of such milestone event within [**] after the date upon which such milestone is achieved, and shall pay Ocular the payment amount for each such milestone within [**] after the end of the Calendar Quarter in which such milestone was achieved:

DEXTENZA		OTX-TIC	
TTM Period Net Sales Threshold	Payment Amount	TTM Period Net Sales Threshold	Payment Amount
Equal to or greater than $[**]	$[**]	Equal to or greater than $[**]	$[**]
Equal to or greater than $[**]	$[**]	Equal to or greater than $[**]	$[**]
Equal to or greater than $[**]	$[**]	Equal to or greater than $[**]	$[**]
Equal to or greater than $[**]	$[**]	Equal to or greater than $[**]	$[**]

Each milestone payment in this Section 8.03 shall be payable only once upon the first achievement of such milestone in a given TTM Period and no amounts shall be due for subsequent or repeated achievements of such milestone in subsequent TTM Period. For clarity, the Net Sales of all Licensed Products in a TTM Period shall be aggregated for purposes of determining whether any milestone in the table above has been met. If more than one of the milestones set forth in the table above are first achieved in a single TTM Period, then Licensee shall pay to Ocular in such TTM Period all of the payments corresponding to all of the milestones achieved in such TTM Period under this Section 8.03. Licensee's total payment obligation under this Section 8.03 shall not exceed [**] dollars ($[**]).

Section 8.04 Royalties.

(a) Subject to the remainder of this Section 8.04, Licensee shall pay Ocular the following royalties on aggregate Net Sales in the Territory of the applicable Licensed Products designated in the column header, at an incremental royalty rate determined by aggregate annual Net Sales of all such applicable Licensed Products in each Calendar Year during the Term in the Territory ("Annual Net Sales"):

DEXTENZA		OTX-TIC	
Portion of Aggregate Annual Net Sales in the Territory	Royalty	Portion of Aggregate Annual Net Sales in the Territory	Royalty
Up to $[**]	[**]%	Up to $[**]	[**]%
$[**] up to and including $[**]	[**]%	$[**] up to and including $[**]	[**]%
Greater than $[**]	[**]%	Greater than $[**]	[**]%

(b) Running royalties paid by Licensee under this Section 8.04 shall be paid on a Licensed Product-by-Licensed Product and Jurisdiction-by-Jurisdiction basis until the latest of (i) expiration of the last-to-expire Valid Claim in the Ocular Patent Rights or Arising Patent Rights that are not Licensee Sole Arising Product Patent Rights assigned to Ocular by Licensee under this Agreement, in each case that Covers the composition of matter, formulation, dosing, or use of the Licensed Product in the Jurisdiction of sale, or (ii) ten (10) years from the First Commercial Sale of such Licensed Product in the Field in such Jurisdiction, or (iii) the expiration of all Regulatory Exclusivity for such Licensed Product in such Jurisdiction (each, a "Royalty Term"). Following the expiration of the Royalty Term with respect to a particular Licensed Product in the Field in a Jurisdiction, the licenses granted by Ocular to Licensee pursuant to Section 2.01(a) with respect to such Licensed Product in the Field in such Jurisdiction shall be perpetual, irrevocable, fully-paid and royalty-free, and freely sublicensable through multiple tiers and not subject to Section 2.02 and Net Sales of such Licensed Product shall no longer be included in the aggregate Net Sales calculation in Section 8.03 and Section 8.04(a).

Section 8.05 Product Royalty Reduction.

(a) If, in a given Jurisdiction, one or more Generic Products becomes commercially available in such Jurisdiction and such Generic Product(s) achieve an aggregate quarterly unit market share in such Jurisdiction of [**]%) or more of the aggregate quarterly unit market share of such Generic Product(s) and the applicable Licensed Product in such Jurisdiction (based on data provided by IQVIA or, if such data is not available, such other reliable data source as agreed by the Parties (such agreement not to be unreasonably withheld)), as measured by unit volume in such Jurisdiction in such Calendar Quarter ("Qualifying Generic Competition"), then royalty payments due to Ocular by Licensee for Net Sales of such Licensed Product in such Jurisdiction shall be reduced by [**] percent ([**]%), and such reduction shall remain in place for the remainder of the applicable Royalty Term as to the applicable Licensed Product in the applicable Jurisdiction in the event that such Qualifying Generic Competition persists for [**] consecutive Calendar Quarters; otherwise, such reduction shall no longer apply beginning in any subsequent Calendar Quarter where such Qualifying Generic Competition no longer exists until and unless such Qualifying Generic Competition once again exists.

(b) In the event that, after the Effective Date, (i) Licensee obtains a license under any Patent Rights or Know-How from any Third Party(ies) that is necessary in order to Commercialize a given Licensed Product in a given Jurisdiction in the Territory; or (ii) Licensee accepts any Third Party agreement of Ocular as In-License Agreement pursuant to Section 2.06(a) and pays any royalties to Ocular on Net Sales of a Licensed Product in the Territory and/or any *pro rata* share of any other licensing consideration associated with such In-License Agreement as described in Section 2.06(a), in accordance with such In-License Agreement, Licensee shall be permitted to deduct [**] percent ([**]%) of royalty payments and [**] percent ([**]%) of any such *pro rata* share of other licensing consideration, in each case as paid by Licensee to such Third Party or to Ocular for such license or sublicense, from the royalty payment otherwise owed to Ocular in accordance with Section 8.04 for the applicable Calendar Quarter.

(c) Notwithstanding the provisions of Section 8.05(a) and Section 8.05(b), in no event shall the total royalty rate reduction(s) allowable under Section 8.05(a) and Section 8.05(b) with respect to a Licensed Product in a Jurisdiction in a Calendar Quarter, alone or together, lead to a reduction of more than [**] percent ([**]%) of the applicable royalty rate determined in accordance with Section 8.04. If any amount that Licensee is entitled to deduct from the royalty payments due to Ocular under Section 8.05(a) or Section 8.05(b) with respect to a Licensed Product is not fully offset against such royalty amounts as a result of the preceding sentence, such amount may be carried forward and applied to future periods until fully exhausted.

Section 8.06 Royalty Payments and Reports.

(a) On a Jurisdiction-by-Jurisdiction basis, until the expiration of the Royalty Term with respect to such Licensed Product in such Jurisdiction, Licensee agrees to provide quarterly written reports to Ocular within [**] after the end of each Calendar Quarter, covering all Net Sales of such Licensed Product in such Jurisdiction by any Licensee Entity, each such written report stating for the period in question the amount of gross sales and Net Sales of each Licensed Product in each Jurisdiction in the Territory during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of royalty payment due on such Net Sales for such Calendar Quarter.

(b) Licensee shall make the royalty payments due hereunder within [**] after the end of each Calendar Quarter.

Section 8.07 Recordkeeping.

(a) Each Licensee Entity shall keep full, clear and accurate records of any Licensed Product that is made, used or sold under this Agreement and of any costs borne by such Licensee Entity for any Joint Global Study, in accordance with the Accounting Standards consistently applied, for a period of at least [**] after the end of the Calendar Year to which the records relate, setting forth the sales of any Licensed Product in sufficient detail to enable royalties and other amounts payable to Ocular hereunder to be determined. Licensee, for itself and on behalf of each Licensee Entity, further agrees to permit its books and records to be

examined by an independent accounting firm selected by Ocular and reasonably acceptable to Licensee no more than once per Calendar Year, to verify any reports and payments delivered under this Agreement during the [**] most recently-ended Calendar Years, upon reasonable notice (which shall be no less than [**] prior notice) and during regular business hours and subject to a reasonable confidentiality agreement. The Parties shall reconcile any underpayment or overpayment within [**] after the accounting firm delivers the results of any audit. Such examination is to be made at the expense of Ocular, except in the event that the results of the audit reveal an underpayment by Licensee of [**] percent ([**]%) or more during the period being audited, in which case reasonable audit fees for such examination shall be paid by Licensee.

(b) Ocular shall keep full, clear and accurate records of costs of performance of the out-of-pocket costs for which Licensee is responsible to reimburse Ocular hereunder, in accordance with Accounting Standards consistently applied, for a period of at least [**] after the end of the Calendar Year to which the records relate, in sufficient detail to enable Licensee's payment obligations. Ocular further agrees to permit its books and records to be examined by an independent accounting firm selected by Licensee and reasonably acceptable to Ocular no more than once per Calendar Year, to verify any invoices delivered in connection with such payment obligations during the [**] most recently-ended Calendar Years, upon reasonable notice (which shall be no less than [**] prior notice) and during regular business hours and subject to a reasonable confidentiality agreement. The Parties shall reconcile any underpayment or overpayment within [**] after the accounting firm delivers the results of any audit. Such examination is to be made at the expense of Licensee, except in the event that the results of the audit reveal an overcharging by Ocular of [**] percent ([**]%) or more during the period being audited, in which case reasonable audit fees for such examination shall be paid by Ocular.

Section 8.08 Currency Conversion. Wherever it is necessary to convert currencies for Net Sales invoiced in a currency other than the Dollar, such conversion shall be made into Dollars at the conversion rate existing in the United States (as reported in the Wall Street Journal) on the last working day of the applicable Calendar Quarter or, if such rate is unavailable, a substitute therefor reasonably selected by Ocular. All payments due to Ocular under this Agreement shall be made without deduction of exchange, collection or other charges. Once the amount of Net Sales paid to Ocular in respect of a particular Calendar Quarter has been converted into Dollars, such amount of Dollars shall be used for the purpose of calculating the total amount of Net Sales during the Calendar Year that includes such Calendar Quarter.

Section 8.09 Methods of Payment. All payments due to Ocular under this Agreement shall be made in Dollars by wire or ACH transfer to a bank account of Ocular, or any Affiliate of Ocular, designated from time to time in writing by Ocular. Ocular may direct that all or any portion of any payment owed by Licensee to Ocular under this Agreement be paid to any Ocular Affiliate.

Section 8.10 Taxes.

(a) Each Party shall be solely responsible for the payment of all taxes imposed by any taxing authority within the United States on such Party's share of income arising from the

activities of such Party under this Agreement, provided that Licensee shall make all payments due to Ocular under this Agreement without any withholding of such taxes. If any payment owed by Licensee to Ocular pursuant to this Agreement is subject to any deduction or withholding for taxes imposed by a taxing authority outside of the United States, then the full amount of any such tax required to be deducted and withheld on such payments will be duly deducted, withheld and timely paid over by Licensee on behalf of Ocular. Any such payment payable under this Agreement with respect to which any such tax has been deducted or withheld pursuant to this Section 8.10 shall be increased as necessary to ensure that, after all required tax deductions and withholdings have been made (including with respect to any such increased amount), the net amount received by Ocular (free and clear of any tax required to be paid over by Licensee or with respect thereto to any non-United States governmental authority) shall be equal to the amount that would have been due to, and received by, Ocular under this Agreement had no such deduction or withholding been required or made.

(b) Notwithstanding anything to the contrary in this Agreement, this Section 8.10(b) shall apply with respect to VAT or any similar tax. All payments by Licensee Entities shall be exclusive of VAT. If any VAT is required in respect of any payments made under this Agreement under applicable Laws, except as provided below, each Licensee Entity shall pay VAT at the applicable rate in respect of any such payments in accordance with local Law whether such amounts are invoiced or not in respect of those payments. To the extent any VAT is due on any amounts payable by Licensee to Ocular:

(i) under Section 8.04 of this Agreement, if such VAT is not recoverable, not creditable, not exempt, or like neutral effect under applicable VAT rules, then (x) the applicable Licensee Entity may deduct such VAT up to [**]% (by way of example, VAT Example #1: [**]. Additionally, any VAT borne by a Licensee Entity for failure to comply with local VAT rules and procedures (such as failure to properly invoice VAT), shall not be an amount borne by Ocular; and

(ii) under any Section of this Agreement other than Section 8.04, pay such VAT to the appropriate Governmental Authority, and pay to Ocular the full amount due, without deduction.

The Parties will cooperate to provide Licensee Entity all documentation required to properly and timely pay VAT amounts described in this Section 8.10(b). If the VAT originally paid or otherwise borne by Ocular is in whole or in part subsequently determined not to have been chargeable, or is fully creditable, eligible for offset, refund or recovery, or otherwise not borne by any Licensee Entity then all necessary steps will be taken by Licensee to obtain a refund of such undue VAT charge from the applicable Governmental Authority and any amount of VAT repaid by such Governmental Authority, or any amounts already offset or credited to Licensee's account will be transferred to Ocular within [**] of such offset, credit, recovery, refund or receipt. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by law, of VAT or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such VAT.

Section 8.11 Late Payments. Interest shall be payable by Licensee on any amounts payable to Ocular under this Agreement which are not paid by the due date for payment. All interest shall accrue and be calculated on a daily basis (both before and after any judgment) at a rate per month equal to the lesser of (a) [**] percentage point above the then-current "prime rate" in effect published in The Wall Street Journal or (b) the maximum rate permissible under applicable Law, for the period from the due date for payment until the date of actual payment. The payment of such interest shall not limit Ocular from exercising any other rights it may have as a consequence of the lateness of any payment.

ARTICLE IX

INTELLECTUAL PROPERTY

Section 9.01 Ownership.

(a) Ownership of the Ocular Technology shall remain vested at all times in Ocular.

(b) Ownership of the Licensee Technology shall remain vested at all times in Licensee.

(c) Each Party shall promptly notify the other Party of any new Arising Product IP. As between the Parties, any such Arising Product IP shall be owned by Ocular. Licensee hereby assigns to Ocular all right, title and interest it or any Licensee Entities may have in or to any Arising Product IP. Other than Arising Product IP, each Party shall solely own all Arising IP conceived, reduced to practice, authored, created or developed solely by or on behalf of such Party or any of its Affiliates in the course of its activities during the Term, and the Parties shall jointly own all Joint Arising IP, with each Party having an undivided half interest in and to such Joint Arising IP, with the right to practice and exploit such Joint Arising IP with no duty of accounting or seeking consent from the other Party, subject only to the applicable licenses granted under this Agreement. All Arising Product IP and Arising IP otherwise owned by Ocular shall be included with the Ocular Technology, and included in the licenses granted to Licensee pursuant to Section 2.01.

(d) Licensee agrees to assist Ocular, or its designee, at Ocular's expense, in every proper way in connection with securing, applying for, registering, perfecting and enforcing Ocular's rights in the Arising IP in any and all countries, including the disclosure to Ocular of all pertinent information and data with respect to this Agreement, the execution of all applications, specifications, oaths, assignments and all other instruments which Ocular shall deem necessary in order to apply for and obtain such rights and in order to assign and convey to Ocular, its successors, assigns and nominees the sole and exclusive right, title and interest in and to the Arising IP.

(e) Each Party shall be solely responsible for payments due under applicable inventor remuneration laws in any Jurisdiction to each inventor as to any Patent Right described

in the foregoing Section 9.01(a)-(b) to which such Party is assigned an ownership interest by such inventor.

Section 9.02 Prosecution of Patent Rights. Subject to the terms of each In-License Agreement:

(a) Ocular shall have the first right, but not the obligation, to file, prosecute and maintain all Ocular Patent Rights and Arising Product Patent Rights, at Ocular's sole cost and expense.

(b) Ocular shall consult with Licensee on the preparation, filing, prosecution and maintenance of all Ocular Patent Rights and Arising Product Patent Rights in the Territory (collectively, the "Ocular Prosecuted Patent Rights"), and shall take into consideration the commercial strategy of Licensee in the Territory. Ocular shall furnish Licensee with copies of each material document that is relevant to such preparation, filing, prosecution and maintenance at least [**] prior (or such shorter period prior if it is not reasonably practicable to provide such copies [**] prior) to filing such document or making any payment due thereunder to allow for review and comment by Licensee and shall consider in good faith timely comments from Licensee thereon. Ocular shall also furnish Licensee with copies of all final filings and responses made to any patent authority in the Territory with respect to the Ocular Prosecuted Patent Rights in a timely manner following submission thereof.

(c) Notwithstanding the foregoing, if Ocular elects not to, or is unable to, file, prosecute or maintain any Ocular Prosecuted Patent Rights in any Jurisdiction, Ocular shall give Licensee prompt notice thereof, and, in such cases, shall allow Licensee to prosecute or maintain such Ocular Prosecuted Patent Rights in such Jurisdiction, at Licensee's cost and expense. Licensee may deduct up to [**] percent ([**]%) of such costs and expenses incurred by Licensee in with respect to the prosecution and maintenance of such Ocular Prosecuted Patent Rights in such Jurisdiction against royalties due to Ocular pursuant to Section 8.04, provided that any such deduction shall not reduce any applicable royalty payment to less than [**] percent ([**]%) of the amount that would otherwise be due and payable to Ocular pursuant to Section 8.04 in any Calendar Quarter. If any amount that Licensee is entitled to deduct from the royalty payments due to Ocular under this Section 9.02(c) with respect to a Licensed Product is not fully offset against such royalty amounts as a result of the preceding sentence, such amount may be carried forward and applied to future periods until fully exhausted.

Section 9.03 Enforcement and Defense. If either Party becomes aware of any Third Party activity in the Territory, including any Development activity (whether or not an exemption from infringement liability for such Development activity is available under applicable Law), that infringes (or that is directed to the Development of a product that would infringe) an Ocular Prosecuted Patent Rights, then the Party becoming aware of such activity shall give prompt written notice to the other Party regarding such alleged infringement or misappropriation (collectively, "Infringement Activity").

Subject to the terms of each In-License Agreement:

(a) Licensee shall have the first right, but not the obligation, to attempt to resolve any Infringement Activity in the Territory by commercially appropriate steps at its own expense, including the filing of an infringement or misappropriation suit using counsel of its own choice. If Licensee fails to resolve such Infringement Activity in the Territory or to initiate a suit with respect thereto by the date that is [**] before any deadline for taking action to avoid any loss of material enforcement rights or remedies, then Ocular shall have the right, but not the obligation, to attempt to resolve such Infringement Activity by commercially appropriate steps at its own expense, including the filing of an infringement or misappropriation suit using counsel of its own choice.

(b) Any amounts recovered by a Party as a result of an action pursuant to Section 9.03(a), whether by settlement or judgment, shall be allocated first to pay to each Third Party counterparty under any In-License Agreement any amounts owed to such Third Party counterparty with respect to such enforcement action and next to reimburse the Parties for all costs and expenses incurred in connection with such proceeding paid by the Parties and not otherwise recovered. Any remaining amount shall be allocated as follows: (i) in the event that Licensee controls the applicable Infringement Activity in the Territory in accordance with Section 9.03(a), retained by Licensee but deemed Net Sales and subject to the royalty obligation to Ocular hereunder; (ii) in the event that Ocular controls the applicable Infringement Activity in the Territory in accordance with Section 9.03(a), [**] percent ([**]%) to Ocular and [**] percent ([**]%) to Licensee.

(c) If a Third Party asserts that an Ocular Prosecuted Patent Rights is invalid or unenforceable in the Territory (other than as part of its defense of the Infringement Activity set forth above) (a "Third Party Challenge"), then Ocular shall have the sole right and, but not the obligation, to defend against such assertion and, at Ocular's request and expense, Licensee shall provide reasonable assistance in defending against such Third Party assertion. Ocular shall (i) keep Licensee reasonably informed regarding such assertion and such defense (including by providing Licensee with drafts of each filing a reasonable period before the deadline for such filing and promptly providing Licensee with copies of all final filings and correspondence), (ii) consult with Licensee on such defense, and (iii) consider in good faith all comments from Licensee regarding such defense. Licensee shall have the right to join as a party to such defense and participate with its own counsel at its sole expense; provided that Ocular shall retain control of such defense.

(d) Should Ocular decide that it is not, or is no longer, interested in defending a Third Party Challenge, it shall promptly (and in any event by the date that is [**] before any deadline for taking action to avoid any loss of material rights) provide Licensee written notice of this decision. In such event, Licensee may elect either of the following:

(i) Licensee may request that Ocular defend (or continue to defend) such Third Party Challenge at Licensee's cost and expense (a "Licensee Directed Challenge Defense") and Ocular shall exercise Commercially Reasonable Efforts as reasonably requested by Licensee to carry out such Licensee Directed Challenge Defense. Ocular shall invoice Licensee for

its costs and expenses incurred in relation to any Licensee Directed Challenge Defense, and Licensee shall pay such invoice within [**] of receipt thereof. Following a successful Licensee Directed Challenge Defense, Licensee may deduct any such costs and expenses incurred by Ocular and reimbursed by Licensee in defending such Licensee Directed Challenge Defense against royalties due to Ocular pursuant to Section 8.04, provided that any such deduction shall not reduce any applicable royalty payment to less than [**] percent ([**]%) of the amount that would otherwise be due and payable to Ocular pursuant to Section 8.04 in any Calendar Quarter. If any amount that Licensee is entitled to deduct from the royalty payments due to Ocular under this Section 9.03(d)(i) with respect to a Licensed Product is not fully offset against such royalty amounts as a result of the preceding sentence, such amount may be carried forward and applied to future periods until fully exhausted; or

(ii) Licensee may defend (or may take over the defense of) such Third Party Challenge at Licensee's sole cost and expense and, at Licensee's request and expense, Ocular shall provide reasonable assistance in defending against such Third Party challenge. Licensee shall (i) keep Ocular reasonably informed regarding such defense (including by providing Ocular with drafts of each filing a reasonable period before the deadline for such filing and promptly providing Ocular with copies of all final filings and correspondence), (ii) consult with Ocular on such defense, and (iii) consider in good faith all comments from Ocular regarding such defense. For the avoidance of doubt, if Licensee elects to exercise its rights under this Section 9.03(d)(ii), then Licensee may not thereafter elect to exercise its rights under Section 9.03(d)(i).

(e) At the request of the enforcing or defending Party, the other Party shall, at the enforcing or defending Party's cost and expense, provide reasonable assistance in any enforcement or defense action undertaken pursuant this Section 9.03 (including entering into a common interest agreement if reasonably deemed necessary by the enforcing or defending Party) and be joined as a party to the suit if necessary for the initiating or defending Party to bring or continue such suit. The non-enforcing or non-defending Party shall always have the right to be represented by counsel of its own selection and its own expense in any suit or other action instituted by the other Party pursuant to this Section 9.03.

Section 9.04 Defense of Third Party Infringement and Misappropriation Claims. Subject to the terms of each In-License Agreement:

(a) If a Third Party asserts that a Patent Right or other right Controlled by it in the Territory is infringed or misappropriated by a Party's activities under this Agreement or a Party becomes aware of a Patent Right or other right that might form the basis for such a claim, the Party first obtaining knowledge of such a claim or such potential claim shall immediately provide the other Party with notice thereof and the related facts in reasonable detail. The Parties shall discuss what commercially appropriate steps, if any, to take to avoid infringement or misappropriation of said Third Party Patent Right or other right controlled by such Third Party in the Territory. If a Third Party asserts that a Patent Right or other right Controlled by it in the Territory is infringed or misappropriated by a Party's activities under this Agreement, then, subject to any indemnification obligation from one Party to the other in respect of such

infringement or misappropriation (in which case, notwithstanding the remainder of this sentence, the indemnifying Party shall have the first right to control such defense in accordance with Section 13.03), such Party shall have the first right, but not the obligation, to defend against such assertion and, at such Party's request and expense, the other Party will provide reasonable assistance in defending against such Third Party assertion. Such Party shall keep the other Party reasonably informed regarding such assertion and such defense.

ARTICLE X

DATA SECURITY AND ADVERSE DRUG EVENTS AND REPORTS

Section 10.01 Data Security. During the Term, each Licensee Entity will maintain safety and facility procedures, data security procedures and other safeguards against the disclosure, destruction, loss, or alteration of Ocular's information in its possession, all in accordance with the standards therefor consistent with customary industry standard.

Section 10.02 Complaints. Each Party shall maintain a record of all non-medical and medical product-related complaints it receives with respect to any Licensed Product in accordance with the applicable Laws of each Jurisdiction where the Licensed Products are commercialized, to include validation, investigation and trending of all complaints, which investigation shall be conducted by a qualified Third Party if necessary to comply with regulatory requirements. Each Party shall notify the other Party of any such complaint received by it in sufficient detail and in accordance with the timeframes and procedures for reporting established, and in any event in sufficient time to allow each Ocular Entity and each Licensee Entity to comply with any and all regulatory requirements imposed upon it, including in accordance with International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("ICH") guidelines. Licensee shall investigate and respond to all such complaints in in any Jurisdiction in the Territory with respect to any Licensed Product as soon as reasonably practicable. All such responses shall be made in accordance with the procedures established pursuant to ICH, FDA, EMA, NMPA and other applicable guidelines, and subject to such additional requirements as may be determined by the JC from time to time. Licensee shall promptly provide Ocular a copy of any such response.

Section 10.03 Adverse Drug Events. Within [**] after the Effective Date, the Parties shall enter into the Safety Data Exchange Agreement. Such Safety Data Exchange Agreement shall provide for the exchange by the Parties of any information of which a Party becomes aware concerning any adverse event experienced by a subject or patient being administered any Licensed Product, whether or not such adverse event is determined to be attributable to any Licensed Product, including any such information received by either Party from any Third Party (subject to receipt of any required consents from such Third Party). It is understood that each Party and in the case of Ocular, the Ocular Entities, and in the case of Licensee, the Licensee Entities, shall have the right to disclose such information if such disclosure is reasonably necessary to comply with applicable Laws or requirements of any applicable Regulatory Authority. Licensee shall be responsible for handling all such returns, suspensions and

withdrawals of each Licensed Product in the Territory at its sole expense, unless otherwise provided for in the Supply Agreement. The Safety Data Exchange Agreement will detail Licensee's responsibilities relating to such recalls, suspensions and withdrawals.

Section 10.04 No Admissions by Licensee in Response to Product Complaints that May Be Adverse to Ocular. If Licensee (including any Licensee Entity) receives any complaint relating to the quality or condition of the Licensed Product or its packaging, or the Trademark or the Patents, from any Third Party, Licensee shall forthwith acknowledge receipt of such complaint but shall not make any admissions in respect thereof which could result in liability to Ocular (or any other Ocular Entity), through indemnification or otherwise, unless such admission is required by Applicable Law or under a court order. Licensee shall notify Ocular in writing as soon as practicable to permit all applicable Ocular Entities to comply with all applicable Laws for any matter relating to the safety of the Licensed Product. Licensee shall offer reasonable cooperation to Ocular (and other Ocular Entities designated by Ocular) in investigating any complaint and the circumstances surrounding it and shall comply with Ocular's standard operating procedures in respect of adverse events, product recall or other related matters, a copy which shall be provided to Licensee.

ARTICLE XI

REPRESENTATIONS, WARRANTIES, AND COVENANTS

Section 11.01 Mutual Representations and Warranties. Each of Licensee and Ocular hereby represents and warrants to the other Party as of the Effective Date that:

(a) it is a corporation or entity duly organized and validly existing under the Laws of the state, municipality, province, administrative division or other jurisdiction of its incorporation or formation;

(b) the execution, delivery and performance of this Agreement by it has been duly authorized by all requisite corporate action;

(c) it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder, and such performance does not conflict with or constitute a breach of any of its agreements with any Third Party;

(d) it has the right to grant the rights and licenses described in this Agreement;

(e) it has not made any commitment to any Third Party in conflict with the rights granted by it hereunder;

(f) to its knowledge, no consent, approval or agreement of any person or Governmental Authority is required to be obtained in connection with the execution and delivery of this Agreement; and

(g) it has not been debarred by the FDA, is not the subject of a conviction described in Section 306 of the FD&C Act, and is not subject to any similar sanction of any other Governmental Authority outside of the U.S., and neither it nor any of its Affiliates has used, in any capacity, any person or entity who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction inside or outside of the U.S.

Section 11.02 Mutual Covenants. Each of Licensee and Ocular hereby covenants to the other Party that:

(a) it will not engage, in any capacity in connection with this Agreement or any ancillary agreement, any person or entity who either has been debarred by the FDA, is the subject of a conviction described in Section 306 of the FD&C Act or is subject to any such similar sanction inside or outside of the U.S., and such Party shall inform the other Party in writing promptly if such Party or any person or entity engaged by such Party who is performing services under this Agreement, or any ancillary agreements, is debarred or is the subject of a conviction described in Section 306 of the FD&C Act or any similar sanction inside or outside of the U.S., or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to such Party's knowledge, is threatened, relating to the debarment or conviction of a Party, any of its Affiliates or any such person or entity performing services hereunder or thereunder;

(b) during the Term, it will not make any commitment to any Third Party in conflict with the rights granted by it hereunder; and

(c) it will comply, and will cause its Affiliates to comply, with all applicable Laws in performing its activities hereunder.

Section 11.03 Additional Ocular Warranties. Ocular hereby represents and warrants to Licensee as of the Effective Date that:

(a) to Ocular's knowledge, Exhibit A contains a list of all Patent Rights that are Controlled by Ocular of any of its Affiliates as of the Effective Date and Cover the Development or Commercialization of the Licensed Products as they exist on the Effective Date in the Field in the Territory and Ocular and its Affiliates do not own and have not in-licensed any Know-How or Patents that Cover the Development or Commercialization of the Licensed Product that are not Controlled by Ocular or its Affiliates;

(b) Ocular is unaware of any challenge in the Territory to the validity or enforceability of any of the Ocular Patent Rights listed in Exhibit A;

(c) to Ocular's knowledge and with respect to the Territory, there is no pending or threatened litigation, arbitration or investigation before any regulatory or administrative body of any country or jurisdiction (including any Governmental Authority), or pertaining to pending or threatened civil, economic, administrative or criminal litigation any country or jurisdiction (including letters asserting claims, complaints, answers, briefs, motion

papers, etc.) that would affect the ownership of assets or business regulation of Ocular or any of its Affiliates, or would negatively impact Ocular's or any of its Affiliates' business and operations, including litigation against such party's management, group leaders, directors and scientists, pertaining to performance of such party's obligations under this Agreement, or pertaining to the conduct of clinical research, including without limitation intellectual property rights;

(d) Ocular has provided Licensee with a redacted version of the Existing In-License Agreement in effect as of the Effective Date. Such redacted version is redacted only to remove confidential or competitively sensitive information not relevant to Licensee as a sublicensee thereunder. To Ocular's knowledge, the Existing In-License Agreement is in full force and effect, and Ocular is not in breach of the Existing In-License Agreement; As of the Effective Date, except for the Existing In-License Agreement, there is no agreement between Ocular or its Affiliates and any Third Party pursuant to which Ocular or its Affiliates have obtained any right or license to the Licensed Products or any intellectual property rights related to the Licensed Products;

(e) During the Term of this Agreement, Ocular shall keep all In-License Agreements (including Existing In-License Agreement) in full force and effect and shall not terminate, amend, waive or otherwise modify (or consent to any of the foregoing) its rights under any In-License Agreement in any manner that materially diminishes the rights or licenses granted to Licensee hereunder, without Licensee's express written consent;

(f) Ocular has not received written notice of any investigations, inquiries, actions or other proceedings pending before or threatened by any Regulatory Authority or other Governmental Authority with respect to the Licensed Products arising from any action or default by Ocular or any of its Affiliates or a Third Party acting on behalf Ocular in the discovery, Manufacture or Development of the Licensed Products; and

(g) Ocular has not received written notice from a Third Party claiming that the development, use, manufacture or sale of any Licensed Product would infringe or misappropriate any intellectual property rights of such Third Party.

Section 11.04 Additional Licensee Warranties and Covenants. Licensee hereby represents, warrants and covenants to Ocular that:

(a) Licensee has (or will have at the anticipated time of launch) the capability to Commercialize Licensed Products in the Territory as contemplated in this Agreement;

(b) each Licensee Entity (other than Licensee) and each Licensee Entity's employees and permitted agents and contractors have executed agreements or have existing obligations under applicable Laws, or, upon their engagement by Licensee or any of its Affiliates, will execute such agreements, requiring automatic assignment to Licensee of all inventions (whether patentable or not) or other Know-how identified, discovered, authored, developed, conceived or reduced to practice during the course of and as the result of their association with Licensee or its Affiliates, and all intellectual property rights therein, and obligating the relevant

individual or entity to maintain as confidential Licensee's Confidential Information related to the Licensed Product as well as Confidential Information of other parties (including Ocular and any Ocular Entity) which such individual or entity may receive, to the extent required to support Licensee's obligations under this Agreement;

(c) to Licensee's knowledge, there is no pending or threatened litigation, arbitration or investigation before any regulatory or administrative body of any country or jurisdiction (including any Governmental Authority), or pertaining to pending or threatened civil, economic, administrative or criminal litigation any country or jurisdiction (including letters asserting claims, complaints, answers, briefs, motion papers, etc.) that would affect the ownership of assets or business regulation of Licensee or any of its Affiliates, or would negatively impact Licensee's or any of its Affiliates' business and operations, including litigation against such party's management, group leaders, directors and scientists, pertaining to performance of such party's obligations under this Agreement, or pertaining to the conduct of clinical research, including without limitation intellectual property rights;

(d) neither Licensee nor any of its Affiliates are (i) state-owned, (ii) subject to any state-owned assets administrations or other authorities with respect to the registration of state-owned assets or (iii) under collective ownership;

(e) Licensee and its Affiliates have (i) passed all annual inspections by Governmental Authorities and (ii) paid all taxes imposed upon such party by any Governmental Authority as such taxes have become due, in each case ((i) and (ii)) since its inception;

(f) neither Licensee nor any of its Affiliates is, and, during the Term, neither Licensee nor any of its Affiliates will become, a relevant scientific research institution or higher level educational school under the Notice of the General Office of the State Council on Issuing the Measures for the Management of Scientific Data, Guo Ban Fa (2018) No. 17, as such Law exists as of the Effective Date; and

(g) the Development to be undertaken under this Agreement will not be funded by the government of Mainland China.

Section 11.05 Anti-Corruption.

(a) Anti-Corruption Provisions. Each Party represents and warrants to the other Party that such Party has not, directly or indirectly, offered, promised, paid, authorized or given, and each Party agrees that such Party will not, in the future, offer, promise, pay, authorize or give, money or anything of value, directly or indirectly, to any Government Official or Other Covered Party for the purpose, pertaining to this Agreement, of: (i) influencing any act or decision of such Government Official or Other Covered Party; (ii) inducing such Government Official or Other Covered Party to do or omit to do an act in violation of a lawful duty; (iii) securing any improper advantage; or (iv) inducing such Government Official or Other Covered Party to influence the act or decision of a Governmental Authority, in order to obtain or retain business, or direct business to, any person or entity, in any way related to this Agreement.

For purposes of this Agreement: (A) “Government Official” means any official, officer, employee or representative of: (1) any Governmental Authority; (2) any public international organization or any department or agency thereof; or (3) any company or other entity owned or controlled by any Governmental Authority; and (B) “Other Covered Party” means any political party or party official, or any candidate for political office.

(b) Anti-Corruption Compliance.

(i) In performing under this Agreement, each Party, on behalf of itself, its respective Affiliates and (in the case of Ocular) other Ocular Entities and (in the case of Licensee) other Licensee Entities, agrees to comply with all applicable anti-corruption Laws, including the Foreign Corrupt Practices Act of 1977, as amended from time to time (“FCPA”) and all anti-corruption Laws of the Territory.

(ii) Each Party represents and warrants to the other Party that such Party is not aware of any Government Official or Other Covered Party having any financial interest in the subject matter of this Agreement or in any way personally benefiting, directly or indirectly, from this Agreement.

(iii) No Party, nor any Affiliate of any Party (and (in the case of Ocular) no other Ocular Entity and (in the case of Licensee) no other Licensee Entity), shall give, offer, promise or pay any political contribution or charitable donation at the request of any Government Official or Other Covered Party that is in any way related to this Agreement or any related activity.

(iv) Licensee Entities shall in all cases, refrain from engaging in any activities or conduct which would cause any Ocular Entity to be in violation of the FCPA and any applicable anti-bribery laws. If any Licensee Entity proposes to provide any information, data or documentation to any governmental or regulatory authority in respect of the Licensed Product, it shall first obtain the prior written approval of Ocular, which will not be unreasonably withheld, or shall provide such information, data or documentation in accordance with Ocular’s written instructions, unless otherwise required by Law.

(v) Licensee agrees that it will, and will cause each of its directors, officers, employees, agents or other representatives who have any direct involvement with any of the management or operations of the business of Licensee under this Agreement, at the request of Ocular, and at least annually, provide Ocular with a certification in the form hereto attached and incorporated by reference as Exhibit D.

(vi) Licensee agrees that should it learn or have reason to know of: (i) any payment, offer, or agreement to make a payment to a foreign official or political party for the purpose of obtaining or retaining business or securing any improper advantage for Ocular under this Agreement or otherwise, or (ii) any other development during the Term that in any way makes inaccurate or incomplete the representations, warranties and certifications of Licensee hereunder given or made as of the date hereof or at any time during the Term, relating

to the FCPA, Licensee will immediately advise Ocular in writing of such knowledge or suspicion and the entire basis known to Licensee therefor.

(vii) Notwithstanding any other provisions contained in this Agreement, Licensee agrees that full disclosure of information relating to a possible violation of the FCPA or the existence and terms of this Agreement, including the compensation provisions hereof, may be made at any time and for any reason to the U.S. government and its agencies, and to whomsoever Ocular determines has a legitimate need to know.

(viii) In the event that a Party violates the FCPA, any anti-corruption Law of the Territory or any other applicable anti-corruption Law, or breaches any provision in this Section 11.05, the other Party shall have the right to unilaterally terminate this Agreement pursuant to Section 14.02, except that the cure period set forth therein shall not apply.

Section 11.06 Exportation of Data. Licensee shall ensure that the export of all Licensee Product Data that Licensee is required to provide to Ocular under this Agreement complies with all applicable Laws in the Territory and shall use Commercially Reasonable Efforts to obtain any approval of any Governmental Authority required, and to take all other steps required under applicable Laws, for such export. To the extent that export of any Licensee Product Data is prohibited by applicable Laws, the Parties will work together in good faith to endeavor to provide Ocular or its designee with rights and access to such Licensee Product Data as close to those described in the preceding sentence as is permitted by applicable Law.

Section 11.07 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH HEREIN, THE INTELLECTUAL PROPERTY RIGHTS PROVIDED BY OCULAR TO LICENSEE HEREIN ARE PROVIDED "AS IS" AND WITHOUT WARRANTY. EXCEPT AS EXPRESSLY SET FORTH HEREIN, EACH OF THE PARTIES EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OR ENFORCEABILITY OF THEIR RESPECTIVE INTELLECTUAL PROPERTY RIGHTS, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

Section 11.08 Limitation of Liability. NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, EXEMPLARY, INDIRECT, CONSEQUENTIAL OR PUNITIVE DAMAGES OR DAMAGES FOR LOSS OF PROFIT OR LOST OPPORTUNITY IN CONNECTION WITH THIS AGREEMENT, ITS PERFORMANCE OR LACK OF PERFORMANCE HEREUNDER, OR ANY LICENSE GRANTED HEREUNDER. THE FOREGOING SHALL NOT LIMIT (a) ANY INDEMNIFICATION OBLIGATIONS HEREUNDER OR (b) REMEDIES AVAILABLE TO EITHER PARTY WITH RESPECT TO A BREACH OF ARTICLE XII OR Section 2.07 OR FRAUD COMMITTED BY THE OTHER PARTY.

ARTICLE XII

CONFIDENTIALITY

Section 12.01 Generally. During the Term and for a period of [**] thereafter, each Party (a) shall maintain in confidence all Confidential Information of the other Party; (b) shall not use such Confidential Information for any purpose except to fulfill its obligations or exercise its rights under this Agreement; and (c) shall not disclose such Confidential Information to anyone other than those of its Affiliates, directors, investors, prospective investors, lenders, prospective lenders, acquirers, prospective acquirers, licensees, prospective licensees, sublicensees, prospective sublicensees, employees, consultants, financial or legal advisors, or other agents or contractors (collectively, "Representatives") who are bound by written obligations of nondisclosure and non-use no less stringent than those set forth in this ARTICLE XII (except that the duration of confidentiality and non-use may be shorter but no less than [**], so long as such shorter duration does not apply to any Confidential Information comprising scientific trade secret information disclosed to such Representatives) and to whom such disclosure, under this Agreement, is necessary in connection with the fulfillment of such Party's obligations or exercise of such Party's rights under this Agreement or in connection with bona fide financing or acquisition activities. Each Party shall (i) ensure that such Party's Representatives who receive any of the other Party's Confidential Information comply with the obligations set forth in this ARTICLE XII and (ii) be responsible for any breach of these obligations by any of its Representatives who receive any of the other Party's Confidential Information. Each Party shall notify the other Party promptly on discovery of any unauthorized use or disclosure of the other's Confidential Information. Notwithstanding anything to the contrary in this ARTICLE XII, Ocular may disclose Licensee's Confidential Information to each Third Party counterparty under any In-License Agreement as reasonably required to fulfill Ocular's obligations under such In-License Agreement, and Licensee acknowledges and agrees that, with respect to any such Confidential Information, such Third Party counterparty(ies) shall only be bound by the confidentiality obligations set forth in the applicable In-License Agreement(s). From and after the Effective Date, any "Confidential Information" (as defined in the Confidentiality Agreement) shall be deemed to be Confidential Information hereunder and subject to the terms of this Agreement.

Section 12.02 Exceptions. The obligations of confidentiality, non-disclosure, and non-use set forth in Section 12.01 shall not apply to, and "Confidential Information" shall exclude, any information to the extent the receiving Party (the "Recipient") can demonstrate that such information: (a) was in the public domain or publicly available at the time of disclosure to the Recipient or any of its Affiliates by the disclosing Party or any of its Affiliates pursuant to this Agreement, or thereafter entered the public domain or became publicly available, in each case other than as a result of any action of the Recipient, or any of its Representatives, in breach of this Agreement or the Confidentiality Agreement; (b) was rightfully known by the Recipient or any of its Affiliates (as shown by its written records) prior to the date of disclosure to the Recipient or any of its Affiliates by the disclosing Party or any of its Affiliates pursuant to this Agreement or the Confidentiality Agreement; (c) was received by the Recipient or any of its Affiliates on an unrestricted basis from a Third Party rightfully in possession of such information

and not under a duty of confidentiality to the disclosing Party or any of its Affiliates; or (d) was independently developed by or for the Recipient or any of its Affiliates without reference to or reliance on the Confidential Information of the other Party or any of its Affiliates (as demonstrated by written records).

Section 12.03 Permitted Disclosures.

(a) Notwithstanding any other provision of this Agreement, Recipient's (or its Affiliates') disclosure of the other Party's Confidential Information shall not be prohibited if such disclosure: (i) is in response to a valid order of a court or other Governmental Authority including the rules and regulations promulgated by the Securities and Exchange Commission (or similar foreign authority) or any other Governmental Authority or (ii) to patent offices in order to seek or obtain Patent Rights or to Regulatory Authorities in order to seek or obtain approval to conduct clinical trials or to gain Regulatory Approval with respect to the Licensed Products as contemplated by this Agreement; provided that such disclosure may be made only to the extent reasonably necessary to respond to such court or other Governmental Authority order to seek or obtain such Patent Rights or Regulatory Approvals and the Recipient (or its applicable Affiliate) shall use Commercially Reasonable Efforts to obtain confidential treatment of such information. If a Recipient is required to disclose Confidential Information pursuant to this Section 12.03(a), prior to any disclosure the Recipient shall, to the extent legally permitted and practicable, provide the disclosing Party with prior written notice of such disclosure in order to permit the disclosing Party to seek a protective order or other confidential treatment of such disclosing Party's Confidential Information.

(b) Each Party acknowledges that the other Party may be required by Law or by stock exchange rules to make public disclosures (including in filings with Government Authorities or stock exchanges) of the terms of this Agreement or certain material developments or material information generated under this Agreement. Each Party agrees that the other Party may make such disclosures as required by Law or by stock exchange rules, provided that the Party seeking such disclosure first provides the other Party a copy of the proposed disclosure, except where prohibited by applicable Law, and provided further that (except to the extent that the Party seeking disclosure is required to disclose such information to comply with applicable Law and rules) if the other Party demonstrates to the reasonable satisfaction of the Party seeking disclosure, within [**] of such Party's providing the copy (or such lesser period of time as required by applicable Law, and provided that the other Party will make reasonable efforts to accommodate a shorter timeframe if requested), that the public disclosure of previously undisclosed information will materially adversely affect the Development or Commercialization of the Licensed Product (including with respect to such Party's intellectual property protection strategy), the Party seeking disclosure will remove from the disclosure such specific previously undisclosed information as the other Party shall reasonably request to be removed.

Section 12.04 Publicity. On or after the Effective Date, each Party may issue a press release announcing the existence of this Agreement at a time, and in a form, to be agreed by the Parties. Additionally, the Parties recognize that each Party may from time to time desire to issue

press releases and make other public statements or public disclosures (each, a "Public Statement") in respect of this Agreement, including the Development or Commercialization of Licensed Products in the Territory. If Licensee desires to make a Public Statement, it shall provide Ocular a copy of such Public Statement at least [**] prior to the date it desires to make such public disclosure. Licensee shall not issue a Public Statement without Ocular's prior written approval, which advance approval shall not be unreasonably withheld, conditioned or delayed. Once any public statement or public disclosure has been approved by Ocular in accordance with the prior sentence, then Licensee may appropriately communicate information contained in such permitted statement or disclosure. Notwithstanding anything to the contrary in this Section 12.04, nothing in this Section 12.04 shall be deemed to limit either Party's rights under Section 12.03.

Section 12.05 Publications. Except for disclosures permitted pursuant to Section 12.02, Section 12.03 or Section 12.04, if Licensee wishes to make a publication or public presentation with respect to its Commercialization of any Licensed Product in the Field in the Territory, Licensee shall deliver to Ocular a copy of the proposed written publication or presentation within [**] prior to submission for publication or presentation. Ocular shall have the right (a) to require modifications to the publication or presentation for patent or any other business reasons, and Licensee will remove all of Ocular's Confidential Information if requested by Ocular and (b) to require a reasonable delay in publication or presentation in order to protect patentable information. If Ocular requests a delay, then Licensee shall delay submission or presentation for a period of [**] (or such shorter period as may be mutually agreed by the Parties) to enable Ocular to file patent applications protecting Ocular' rights in such information. For clarity, Licensee shall not make any publication or public presentation (i) with respect to the Development or Manufacturing of the Licensed Products; or (ii) which includes any CMC data related to the Licensed Products, in each case without Ocular's prior written consent, which Ocular may withhold in its sole discretion.

Section 12.06 Injunctive Relief. Each Party acknowledges and agrees that there may be no adequate remedy at law for any breach of its obligations under this ARTICLE XII, that any such breach may result in irreparable harm to the other Party and, therefore, that upon any such breach or any threat thereof, such other Party may seek appropriate equitable relief in addition to whatever remedies it might have at law, without the necessity of showing actual damages.

ARTICLE XIII

INDEMNIFICATION

Section 13.01 Indemnification by Ocular. Ocular shall indemnify, hold harmless and defend Licensee and its Affiliates, and their respective directors, officers, consultants, agents, contractors and employees (the "Licensee Indemnitees") from and against any and all Third Party suits, claims, actions, demands, liabilities, expenses, costs, damages, deficiencies, obligations or losses (including reasonable attorneys' fees, court costs, witness fees, damages, judgments, fines and amounts paid in settlement) ("Losses") to the extent that such Losses arise out of (a) any

breach of this Agreement by Ocular, (b) the Development, Manufacture (excluding Losses arising out of infringement of Third Party Patent Rights) or Commercialization of any Licensed Product by or on behalf of any Ocular Entity or (c) the gross negligence or willful misconduct of any Ocular Indemnitee. Notwithstanding the foregoing, Ocular shall not have any obligation to indemnify the Licensee Indemnitees to the extent that the applicable Losses arise out of the scenarios set forth in Section 13.02(a), Section 13.02(b) or Section 13.02(c) below.

Section 13.02 Indemnification by Licensee. Licensee shall indemnify, hold harmless and defend Ocular and its Affiliates, and their respective directors, officers, consultants, agents, contractors and employees (the "Ocular Indemnitees") from and against any and all Losses, to the extent that such Losses arise out of (a) any breach of this Agreement by Licensee, (b) the Development or Commercialization of any Licensed Product by or on behalf of any Licensee Entity or (c) the gross negligence or willful misconduct of any Licensee Indemnitee. Notwithstanding the foregoing, Licensee shall not have any obligation to indemnify the Ocular Indemnitees to the extent that the applicable Losses arise out of the scenarios set forth in Section 13.01(a), Section 13.01(b) or Section 13.01(c) above.

Section 13.03 Procedure. In the event of a claim by a Third Party against a Licensee Indemnitee or Ocular Indemnitee entitled to indemnification under this Agreement ("Indemnified Party"), the Indemnified Party shall promptly notify the Party obligated to provide such indemnification ("Indemnifying Party") in writing of the claim and the Indemnifying Party shall undertake and solely manage and control, at its sole expense, the defense of the claim and its settlement. The Indemnified Party shall cooperate with the Indemnifying Party. The Indemnified Party may, at its option and expense, be represented in any such action or proceeding by counsel of its choice. The Indemnifying Party shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the Indemnifying Party's written consent. The Indemnifying Party shall not settle any such claim unless such settlement fully and unconditionally releases the Indemnified Party from all liability relating thereto and does not impose any obligations on the Indemnified Party, unless the Indemnified Party otherwise agrees in writing. No Indemnified Party may settle any claim for which it is being indemnified under this Agreement without the Indemnifying Party's prior written consent.

Section 13.04 Insurance. Licensee shall, at its own expense, obtain and maintain insurance with a reputable insurance carrier with respect to the Licensee Entities' Development and Commercialization of Licensed Products in the Field in the Territory under this Agreement in such type and amount and subject to such deductibles and other limitations as biopharmaceutical companies in the Territory customarily maintain with respect to the Development and Commercialization of similar products. Such insurance policy shall provide product liability coverage and broad form contractual liability coverage for Licensee's indemnification obligations under this Agreement and shall name the Ocular Indemnitees as additional insureds. Licensee shall provide a copy of such insurance policy to Ocular upon reasonable request by Ocular. Licensee shall provide Ocular with written notice at least [**] prior to any cancellation, non-renewal or material change in such insurance. If Licensee does not obtain replacement insurance providing comparable coverage within such [**] period, Ocular

shall have the right to terminate this Agreement effective at the end of such [**] period without notice or any additional waiting periods. This Section 13.04 shall survive expiration or termination of this Agreement and last until [**] after the last sale of any Licensed Product in the Field in the Territory by any Licensee Entity.

ARTICLE XIV

TERM AND TERMINATION

Section 14.01 Term. The term of this Agreement shall begin on the Effective Date and, unless earlier terminated in accordance with the terms of this ARTICLE XIV (Term and Termination), will expire upon the expiration of the last-to-expire Royalty Term (the "Term").

Section 14.02 Termination for Breach. Subject to the terms and conditions of this Section 14.02 (Termination for Breach), a Party (the "Non-Breaching Party") shall have the right, in addition to any other rights and remedies available to such Party at law or in equity, to terminate this Agreement in the event the other Party (the "Breaching Party") is in material breach of its obligations under this Agreement. The Non-Breaching Party shall first provide written notice to the Breaching Party, which notice shall identify with particularity the alleged breach (the "Breach Notice"). With respect to material breaches of any payment provision hereunder, the Breaching Party shall have a period of [**] after such Breach Notice is provided to cure such breach. With respect to all other breaches, the Breaching Party shall have a period of [**] after such Breach Notice is provided to cure such breach. If such breach is not cured within the applicable period set forth above, the Non-Breaching Party may, at its election, terminate this Agreement upon written notice to the Breaching Party, provided that, in the event the Breaching Party disputes such allegation of breach, for so long as the Breaching Party continues to dispute such allegation in good faith, the termination shall not become effective unless and until such dispute is resolved in such Non-Breaching Party's favor. The waiver by either Party of any breach of any term or condition of this Agreement shall not be deemed a waiver as to any subsequent or similar breach.

Section 14.03 Termination for Bankruptcy and Rights in Bankruptcy.

(a) To the extent permitted under applicable Law, if, at any time during the Term, an Event of Bankruptcy (as defined below) relating to either Party (the "Bankrupt Party") occurs, the other Party (the "Other Party") shall have, in addition to all other legal and equitable rights and remedies available to such Party, the option to terminate this Agreement upon [**] written notice to the Bankrupt Party. It is agreed and understood that, if the Other Party does not elect to terminate this Agreement upon the occurrence of an Event of Bankruptcy, except as may otherwise be agreed with the trustee or receiver appointed to manage the affairs of the Bankrupt Party, the Other Party shall continue to make all payments required of it under this Agreement as if the Event of Bankruptcy had not occurred, and the Bankrupt Party shall not have the right to terminate any license granted herein. The term "Event of Bankruptcy" means: (a) filing in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of the Bankrupt Party or of its assets or (b) being served

with an involuntary petition against the Bankrupt Party, filed in any insolvency proceeding, where such petition is not dismissed within [**] after the filing thereof.

(b) All rights and licenses granted under or pursuant to this Agreement by Licensee and Ocular are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party. The Parties acknowledge and agree that payments made under Section 8.02 (Clinical Development Milestone and Clinical Development Support Payments) or Section 8.03 (Commercial Milestone Payments) or pursuant to any Supply Agreement shall not (x) constitute royalties within the meaning of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction or (y) relate to licenses of intellectual property hereunder.

Section 14.04 Termination on Ocular's Change in Control. In the event of a Change in Control of Ocular or any global licensing agreement with a Third Party which includes any Jurisdiction, Ocular shall have the right to terminate this Agreement and redeem all rights licensed by Ocular to Licensee hereunder at a redemption price of, [**] percent ([**]%) of the upfront and milestone payments Licensee has actually paid to Ocular under Section 8.01, Section 8.02 and Section 8.03, plus any costs and expenses that have been incurred and accrued by Licensee. Such right shall be exercisable by Ocular within [**] after the closing of such Change in Control transaction upon [**] written notice to Licensee, and such redemption price shall be due and payable concurrent with such notice.

Section 14.05 Termination at Will by Licensee. At any time after completion of the Phase 3 Clinical Trial for OTX-TIC, Licensee may terminate this Agreement for any or no reason upon giving three (3) months' notice to Ocular.

Section 14.06 Effect of Termination.

(a) In the event of any termination (but not expiration) of this Agreement, the following shall apply:

(i) All license grants in this agreement from Ocular to Licensee shall immediately terminate;

(ii) Licensee shall cease using the Ocular Technology and return all inventory of the Product Materials to Ocular, together with all copies of the Ocular Know-How and other Confidential Information of Ocular in the possession or control of Licensee or any of its Representatives;

(iii) Licensee shall, at Ocular's written request, to the extent feasible under applicable Law, promptly: (A) assign and transfer to Ocular all confidentiality and other agreements, and Arising IP solely relating to any Licensed Product, and solely to the extent in any Licensee Entity's possession or control; (B) assign and transfer to Ocular all Regulatory Filings and Regulatory Approvals for the Licensed Product in the Territory Controlled by the Licensee Entities; (C) disclose to Ocular all documents embodying the foregoing that are in any Licensee Entity's possession or control or that any Licensee Entity is able to obtain using reasonable efforts; and (D) provide to Ocular a copy of all Licensee Product Data then in the possession of Licensee and any other Licensee Entity;

(iv) At Ocular's request, Licensee shall promptly take all action that may be reasonably required to transfer all customer lists, promotional materials and any other information it has generated for selling the Licensed Product in the Territory, as well as any remaining inventories of Licensed Product to Ocular or a Third Party designated by Ocular. In addition, Licensee shall promptly transfer to Ocular or to the legal entity designated by Ocular all documents Controlled by Licensee relating to the Licensed Product and Licensee Regulatory Documents (including Regulatory Approvals) necessary for a smooth transition of the right of Licensee to sell Licensed Product back to Ocular; all rights granted by Ocular to Licensee (including to any Licensee Entity) under this Agreement shall revert to Ocular (and Licensee shall reasonably cooperate with Ocular (or its designated Ocular Entities) to take all necessary steps, at Ocular's option, to cancel or transfer to Ocular all registrations made by Licensee, if any, of any Trademark associated with any Licensed Product;

(v) Licensee (including each Licensee Entity) shall cease forthwith the use of all samples, advertising and promotional literature, technical data, point of sale and other material relating to the Licensed Product and in the possession or under the control of Licensee, or any Licensee Entity and its sales representatives, and shall destroy them and certify such destruction to Ocular in writing. Licensee shall also cease immediately the use of any Internet website relating to the Licensed Product as well as any Trademark associated with any Licensed Product;

(vi) Licensee hereby grants, and shall cause each Licensee Entity to grant, to Ocular an exclusive (even as to Licensee and each Licensee Entity), royalty-free, worldwide, sublicensable, transferable, perpetual, irrevocable, royalty-free license under Licensee Technology as set forth in Section 2.01(b);

(vii) The rights to the Licensee Product Data granted to Ocular under Section 2.05(a) shall be deemed automatically revised to be worldwide;

(viii) The costs associated with the activities set forth in subsections (a)(ii), (a)(iii) and (a)(iv) of this Section 14.04 shall be borne by (A) Licensee, in the event of termination of this Agreement by Ocular pursuant to Section 14.02 or Section 14.03; (B) Ocular in the event of termination of this Agreement by Licensee pursuant to Section 14.02 or Section 14.03; (C) Ocular in the event of termination of this Agreement by Ocular pursuant to Section 14.04; and (D) Licensee in the event of termination of this Agreement by Licensee pursuant to Section 14.05; and

(ix) Notwithstanding any expiration or termination of this Agreement, the Safety Data Exchange Agreement (with respect to Licensee's obligations thereunder) shall continue in accordance with its terms.

Section 14.07 Survival; Accrued Rights. The following articles and sections of this Agreement shall survive expiration or early termination for any reason: ARTICLE I, Section 2.01(b), Section 4.02 (solely with respect to applicable payment obligations accrued prior to termination or expiration), Section 5.01 (solely with respect to applicable payment obligations accrued prior to termination or expiration), ARTICLE VIII (solely with respect to applicable payment obligations accrued prior to termination or expiration), Section 9.01, Section 11.07, Section 11.08, ARTICLE XII, ARTICLE XIII, Section 14.03(b), Section 14.06, Section 14.07, ARTICLE XV, ARTICLE XVI and ARTICLE XVII. In any event, expiration or termination of this Agreement shall not relieve either Party of any liability which accrued hereunder prior to the effective date of such expiration or termination nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement, nor prejudice either Party's right to obtain performance of any obligation.

ARTICLE XV

DISPUTE RESOLUTION; GOVERNING LAW

Section 15.01 Arbitration. Subject to Section 15.01(d), any disputes, claims or controversies in connection with this Agreement, including any questions regarding its formation, existence, validity, enforceability, performance, interpretation, breach or termination, that are not resolved in accordance with ARTICLE III and not subject to a Party's final decision-making authority in accordance with ARTICLE III (except with regard to a dispute, claim or controversy with respect to which Party has final decision-making authority thereunder) shall be referred to and finally resolved by binding arbitration under the American Arbitration Association ("AAA") in accordance with its Commercial Arbitration Rules (the "Rules"), which

rules are deemed to be incorporated by reference into this Section 15.01, in the manner described below:

(a) Arbitration Request. If a Party intends to begin an arbitration to resolve a dispute arising under this Agreement, such Party shall provide written notice (the "Arbitration Request") to the other Party of such intention and the issues for resolution. Any such dispute that is not to be resolved in accordance with Section 15.01(d) shall be resolved in accordance with Section 15.01(c), any such dispute that relates to validity or enforceability of a Patent Right shall be resolved in accordance with Section 15.01(d).

(b) Additional Issues. Within [**] after the receipt of an Arbitration Request, the other Party may, by written notice, add additional issues for resolution.

(c) General Arbitration Procedure for Disputes. The seat of arbitration will be in New York, New York unless other venue is agreed upon by Parties, and it will be conducted in the English language. The arbitrators may not decide based on equity. Unless agreed by the Parties to choose a single common arbitrator, the arbitration will be conducted by three (3) arbitrators, with one (1) appointed by each Party, according to the Rules. The two (2) arbitrators appointed by the Parties will by mutual agreement appoint the third arbitrator, who will preside over the arbitration. Any dispute or omission regarding the appointment of the arbitrators by the Parties, as well as the choice of the third arbitrator, will be resolved by the AAA. The arbitral award shall be final, definitive and binding on the Parties and their successors. The Parties reserve the right to apply to a competent judicial court to obtain urgent remedies to protect rights before establishment of the arbitration panel, without such recourse being considered as a waiver of arbitration. Except as otherwise determined by the arbitrators, the Parties shall each bear half of the fees and expenses of the arbitrators and AAA, and each Party shall bear the costs and fees of its attorneys. Nothing in this Agreement shall be deemed as preventing either Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, Confidential Information, Know-How, intellectual property rights or any other proprietary right or otherwise to avoid irreparable harm. If the issues in dispute involve scientific or technical matters, any arbitrators chosen hereunder shall have educational training or experience sufficient to demonstrate a reasonable level of knowledge in the field of biotechnology and pharmaceuticals. Judgment on the award rendered by the arbitrator may be entered in any court having jurisdiction thereof. The Parties intend that each award rendered by an Arbitrator hereunder shall be entitled to recognition and enforcement under the United Nations Convention on the Recognition and Enforcement of Arbitral Awards (New York, 1958).

(d) Intellectual Property Disputes. Unless otherwise agreed by the Parties, a dispute between the Parties relating to the validity or enforceability of any Patent Right shall not be subject to arbitration and shall be submitted to a court or patent office of competent jurisdiction in the relevant country or jurisdiction in which such patent was issued or, if not issued, in which the underlying patent application was filed.

Section 15.02 Choice of Law. This Agreement and all amendments, modifications, alterations, or supplements hereto, and the rights of the Parties hereunder, shall be construed under and governed by the Laws of the State of New York, exclusive of its conflicts of laws principles.

Section 15.03 Language. This Agreement has been prepared in the English language and the English language shall control its interpretation. All consents, notices, reports and other written documents to be delivered or provided by a Party under this Agreement shall be in the English language, and in the event of any conflict between the provisions of any document and the English language translation thereof, the terms of the English language translation shall control.

ARTICLE XVI

ASSIGNMENT AND ACQUISITIONS

Section 16.01 Assignment.

(a) Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by either Party (and, for these purposes, a merger, sale of assets, operation of law or other transaction shall be deemed an assignment) without the prior written consent of the other Party. Notwithstanding the foregoing, either Party may, without the other Party's written consent, assign this Agreement and its rights and obligations hereunder in whole or in part to (i) an Affiliate of such Party or (ii) a Third Party that acquires, by or otherwise in connection with, a merger, sale of assets or otherwise, all or substantially all of the business of such Party to which the subject matter of this Agreement relates; provided that the assignee agrees in writing to assume all of such Party's obligations under this Agreement. The assigning Party will remain responsible for the performance by its assignee of this Agreement or any obligations hereunder so assigned.

(b) The terms of this Agreement will be binding upon and will inure to the benefit of the successors, heirs, administrators and permitted assigns of the Parties. Any purported assignment in violation of this Section 16.01 will be null and void ab initio.

Section 16.02 Acquisitions. Each Party agrees that, in the event that a Party (the "Acquired Party") is acquired through a Change in Control by one or more persons or entities (collectively, the "Acquirer"), the Acquired Party shall be deemed not to "Control" for purposes of this Agreement, and the non-Acquired Party shall not obtain any rights or access under this Agreement to, any Know-How or Patent Rights owned by or licensed to such Acquirer, or any of such Acquirer's Affiliates that were not Affiliates of the Acquired Party immediately prior to the consummation of such Change in Control ("Existing Acquirer Affiliates"), that were not already within Ocular Technology (if the Acquired Party is Ocular) or Licensee Technology (if the Acquired Party is Licensee) immediately prior to the consummation of such Change in Control. Each Party shall notify the other Party promptly after any Change in Control of such Party.

ARTICLE XVII

MISCELLANEOUS

Section 17.01 Force Majeure. Subject to the terms of each In-License Agreement, If either Party shall be delayed, interrupted in or prevented from the performance of any obligation hereunder by reason of force majeure, which may include any act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, act of terrorism, government action, strike or labor differences, in each case outside of such Party's reasonable control, such Party shall not be liable to the other therefor, and the time for performance of such obligation shall be extended for a period equal to the duration of the force majeure event which occasioned the delay, interruption or prevention. The Party invoking the force majeure rights of this Section 17.01 must notify the other Party by courier or overnight dispatch (e.g., Federal Express) within a period of [**] after both the first and last day of the force majeure event unless the force majeure event renders such notification impossible, in which case notification will be made as soon as possible. If the delay resulting from the force majeure event exceeds [**], the other Party may terminate this Agreement immediately upon written notice to the Party invoking the force majeure rights of this Section 17.01.

Section 17.02 Entire Agreement. This Agreement, together with the exhibits and schedules attached hereto, constitutes the entire agreement between Ocular or any of its Affiliates, on the one hand, and Licensee or any of its Affiliates, on the other hand, with respect to the subject matter hereof, supersedes all prior understandings and writings between Ocular or any of its Affiliates, on the one hand, and Licensee or any of its Affiliates, on the other hand relating to such subject matter, including the Confidentiality Agreement, and, subject to Section 12.01, shall not be modified, amended or terminated, except by another agreement in writing executed by the Parties.

Section 17.03 Severability. If, under applicable Law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision of this Agreement (such invalid or unenforceable provision, a "Severed Clause"), it is mutually agreed that this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use their reasonable efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement.

Section 17.04 Notices. Any notice required or permitted to be given under this Agreement shall be in writing and shall be mailed by internationally recognized express delivery service, or sent by facsimile and confirmed by mailing, as follows (or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith):

If to Ocular:

General Counsel

Ocular Therapeutix
24 Crosby Drive
Bedford, MA 01730
Attention: General Counsel
Facsimile: +1-781-275-7562

With a copy to (which shall not constitute notice for purposes of this Agreement):

WilmerHale LLP
60 State Street
Boston, Massachusetts 02109
Attention: Steven D. Barrett, Esq.
Facsimile: (617) 526-5000

If to Licensee:

Affamed Therapeutics Limited
Room 3306-3307
Two Exchange Square
8 Connaught
Hong Kong

With a copy to (which shall not constitute notice for purposes of this Agreement):

Cooley LLP
3175 Hanover Street
Palo Alto, California 94304-1130
Attn: Lila Hope, Esq.
Office: (650) 843-5735
Facsimile: (650) 849-7400

Any such notice shall be deemed to have been given (a) when delivered if personally delivered, (b) on receipt if sent by overnight courier or (c) on receipt if sent by mail.

Section 17.05 Agency. Neither Party is, nor will be deemed to be a partner, employee, agent or representative of the other Party for any purpose. Each Party is an independent contractor of the other Party. Neither Party shall have the authority to speak for, represent or obligate the other Party in any way without prior written authority from the other Party.

Section 17.06 No Waiver. Any omission or delay by either Party at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof, by the other Party, shall not constitute a waiver of such Party's rights to the future enforcement of any of its rights under this Agreement. Any waiver by a Party of a particular breach or default by the other Party shall not operate or be construed as a waiver of any subsequent breach or default by the other Party.

Section 17.07 Cumulative Remedies. Except as may be expressly set forth herein, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law or in equity.

Section 17.08 Third Party Beneficiary Rights. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, other than (a) to the extent provided in Section 13.01, the Licensee Indemnitees and (b) to the extent provided in Section 13.02, the Ocular Indemnitees.

Section 17.09 Performance by Affiliates, Sublicensees or Subcontractors. To the extent that this Agreement imposes any obligation on any Licensee Entity, Licensee shall cause such Licensee Entity to perform such obligation. Either Party may use one or more of its Affiliates to perform its obligations and duties hereunder; provided that such Party so notifies the other Party in writing and provided, further, that such Party shall remain liable hereunder for the prompt payment and performance of all of its obligations hereunder.

Section 17.10 Counterparts. This Agreement may be executed in counterparts, all of which taken together shall be regarded as one and the same instrument.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties have executed this Agreement through their duly authorized representatives to be effective as of the Effective Date.

OCULAR THERAPEUTIX, INC.

By: /s/ Antony Mattessich

Name: Antony Mattessich

Title: President & Chief Executive Officer

AFFAMED THERAPEUTICS LIMITED

By: /s/ Dr. Dayao Zhao

Name: Dr. Dayao Zhao

Title: Chief Executive Officer

Exhibit 31.1

CERTIFICATIONS

I, Antony Mattessich, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Ocular Therapeutix, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 5, 2020

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 5, 2020

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, 2020 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 5, 2020

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, 2020 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 5, 2020

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