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

FORM 10-Q

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

For the quarterly period ended March 31, 2018

OR

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER 000-51122

EyePoint Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

26-2774444
(I.R.S. Employer
Identification No.)

480 Pleasant Street
Watertown, MA
(Address of principal executive offices)

02472
(Zip Code)

(617) 926-5000
(Registrant's telephone number, including area code)

pSivida Corp.
(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

Emerging growth company

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

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

There were 54,029,917 shares of the registrant's common stock, \$0.001 par value, outstanding as of May 7, 2018.

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Financial Statements

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)
(In thousands, except share amounts)

	March 31, 2018	June 30, 2017
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,346	\$ 16,898
Accounts and other receivables	478	251
Prepaid expenses and other current assets	851	591
Total current assets	17,675	17,740
Property and equipment, net	250	313
Intangible assets, net	31,973	364
Other assets	110	110
Restricted cash	150	150
Total assets	\$ 50,158	\$ 18,677
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,760	\$ 1,016
Accrued expenses	3,215	4,224
Accrued development milestone	15,000	—
Deferred revenue	240	50
Total current liabilities	21,215	5,290
Long-term debt	12,850	—
Derivative liability	6,957	—
Other long-term liabilities	938	51
Total liabilities	41,960	5,341
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$.001 par value, 5,000,000 shares authorized, none issued and outstanding	—	—
Common stock, \$.001 par value, 120,000,000 shares authorized, 53,909,917 and 39,356,999 shares issued and outstanding at March 31, 2018 and June 30, 2017, respectively	54	39
Additional paid-in capital	336,870	323,284
Accumulated deficit	(329,563)	(310,820)
Accumulated other comprehensive income	837	833
Total stockholders' equity	8,198	13,336
Total liabilities and stockholders' equity	\$ 50,158	\$ 18,677

See notes to condensed consolidated financial statements

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EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended		Nine Months Ended	
	March 31,		March 31,	
	2018	2017	2018	2017
Revenues:				
Collaborative research and development	\$ 524	\$ 372	\$ 1,125	\$ 6,108
Royalty income	404	218	1,121	730
Total revenues	<u>928</u>	<u>590</u>	<u>2,246</u>	<u>6,838</u>
Operating expenses:				
Research and development	3,325	3,324	11,413	10,667
General and administrative	2,281	2,426	7,325	8,611
Total operating expenses	<u>5,606</u>	<u>5,750</u>	<u>18,738</u>	<u>19,278</u>
Loss from operations	(4,678)	(5,160)	(16,492)	(12,440)
Interest and other income	25	20	74	71
Change in fair value of derivative liability	(2,325)	—	(2,325)	—
Net loss	<u>\$ (6,978)</u>	<u>\$ (5,140)</u>	<u>\$ (18,743)</u>	<u>\$ (12,369)</u>
Net loss per common share:				
Basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.15)</u>	<u>\$ (0.43)</u>	<u>\$ (0.36)</u>
Weighted average common shares:				
Basic and diluted	<u>45,644</u>	<u>34,366</u>	<u>43,184</u>	<u>34,238</u>
Net loss	<u>\$ (6,978)</u>	<u>\$ (5,140)</u>	<u>\$ (18,743)</u>	<u>\$ (12,369)</u>
Other comprehensive income (loss):				
Foreign currency translation adjustments	1	—	4	(30)
Net unrealized gain on marketable securities	—	1	—	2
Other comprehensive income (loss)	<u>1</u>	<u>1</u>	<u>4</u>	<u>(28)</u>
Comprehensive loss	<u>\$ (6,977)</u>	<u>\$ (5,139)</u>	<u>\$ (18,739)</u>	<u>\$ (12,397)</u>

See notes to condensed consolidated financial statements

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)
(In thousands, except share amounts)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	Par Value Amount				
Balance at July 1, 2016	34,172,919	\$ 34	\$312,208	\$ (292,213)	\$ 852	\$ 20,881
Net loss	—	—	—	(12,369)	—	(12,369)
Other comprehensive loss	—	—	—	—	(28)	(28)
Issuance of stock, net of issue costs	1,411,686	1	2,152	—	—	2,153
Exercise of stock options	84,080	—	99	—	—	99
Stock-based compensation	—	—	1,774	—	—	1,774
Balance at March 31, 2017	<u>35,668,685</u>	<u>\$ 35</u>	<u>\$316,233</u>	<u>\$ (304,582)</u>	<u>\$ 824</u>	<u>\$ 12,510</u>
Balance at July 1, 2017	39,356,999	\$ 39	\$323,284	\$ (310,820)	\$ 833	\$ 13,336
Net loss	—	—	—	(18,743)	—	(18,743)
Other comprehensive income	—	—	—	—	4	4
Issuance of stock, net of issue costs	14,506,324	15	11,590	—	—	11,605
Fair value of warrant issued	—	—	268	—	—	268
Vesting of performance stock units	46,594	—	(2)	—	—	(2)
Stock-based compensation	—	—	1,730	—	—	1,730
Balance at March 31, 2018	<u>53,909,917</u>	<u>\$ 54</u>	<u>\$336,870</u>	<u>\$ (329,563)</u>	<u>\$ 837</u>	<u>\$ 8,198</u>

See notes to condensed consolidated financial statements

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EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	Nine Months Ended	
	March 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	\$(18,743)	\$(12,369)
Adjustments to reconcile net loss to cash flows from operating activities:		
Amortization of intangible assets	366	542
Depreciation of property and equipment	126	59
Stock-based compensation expense	1,730	1,774
Change in fair value of derivative liability	2,325	—
Amortization of bond discount on marketable securities	—	(9)
Amortization of noncurrent portion of deferred revenue	—	(5,584)
Changes in current assets and liabilities:		
Accounts receivable and other current assets	(175)	(131)
Accounts payable and accrued expenses	(1,632)	(424)
Deferred revenue	190	109
Deferred rent	(13)	(5)
Net cash used in operating activities	<u>(15,826)</u>	<u>(16,038)</u>
Cash flows from investing activities:		
Purchases of marketable securities	—	(5,052)
Maturities of marketable securities	—	16,243
Acquisition of Icon Bioscience Inc., net of cash acquired	(15,072)	—
Purchases of property and equipment	(63)	(21)
Proceeds from sale of property and equipment	—	33
Net cash (used in) provided by investing activities	<u>(15,135)</u>	<u>11,203</u>
Cash flows from financing activities:		
Proceeds from issuance of stock, net of issuance costs	16,310	2,305
Proceeds from issuance of long-term debt	15,000	—
Payment of debt issue costs	(905)	—
Exercise of stock options	—	99
Net cash provided by financing activities	<u>30,405</u>	<u>2,404</u>
Effect of foreign exchange rate changes on cash and cash equivalents	4	(11)
Net decrease in cash and cash equivalents	<u>(552)</u>	<u>(2,442)</u>
Cash and cash equivalents at beginning of period	<u>16,898</u>	<u>15,313</u>
Cash and cash equivalents at end of period	<u>\$ 16,346</u>	<u>\$ 12,871</u>
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment	\$ —	\$ 22
Accrued acquisition costs	1,737	—
Accrued development milestone	15,000	—
Stock issuance costs	143	152
Debt issue costs	307	—
Accrued term loan exit fee	900	—
Fair value of second tranche purchase liability	4,734	—
Fair value of warrants issued with debt	360	—

See notes to condensed consolidated financial statements

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Operations and Basis of Presentation

The accompanying condensed consolidated financial statements of EyePoint Pharmaceuticals, Inc. (formerly pSivida Corp.) and subsidiaries (collectively, the “Company”) as of March 31, 2018 and for the three and nine months ended March 31, 2018 and 2017 are unaudited. Certain information in the footnote disclosures of these financial statements has been condensed or omitted in accordance with the rules and regulations of the Securities and Exchange Commission (the “SEC”). These financial statements should be read in conjunction with the Company’s audited consolidated financial statements and footnotes included in its Annual Report on Form 10-K for the fiscal year ended June 30, 2017 (“fiscal 2017”). In the opinion of management, these statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended June 30, 2017, and include all adjustments, consisting only of normal recurring adjustments, that are necessary for the fair presentation of the Company’s financial position, results of operations, comprehensive loss and cash flows for the periods indicated. The preparation of financial statements in accordance with U.S. generally accepted accounting principles (“GAAP”) requires management to make assumptions and estimates that affect, among other things, (i) reported amounts of assets and liabilities; (ii) disclosure of contingent assets and liabilities at the date of the consolidated financial statements; and (iii) reported amounts of revenues and expenses during the reporting period. The results of operations for the three and nine months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the entire fiscal year or any future period.

The Company is a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products for the treatment of eye diseases. The Company’s lead product, DEXYCU™ (dexamethasone intraocular suspension) 9%, was approved by the U.S. Food and Drug Administration (“FDA”) in February 2018 for the treatment of post-operative inflammation. DEXYCU is administered as a single dose at the end of ocular surgery and is the first long-acting intraocular product approved by the FDA for the treatment of post-operative inflammation. DEXYCU utilizes the Company’s proprietary Verisome® drug-delivery platform, which allows for a single injection that releases drug over time. There are over four million cataract surgeries performed annually in the United States (“U.S.”) and the Company plans to launch DEXYCU in the U.S. in the first half of 2019 with a primary focus on its use following cataract surgery. The Company’s lead product candidate is YUTIQ™ for the treatment of non-infectious uveitis affecting the posterior segment of the eye (“three-year uveitis”). Injected into the eye in an office visit, YUTIQ is a tiny micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained constant (zero order release) basis for approximately three years. On March 19, 2018, the FDA accepted the Company’s New Drug Application (“NDA”) for YUTIQ and it has set an FDA Prescription Drug User Fee Act (“PDUFA”) action date of November 5, 2018. YUTIQ is based on the Company’s proprietary Durasert™ sustained-release drug delivery technology platform, which can deliver drugs for predetermined periods of time ranging from months to years. Posterior segment uveitis is the third leading cause of blindness in the U.S. and affects between 55,000 to 120,000 people. If approved in November 2018, we expect to launch YUTIQ in the U.S. in the first half of 2019.

The Company has financed its operations primarily from sales of equity securities, debt and the receipt of license fees, milestone payments, research and development funding and royalty income from its collaboration partners. The Company has a history of operating losses and, to date, has not had significant recurring cash inflows from revenue. The Company’s anticipated recurring use of cash to fund operations in combination with no probable source of additional capital raises substantial doubt about its ability to continue as a going concern for one year from the issuance of its financial statements. The Company believes that its cash and cash equivalents of \$16.3 million at March 31, 2018, and expected proceeds from existing collaboration agreements, will enable the Company to maintain its current and planned operations (including continuation of its two Phase 3 clinical trials for YUTIQ and commercial launch of DEXYCU and, if approved, YUTIQ) through approximately the third quarter of calendar year 2018. In order to extend the Company’s ability to fund its operations beyond then, including its planned U.S. commercial launch of DEXYCU and, if approved, YUTIQ, the Company has filed a preliminary proxy statement for a special meeting of stockholders to be held on June 22, 2018 for the purpose of approving, among other things, the issuance of up to approximately \$25.5 million of units (each, a “Unit”), with each Unit consisting of (i) one share of the Company’s common stock and (ii) one warrant to purchase one share of the Company’s common stock (the “Second Tranche Transaction”). The Company may also draw down an additional \$5.0 million pursuant to a credit agreement among the Company, as borrower, SWK Funding LLC, as agent, and the lenders party thereto from time to time, subject to a minimum capital raise of at least \$20 million of net cash proceeds from an additional equity offering, which would be satisfied by the Second Tranche Transaction, or permitted subordinated debt financing (“Minimum Capital Raise”). There is no assurance that the Company will receive significant revenues from its planned commercialization of DEXYCU or, if approved, YUTIQ, or from its product license revenues under existing collaboration agreements or be able to obtain financing from any other sources. The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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New accounting pronouncements are issued periodically by the Financial Accounting Standards Board (“FASB”) and are adopted by the Company as of the specified effective dates. Unless otherwise disclosed below, the Company believes that recently issued and adopted pronouncements will not have a material impact on the Company’s financial position, results of operations and cash flows or do not apply to the Company’s operations.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers* (Topic 606) (“ASU 2014-09”), which requires an entity to recognize revenue in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the transfer of promised goods or services to customers. The standard will replace most existing revenue recognition guidance in U.S. GAAP. In August 2015, the FASB issued ASU 2015-14, which officially deferred the effective date of ASU 2014-09 by one year, while also permitting early adoption. As a result, ASU 2014-09 will become effective on July 1, 2018. The Company has initiated an assessment of the potential changes from adopting ASU 2014-09 and two revenue streams are expected to be impacted under the standard. The Company plans to adopt the new standard effective July 1, 2018 using the modified retrospective method. The Company is still evaluating aspects of ASU 2014-09 and has not determined how it may impact its consolidated financial statements or related disclosures.

In February 2016, the FASB issued ASU No. 2016-02, *Leases*. The new standard establishes a right-of-use (“ROU”) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. As a result, ASU 2016-02 will become effective on July 1, 2019. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is evaluating the impact the adoption of this standard will have on its consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* (“ASU 2017-01”), to clarify the definition of a business by adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets versus businesses. ASU 2017-01 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. The Company adopted this standard early to account for the acquisition of Icon Bioscience, Inc. (“Icon”) (see Note 3).

2. Summary of Significant Accounting Policies

Fair Value Measurements

The Company accounts for certain assets and liabilities at fair value. The hierarchy below lists three levels of fair value based on the extent to which inputs used in measuring fair value are observable in the market. The Company categorizes each of its fair value measurements in one of these three levels based on the lowest level input that is significant to the fair value measurement in its entirety. These levels are:

- Level 1 – Inputs are quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets and liabilities.
- Level 2 – Inputs are directly or indirectly observable in the marketplace, such as quoted prices for similar assets or liabilities in active markets or quoted prices for identical assets or liabilities with insufficient volume or infrequent transaction (less active markets).
- Level 3 – Inputs are unobservable estimates that are supported by little or no market activity and require the Company to develop its own assumptions about how market participants would price the assets or liabilities.

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Impairment of Intangible Assets

The Company's finite life intangible assets include its newly acquired DEXYCU product and its previously acquired Durasert and Tethadur™ patented technologies. The Durasert and Tethadur intangible assets were amortized on a straight-line basis over twelve years and became fully amortized as of December 31, 2017. The DEXYCU intangible asset is being amortized based on the pattern in which the economic benefits of the intangible asset are expected to be consumed. The intangible asset lives were determined based upon the anticipated period that the Company would derive future cash flows from the intangible assets, considering the effects of legal, regulatory, contractual, competitive and other economic factors. The Company continually monitors whether events or circumstances have occurred that indicate that the remaining estimated useful life of its intangible assets may warrant revision. The Company assesses potential impairments to its intangible assets when there is evidence that events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An impairment loss is recognized when the future undiscounted net cash flows expected to result from the use of an asset are less than its carrying value. If the Company considers an asset to be impaired, the impairment charge to be recognized is measured by the amount by which the carrying value of the asset exceeds its estimated fair value.

Derivative Instruments

Derivative financial liabilities are recorded at fair value, with gains and losses arising from changes in fair value recognized in change in fair value of derivative liability within the consolidated statements of operations and comprehensive loss at each period end while such instruments are outstanding. The derivative liabilities are being valued using Monte Carlo simulation models. Refer to Notes 8 and 9 for additional information.

3. Acquisition of Icon Bioscience, Inc.

On March 28, 2018, the Company and its newly-created wholly-owned subsidiary, Oculus Merger Sub, Inc., acquired Icon, a specialty biopharmaceutical company, through a reverse triangular merger (the "Icon Acquisition") pursuant to an Agreement and Plan of Merger (the "Merger Agreement") between the Company, Icon, and Shareholder Representative Services LLC ("SRS"), solely in its capacity as representative of Icon's securityholders. The Icon Acquisition will be accounted for as an asset acquisition because substantially all of the fair value of the gross assets acquired were deemed to be concentrated in a group of similar identifiable assets related to Icon's lead product, DEXYCU. A portion of the Icon Acquisition was funded by an equity financing and a debt financing, both of which closed concurrently with the Icon Acquisition (see Notes 8 and 9).

Pursuant to the Merger Agreement, the Company made a closing payment of \$15.0 million to SRS, net of an estimated \$127,000 working capital adjustment, and is obligated to pay certain post-closing contingent cash payments upon the achievement of specified milestones and based upon certain net sales and partnering revenue standards, in each case subject to the terms and conditions set forth in the Merger Agreement. These include but are not limited to (i) a one-time development milestone of \$15.0 million payable in cash upon the first commercial sale of DEXYCU in the United States, (ii) sales milestone payments totaling up to \$95.0 million upon the achievement of certain sales thresholds and subject to certain Centers for Medicare & Medicaid Services reimbursement conditions set forth in the Merger Agreement, (iii) quarterly earn-out payments equal to 12% on net sales of DEXYCU in a given year, which earn-out payments will increase to 16% of net sales of DEXYCU in such year beginning in the calendar quarter for such year to the extent aggregate annual consideration of DEXYCU exceeds \$200.0 million in such year, (iv) quarterly earn-out payments equal to 20% of partnering revenue received by the Company for DEXYCU outside of the United States, and (v) single-digit percentage quarterly earn-out payments with respect to net sales and/or partnering income, if any, resulting from future clinical development, regulatory approval and commercialization of any other product candidates the Company acquired in the Icon Acquisition.

The purchase price on the date of the Icon Acquisition was \$32.0 million, comprised of the closing consideration of \$15.0 million, including the assumption of an estimated \$127,000 of net current liabilities of Icon, the contingent development milestone payment of \$15.0 million and transaction costs of approximately \$2.0 million. Given the stage of development of DEXYCU, the Company has determined these payments do not represent research and development costs. The contingent consideration in the form of sales milestones will be capitalized as additional intangible assets when any such consideration becomes probable and can be reasonably estimated. Sales-based royalty payments will be expensed as incurred.

The \$32.0 million purchase price was allocated to a single finite-lived intangible asset with an expected amortization life of approximately 13 years. The amortization expense will be based on the pattern in which the economic benefits of the intangible asset are expected to be consumed. The acquisition did not have a net tax impact due to a full valuation allowance against the acquired net deferred tax assets.

4. License and Collaboration Agreements

Alimera

Under a collaboration agreement with Alimera, as amended in March 2008 (the “Prior Alimera Agreement”), the Company licensed to Alimera the rights to develop, market and sell certain product candidates, including ILUVIEN® for diabetic macular edema (“DME”), and Alimera assumed all financial responsibility for the development of the licensed products. In addition, the Company was entitled to receive 20% of any net profits (as defined) on sales of each licensed product (including ILUVIEN) by Alimera, measured on a quarter-by-quarter and country-by-country basis. Alimera was entitled to recover 20% of previously incurred and unapplied net losses (as defined) for commercialization of each product in a country, but only by an offset of up to 4% of the net profits earned in that country each quarter, reducing the Company’s net profit share to 16% in each country until those net losses were recouped. In the event that Alimera sublicensed commercialization in any country, the Company was entitled to 20% of royalties and 33% of non-royalty consideration received by Alimera, less certain permitted deductions. The Company was also entitled to reimbursement of certain patent maintenance costs with respect to the patents licensed to Alimera.

Because the Company had no remaining performance obligations under the Prior Alimera Agreement, all amounts received from Alimera were generally recognized as revenue upon receipt or at such earlier date, if applicable, on which any such amounts were both fixed and determinable and reasonably assured of collectability. In instances when payments were received and subject to a contingency, revenue was deferred until such contingency was resolved.

On July 10, 2017, the Company entered into a further amended and restated collaboration agreement (the “Amended Alimera Agreement”), pursuant to which the Company (i) licensed its Durasert three-year uveitis product candidate (called YUTIQ in the U.S. and planned to be called ILUVIEN in Europe, the Middle East and Africa (“EMEA”)) to Alimera for the EMEA and (ii) converted the net profit share arrangement for each licensed product (including ILUVIEN) under the Prior Alimera Agreement to a sales-based royalty on a calendar quarter basis commencing July 1, 2017, with payments from Alimera due 60 days following the end of each quarter.

Sales-based royalties start at the rate of 2%. Commencing January 1, 2019 (or earlier under certain circumstances), the sales-based royalty will increase to 6% on aggregate calendar year net sales up to \$75 million and 8% in excess of \$75 million. Alimera’s share of contingently recoverable accumulated ILUVIEN commercialization losses under the Prior Alimera Agreement, capped at \$25 million, are to be reduced as follows: (i) \$10.0 million was cancelled in lieu of an upfront license fee on the effective date of the Amended Alimera Agreement; (ii) for calendar years 2019 and 2020, 50% of earned sales-based royalties in excess of 2% will be offset against the quarterly royalty payments otherwise due from Alimera; (iii) on January 1, 2020, another \$5 million will be cancelled, provided, however, that such date of cancellation may be extended under certain circumstances related to Alimera’s regulatory approval process for ILUVIEN for three-year uveitis, with such extension, if any, subject to mutual agreement by the parties; and (iv) commencing in calendar year 2021, 20% of earned sales-based royalties in excess of 2% will be offset against the quarterly royalty payments due from Alimera until such time as the balance of the original \$25 million of recoverable commercialization losses has been fully recouped.

Following the completion of the Amended Alimera Agreement, the Company withdrew its previously filed EU marketing approval application and its EU orphan drug designation for three-year uveitis, and Alimera was responsible for filing a Type II variation for ILUVIEN for the treatment of three-year uveitis. In January 2018, Alimera received validation of a Type II variation submitted in December 2017 in all seventeen European countries in which it previously received regulatory approval for ILUVIEN for DME. If the variation is approved, Alimera plans to commercialize the three-year uveitis indication under its ILUVIEN trademark.

Revenue under the Prior Alimera Agreement and/or the Amended Alimera Agreement totaled \$234,000 and \$290,000 for the three months ended March 31, 2018 and 2017, respectively, and \$524,000 and \$325,000 for the nine months ended March 31, 2018 and 2017, respectively. In addition to patent fee reimbursements in both periods, the Company earned (i) \$378,000 of sales-based royalties for the nine months ended March 31, 2018 attributable to the first and second quarters of fiscal 2018 (recorded as royalty income under the Amended Alimera Agreement) and (ii) \$50,000 of net profits in the three months ended September 30, 2017 attributable to the fourth quarter of fiscal 2017 (recorded as collaborative research and development revenue under the Prior Alimera Agreement).

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Pfizer

In June 2011, the Company and Pfizer, Inc. (“Pfizer”) entered into an Amended and Restated Collaborative Research and License Agreement (the “Restated Pfizer Agreement”) to focus solely on the development of a sustained-release bioerodible micro-insert injected into the subconjunctiva designed to deliver latanoprost for human ophthalmic disease or conditions other than uveitis (the “Latanoprost Product”). Pfizer made an upfront payment of \$2.3 million and the Company agreed to provide Pfizer options under various circumstances for an exclusive, worldwide license to develop and commercialize the Latanoprost Product.

The estimated selling price of the combined deliverables under the Restated Pfizer Agreement of \$6.7 million was partially recognized as collaborative research and development revenue over the estimated performance period using the proportional performance method with costs associated with developing the Latanoprost Product reflected in operating expenses in the period in which they have been incurred. No collaborative research and development revenue was recorded during the three months ended September 30, 2016.

On October 25, 2016, the Company notified Pfizer that it had discontinued development of the Latanoprost Product, which provided Pfizer a 60-day option to acquire a worldwide license in return for a \$10.0 million payment and potential sales-based royalties and development, regulatory and sales performance milestone payments. Pfizer did not exercise its option and the Restated Pfizer Agreement automatically terminated on December 26, 2016. The remaining deferred revenue balance of \$5.6 million was recognized as revenue in the three-month period ended December 31, 2016.

Bausch & Lomb

Pursuant to a licensing and development agreement, as amended, Bausch & Lomb has a worldwide exclusive license to make and sell Retisert in return for royalties based on sales. Royalty income totaled \$221,000 and \$218,000 for the three months ended March 31, 2018 and 2017, respectively, and \$742,000 and \$730,000 for the nine months ended March 31, 2018 and 2017, respectively. Accounts receivable from Bausch & Lomb totaled \$223,000 at March 31, 2018 and \$246,000 at June 30, 2017.

OncoSil Medical

The Company entered into an exclusive, worldwide royalty-bearing license agreement in December 2012, amended and restated in March 2013, with OncoSil Medical UK Limited (f/k/a Enigma Therapeutics Limited), a wholly owned subsidiary of OncoSil Medical Ltd (“OncoSil”) for the development of BrachySil, the Company’s BioSilicon product candidate for the treatment of pancreatic and other types of cancer. The Company received an upfront fee of \$100,000 and is entitled to 8% sales-based royalties, 20% of sublicense consideration and milestone payments based on aggregate product sales. OncoSil is obligated to pay an annual license maintenance fee of \$100,000 by the end of each calendar year, the most recent of which was received in December 2017. For each calendar year commencing with 2014, the Company is entitled to receive reimbursement of any patent maintenance costs, sales-based royalties and sub-licensee sales-based royalties earned, but only to the extent such amounts, in the aggregate, exceed the \$100,000 annual license maintenance fee. As of March 31, 2018, OncoSil has not received regulatory approval in any jurisdiction, although an application for CE Mark approval in Europe is pending. The Company has no consequential performance obligations under the OncoSil license agreement and, accordingly, any amounts to which the Company is entitled under the agreement are recognized as revenue on the earlier of receipt or when collectability is reasonably assured. Revenue related to the OncoSil agreement totaled \$100,000 for the three and nine-month periods ended March 31, 2018 and 2017, respectively. As of March 31, 2018, no deferred revenue was recorded for this agreement.

Evaluation Agreements

The Company from time to time enters into funded agreements to evaluate the potential use of its technology systems for sustained release of third party drug candidates in the treatment of various diseases. Consideration received is generally recognized by the Company as revenue over the term of the feasibility study agreement. Revenue recognition for consideration, if any, related to a license option right is assessed based on the terms of any such future license agreement or is otherwise recognized at the completion of the evaluation agreement. Revenues under evaluation agreements totaled \$470,000 and \$80,000 for the three months ended March 31, 2018 and 2017, respectively, and \$875,000 and \$91,000 for the nine months ended March 31, 2018 and 2017, respectively. Deferred revenue for these agreements totaled \$240,000 and \$50,000 at March 31, 2018 and June 30, 2017, respectively.

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5. Intangible Assets

The reconciliation of intangible assets for the nine months ended March 31, 2018 and for the year ended June 30, 2017 was as follows (in thousands):

	Nine Months Ended March 31, 2018	Year Ended June 30, 2017
Patented technologies		
Gross carrying amount at beginning of period	\$ 35,610	\$ 36,196
Acquisition of Icon Bioscience	31,973	—
Foreign currency translation adjustments	739	(586)
Gross carrying amount at end of period	<u>68,322</u>	<u>35,610</u>
Accumulated amortization at beginning of period	(35,246)	(35,094)
Amortization expense	(366)	(724)
Foreign currency translation adjustments	(737)	572
Accumulated amortization at end of period	<u>(36,349)</u>	<u>(35,246)</u>
Net book value at end of period	<u>\$ 31,973</u>	<u>\$ 364</u>

The Company historically amortized its intangible assets with finite lives on a straight-line basis over their respective estimated useful lives. Amortization of intangible assets totaled \$0 and \$180,000 for the three months ended March 31, 2018 and 2017, respectively, and \$366,000 and \$542,000 for the nine months ended March 31, 2018 and 2017, respectively. At March 31, 2018, the carrying value of each of the Durasert and Tethadur intangible assets was amortized to zero.

In connection with the Icon Acquisition (see Note 3), the initial purchase price of \$32.0 million was attributed to the DEXYCU product intangible asset. This finite-lived intangible asset will be amortized proportionate to projected DEXYCU product revenues over its expected useful life. No amortization expense was recorded related to DEXYCU for the three months ended March 31, 2018 and no amortization is expected for the remainder of fiscal year 2018 or until such time as the commercial sales of the product are commenced.

6. Accrued Expenses

Accrued expenses consisted of the following at March 31, 2018 and June 30, 2017 (in thousands):

	March 31, 2018	June 30, 2017
Clinical trial costs	\$ 722	\$ 1,984
Personnel costs	1,144	1,632
Professional fees	1,282	590
Other	67	18
	<u>\$ 3,215</u>	<u>\$ 4,224</u>

In January 2017, the Company entered into retention bonus agreements with five employees. Under these agreements (a) cash payments totaling \$319,000 were made on December 22, 2017 and (b) subject to continuing employment, a total of 305,616 restricted stock units (“RSUs”) of an equal value were granted at that date based on a closing share price of \$1.045 per share with a one-year vesting period. Included in personnel costs in the above table were \$0 and \$160,000 at March 31, 2018 and June 30, 2017, respectively, representing pro rata accrual of the cash bonus component.

At March 31, 2018, approximately \$858,000 of accrued professional fees were directly attributable to services rendered in the Icon Acquisition, the Equity Transactions (as defined in Note 9) and the transactions contemplated by the Credit Agreement (as defined in Note 8).

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7. Restructuring

In July 2016, the Company announced its plan to consolidate its research and development activities in its U.S. facility. Following employee consultations under local U.K. law, the Company determined to close its U.K. research facility and terminated the employment of its U.K. employees. The U.K. facility lease, set to expire on August 31, 2016, was extended through November 30, 2016 to facilitate an orderly transition and the required restoration of the premises. A summary reconciliation of the restructuring costs for the nine months ended March 31, 2017 is as follows (in thousands):

	<u>Balance at June 30, 2016</u>	<u>Charged to Expense</u>	<u>Payments</u>	<u>Balance at March 31, 2017</u>
Termination benefits	\$ 118	\$ 273	\$ (391)	\$ —
Facility closure	40	73	(113)	—
Other	29	126	(155)	—
	<u>\$ 187</u>	<u>\$ 472</u>	<u>\$ (659)</u>	<u>\$ —</u>

The Company recorded approximately \$472,000 of restructuring costs during the nine months ended March 31, 2017. These costs consisted of (i) \$273,000 of additional employee severance for discretionary termination benefits upon notification of the affected employees in accordance with ASC 420, *Exit or Disposal Cost Obligations*; and (ii) \$199,000 of professional fees, travel and lease extension costs.

In addition, for the three months ended September 30, 2016, the Company recorded \$99,000 of non-cash stock-based compensation expense in connection with the extension of the exercise period through June 30, 2017 for all vested stock options held by the U.K. employees at July 31, 2016 and a \$133,000 credit to stock-based compensation expense to account for forfeitures of all non-vested stock options at that date.

The Company paid all of the restructuring costs associated with the plan of consolidation as of March 31, 2017.

8. Term Loan Agreement

On March 28, 2018 (the “Closing Date”), the Company entered into a Credit Agreement (the “Credit Agreement”) among the Company, as borrower, SWK Funding LLC, as agent (the “Agent”), and the lenders party thereto from time to time (the “Lenders”), providing for a senior secured term loan of up to \$20 million (the “Loan”). On the Closing Date, \$15 million of the Loan was advanced (the “Initial Advance”). The remaining \$5 million of the Loan may be advanced between the Closing Date and December 31, 2018, subject to satisfying the Minimum Capital Raise (the “Additional Advance”). The Loan may be increased by \$10 million upon the request of the Company, subject to obtaining additional loan commitments and satisfaction of certain conditions in the Credit Agreement.

The Loan is due and payable on March 27, 2023 (the “Maturity Date”). The Loan bears interest at a per annum rate of the three-month LIBOR rate (subject to a 1.5% floor) plus 10.50%. The Credit Agreement permits the Company to pay interest only on the principal amount for the first eight payments (payments are due on a quarterly basis commencing May 15, 2018). Following the interest-only period, the Company will be required to make quarterly payments of interest, plus repayments of the principal in an aggregate amount of up to \$1,250,000 per quarter (the “Quarterly Principal Repayment Cap”). Subject to the Quarterly Principal Repayment Cap, the amount of any quarterly principal payments during any fiscal year of the Company is based on (x) a percentage of the year-to-date net revenue of the Company through the end of such quarter less (y) any prior quarterly principal and interest payments made during such fiscal year. In addition, the Company paid an upfront fee of 1.5% of the aggregate principal amount of the Loan. The Company is required to pay an exit fee equal to 6% of the aggregate principal amount advanced under the Credit Agreement (the “Exit Fee”). The portion of the Exit Fee on the Initial Advance, which is included in other long-term liabilities in the accompanying condensed consolidated balance sheet, is being accrued as interest expense over the term of the Loan using the effective interest method.

Upon the occurrence of a bankruptcy-related event of default, all amounts outstanding with respect to the Loan become due and payable immediately and upon the occurrence of any other Event of Default (as defined in the Credit Agreement), all or any amounts

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outstanding with respect to the Loan may become due and payable upon request of the Agent or majority Lenders. Additionally, subject to certain exceptions, the Company is required to make mandatory prepayments of the Loan with the proceeds of assets sales and insurance proceeds. The Company may make a voluntary prepayment of the Loan, in whole, but not in part, at any time on or after the first anniversary of the Closing Date. All mandatory and voluntary prepayments of the Loan are subject to the payment of prepayment premiums as follows: (i) in the case of mandatory prepayments, if prepayment occurs prior to the first anniversary of the Closing Date, a customary make-whole amount equal to the amount of interest that would have accrued on the principal amount so prepaid had it remained outstanding through the first anniversary of the Closing Date, (ii) if prepayment occurs on or after the first anniversary of the Closing Date, but prior to the second anniversary of the Closing Date, 6% of the aggregate amount of the principal prepaid and (iii) if prepayment occurs on or after the second anniversary of the Closing Date, but prior to the third anniversary of the Closing Date, an amount equal to 1% of the principal prepaid. No prepayment premium is due on any principal prepaid on or after the third anniversary of the Closing Date.

In connection with the Loan, the Company issued a warrant (the "SWK Warrant") to the Agent to purchase (a) 409,091 shares of Company common stock (the "Initial Advance Warrant Shares") at an exercise price equal to \$1.10 and (b) an aggregate number of shares of the Company's common stock determined by multiplying the Additional Advance by 3% and then dividing such number by the consolidated closing bid price of a share of the Company's common stock on Nasdaq immediately preceding the closing of the Additional Advance (the "Additional Advance Warrant Shares"). The exercise price for the Additional Advance Warrant Shares shall be equal to the consolidated closing bid price of the Company's common stock on Nasdaq immediately preceding the closing of the Additional Advance. The SWK Warrant is exercisable (i) with respect to the Initial Advance Warrant Shares, any time on or after the Closing Date until the close of business on the 7-year anniversary of the Initial Advance and (ii) with respect to the Additional Advance Warrant Shares, any time on or after the closing of the Additional Advance until the close of business on the 7-year anniversary of the Additional Advance. The Agent may exercise the SWK Warrant on a cashless basis at any time. In the event the Agent exercises the SWK Warrant on a cashless basis the Company will not receive any proceeds.

The Additional Advance Warrant Shares is recorded as a liability on the Company's Condensed Consolidated Balance Sheet and will be remeasured at fair value at each reporting period. The aggregate fair value of the Additional Advance Warrant Shares at the issuance date was \$69,000. The Initial Advance warrants were recorded as equity on the Company's balance sheet at their relative fair value of \$284,000. The remaining \$14.6 million of the proceeds received were allocated to the Initial Advance term loan.

In addition to the discount created from the allocation of proceeds and the 1.5% upfront fee, the Company incurred legal and other transaction costs in connection with obtaining the Loan. The upfront fee, the Exit Fee and the legal costs, for an aggregate of \$2.1 million, were ratably allocated to each of the two tranches of the Loan based upon the total principal amount available to the Company under each tranche. Total debt discount at the issuance date of \$1.8 million related to the Initial Advance consists of the fair value of the Initial Advance Warrant Shares, plus the upfront fee, Exit Fee and legal costs allocated to the Initial Advance. This amount is being amortized as additional interest expense over the term of the Loan using the effective interest method. Total debt discount on the issuance date of \$299,000 related to the Additional Advance consists of the fair value of the Additional Advance Warrant Shares, plus the fair value of the embedded derivative, the upfront fee, and legal costs allocated to the Additional Advance. This amount was recorded as a prepaid expense and is being amortized ratably from the Closing Date through December 31, 2018. Upon a drawdown of the Additional Advance, the remaining unamortized costs will be reclassified to debt discount and will be amortized over the remaining life of the Additional Advance term loan using the effective interest method.

9. Stockholders' Equity

2018 Equity Financing

On the Closing Date, the Company entered into a Securities Purchase Agreement (the "First Tranche Securities Purchase Agreement") with EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. (collectively, the "First Tranche Investors"), pursuant to which the Company offered and sold to the First Tranche Investors an aggregate of 8,606,324 shares of the Company's common stock at a purchase price of \$1.10 per share (the "First Tranche Purchase Price") for aggregate gross proceeds of approximately \$9.5 million (the "First Tranche Transaction").

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On the Closing Date, the Company entered into a Second Securities Purchase Agreement (the “Second Tranche Securities Purchase Agreement” and together with the First Tranche Securities Purchase Agreement, the “Securities Purchase Agreements”) with the First Tranche Investors and another accredited investor (collectively, the “Second Tranche Investors”), pursuant to which the Company will, subject to the approval of the Company’s stockholders, offer and sell to the Second Tranche Investors an aggregate of approximately \$25.5 million of Units, subject to a maximum of 27,250,000 units, with each Unit consisting of (a) one share of the Company’s common stock and (b) one warrant to purchase a share of the Company’s common stock (the “Second Tranche Transaction” and together with the First Tranche Transaction, the “Equity Transactions”). The First Tranche Investors have the option at any time prior to the closing of the Second Tranche Transaction to allocate the purchase of up to 50% of the Units being issued and sold to them in the Second Tranche Transaction to one or more accredited investors, subject to certain conditions set forth in the Second Securities Purchase Agreement.

The purchase price for each share of the Company’s common stock to be issued in the Second Tranche Transaction will be an amount equal to the lower of (a) \$1.265 (which is a 15% premium to the First Tranche Purchase Price) and (b) a 20% discount to the volume weighted average price (“VWAP”) of the shares of the Company’s common stock on Nasdaq for the 20 trading days immediately prior to the closing of the Second Tranche Transaction; provided, however, that the purchase price cannot be lower than \$0.88, which is a 20% discount to the First Tranche Purchase Price.

The warrants to be issued in the Second Tranche Transaction (each a “Second Tranche Warrant,” and collectively, the “Second Tranche Warrants”) will be exercisable any time on or after the closing of the Second Tranche Transaction until on or prior to the close of business on the 15th business day following the date on which the holders of the Second Tranche Warrants receive written notice from the Company that the Centers for Medicare & Medicaid Services (“Medicare”) has announced that a new C-Code has been established for DEXYCU and will be effective at the start of the first calendar quarter after such notice. The exercise price of each Second Tranche Warrant to be issued in the Second Tranche Transaction will be an amount equal to the lower of (a) \$1.43 (a 30% premium to the First Tranche Purchase Price) and (b) a 20% discount to the VWAP of the shares of the Company’s common stock on Nasdaq for the 20 trading days immediately prior to the exercise of a Second Tranche Warrant; provided, however, that the exercise price cannot be lower than \$0.88, which is a 20% discount to the First Tranche Purchase Price.

The aggregate gross proceeds from the Second Tranche Transaction are expected to be approximately \$25.5 million, not including any proceeds from the exercise of the Second Tranche Warrants.

The Company has determined that the Company’s common stock issued in the First Tranche Transaction and the future obligation to issue Units in the Second Tranche Transaction are freestanding instruments. The Company’s common stock issued in the First Tranche Transaction is recorded to equity on the Company’s Balance Sheet and will not be measured at fair value at each reporting period. The future obligation to issue Units in the Second Tranche Transaction is recorded as a liability on the Company’s Balance Sheet and will be remeasured at fair value at each reporting period.

The Company has determined that the First Tranche Transaction and the Second Tranche Transaction should be accounted for as a single transaction. Accordingly, the total consideration received on the issuance date of \$9.5 million was first allocated to the future obligation to issue Units in the Second Tranche Transaction at fair value as of the issuance date, with the residual amount allocated to the Company’s common stock issued in the First Tranche Transaction. Further, issuance costs of \$343,000 were allocated to each of the freestanding instruments on the basis of relative fair value. A net amount of approximately \$4.6 million was allocated to the Company’s common stock issued in the First Tranche Transaction and the future obligation to issue Units in the Second Tranche Transaction, respectively, as of the issuance date. As of March 31, 2018, the fair value of the Second Tranche Transaction liability was approximately \$6.9 million and the Company recorded the \$2.2 million change in fair value in the Consolidated Statement of Comprehensive Loss.

ATM Facility

In February 2017, the Company entered into an ATM program pursuant to which, under its Form S-3 shelf registration statement, the Company may, at its option, offer and sell shares of its common stock from time to time for an aggregate offering price of up to \$20.0 million. The Company will pay the sales agent a commission of up to 3.0% of the gross proceeds from the sale of such shares. The Company’s ability to sell shares under the ATM program was subject to the listing rules of the Australian Securities Exchange (“ASX”) prior to the Company’s removal from the official list of the ASX on May 7, 2018 (“ASX Delisting”), which limited the number of shares the Company may issue in any 12-month period without stockholder approval, as well as other applicable rules and regulations of Nasdaq. During the three months ended March 31, 2017, the Company incurred \$223,000 of legal, accounting and other costs to establish and activate the ATM program.

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During the nine months ended March 31, 2018, the Company sold 5,900,000 shares of its common stock under the ATM program at a weighted average price of \$1.23 per share for gross proceeds of approximately \$7.3 million. Share issue costs, including sales agent commissions, totaled \$239,000 for the nine months ended March 31, 2018. The Company did not sell any shares of its common stock pursuant to the ATM program during the three months ended March 31, 2018. During the three and nine months ended March 31, 2017, the Company sold 1,411,686 shares of its common stock under the ATM program at a weighted price of \$1.74 for gross proceeds of \$2.45 million. Share issue costs, including sales agent commissions, totaled \$76,000.

Warrants to Purchase Common Shares

The following table provides a reconciliation of warrants to purchase shares of the Company's common stock for the nine months ended March 31, 2018 and 2017:

	Nine Months Ended March 31,			
	2018		2017	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of period	623,605	\$ 2.50	623,605	\$ 2.50
Issued	409,091	1.10	—	—
Expired	(623,605)	2.50	—	—
Balance and exercisable at end of period	<u>409,091</u>	<u>\$ 1.10</u>	<u>623,605</u>	<u>\$ 2.50</u>

In connection with the Loan (see Note 8), the Company (i) issued a warrant to purchase 409,091 shares of the Company's common stock at an exercise price of \$1.10 per share with a seven-year term and (ii) has contingently issuable warrants that are issuable in the event the Company draws down the additional tranche of debt. This contingently issuable warrant has been classified as a liability as the settlement amount is predominantly based upon a fixed dollar amount with a variable number of shares.

Equity Incentive Plans

The 2016 Long-Term Incentive Plan (the "2016 Plan"), approved by the Company's stockholders on December 12, 2016 (the "Adoption Date"), provides for the issuance of up to 3,000,000 shares of the Company's common stock reserved for issuance under the 2016 Plan plus any additional shares of the Company's common stock that were available for grant under the 2008 Incentive Plan (the "2008 Plan") at the Adoption Date or would otherwise become available for grant under the 2008 Plan as a result of subsequent termination or forfeiture of awards under the 2008 Plan. At March 31, 2018, a total of 5,483,977 shares of the Company's common stock were authorized for issuance under the 2016 Plan, which included 1,380,530 stock options and 200,000 restricted stock units that were forfeited under the 2008 Plan during the nine months ended March 31, 2018. At March 31, 2018, a total of 3,575,361 shares were available for new awards.

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Stock Options

The following table provides a reconciliation of stock option activity under the Company's equity incentive plans for the nine months ended March 31, 2018:

	<u>Number of Options</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Contractual Life</u> (in years)	<u>Aggregate Intrinsic Value</u> (in thousands)
Outstanding at July 1, 2017	6,045,685	\$ 3.34		
Granted	530,000	1.58		
Forfeited	(1,470,530)	3.48		
Outstanding at March 31, 2018	<u>5,105,155</u>	<u>\$ 3.12</u>	<u>5.54</u>	<u>\$ 41</u>
Exercisable at March 31, 2018	<u>3,207,063</u>	<u>\$ 3.36</u>	<u>3.71</u>	<u>\$ 20</u>

During the nine months ended March 31, 2018, the Company granted 290,000 options to employees with ratable annual vesting over 3 years, 100,000 options to non-executive directors with 1-year cliff vesting, 40,000 options to a newly appointed non-executive director with ratable annual vesting over 3 years and 100,000 options to an external consultant with 6.5 months cliff vesting at June 30, 2018. In accordance with ASX Listing Rules, all equity awards authorized by the Compensation Committee of the Board to the Company's executive and non-executive directors were subject to stockholder approval prior to ASX Delisting, with the grant date fair value measured at the stockholder approval date and vesting measured from the Compensation Committee authorization date. All option grants have a 10-year term. The weighted-average grant date fair value of these options was \$0.56 per share. In determining the grant date fair value of option awards under the 2016 Plan during the nine months ended March 31, 2018, the Company applied the Black-Scholes option pricing model based on the following key assumptions:

Option life (in years)	5.50 - 6.00
Stock volatility	59.5% - 64.4%
Risk-free interest rate	2.18% - 2.68%
Expected dividends	0%

Options to purchase a total of 645,942 shares of the Company's common stock vested during the nine months ended March 31, 2018.

Time-Vested Restricted Stock Units

Time-vested restricted stock unit awards ("RSUs") issued to date under the 2016 Plan generally vest on a ratable annual basis over 3 years. The related stock-based compensation expense is recorded over the requisite service period, which is the vesting period. The fair value of all time-vested RSUs is based on the closing share price of the Company's common stock on the date of grant.

In connection with retention bonus agreements entered into in January 2017 (see Note 6), a total of 305,616 RSUs were issued on December 22, 2017 subject to one-year cliff vesting.

The following table provides a reconciliation of RSU activity under the 2016 Plan for the nine months ended March 31, 2018:

	<u>Number of Restricted Stock Units</u>	<u>Weighted Average Grant Date Fair Value</u>
Nonvested at July 1, 2017	248,500	\$ 1.77
Granted	425,616	1.07
Forfeited	(45,000)	1.77
Nonvested at March 31, 2018	<u>629,116</u>	<u>\$ 1.30</u>

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At March 31, 2018, the weighted average remaining vesting term of the RSUs was one year.

Performance-Based Stock Units

Performance Stock Units (“PSUs”) have been awarded to certain employees. The performance conditions associated with the PSU awards are as follows: (a) for one third of the PSUs, upon an FDA acceptance of the Company’s NDA submission of YUTIQ for review on or before March 31, 2018 and (b) for two-thirds of the PSUs, upon an FDA approval of YUTIQ on or before March 31, 2019. For each performance criteria that is achieved, 50% of the PSUs that are associated with that performance condition will vest at the achievement date and 50% will vest on the first anniversary of such date, in each case subject to continued employment through such date. As a result of the achievement of the first performance condition on March 19, 2018, 48,332 PSUs vested at that date and the other 48,332 PSUs became subject to a service-based condition with a vesting date of March 19, 2019. As of March 31, 2018, the second performance condition associated with the PSUs was not yet deemed probable of achievement and, accordingly, stock-based compensation has not been recorded for that portion of the PSUs during the nine months ended March 31, 2018.

The following table provides a reconciliation of PSU activity under the 2016 Plan for the nine months ended March 31, 2018:

	Number of Performance Stock Units	Weighted Average Grant Date Fair Value
Outstanding at July 1, 2017	210,000	\$ 1.77
Granted	115,000	1.13
Vested	(48,332)	1.52
Forfeited	(35,000)	1.77
Outstanding at March 31, 2018	<u>241,668</u>	<u>\$ 1.52</u>

The weighted average remaining vesting term of the PSUs associated with the first performance condition was approximately 11.6 months.

Deferred Stock Units

A total of 67,500 deferred stock units (“DSUs”) were issued to incumbent non-executive directors and ratified at the December 15, 2017 annual meeting of stockholders. The DSUs vest on June 27, 2018. Subsequent to vesting, the DSUs will be settled in shares of the Company’s common stock upon the earliest to occur of (i) each director’s termination of service on the Company’s Board of Directors and (ii) the occurrence of a change of control as defined in the award agreement. Upon Dr. Barry’s termination of service on the Company’s board of directors on May 7, 2018, all of Dr. Barry’s DSUs (12,500) vested in full.

The weighted average grant date fair value of the DSUs was \$1.13. At March 31, 2018, the weighted average remaining vesting term of the DSUs was approximately 3 months.

Inducement Option Grant

At June 30, 2017 and March 31, 2018, there were 850,000 stock options outstanding that were issued as an inducement award to the Company’s President and CEO in September 2016. The options have an exercise price of \$3.63 per share, a 10-year term and are subject to pro rata annual vesting over 4 years. Although the stock options were not awarded under the 2008 Plan, the stock options are subject to and governed by the terms and conditions of the 2008 Plan. A total of 212,500 of these options vested during the nine months ended March 31, 2018.

[Table of Contents](#)**Market-Based Restricted Stock Units**

The following table provides a reconciliation of market-based restricted stock units for the nine months ended March 31, 2018:

	Number of Market-Based Stock Units	Weighted Average Grant Date Fair Value
Outstanding at July 1, 2017	700,000	\$ 1.35
Forfeited	(200,000)	1.09
Outstanding at March 31, 2018	<u>500,000</u>	<u>\$ 1.45</u>

At June 30, 2017, there were 700,000 market-based Restricted Stock Units (“market-based RSUs”) outstanding, which included 500,000 issued as an inducement award to the Company’s President and CEO and 200,000 issued to another employee under the 2008 Plan. At March 31, 2018, there were 500,000 market-based RSUs outstanding due to a forfeiture of 200,000 market-based RSUs upon an employee’s resignation. Subject to a service condition, the number of shares underlying the one remaining market-based RSU that vests will be based upon a relative percentile rank of the 3-year change in the closing price of the Company’s common stock compared to that of the companies that make up the Nasdaq Biotechnology Index. The Company estimated the fair value of the market-based RSUs using a Monte Carlo valuation model on the respective dates of grant.

Stock-Based Compensation Expense

The Company’s consolidated statements of comprehensive loss included total compensation expense from stock-based payment awards for the three and nine months ended March 31, 2018 and 2017, as follows (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2018	2017	2018	2017
Compensation expense included in:				
Research and development	\$ 315	\$ 267	\$ 907	\$ 803
General and administrative	<u>128</u>	<u>377</u>	<u>823</u>	<u>971</u>
	<u>\$ 443</u>	<u>\$ 644</u>	<u>\$1,730</u>	<u>\$1,774</u>

In connection with termination benefits provided to the Company’s former Chief Executive Officer, the vesting of certain options was accelerated in accordance with the terms of the options, the exercise period for all vested options was extended through September 14, 2017, and all remaining non-vested options were forfeited. Additionally, in connection with the U.K. restructuring, the exercise period of all vested options held by the former U.K. employees was extended through June 30, 2017 and all non-vested options were forfeited. These option modifications and forfeitures were accounted for in the quarter ended September 30, 2016, the net effect of which resulted in an approximate \$274,000 increase of stock-based compensation expense included in general and administrative expense and an approximate \$35,000 reduction of stock-based compensation expense included in research and development expense for the nine months ended March 31, 2017 in the table above.

In connection with termination benefits provided to the Company’s former Vice President, Corporate Affairs and General Counsel, the vesting of certain non-vested options was accelerated in accordance with the terms of the options, the exercise period for all vested options was extended through June 26, 2018 and all remaining non-vested options were forfeited. The option modification and forfeitures were accounted for in the quarter ended December 31, 2016, the net effect of which resulted in an approximate \$117,000 reduction of stock-based compensation expense included in general and administrative expense for the nine months ended March 31, 2017 in the table above.

At March 31, 2018, there was approximately \$2.4 million of unrecognized compensation expense related to outstanding equity awards under the 2016 Plan, the 2008 Plan and the inducement awards to the Company’s President and CEO that is expected to be recognized as expense over a weighted-average period of approximately 1.42 years.

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10. Fair Value Measurements

The following tables summarize the Company's assets and liabilities carried at fair value measured on a recurring basis at March 31, 2018 and June 30, 2017 by valuation hierarchy (in thousands):

	March 31, 2018			
	Total carrying value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 6,800	\$ 6,800	\$ —	\$ —
	<u>\$ 6,800</u>	<u>\$ 6,800</u>	<u>\$ —</u>	<u>\$ —</u>
Liabilities:				
Derivative liabilities	\$ 6,957	\$ —	\$ —	\$ 6,957
	<u>\$ 6,957</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6,957</u>
	June 30, 2017			
	Total carrying value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 13,521	\$ 13,521	\$ —	\$ —
	<u>\$ 13,521</u>	<u>\$ 13,521</u>	<u>\$ —</u>	<u>\$ —</u>

Financial instruments that potentially subject the Company to concentrations of credit risk have historically consisted principally of cash and cash equivalents. At March 31, 2018 and June 30, 2017, substantially all of the Company's interest-bearing cash equivalent balances were concentrated in one U.S. Government money market fund that has investments consisting primarily of U.S. Government Agency debt, U.S. Treasury Repurchase Agreements and U.S. Government Agency Repurchase Agreements. These deposits may be redeemed upon demand and, therefore, generally have minimal risk. The Company's cash equivalents are classified within Level 1 on the basis of valuations using quoted market prices.

The Second Tranche Transaction was determined to be liability classified (see Note 9), which requires that the liability be measured at fair value each period with changes in fair value being recorded as component of net income (loss) in the statement of operations. This valuation was determined to be a level 3 valuation because it includes unobservable inputs. The Second Tranche Transaction liability was valued using a Monte Carlo simulation valuation model. This model incorporated several inputs, including the Company's common stock price on the date of valuation, the historical volatility of the price of the Company's common stock, the risk-free interest rate and management's assessment of the probability and timing of the issuance of the units occurring. A significant fluctuation in the Company's stock price or the Company's estimate of the number of units to be issued could result

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in a material increase or decrease in the fair value of the Second Tranche liability. Significant assumptions used to value this liability are as follows:

	March 28, 2018 (Date of Issuance)	March 31, 2018
Volatility	54.20%	52.50%
Risk free interest rate	1.70%	1.70%
Estimated date of stockholder approval	June 2018	June 2018
Estimated number of units issuable	26,900,000	25,300,000
Valuation date stock price	\$1.07	\$1.22

The Additional Advance Warrants were determined to be liability classified (see Note 8), which requires that the liability be measured at fair value each period with changes in fair value being recorded as a component of net income (loss) in the condensed consolidated statement of comprehensive income (loss). This valuation was determined to be a level 3 valuation because it includes unobservable inputs. The Additional Advance Warrant liability was valued using a Monte Carlo simulation valuation model. This model incorporated several inputs including the Company's common stock price on the date of valuation, the historical volatility of the price of the Company's common stock, the risk-free interest rate and management's assessments of the probability of the Additional Advance being drawn upon. Significant assumptions used to value this liability are as follows:

	March 28, 2018 (Date of Issuance)	March 31, 2018
Volatility	55.20%	55.20%
Risk free interest rate	1.70%	1.70%
Term (in years)	7	7
Dividend rate	0%	0%
Valuation date stock price	\$ 1.07	\$ 1.22
Probability of issuance	80%	80%

The following table sets forth a summary of changes in the fair value of the Company's derivative liability for which fair value is determined by Level 3 inputs (in thousands):

Balance at June 30, 2017	\$ —
Initial fair value of warrant liability	4,632
Change in fair value	<u>2,325</u>
Balance at March 31, 2018	<u>\$6,957</u>

11. Income Taxes

The Company recognizes deferred tax assets and liabilities for estimated future tax consequences of events that have been recognized in the financial statements or tax returns. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using the enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established if, based on management's review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax assets will not be realized. Because of its historical losses from operations, the Company established a valuation allowance for the net deferred tax assets. The Company did not record any income tax expense or benefit for the three and nine months ended March 31, 2018 and 2017.

For the three and nine months ended March 31, 2018 and 2017, the Company had no significant unrecognized tax benefits. At March 31, 2018 and June 30, 2017, the Company had no accrued penalties or interest related to uncertain tax positions.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Tax Act") was enacted which, amongst other corporate and individual tax law changes, lowered the federal corporate income tax rate to 21% effective January 1, 2018. Because the Company provides a full valuation allowance for all of its net deferred tax assets, there is no effect of the Tax Act on the Company's consolidated financial statements as of and for the three and nine months ended March 31, 2018.

12. Commitments and Contingencies

Operating Leases

The Company leases approximately 13,650 square feet of combined office and laboratory space in Watertown, Massachusetts under a lease with a term from March 2014 through April 2019, with a five-year renewal option at market rates. The Company provided a cash-collateralized \$150,000 irrevocable standby letter of credit as security for the Company's obligations under the lease. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts.

Commencing July 1, 2017, the Company leases approximately 3,000 square feet of office space in Liberty Corner, New Jersey under a lease term extending through June 2022, with two five-year renewal options at 95% of the then-prevailing market rates. In addition to base rent, the Company is obligated to pay its proportionate share of building operating expenses and real estate taxes in excess of base year amounts.

Legal Proceedings

The Company is subject to various other routine legal proceedings and claims incidental to its business, which management believes will not have a material effect on the Company's financial position, results of operations or cash flows.

13. Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. For periods in which the Company reports net income, diluted net income per share is determined by adding to the basic weighted average number of common shares outstanding the total number of dilutive common equivalent shares using the treasury stock method, unless the effect is anti-dilutive. Potentially dilutive shares were not included in the calculation of diluted net loss per share for each of the three and nine months ended March 31, 2018 and 2017 as their inclusion would be anti-dilutive.

Potential common stock equivalents excluded from the calculation of diluted earnings per share because the effect would have been anti-dilutive were as follows:

	<u>Three Months Ended March 31,</u>		<u>Nine Months Ended March 31,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Options outstanding	5,955,155	6,797,691	5,955,155	6,797,691
Warrants outstanding	409,091	623,605	409,091	623,605
Restricted stock units outstanding	1,129,116	700,000	1,129,116	700,000
Performance stock units outstanding	241,668	—	241,668	—
Deferred stock units outstanding	67,500	—	67,500	—
	<u>7,802,530</u>	<u>8,121,296</u>	<u>7,802,530</u>	<u>8,121,296</u>

13. Subsequent Events

On April 26, 2018, the Company filed a preliminary proxy statement with the Securities and Exchange Commission in connection with a special meeting of stockholders to be held on June 22, 2018. The purpose of the special meeting will be to seek (i) stockholder approval of the issuance of a maximum of 27,250,000 Units pursuant to the Second Tranche Securities Purchase Agreement (see Note 9) and (ii) stockholder approval of an amendment of the Company's Certificate of Incorporation, as amended, to increase the number of authorized shares of the Company's common stock from 120,000,000 shares to 150,000,000 shares.

The Company was removed from the official list of ASX at the close of trading on May 7, 2018.

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

Note Regarding Forward-Looking Statements

Various statements made in this Quarterly Report on Form 10-Q are forward-looking and involve risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Such statements give our current expectations or forecasts of future events and are not statements of historical or current facts. These statements include, among others, statements about:

- the planned launch of DEXYCU and, if approved, YUTIQ, in the first half of 2019;
- the potential advantages of DEXYCU, YUTIQ and our other product candidates;
- our ability to manufacture DEXYCU and, if approved, YUTIQ, or any future products or product candidates in sufficient quantities and quality;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- the sufficiency of our cash and cash equivalents to fund our operations through approximately the third quarter of calendar year 2018;
- our ability to obtain additional capital in sufficient amounts and on terms acceptable to us, and the consequences of failing to do so;
- future expenses and capital expenditures;
- our expectations regarding the timing and design of our clinical development plans;
- our ability to establish or maintain collaborations and obtain milestone, royalty and/or other payments from any such collaborators;
- the ability of Alimera Sciences, Inc. (“Alimera”) to obtain regulatory approval of and commercialize three-year uveitis in Europe, the Middle East and Africa (“EMEA”) under its ILUVIEN® brand name;
- the implication of results from pre-clinical and clinical trials and our other research activities;
- our intentions regarding our research into other uses and applications of our Durasert technology platform;
- our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for DEXYCU, YUTIQ and our other product candidates, and to avoid claims of infringement of third party intellectual property rights;
- our expectation that we will continue to incur significant expenses and that our operating losses and our net cash outflows to fund operations will continue for the foreseeable future;
- the scope and duration of intellectual property protection; and
- the effect of legal and regulatory developments.

Forward-looking statements also include statements other than statements of current or historical fact, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as “likely”, “expect”, “intend”, “anticipate”, “believe”, “estimate”, “plan”, “project”, “forecast” and “outlook”.

The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements: uncertainties with respect to: our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; successful commercialization of, and receipt of revenues from, ILUVIEN for DME, which depends on Alimera’s ability to continue as a going concern; Alimera’s ability to obtain additional marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN; the number of clinical trials and data required for marketing approval for YUTIQ in the U.S.; our ability to use data in promotion for YUTIQ which includes clinical trials outside the U.S.; our ability to successfully commercialize DEXYCU in the U.S.; our ability to obtain stockholder

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approval for portions of the EW Healthcare Partners investment; our ability to successfully build a commercial infrastructure and enter into commercial agreements for the launch of DEXYCU and YUTIQ, if approved; our ability to successfully commercialize YUTIQ, if approved, in the U.S.; potential off-label sales of ILUVIEN for uveitis; consequences of FA side effects; the development of our next-generation Durasert shorter-duration treatment for uveitis; potential declines in Retisert® royalties; our ability to market and sell products; the success of current and future license agreements, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; our dependence on contract research organizations, vendors and investigators; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; effects of the potential U.K. exit from the EU; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under Item 1A of this Form 10-Q for the quarterly period ended March 31, 2018 describe major risks to our business, and you should read and interpret any forward-looking statements together with these risks. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

Our Business

We are a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products for the treatment of eye diseases. Our lead product, DEXYCU™ (dexamethasone intraocular suspension) 9%, was approved by the U.S. Food and Drug Administration (“FDA”) in February 2018 for the treatment of post-operative inflammation. DEXYCU is administered as a single dose at the end of ocular surgery and is the first long-acting intraocular product approved by the FDA for the treatment of post-operative inflammation. DEXYCU utilizes our proprietary Verisome® drug-delivery platform, which allows for a single injection that releases drug over time. There are over four million cataract surgeries performed annually in the United States (“U.S.”) and we plan to launch DEXYCU in the U.S. in the first half of 2019 with a primary focus on its use following cataract surgery. Our lead product candidate is YUTIQ™ for the treatment of non-infectious uveitis affecting the posterior segment of the eye (“three-year uveitis”). Injected into the eye in an office visit, YUTIQ is a tiny micro-insert that delivers a micro-dose of a corticosteroid to the back of the eye on a sustained constant (zero order release) basis for approximately three years. On March 19, 2018, the FDA accepted our New Drug Application (“NDA”) for YUTIQ and it has set an FDA Prescription Drug User Fee Act (“PDUFA”) action date of November 5, 2018. YUTIQ is based on our proprietary Durasert™ sustained-release drug delivery technology platform, which can deliver drugs for predetermined periods of time ranging from months to years. Posterior segment uveitis is the third leading cause of blindness in the U.S. and affects between 55,000 to 120,000 people. If approved in November 2018, we expect to launch YUTIQ in the U.S. in the first half of 2019.

Both Phase 3 clinical trials investigating YUTIQ met their primary efficacy endpoint of prevention of recurrence of disease through six months with statistical significance ($p < 0.001$, intent to treat analysis) and with safety data consistent with the known effects of ocular corticosteroid use. Statistical significance for efficacy and encouraging safety results were maintained through 12 months of follow-up in both Phase 3 clinical trials. In Europe, we filed a marketing authorization application (“MAA”) in June 2017 and subsequently withdrew the application after out-licensing the European rights for YUTIQ to Alimera. In January 2018, Alimera received validation of a Type II variation submitted in all seventeen European countries in which it previously received regulatory approval for ILUVIEN for DME. If the variation is approved, Alimera plans to commercialize the uveitis indication under its ILUVIEN trademark.

ILUVIEN is an injectable, sustained-release micro-insert that provides three years of treatment of DME from a single injection. ILUVIEN and YUTIQ are based on the same technology and deliver the same corticosteroid, FA. ILUVIEN was developed in collaboration with, and is licensed to and sold by Alimera. Pursuant to a collaboration agreement with Alimera, as amended in March 2008 (the “Prior Alimera Agreement”), ILUVIEN has been sold directly in the United Kingdom (“U.K.”) and Germany since 2013, in the U.S. and Portugal since 2015 and in Austria and Ireland beginning in 2017. ILUVIEN also has marketing approvals in 12 other European countries.

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Alimera has sublicensed distribution, regulatory and reimbursement matters for ILUVIEN in Australia and New Zealand, Canada, Italy, Spain, France and numerous countries in in the Middle East. In July 2017, we entered into a further amended and restated collaboration agreement (the “Amended Alimera Agreement”), pursuant to which we (i) licensed our Durasert three-year uveitis product candidate (called YUTIQ in the U.S. and planned to be called ILUVIEN in the EMEA) to Alimera for the EMEA and (ii) converted the net profit share arrangement for each licensed product (including ILUVIEN) under the Prior Alimera Agreement to a sales-based royalty on a calendar quarter basis commencing July 1, 2017, with payments from Alimera due 60 days following the end of each quarter.

Our development programs are focused primarily on developing sustained release drug products using our proven Durasert technology platform to deliver small molecule drugs to treat uveitis, wet age-related macular degeneration, glaucoma and other diseases.

DEXYCU™, YUTIQ™ and Durasert™ are our trademarks. Retisert® is Bausch & Lomb’s trademark. ILUVIEN® is Alimera’s trademark. Information with respect to ILUVIEN, including regulatory and marketing information, and Alimera’s plans and intentions, reflects information publicly disclosed by Alimera.

Quarterly Overview

The three months ended March 31, 2018 were highlighted by the following events:

- On March 19, 2018, the FDA accepted our NDA for YUTIQ and set an FDA PDUFA action date of November 5, 2018;
- On March 28, 2018, we completed the acquisition (the “Icon Acquisition”) of Icon Bioscience, Inc. (“Icon”);
- On March 28, 2018, in connection with the Icon Acquisition, SWK Funding LLC (SWK Funding”), a wholly-owned subsidiary of SWK Holdings Corporation, entered into a credit agreement (“the Credit Agreement”), pursuant to which the lenders party thereto provided to us a non-dilutive term loan in the principal amount of \$15 million (the “Loan”), which may be increased by (i) an additional \$5 million at our request on or before December 31, 2018 (the “Additional Advance”) or (ii) an additional \$10 million at our request and subject to obtaining additional loan commitments and, in each case subject to the satisfaction of certain conditions (as set forth in the Credit Agreement) (the “Debt Financing”);
- On March 28, 2018, in connection with the Debt Financing, we issued a warrant (the “SWK Warrant”) to SWK Funding to purchase (i) 409,091 shares of our common stock (the “Initial Advance Warrant Shares”) at an exercise price equal to the consolidated closing bid price of a share of Common Stock on the Nasdaq Global Market immediately preceding the issuance of Initial Advance Warrant Shares and (ii) shares of our common stock equal to 3% of the Additional Advance (the “Additional Advance Warrant Shares”) at an exercise price equal to the consolidated closing bid price of a share of our common stock on the Nasdaq Global Market immediately preceding the issuance of the Additional Advance Warrant Shares. The SWK Warrant is exercisable (x) with respect to the Initial Advance Warrant Shares, any time on or after the closing of the Debt Financing until the close of business on the 7-year anniversary of the Initial Advance and (y) with respect to the Additional Advance Warrant Shares, any time on or after the closing of the Additional Advance until the close of business on the 7- year anniversary of the Additional Advance;
- On March 28, in connection with the Icon Acquisition, we entered into a securities purchase agreement (the “First Tranche Securities Purchase Agreement”), with EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P (collectively, the “First Tranche Investors”) pursuant to which we sold an aggregate of 8,606,324 shares of our common stock for gross proceeds of \$9.5 million (the “First Tranche Transaction”); and
- On March 28, 2018, in connection with the Icon Acquisition and the execution of the First Tranche Securities Purchase Agreement, we entered into a securities purchase agreement (the “Second Tranche Securities Purchase Agreement”) with the First Tranche Investors and certain other accredited investors (collectively, the “Second Tranche Investors”), pursuant to which we will sell, subject to the approval of our stockholders, an aggregate of approximately \$25.5 million of units (each, a “Unit”), with each Unit consisting of (i) one share of our common stock and (ii) one warrant to purchase a share of common stock (the “Second Tranche Transaction” and together with the First Tranche Transaction, the “Equity Transactions”).

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Critical Accounting Policies and Estimates

The preparation of consolidated financial statements in conformity with GAAP requires that we make certain estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates, judgments and assumptions on historical experience, anticipated results and trends, and on various other factors that we believe are reasonable under the circumstances at the time. By their nature, these estimates, judgments and assumptions are subject to an inherent degree of uncertainty. Actual results may differ from our estimates under different assumptions or conditions. In our Annual Report on Form 10-K for the fiscal year ended June 30, 2017 (the “2017 Annual Report”), we set forth our critical accounting policies and estimates, which included revenue recognition and recognition of expense in outsourced clinical trial agreements. There have been no material changes to our critical accounting policies from the information provided in our 2017 Annual Report.

Derivative Liabilities

Derivative financial liabilities on initial recognition are recorded at fair value. They are subsequently held at fair value, with gains and losses arising from changes in fair value recognized in the condensed consolidated statement of comprehensive income (loss).

The rights contained in the Second Tranche Transactions were determined to be a freestanding financial instrument, which is liability classified and requires that the liability be measured at fair value each period with changes in fair value recorded as a component of net income (loss) in the condensed consolidated statement of comprehensive income (loss). The Second Tranche Transaction liability was valued using a Monte Carlo simulation valuation model. This model incorporated several inputs, including our common stock price on the date of valuation, the historical volatility of the price of our common stock, the risk-free interest rate and our assessment of the probability and timing of the issuance of the Units occurring. A significant fluctuation in our stock price or our estimate of the number of Units to be issued could result in a material increase or decrease in the fair value of the Second Tranche Transaction liability.

We have recorded the SWK Warrant issuable for shares of our common stock issued in connection with the Debt Financing as derivative financial liabilities. The SWK Warrant is initially recorded at fair value with gains and losses arising from changes in fair value recognized in the condensed consolidated statements of comprehensive income (loss) at each period end while such instruments are outstanding. The derivative liability was valued using a Monte Carlo simulation valuation model. This model incorporated several inputs, including our common stock price on the date of valuation, the historical volatility of the price of our common stock, the risk-free interest rate and our assessments of the probability of the Additional Advance being drawn upon.

[Table of Contents](#)**Results of Operations****Three Months Ended March 31, 2018 Compared to Three Months Ended March 31, 2017:**

	Three Months Ended		Change	
	2018	2017	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	\$ 524	\$ 372	\$ 152	41%
Royalty income	404	218	186	85%
Total revenues	<u>928</u>	<u>590</u>	<u>338</u>	<u>57%</u>
Operating expenses:				
Research and development	3,325	3,324	1	0%
General and administrative	2,281	2,426	(145)	(6)%
Total operating expenses	<u>5,606</u>	<u>5,750</u>	<u>(144)</u>	<u>(3)%</u>
Loss from operations	(4,678)	(5,160)	482	9%
Interest and other income	25	20	5	25%
Change in fair value of derivative liability	(2,325)	—	(2,325)	na
Net loss	<u>\$(6,978)</u>	<u>\$(5,140)</u>	<u>\$(1,838)</u>	<u>(36)%</u>

Revenues

Collaborative research and development revenues totaled \$524,000 for the three months ended March 31, 2018 compared to \$372,000 for the three months ended March 31, 2017. This increase was attributable primarily to a \$390,000 increase in revenues recognized from feasibility study agreements, partially offset by \$252,000 of net profits received in the prior year period under the Prior Alimera Agreement.

In July 2017, we restructured the Alimera collaboration agreement to (a) license our Durasert three-year uveitis product candidate (called YUTIQ in the U.S and planned to be called ILUVIEN in the EMEA) in the EMEA to Alimera and (b) convert the net profit share arrangement to a sales-based royalty for all ILUVIEN licensed indications. We expect this conversion to result in increased revenues from Alimera over time, as well as better predictability and consistency of revenues to be recognized from Alimera. Based on 60-day payment terms from Alimera following the end of each calendar quarter, we expect that sales-based royalties earned from Alimera will be recognized as revenues one quarter in arrears. Starting in the three months ended December 31, 2017, these sales-based royalties earned from Alimera are being recorded as royalty income, whereas amounts previously earned pursuant to the net profit share arrangement were classified as collaborative research and development revenue.

Royalty income for the three months ended March 31, 2018 increased by \$186,000, or 85%, to \$404,000 compared to \$218,000 for the three months ended March 31, 2017, attributable to \$183,000 of sales-based royalties earned from Alimera. Retisert royalty income was flat on a year-over-basis and we do not expect Retisert royalty income to increase significantly, and it may decline.

Research and Development

Research and development expenses totaled \$3.3 million for each of the three-month periods ended March 31, 2018 and 2017. Increases of \$168,000 in clinical, regulatory and medical affairs professional services associated with our YUTIQ Phase 3 development and \$230,000 of U.S. personnel and benefit costs, including stock-based compensation, were substantially offset by decreases of \$270,000 in clinical and pre-clinical trial costs and \$180,000 of amortization of intangible assets that were fully amortized at December 31, 2017. We expect total fiscal 2018 research and development expense to increase by approximately 10 - 15% compared to fiscal 2017, due primarily to pre-commercialization headcount and other costs for DEXYCU and YUTIQ manufacturing, quality assurance and medical affairs and ongoing regulatory professional services related to our recent NDA filing and ongoing FDA review of YUTIQ.

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General and Administrative

General and administrative expenses decreased by \$145,000, or 6%, to \$2.3 million for the three months ended March 31, 2018 from \$2.4 million for the same period in the prior year, attributable primarily to a \$250,000 decrease of stock-based compensation, due primarily to equity award forfeitures that resulted from the March 2018 resignation of our EVP of Corporate and Commercial Development and a \$134,000 net decrease in professional fees, partially offset by a \$122,000 increase in personnel and benefit costs and \$85,000 of legal and consulting costs related to our removal from the official list of the Australian Securities Exchange (“ASX”). We expect general and administrative expense to increase in our fiscal fourth quarter compared to the current period as a result of (i) professional fees incurred in connection with accounting for the Icon Acquisition, the Equity Transactions and the Credit Agreement; (ii) planned headcount increases in finance and human resources as part of our planned commercialization efforts; and (iii) the ongoing legal, consulting and transfer agent costs for the ASX delisting process.

Change in Fair Value of Derivative Liability

The future obligation to issue Units in the Second Tranche Transaction was measured at fair value and recorded as a derivative liability on our balance sheet upon consummation of the First Tranche Transaction and is remeasured at fair value at each balance sheet date. At March 31, 2018, the fair value re-measurement resulted in a \$2.3 million change in fair value of derivative liability that was recorded as a component of non-operating expense for the three months ended March 31, 2018.

Nine Months Ended March 31, 2018 Compared to Nine Months Ended March 31, 2017:

	Nine Months Ended March 31,		Change	
	2018	2017	Amounts	%
	(In thousands except percentages)			
Revenues:				
Collaborative research and development	\$ 1,125	\$ 6,108	\$(4,983)	(82)%
Royalty income	1,121	730	391	54%
Total revenues	<u>2,246</u>	<u>6,838</u>	<u>(4,592)</u>	<u>(67)%</u>
Operating expenses:				
Research and development	11,413	10,667	746	7%
General and administrative	7,325	8,611	(1,286)	(15)%
Total operating expenses	<u>18,738</u>	<u>19,278</u>	<u>(540)</u>	<u>(3)%</u>
Loss from operations	(16,492)	(12,440)	(4,052)	(33)%
Interest and other income	74	71	3	4%
Change in fair value of derivative liability	(2,325)	—	(2,325)	na
Net loss	<u>\$(18,743)</u>	<u>\$(12,369)</u>	<u>\$(6,374)</u>	<u>(52)%</u>

Revenues

Collaborative research and development revenues totaled \$1.1 million for the nine months ended March 31, 2018 compared to \$6.1 million for the nine months ended March 31, 2017. This decrease was predominantly attributable to \$5.6 million of revenue recognized in the prior year period upon the termination of the Amended and Restated Collaborative Research and License Agreement with Pfizer, Inc. In addition, revenues earned from feasibility study agreements increased by \$784,000 and net profits received from Alimera under the Prior Alimera Agreement decreased by \$202,000 for the nine months ended March 31, 2018 compared to the prior year period.

Royalty income for the nine months ended March 31, 2018 increased by \$391,000, or 54%, to \$1.1 million compared to \$730,000 for the nine months ended March 31, 2017, attributable predominantly to \$379,000 of sales-based royalties earned from Alimera under the Amended Alimera Agreement.

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Research and Development

Research and development expenses increased by \$746,000, or 7%, to approximately \$11.4 million for the nine months ended March 31, 2018 from approximately \$10.7 million for the nine months ended March 31, 2017, attributable primarily to a \$1.7 million increase in professional services associated primarily with our YUTIQ three-year uveitis Phase 3 clinical development program and regulatory filings and \$628,000 of U.S. personnel and benefit costs, including stock-based compensation, partially offset by decreases of \$903,000 of CRO costs for our YUTIQ three-year uveitis clinical development and \$690,000 of prior year personnel and legal costs associated with the U.K. restructuring.

General and Administrative

General and administrative expenses decreased by \$1.3 million, or 15%, to approximately \$7.3 million for the nine months ended March 31, 2018 from approximately \$8.6 million for the same period in the prior year, attributable primarily to (i) \$876,000 of personnel and related costs, of which \$1.2 million represented prior year severance compensation to our former CEO and our former Vice President, Corporate Affairs and General Counsel, (ii) \$571,000 of professional fees, substantially related to the prior year management change and Alimera arbitration proceedings and (iii) \$149,000 of stock-based compensation, of which \$266,000 was due to equity award forfeitures that resulted from the March 2018 resignation of our EVP of Corporate and Commercial Development, partially offset by increases of (i) \$98,000 for facility and related costs, including our New Jersey office lease that commenced July 1, 2017 and (ii) a \$103,000 increase in stockholder meeting and stock exchange costs, which included an initial \$85,000 of costs incurred related to our ASX Delisting.

Change in Fair Value of Derivative Liability

The future obligation to issue Units in the Second Tranche Transaction was measured at fair value and recorded as a derivative liability on our balance sheet upon consummation of the First Tranche Transaction and is remeasured at fair value at each balance sheet date. At March 31, 2018, the fair value re-measurement resulted in a \$2.3 million change in fair value of derivative liability that was recorded as a component of non-operating expense for the nine months ended March 31, 2018.

Liquidity and Capital Resources

Our fiscal 2018 year-to-date operations were financed primarily from existing capital resources at June 30, 2017, gross proceeds of \$7.3 million from sales of 5,900,000 shares of common stock under our existing at-the-market (“ATM”) program and the First Tranche Transaction and Debt Financing that resulted in gross proceeds of \$24.5 million, \$15.0 million of which was used to fund the closing payment to acquire Icon and \$1.1 million was used to pay certain financing and transaction costs. At March 31, 2018, our principal sources of liquidity were cash and cash equivalents that totaled \$16.3 million. Upon an approval by our stockholders of the Second Tranche Transaction, we will receive additional net proceeds of approximately \$25.5 million from the sale of the Units pursuant to the Second Tranche Securities Purchase Agreement.

As of March 31, 2018, our debt consists of \$15 million, which amount represents the amount outstanding under the Loan pursuant to the Credit Agreement. The Loan is due and payable on March 27, 2023 (the “Maturity Date”). The Loan bears interest at a per annum rate of the three-month London Interbank Offered Rate (“LIBOR”), subject to a 1.5% floor, plus 10.50%. The Credit Agreement permits us to pay interest only on the principal amount loaned thereunder for the first eight payments (payments are due on a quarterly basis). Following the interest-only period, we will be required to make quarterly payments of interest, plus repayments of the principal amount loaned under the Credit Agreement in an aggregate amount of up to \$1,250,000 per quarter (the “Quarterly Principal Repayment Cap”). Subject to the Quarterly Principal Repayment Cap, the amount of any quarterly principal payments during any fiscal year is based on (x) a percentage of our year-to-date net revenue through the end of such quarter less (y) any prior quarterly principal and interest payments made during such fiscal year. In addition, we paid an upfront fee of 1.5% of the aggregate principal amount of the Loan. We are also required to pay an exit fee equal to 6% of the aggregate principal amount advanced under the Credit Agreement.

Subject to certain exceptions, we are required to make mandatory prepayments of the Loan with the proceeds of assets sales and insurance proceeds. In addition, we may make a voluntary prepayment of the Loan, in whole, but not in part, at any time on or after the first anniversary of March 28, 2018. All mandatory and voluntary prepayments of the Loan are subject to the payment of prepayment premiums as follows: (i) in the case of mandatory prepayments, if prepayment occurs prior to the first anniversary of March 28, 2018, a customary make-whole amount equal to the amount of interest that would have accrued on the principal amount so prepaid had it remained outstanding through the first anniversary of March 28, 2018, (ii) if prepayment occurs on or after the first anniversary of March 28, 2018 but prior to the second anniversary of March 28, 2018, 6% of the aggregate amount of the principal prepaid and (iii) if prepayment occurs on or after the second anniversary of March 28, 2018 but prior to the third anniversary of March 28, 2018, an amount equal to 1% of the principal prepaid. No prepayment premium is due on any principal prepaid on or after the third anniversary of March 28, 2018.

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With the exception of net income for the fiscal year ended June 30, 2015 resulting from our receipt of the \$25.0 million ILUVIEN FDA-approval milestone, we have predominantly incurred operating losses since inception, and at March 31, 2018 we had a total accumulated deficit of \$329.6 million. We do not currently have any significant assured sources of future revenue, and our anticipated recurring use of cash to fund operations in combination with no probable source of additional capital raises substantial doubt about our ability to continue as a going concern for one year from the issuance of our financial statements included in this Quarterly Report on Form 10-Q. We have historically financed our operations primarily from the proceeds of sales of our equity securities and receipt of license fees, milestone payments, research and development funding and royalty income from our collaboration partners. We believe that our cash and cash equivalents of \$16.3 million at March 31, 2018 and expected cash inflows under existing collaboration agreements will enable us to fund our current and planned operations (including continuation of our two Phase 3 clinical trials for YUTIQ and plans for commercial launch of DEXYCU and, if approved, YUTIQ) through approximately the third quarter of calendar year 2018. In order to extend our ability to fund our operations beyond then, including our planned U.S. commercial launch of DEXYCU and, if approved, YUTIQ, we have filed a preliminary proxy statement for a special meeting of stockholders to be held on June 22, 2018 for the purpose of approving, among other things, the issuance of up to approximately \$25.5 million of Units, with each Unit consisting of (a) one share of the Company's common stock and (b) one warrant to purchase one share of our common stock. We may also draw down an additional \$5.0 million pursuant to a Credit Agreement among the Company, as borrower, SWK Funding LLC, as agent, and the lenders party thereto from time to time, subject to a minimum capital raise of at least \$20 million of net cash proceeds from an additional equity offering, which would be satisfied by the Second Tranche Transaction, or permitted subordinated debt financing ("Minimum Capital Raise"). There is no assurance that we will receive significant revenues from the planned commercialization of DEXYCU or, if approved, YUTIQ, or from license revenues from ILUVIEN® or be able to obtain financing from any other sources.

The additional capital we will require will be influenced by many factors, including, but not limited to:

- whether our stockholders approve the Second Tranche Transaction at our special meeting of stockholders;
- the success and timing of our commercialization efforts with respect to DEXYCU;
- whether we are required to make additional milestone and earn-out payments to the former security-holders of Icon;
- the amount of future revenues we receive with respect to our planned commercialization of DEXYCU and, if approved by the FDA, YUTIQ and license revenues from ILUVIEN for DME and, if and when approved in the EMEA, of ILUVIEN for posterior uveitis;
- the timing, cost and success of our clinical development, regulatory approval and planned direct U.S. commercialization of YUTIQ;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- the amount of Retisert royalties and other payments we receive under collaboration agreements;
- whether and when we are able to enter into strategic arrangements for our products or product candidates and the nature of those arrangements;
- timely and successful development, regulatory approval and commercialization of our products and product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims;
- changes in our operating plan, resulting in increases or decreases in our need for capital; and
- our views on the availability, timing and desirability of raising capital.

We do not know if additional capital will be available when needed or on terms favorable to us or our stockholders. Collaboration, licensing or other agreements may not be available on favorable terms, or at all. We do

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not know if our stockholders will approve the Second Tranche Transaction. We do not know the extent to which we will be able to establish commercial and other capabilities to successfully launch DEXYCU or, if approved, YUTIQ. Although we expect that our restructured Alimera collaboration agreement will provide a more consistent flow of royalty income, we do not know the extent to which Alimera will achieve increasing revenues from its commercialization of ILUVIEN for DME and, if approved in the EMEA, for posterior segment uveitis. If we seek to sell shares under our ATM program or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the rules and regulations of the Nasdaq Global Market require us to obtain stockholder approval for sales of our equity securities under certain circumstances, which could delay or prevent us from raising additional capital from such sales. Also, the state of the economy and financial and credit markets at the time or times we seek any additional financing may make it more difficult or expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders' equity, and funding through collaboration agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may delay, reduce the scope of, or eliminate research or development programs, potential independent commercialization of DEXYCU and, if approved, YUTIQ or other new products, if any, and postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs, or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

Our consolidated statements of historical cash flows are summarized as follows (in thousands):

	Nine Months Ended		Change
	March 31,		
	2018	2017	
Net loss:	\$(18,743)	\$(12,369)	\$ (6,374)
Changes in operating assets and liabilities	(1,630)	(451)	(1,179)
Other adjustments to reconcile net loss to cash flows from operating activities	4,547	(3,218)	7,765
Net cash used in operating activities	<u>\$(15,826)</u>	<u>\$(16,038)</u>	<u>\$ 212</u>
Net cash (used in) provided by investing activities	<u>\$(15,135)</u>	<u>\$ 11,203</u>	<u>\$(26,338)</u>
Net cash provided by financing activities	<u>\$ 30,405</u>	<u>\$ 2,404</u>	<u>\$ 28,002</u>

For the nine months ended March 31, 2018, net cash used in operating activities decreased by \$212,000 compared to the nine months ended March 31, 2017, due primarily to a combination of higher operating cash inflows partially offset by higher operating cash outflows. Increases in operating cash inflows of approximately \$820,000 consisted of \$665,000 of proceeds from new feasibility study agreements and an increase of \$189,000 of cash inflows from Alimera, related primarily to \$379,000 of royalty income attributable to the July 2017 restructuring of our collaboration agreement with Alimera. Increases in operating cash outflows of approximately \$608,000 consisted primarily of approximately \$1.4 million of consulting services, related primarily to our YUTIQ NDA filing and clinical development program and \$132,000 of third-party research and development costs, partially offset by (i) a \$484,000 decrease in personnel and related costs, due primarily to severance compensation paid in the prior year to our former CEO, our former Vice President, Corporate Affairs and General Counsel and our former U.K. employees, partially offset by higher year over year incentive compensation payments, the December 2017 payment of the cash portion of certain retention bonus agreements and headcount increases; (ii) \$285,000 of patent legal fees and (ii) \$208,000 of CRO payments associated with our YUTIQ clinical development.

Net cash used in investing activities during the nine months ended March 31, 2018 consisted primarily of a \$14.9 million closing payment for the Icon Acquisition plus \$237,000 of transaction costs paid, net of \$38,000 of cash acquired. Net cash provided by investing activities during the nine months ended March 31, 2017 consisted predominantly of \$11.2 million of maturities of marketable securities, net of purchases. There were no purchases or maturities of marketable securities during the nine months ended March 31, 2018.

Net cash provided by financing activities for the nine months ended March 31, 2018 consisted of the following:

- (i) \$9.3 million of net proceeds received from the March 28, 2018 sale of 8,606,324 shares of common stock, representing the First Tranche Transaction in connection with the Icon Acquisition;

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- (ii) \$7.0 million of proceeds, net of share issue costs, from sales of 5,900,000 shares of common stock under our ATM program; and
- (iii) \$14.1 million of proceeds from the Loan under the Credit Agreement, net of issue costs.

For the nine months ended March 31, 2017, net cash provided by financing activities consisted of \$2.3 million of proceeds, net of program and share issue costs, from sales of 1,411,686 shares of common stock under our ATM program and \$99,000 from the exercise of stock options.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of March 31, 2018 that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that would be material to investors.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to various market risks, which may result in potential losses arising from adverse changes in market rates, such as interest rates. We do not enter into derivatives or other financial instruments for trading or speculative purposes and do not believe we are exposed to material market risk with respect to our cash and cash equivalents.

As of March 31, 2018, we had cash and cash equivalents of \$16.3 million. We do not engage in any hedging activities against changes in interest rates. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an immediate 10% increase in interest rates would have a significant impact on the realized value of our investments.

The interest rate on our Loan under the Credit Agreement is variable based on the three-month LIBOR, subject to a 1.5% floor, plus 10.50%. Accordingly, such interest rate is affected by changes in market interest rates. As of March 31, 2018, we had \$15.0 million of aggregate principal amount outstanding under the Credit Agreement. As of March 31, 2018, the three-month LIBOR was 2.31%. A hypothetical 1% increase in the three-month LIBOR would result in \$150,000 in incremental annual interest expense under the Loan.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2018. The term “disclosure controls and procedures”, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2018, our principal executive officer and principal 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

During the quarter ended March 31, 2018, there have been no changes in our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1A. Risk Factors

The risk factors set forth below amend and restate the risk factors contained in our Annual Report on Form 10-K for the annual period ended June 30, 2017, which was filed with the SEC on September 13, 2017 and amended on October 30, 2017. The occurrence of any one or more of these risks could materially harm our business, operating results, financial condition and prospects. These risks and uncertainties could also cause actual results to differ materially and adversely from those expressed or implied by forward-looking statements that we make from time to time. Please see “Note Regarding Forward-Looking Statements” appearing at the beginning of Item 2 of this Form 10-Q.

RISKS RELATED TO OUR BUSINESS, FINANCIAL POSITION AND OUR CAPITAL RESOURCES

We will need additional capital to fund our operations and continue as a going concern. If we are unable to obtain sufficient capital, we will need to curtail and reduce our operations and costs, and modify our business strategy.

Our operations have consumed substantial amounts of cash. To date, we have financed our operations primarily through the sale and issuance of capital stock and debt and the receipt of license fees, milestone payments, research and development funding and royalty payments from our collaboration partners. As of March 31, 2018, our cash and cash equivalents were \$16.3 million. We believe that our existing capital resources, together with expected payments from existing collaborations, should enable us to fund our operations as currently planned through approximately the third quarter of calendar year 2018. However, changing circumstances may cause us to consume capital faster than we currently anticipate, and we may need to spend more money than currently expected because of such circumstances. Our ability to fund our planned operations beyond that time, including obtaining regulatory approval for YUTIQ, commercializing DEXYCU and, if approved, YUTIQ, and continuing our research and development program for our other product candidates, will require additional capital. In addition, our current plan to commercialize DEXYCU and YUTIQ ourselves in the United States will require significant operating cost investment related to product manufacturing, marketing, sales, distribution and other commercialization costs.

To meet our capital needs, we are considering multiple alternatives, including but not limited to, equity financings, debt financings, corporate collaborations, partnerships and other strategic transactions and funding opportunities. For instance, in order to address a portion of our capital needs, we are seeking approval of our stockholders at a special meeting to be held on June 22, 2018 to issue up to approximately \$25.5 million of units, with each unit consisting of (i) one share of our common stock and (ii) one warrant to purchase one share of our common stock (the “Second Tranche Transaction”). In addition, we may also draw down an additional \$5.0 million from our existing lender if the Second Tranche Transaction is approved and consummated. However, there can be no assurance that we will be able to receive such stockholder approval and complete the Second Tranche Transaction and such additional debt draw down or complete any one or more of such other transactions on acceptable terms or otherwise. These factors raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm has included an explanatory paragraph in its report on our financial statements for the year ended June 30, 2017 related to our ability to continue as a going concern.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will need to curtail and reduce our operations and costs, and modify our business strategy which may require us to, among other things:

- significantly delay, scale back or discontinue the development or commercialization of one or more of our products or product candidates or one or more of our other research and development initiatives;
- seek partners or collaborators for one or more of our products or product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- sell or license on unfavorable terms our rights to one or more of our technologies, products or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- seek to sell our company at an earlier stage than would otherwise be desirable or on terms that are less favorable than might otherwise be available.

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We have incurred significant losses since our inception and anticipate that we will continue to incur losses for the foreseeable future.

We have incurred significant losses since our inception, have not generated significant revenue from commercial sales of our products and, with exception of fiscal year 2010 and fiscal year 2015, we have never been profitable. Investment in drug development is highly speculative because it entails substantial upfront operating expenses and significant risk that a product candidate will fail to successfully complete clinical trials, gain regulatory approval or become commercially viable. We continue to incur significant research, development and other expenses related to our ongoing operations, including development of YUTIQ and other early stage and/or potential product candidates and commercialization of DEXYCU. For the nine months ended March 31, 2018, we had a net loss of \$18.7 million, and we had a total accumulated deficit of \$329.6 million at March 31, 2018.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will continue to be significant if, and as, we:

- begin to commercialize DEXYCU and, if approved, YUTIQ and further scale up our manufacturing and distribution capabilities to commercialize DEXYCU and, if approved, YUTIQ or any other product candidate for which we may obtain regulatory approval;
- adapt our regulatory compliance efforts to incorporate requirements applicable to marketed drugs;
- add operational, financial and management information systems and personnel, including personnel to support commercialization efforts;
- hire additional commercial, clinical, manufacturing and scientific personnel and engage third party commercial, clinical, manufacturing organizations;
- continue the research and pre-clinical and clinical development of our product candidates;
- initiate additional pre-clinical, clinical or other studies or trials for our product candidates;
- further develop the manufacturing process for our product candidates;
- change or add additional manufacturers or suppliers;
- seek regulatory approvals for our product candidates that successfully complete clinical trials;
- seek to identify and validate additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, protect and expand our intellectual property portfolio;
- attract and retain skilled personnel;
- create additional infrastructure to support our product development and planned future commercialization efforts; and
- experience any delays or encounter issues with any of the above.

The net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. In any particular quarter or quarters, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline.

We may never achieve profitability from future operations.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory approvals necessary for, the manufacture and commercialization of our products and product candidates. Our operations have consumed substantial amounts of cash. To date, we have financed our operations primarily through the sale and issuance of capital stock and debt and the receipt of license fees, milestone payments, research and development funding and

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royalty income from our collaboration partners. To become and remain profitable, we and/or our licensees must succeed in developing and commercializing products that generate significant revenue. This will require us or our licensees to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates, manufacturing, marketing and selling any products for which we or our licensees may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. To date, none of our approved licensed products, including Vitrasert, Retisert and ILUVIEN, has generated significant revenues to us from sales. We have not yet commercialized DEXYCU and YUTIQ has not yet obtained regulatory approval. We do not know when DEXYCU or, if approved, YUTIQ, or any of our other product candidates, if approved, will generate revenue for us, if at all. We may never succeed in these activities and, even if we do, we may never generate revenues significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately project when or if we will be able to achieve profitability from operations. Even if we do so, 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. Our ability to generate revenue from our current or future products and product candidates will depend on a number of factors, including:

- our ability to successfully commercialize DEXYCU and, if approved, YUTIQ;
- our ability to complete and submit applications to, and obtain regulatory approval from, foreign regulatory authorities, if we choose to commercialize DEXYCU outside the United States and, if approved, YUTIQ, in unpartnered jurisdictions outside the United States;
- the size of the markets in the territories for which we gain regulatory approval;
- our ability to develop a commercial organization capable of sales, marketing and distribution for DEXYCU and, if approved, YUTIQ, and any of our other product candidates for which we may obtain marketing approval;
- our ability to enter into and maintain commercially reasonable agreements with wholesalers, distributors and other third parties in our supply chain;
- our success in establishing a commercially viable price for our products;
- our ability to manufacture commercial quantities of our products at acceptable cost levels;
- our ability to obtain coverage and adequate reimbursement from third parties, including government payors; and
- our ability to successfully complete development activities, including the necessary clinical trials, with respect to our other product candidates.

We will need to raise additional funds in the future, which may not be available on favorable terms and may be dilutive to stockholders or impose operational restrictions.

We will need to raise additional capital in the future to help fund our commercialization of DEXYCU and, if approved, YUTIQ, and for the development and commercialization of our product candidates. The amount of additional capital we will require will be influenced by many factors, including, but not limited to:

- the success of our commercialization of DEXYCU for the treatment of postoperative inflammation including, among other things, patient and physician acceptance of DEXYCU and our ability to obtain adequate coverage and reimbursement for DEXYCU;
- the cost and timing of commercialization activities for DEXYCU, including product manufacturing, marketing, sales and distribution;
- the amount of revenues we earn from commercial sales of DEXYCU;

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- the timing, cost and success of our clinical development, regulatory approval and planned direct United States (“U.S.”) commercialization of YUTIQ;
- the amount of future revenues we receive with respect to the commercialization of ILUVIEN for DME and, if approved in Europe, the Middle East and Africa (collectively, the “EMEA”), ILUVIEN for posterior segment uveitis;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- the amount of Retisert royalties and other payments we receive under collaboration agreements;
- whether and when we are able to enter into strategic arrangements for our products or product candidates and the nature of those arrangements;
- timely and successful development, regulatory approval and commercialization of other potential product candidates;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims;
- changes in our operating plan, resulting in increases or decreases in our need for capital;
- our views on the availability, timing and desirability of raising capital; and
- the costs of operating as a public company.

We do not know if additional capital will be available to us when needed or on terms favorable to us or our stockholders. Collaboration, licensing or other commercial agreements may not be available on favorable terms, or at all. We do not know the extent to which we will receive funds from the commercialization of DEXYCU, ILUVIEN, Retisert or, if approved, YUTIQ. If we seek to sell our equity securities under our at-the-market (“ATM”) program or in another offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the rules and regulations of the Nasdaq Stock Market (“Nasdaq”) require us to obtain shareholder approval for sales of our equity securities under certain circumstances, which could delay or prevent us from raising additional capital from such sales. By way of example, we are seeking stockholder approval at a special meeting to be held on June 22, 2018 to consummate the Second Tranche Transaction. Also, the state of the economy and financial and credit markets at the time or times we seek any additional financing may make it more difficult or more expensive to obtain. If available, additional equity financing may be dilutive to stockholders, debt financing may involve restrictive covenants or other unfavorable terms and dilute our existing stockholders’ equity, and funding through collaboration, licensing or other commercial agreements may be on unfavorable terms, including requiring us to relinquish rights to certain of our technologies or products. If adequate financing is not available if and when needed, we may delay, reduce the scope of, or eliminate research or development programs, planned independent U.S. commercialization of DEXYCU, YUTIQ, if approved, or other new products, if any, postpone or cancel the pursuit of product candidates, including pre-clinical and clinical trials and new business opportunities, reduce staff and operating costs, or otherwise significantly curtail our operations to reduce our cash requirements and extend our capital.

The anticipated benefits of the Icon Acquisition may not be fully realized and may take longer to realize than expected.

On March 28, 2018 (the “Closing Date”), we and our wholly-owned subsidiary, Oculus Merger Sub, Inc. (“Merger Sub”), entered into an Agreement and Plan of Merger (the “Merger Agreement”) with Icon Bioscience, Inc. (“Icon”) and the other signatories thereto, pursuant to which we acquired Icon through a reverse triangular merger (the “Icon Acquisition”). The Icon Acquisition was consummated on the Closing Date. The anticipated benefits of the Icon Acquisition may not be fully realized and may take longer to realize than expected. The Icon Acquisition involved the integration of Icon’s product, DEXYCU, and product candidates and technology with our existing clinical development programs, and there are uncertainties inherent in such integration. We have devoted and will continue to devote significant management attention and resources to the Icon integration and to the commercialization of DEXYCU and further development of Icon’s product candidates and other programs. Delays or unexpected difficulties in the integration process could adversely affect our business, financial results and financial condition. Even if we were able to conduct the integration successfully, we may not realize the full achievement of the benefits of the Icon Acquisition within a reasonable period of time. In addition, we may have not yet discovered during the due diligence process all known and unknown factors regarding Icon that could produce unintended and unexpected consequences for us. Undiscovered factors could cause us to incur potentially material financial liabilities, and prevent us from achieving the expected benefits from the Icon Acquisition within our desired time frames, if at all.

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Our profitability will be impaired by our obligations to make royalty and milestone payments to the former securityholders of Icon and other third party collaborators.

In connection with the Icon Acquisition, we made a \$15.0 million cash payment upon the closing of the Icon Acquisition and are obligated to pay certain post-closing contingent cash payments upon the achievement of specified milestones and based upon certain net sales and partnering revenue standards, in each case subject to the terms and conditions set forth in the Agreement and Plan of Merger with Icon and the other signatories thereto. These include but are not limited to (i) a one-time cash payment of \$15.0 million payable upon the first commercial sale of DEXYCU in the United States, (ii) sales milestone payments totaling up to \$95.0 million upon the achievement of certain sales thresholds and subject to certain Centers for Medicare & Medicaid Services reimbursement conditions set forth in the Merger Agreement, (iii) quarterly earn-out payments equal to 12% on net sales of DEXYCU, which earn-out payments will increase to 16% of net sales of DEXYCU in a given year beginning in the calendar quarter for a given year to the extent aggregate annual consideration of DEXYCU exceeds \$200.0 million in such year, (iv) quarterly earn-out payments equal to 20% of partnering revenue received by us for DEXYCU outside of the United States, and (v) single-digit percentage quarterly earn-out payments with respect to net sales and/or partnering income, if any, resulting from future clinical development, regulatory approval and commercialization of any other product candidates we acquired in the Icon Acquisition.

Even if we are able to successfully launch DEXYCU, our profitability will be impaired by our obligations to make payments to the former securityholders of Icon. Although we believe, under such circumstances, that the increase in revenue will exceed the corresponding payments, our obligations to the former securityholders of Icon and other third-party collaborators could have a material adverse effect on our business, financial condition and results of operations if we are unable to manage our operating costs and expenses at profitable levels.

Our failure to comply with the covenants or other terms of the Credit Agreement, including as a result of events beyond our control, could result in a default under the Credit Agreement that could materially and adversely affect the ongoing viability of our business.

On the Closing Date, we entered into a Credit Agreement (the “Credit Agreement”) with SWK Funding LLC, as agent (the “Agent”), and the lenders party thereto (the “Lenders”), providing for a senior secured term loan of up to \$20 million (the “Loan”). On the Closing Date, \$15 million of the Loan was advanced. The remaining \$5 million may be advanced between the Closing Date and December 31, 2018, subject to our ability to raise at least \$20 million of net cash proceeds from an additional equity offering or permitted subordinated debt financing (the “Minimum Capital Raise”).

The Loan is due and payable on March 27, 2023. The proceeds of the Loan were used to fund a portion of the Icon Acquisition and to pay fees and expenses related to the Credit Agreement and Icon Acquisition. The Loan bears interest at a per annum rate of three-month LIBOR (subject to a 1.5% floor) plus 10.50%. The Credit Agreement permits us to pay interest only on the principal amount loaned thereunder for the first eight payments (payments are due on a quarterly basis). Following the interest-only period, we will be required to make quarterly payments of interest, plus repayments of the principal amount under the Credit Agreement in an aggregate amount of up to \$1,250,000 per quarter. Upon repayment of the Loan, we are also required to pay an exit fee equal to 6% of the aggregate principal amount advanced under the Credit Agreement.

In addition, the repayment of all unpaid principal and accrued interest under the Loan may be accelerated upon consummation of a specified change of control transaction or the occurrence of certain events of default (as specified in the Credit Agreement), including, among other things:

- our default in a payment obligation under the Credit Agreement;
- our default in a payment obligation under any of our other debt agreements evidencing indebtedness in an aggregate principal amount in excess of \$250,000;
- our breach of the negative covenants or, subject to specified cure periods, other terms of the Credit Agreement;

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- invalidity of the Loan documents, including the Agent ceasing to have a first priority, perfected security interest on any material portion of the collateral;
- the occurrence of a material adverse effect (as specified in the Credit Agreement); and
- certain specified insolvency and bankruptcy-related events.

Subject to any applicable cure period set forth in the Credit Agreement, upon the occurrence of a bankruptcy-related event of default, all amounts outstanding with respect to the Loan (principal, accrued interest, exit fee and any prepayment fees) would become due and payable immediately and upon the occurrence of any other event of default, the Agent may, and upon the written request of the majority Lenders shall, accelerate all or any amounts outstanding with respect to the Loan. Our assets or cash flow may not be sufficient to fully repay our obligations under the Credit Agreement if the obligations thereunder are accelerated upon an event of default. Further, if we are unable to repay, refinance or restructure our obligations under the Credit Agreement, the Lenders could proceed to protect and enforce their rights under the Credit Agreement by exercising such remedies as are available to the Lenders thereunder and in respect thereof under applicable law, either by suit in equity or by action at law, or both, whether for specific performance of any covenant or other agreement contained in the Credit Agreement or in aid of the exercise of any power granted in the Credit Agreement. The foregoing would materially and adversely affect the ongoing viability of our business.

Our Credit Agreement contains restrictions that limit our flexibility in operating our business.

The Credit Agreement contains various covenants that limit our ability to engage in specified types of transactions without the Lenders' prior consent. These covenants limit our ability to, among other things:

- sell, transfer, lease or dispose of our assets;
- create, incur or assume additional indebtedness;
- encumber or permit liens on certain of our assets;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to, our common stock;
- make specified investments (including loans and advances);
- consolidate, merge, sell or otherwise dispose of all or substantially all of our assets;
- enter into certain transactions with our affiliates;
- permit our cash and cash equivalents held in certain deposit accounts to be less than \$4,000,000 at any month end; provided, that, after February 15, 2019, such amount shall not be less than \$24,000,000 if the Minimum Capital Raise has not been satisfied; and
- permit our aggregate revenue and earnings before interest, taxes, depreciation, and amortization to fall below certain agreed projection levels.

The covenants in our Credit Agreement may limit our ability to take certain actions that may be in our long-term best interests. In the event that we breach one or more covenants, the Lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, plus penalties and interest, including the exit fee and any prepayment fees, terminate their commitments to extend further credit and foreclose on the collateral granted to them to secure such indebtedness. Such repayment could have a material adverse effect on our business, operating results and financial condition.

Certain potential payments to the Lenders could impede a sale of our company.

Subject to certain exceptions, we are required to make mandatory prepayments of the Loan with the proceeds derived from assets sales and insurance proceeds. In addition, we may make a voluntary prepayment of the Loan, in whole, but not in part, at any time on or after the first anniversary of the Closing Date. All mandatory and voluntary prepayments of the Loan are subject to the payment of prepayment premiums as follows: (i) in the case of

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mandatory prepayments, if prepayment occurs prior to the first anniversary of the Closing Date, a customary make-whole amount equal to the amount of interest that would have accrued on the principal amount so prepaid had it remained outstanding through the first anniversary of the Closing Date, (ii) if prepayment occurs on or after the first anniversary of the Closing Date but prior to the second anniversary of the Closing Date, 6% of the aggregate amount of the principal prepaid and (iii) if prepayment occurs on or after the second anniversary of the Closing Date but prior to the third anniversary of the Closing Date, an amount equal to 1% of the principal prepaid. No prepayment premium is due on any principal prepaid on or after the third anniversary of the Closing Date. These provisions may make it more costly for a potential acquirer to engage in a business combination transaction with us. Provisions that have the effect of discouraging, delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

To service our indebtedness, we will require a significant amount of cash and our ability to generate cash depends on many factors beyond our control.

Our ability to make cash payments on our indebtedness will depend on our ability to generate significant operating cash flow in the future. This ability is, to a significant extent, subject to general economic, financial, competitive, legislative, regulatory and other factors, that will be beyond our control. In addition, our business may not generate sufficient cash flow from operations to enable us to pay our indebtedness or to fund our other liquidity needs. In any such circumstance, we may need to refinance all or a portion of our indebtedness, on or before maturity. We may not be able to refinance any indebtedness on commercially reasonable terms or at all. If we cannot service our indebtedness, we may have to take actions such as selling assets, seeking additional equity or reducing or delaying capital expenditures, strategic acquisitions and investments. Any such action, if necessary, may not be effected on commercially reasonable terms or at all. The instruments governing our indebtedness may restrict our ability to sell assets and our use of the proceeds from such sales.

Our ability to use our net operating loss carryforwards and other tax attributes may be limited.

As of March 31, 2018, we had U.S. net operating loss (“NOL”) carryforwards of approximately \$149.3 million for U.S. federal income tax and approximately \$98.8 million of state income tax purposes available to offset future taxable income and U.S. federal and state research and development tax credits of approximately \$1.2 million, prior to consideration of annual limitations that may be imposed under Section 382 of the Internal Revenue Code of 1986, as amended (“Section 382”). The U.S. NOL carryforwards begin to expire in 2023 if not utilized.

Our U.S. NOL and tax credit carryforwards could expire unused and be unavailable to offset future income tax liabilities. Under Section 382, and corresponding provisions of U.S. state law, if a corporation undergoes an “ownership change,” generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation’s ability to use its pre-change U.S. NOLs and other pre-change tax attributes, such as research and development tax credits, to offset its post-change income may be limited. Our most recent analyses under Section 382 were performed through 2017 and we cannot forecast or otherwise determine our ability to derive benefit from our various federal or state tax attribute carryforwards. As a result, if we earn net taxable income, our ability to use our pre-change U.S. NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of U.S. NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including through completed or contemplated financings, some of which may be outside of our control. If we determine that an ownership change has occurred and our ability to use our historical net operating loss and tax credit carryforwards is materially limited, it would harm our future operating results by effectively increasing our future tax obligations.

Our operating results may fluctuate significantly from period to period.

Our operating results have fluctuated significantly from period to period in the past and may continue to do so in the future due to many factors, including:

- the costs of our commercialization efforts;
- costs of internally funded research and development, including contract research organizations (“CROs”) and other costs related to clinical development and costs of pre-clinical studies and research;

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- developments with respect to our products and product candidates, both licensed and independently developed, including pre-clinical and clinical trial data and results, regulatory developments and marketing and sales results;
- timing, receipt and amount of revenues, including receipt and recognition of collaborative research and development, licensing, milestone, royalty and other payments;
- announcement, execution, amendment and termination of collaboration and other commercial agreements;
- scope, duration and success of collaboration and other commercial agreements;
- general and industry-specific adverse economic conditions that may affect, among other things, our and our collaborators' operations and financial results; and
- changes in accounting estimates, policies or principles and intangible asset impairments.

Due to fluctuations in our operating results, quarterly comparisons of our financial results may not necessarily be meaningful, and investors should not rely upon such results as an indication of future performance. In addition, investors may react adversely if our reported operating results are less favorable than in a prior period or are less favorable than those anticipated by investors in the financial community, which may result in decreases in our stock price.

RISKS RELATED TO THE COMMERCIALIZATION OF OUR PRODUCTS AND PRODUCT CANDIDATES

We have no history of commercializing products, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been largely focused on raising capital and developing Retisert, ILUVIEN, YUTIQ and our other product candidates, including undertaking pre-clinical studies and conducting clinical trials. Bausch & Lomb and Alimera Sciences, Inc. ("Alimera") were responsible for completing the clinical development of, obtaining regulatory approval for, and initiating the commercial launch of Retisert and ILUVIEN, respectively under our license agreements with each of them. Icon completed the clinical development of, and obtained regulatory approval for, DEXYCU. To date, we have not yet demonstrated our ability to successfully complete clinical development through the submission and attainment of marketing approvals for any product candidate, manufacture at commercial scale, or, with the exception of Retisert and ILUVIEN, arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing drugs.

Our current business strategy relies heavily on our ability to successfully commercialize DEXYCU and, if approved, YUTIQ, in the United States. Our approved products may not achieve market acceptance or be commercially successful.

Our ability to successfully commercialize DEXYCU and, if approved, YUTIQ, in the United States is critical to the execution of our business strategy. Neither DEXYCU nor YUTIQ, if approved, may achieve market acceptance among retinal specialists and other doctors, patients, government health administration authorities and other third-party payors, and may not be commercially successful in the United States. The degree of market acceptance and commercial success of our approved products will depend on a number of factors, including the following:

- the acceptance of our products by patients and the medical community and the availability, perceived advantages and relative cost, safety and efficacy of alternative and competing treatments;
- our ability to obtain reimbursement for our products from third party payors at levels sufficient to support commercial success;
- the cost effectiveness of our products;
- the effectiveness of our marketing, sales and distribution strategies and operations;

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- our ability and the ability of our contract manufacturing organizations (“CMOs”), as applicable, to manufacture commercial supplies of our products, to remain in good standing with regulatory agencies, and to develop, validate and maintain commercially viable manufacturing processes that are, to the extent required, compliant with current good manufacturing practice (“cGMP”) regulations;
- the degree to which the approved labeling supports promotional initiatives for commercial success;
- a continued acceptable safety profile of our products;
- results from additional clinical trials of our products or further analysis of clinical data from completed clinical trials of our products by us or our competitors;
- our ability to enforce our intellectual property rights;
- our products’ potential advantages over other therapies;
- our ability to avoid third-party patent interference or patent infringement claims; and
- maintaining compliance with all applicable regulatory requirements.

As many of these factors are beyond our control, we cannot assure you that we will ever be able to generate meaningful revenues through product sales. In particular, if governments, private insurers, governmental insurers and other third-party payors do not provide adequate and timely coverage and reimbursement levels for our products or limit the frequency of administration, the market acceptance of our products and product candidates will be limited. Governments, governmental insurers, private insurers and other third-party payors attempt to contain healthcare costs by limiting coverage and the level of reimbursement for products and, accordingly, they may challenge the price and cost-effectiveness of our products, or refuse to provide coverage for our products. Any inability on our part to successfully commercialize DEXYCU and, if approved, YUTIQ, and our other product candidates in the United States or any foreign territories where they may be approved, or any significant delay in such approvals, could have a material adverse impact on our ability to execute upon our business strategy and our future business prospects.

If we are unable to enter into agreements with third parties to market and sell DEXYCU and, if approved, YUTIQ, we may be unable to generate any revenue from these products.

We currently have limited sales, marketing or distribution capabilities, our approved products are commercialized by others and, as a company, we have no experience in commercializing products. We intend to commercialize DEXYCU and, if approved, YUTIQ, in the U.S. ourselves through a contract sales organization (“CSO”), although we have not yet entered into any agreements with CSOs. Direct commercialization would require us to develop sales and marketing capabilities and to make a significant financial investment. In addition, any CSO that we may use may not dedicate sufficient resources to the commercialization of our products or may otherwise fail in its commercialization due to factors beyond our control. Additionally, any CSO that we may use may fail to comply with applicable legal or regulatory requirements, or may enter into agreements with other parties that have products and services that could compete with our products.

In the event that we fail to successfully launch and commercialize DEXYCU or, if approved, YUTIQ, through a CSO, we may also enter into a strategic collaboration with a third party. We face significant competition in seeking appropriate strategic collaborators, and these strategic collaborations can be intricate and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any strategic collaborations because of the numerous risks and uncertainties associated with establishing strategic partnerships.

We do not know if we will decide to directly commercialize any other product candidates ourselves, if approved. If we decide to commercialize a product in one or more countries, there is no assurance we will be able to hire and manage a successful sales and marketing capability or have the financial resources necessary to fund independent commercialization of any products in any country.

Even if the FDA were to grant approval of YUTIQ, the terms of the approval may limit its commercial potential.

Even if we were to successfully obtain approval from the FDA for YUTIQ, any such approval might significantly limit the indications for use or patient populations, require that black box warnings, contraindications or warnings and precautions be included on the product labeling, require expensive and time-consuming post-approval clinical trials, a Risk Evaluation and Mitigation Strategy (“REMS”), or surveillance as conditions of approval, or otherwise through product labeling limit the claims that we may make, any of which may impede the successful commercialization of YUTIQ. Depending on the extent of any REMS requirements, our costs to commercialize YUTIQ may increase significantly and distribution restrictions could limit sales. Further, if the approval of YUTIQ contains other significant product label limitations, our ability to address our full target market will be reduced and our ability to realize the full market potential of YUTIQ will be harmed and we may have to limit our sales and marketing efforts.

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Even if we are able to commercialize our products, the products may become subject to unfavorable pricing regulations, third-party reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Some countries require approval of the sale price of a product 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, which could negatively impact the revenues we are able to generate from the sale of the product in that particular country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more of our products.

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover 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 companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors also may seek additional clinical evidence, beyond the data required to obtain marketing approval, demonstrating clinical benefits and value in specific patient populations, before covering our products for those patients. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. For example, under current Medicare policy, payment to hospital outpatient departments and ambulatory surgical centers for products furnished to patients during a procedure is typically packaged into the payment for the associated procedure and thus not paid separately. Products granted pass-through status are excluded from this payment packaging policy and receive separate payment from the associated procedure for a period of three years. While DEXYCU may be granted pass-through status and receive separate payment in these settings from Medicare for a period of three years, at the end of that three year period, payment for DEXYCU may be packaged into the payment for the associated procedure and no longer be paid separately, which we expect will materially decrease our revenues from sales of DEXYCU and correspondingly have a material adverse effect on our results of operations and financial condition.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacturing, selling and distribution costs. 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 profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

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If we successfully commercialize any of our products, we may participate in the Medicaid Drug Rebate program. Participation is required for federal funds to be available for our covered outpatient drugs under Medicaid and, if applicable, Medicare Part B. Under the Medicaid Drug Rebate Program, we would be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program as a condition of having federal funds being made available to the states for our drugs under Medicaid and, if applicable, Part B of the Medicare program.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the Public Health Service's 340B drug pricing program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily-defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients.

In addition, in order to be eligible to have its products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, a manufacturer also must participate in the U.S. Department of Veterans Affairs, or VA, Federal Supply Schedule, or FSS, pricing program. Under this program, the manufacturer is obligated to make its innovator and single source products available for procurement on an FSS contract and charge a price to four federal agencies—VA, U.S. Department of Defense, or DoD, Public Health Service and U.S. Coast Guard—that is no higher than the statutory Federal Ceiling Price. Moreover, pursuant to regulations issued by the DoD Defense Health Agency to implement Section 703 of the National Defense Authorization Act for Fiscal Year 2008, manufacturers are required to provide rebates on utilization of their innovator and single source products that are dispensed to TRICARE beneficiaries by TRICARE network retail pharmacies. The requirements under the 340B, FSS, and TRICARE programs could reduce the revenue we may generate from any products that are commercialized in the future and could adversely affect our business and operating results.

We intend to ship YUTIQ, if approved, directly to physician offices or clinics to be administered to patients. YUTIQ will be shipped to physician offices or clinics primarily through specialty pharmacies and distributors and billed to doctors under a "buy and bill" model. Physicians may be unwilling to purchase our products, especially given the relatively high per unit price we expect to charge for YUTIQ. We also may not be able to obtain a permanent "J" code for YUTIQ, thereby limiting our ability to obtain reimbursement from Medicare and making it more difficult for us to obtain reimbursement from commercial or Medicare Advantage plans.

We intend to ship DEXYCU to ambulatory surgical centers ("ASCs") or to hospital outpatient surgical centers through specialty pharmacies. We intend that DEXYCU will be reimbursed for Medicare Part B patients through a transitional pass through payment utilizing a "C" code. However, DEXYCU may not qualify for a C code or transitional pass through payment and therefore may be subject to cataract bundled payment rates, which would significantly limit our ability to gain utilization and subsequent revenues. In addition, ASCs and hospital outpatient surgical centers may find the administrative burden of submitting Medicare Part B claims for DEXYCU with a C code too burdensome and may have their invoices rejected for payment due to billing errors, which may discourage them from utilizing DEXYCU. They may also be unable to efficiently delineate between patients who have Medicare Part B payment coverage, Medicare Advantage coverage and commercial coverage and thus no longer utilize DEXYCU due to the insurance payment differences between these different insurance types.

If we successfully commercialize any of our products and if we participate in the Medicaid drug rebate program or other governmental pricing programs, failure to comply with reporting and payment obligations under these programs could result in additional reimbursement requirements, penalties, sanctions, and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The Medicaid Drug Rebate Program and other governmental pricing programs require participating manufacturers to report pricing data to various government agencies. Pricing calculations vary among products and programs and include average manufacturer price and best price for the Medicaid Drug Rebate Program, average sales price for certain categories of drugs that are paid under Part B of the Medicare program, and non-federal average manufacturer price for the VA FSS pricing program. If we successfully commercialize any of our products and participate in such governmental pricing programs, we will be liable for errors associated with our submission of pricing data. That liability could be significant. For example, if we are found to have knowingly submitted false average manufacturer price, average sales price, best price, or non-federal average manufacturer price information to the government, or fail to timely submit such information, we may be liable for significant civil monetary penalties. The foregoing also could be grounds for other sanctions, such as termination from the Medicaid Drug Rebate Program.

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Even though we have obtained regulatory approval for DEXYCU, we will still face extensive FDA regulatory requirements and may face future regulatory difficulties.

Even though regulatory approval for DEXYCU has been obtained in the United States, the FDA and state regulatory authorities may still impose significant restrictions on the indicated uses or marketing of DEXYCU, or impose ongoing requirements for potentially costly post-approval studies or post-marketing surveillance. For example, as part of its approval of DEXYCU for the treatment of postoperative inflammation, the FDA required that a Phase 3/4 prospective, randomized, active treatment-controlled, parallel-design multicenter trial be conducted to evaluate the safety of DEXYCU for the treatment of inflammation following ocular surgery for childhood cataract. This pediatric study may require us to undergo a costly and time-consuming development process.

We are also subject to ongoing FDA requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, record-keeping and reporting of safety and other post-marketing information. The holder of an approved NDA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the NDA. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials must comply with FDA regulations and may be subject to other potentially applicable federal and state laws. The applicable regulations in countries outside the United States grant similar powers to the competent authorities and impose similar obligations on companies.

In addition, manufacturers of drug products and their facilities are subject to payment of substantial user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and adherence to commitments made in the NDA. We will also need to comply with some of the FDA's manufacturing regulations for devices with respect to the micro-insert for YUTIQ. In addition to cGMP, the FDA requires that our micro-insert comply with the Quality System Regulation, or QSR, which sets forth the FDA's manufacturing quality standards for medical devices, and other applicable government regulations and corresponding foreign standards. If we, or a regulatory authority, discover previously unknown problems with DEXYCU, such as adverse events of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory authority may impose restrictions relative to DEXYCU or the manufacturing facility, including requiring recall or withdrawal of the product from the market, suspension of manufacturing, or other FDA action or other action by foreign regulatory authorities.

If we fail to comply with applicable regulatory requirements for DEXYCU or, if approved, YUTIQ, a regulatory authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, modify or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or a pending application for marketing authorization or supplements to an NDA or to an application for marketing authorization submitted by us;
- seize our product; and/or
- refuse to allow us to enter into supply contracts, including government contracts.

Our relationships with physicians, patients and payors in the U.S. are subject to applicable anti-kickback, fraud and abuse laws and regulations. In addition, we will be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. Our failure to comply with these laws could expose us to criminal, civil and administrative sanctions, reputational harm, and could harm our results of operations and financial conditions.

Our current and future operations with respect to the commercialization of DEXYCU and, if approved, YUTIQ, are subject to various U.S. federal and state healthcare laws and regulations. These laws impact, among other things, our proposed sales, marketing, support and education programs and constrain our business and financial arrangements and relationships with third-party payors, healthcare professionals and others who may prescribe, recommend, purchase or provide our products, and other parties through which we market, sell and distribute our products. Finally, our current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws include, but are not limited to, the following:

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- The U.S. federal Anti-Kickback Statute prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order, or arranging for or recommending the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and Medicare patients, prescribers, purchasers and formulary managers on the other. In addition, the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution and administrative sanction, the exemptions and safe harbors are drawn narrowly, and practices or arrangements that involve remuneration may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection, and therefore would be subject to a facts and circumstances analysis to determine potential Anti-Kickback statute liability.
- The U.S. civil False Claims Act (which can be enforced through “qui tam,” or whistleblower actions, by private citizens on behalf of the federal government) prohibits any person from, among other things, knowingly presenting, or causing to be presented false or fraudulent claims for payment of government funds or knowingly making, using or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the U.S. federal government. Many pharmaceutical and other healthcare companies have been investigated or subject to lawsuits by whistleblowers and have reached substantial financial settlements with the federal government under the False Claims Act for a variety of alleged improper marketing activities, including providing free product to customers with the expectation that the customers would bill federal programs for the product; providing consulting fees, grants, free travel, and other benefits to physicians to induce them to prescribe the company’s products; and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, the government and private whistleblowers have pursued False Claims Act cases against pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses. Pharmaceutical and other healthcare companies also are subject to other federal false claim laws, including federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.
- The U.S. federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for healthcare benefits, items or services by a healthcare benefit program, which includes both government and privately funded benefits programs; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.
- HIPAA, as amended by the Health Information Technology and Clinical Health Act (“HITECH”) and its implementing regulations, impose certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and impose notification obligations in the event of a breach of the privacy or security of individually identifiable health information.
- Numerous federal and state laws and regulations that address privacy and data security, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act, or FTC Act), govern the collection, use, disclosure and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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- The majority of states have adopted analogous laws and regulations, including state anti-kickback and false claims laws, that may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payer, including private insurers. Other states have adopted laws that, among other things, require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities.
- The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to Centers for Medicare & Medicaid Services information related to certain payments made in the preceding calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance or reporting requirements in multiple jurisdictions increase the possibility that a healthcare or pharmaceutical company may fail to comply fully with one or more of these requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with applicable fraud and abuse or other healthcare laws and regulations or guidance. 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 from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting requirements if we become subject to a corporate integrity agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to the same criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our financial condition and divert resources and the attention of our management from operating our business.

The occurrence of any event or penalty described above may inhibit our ability to commercialize DEXYCU and, if approved, YUTIQ in the United States and generate revenues, which would have a material adverse effect on our business, financial condition and results of operations.

If the market opportunities for our products and product candidates are smaller than we believe they are, our results of operations may be adversely affected and our business may suffer.

We focus our research and product development primarily on treatments of eye diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our products and product candidates, are based on estimates. These estimates may prove to be incorrect and new studies or clinical trials may change the estimated incidence or prevalence of these diseases. The number of patients in the U.S. and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

If any of our products were to become the subject of problems related to their safety, our business would be seriously harmed.

All of our approved products will be subject to continued oversight by the FDA or other foreign regulatory bodies, and we cannot assure you that newly discovered or developed safety issues will not arise. Although we have seen no issues to date, we cannot rule out that issues may arise in the future. For example, with the use of any newly marketed drug by a wider patient population, serious adverse events may occur from time to time that initially do not appear to relate to the drug itself. If such events are subsequently associated with the drug, or if any other safety issues emerge, we or our collaboration partners may voluntarily, or FDA or other regulatory authorities may require that we suspend or cease marketing of our approved products or modify how we or they market our approved products. In addition, newly discovered safety issues may subject us to substantial potential liabilities, and adversely affect our financial condition and business.

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The Affordable Care Act and any changes in healthcare laws may increase the difficulty and cost for us to commercialize DEXYCU and obtain marketing approval of and commercialize YUTIQ in the United States, and affect the prices we may obtain.

The United States has enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing of DEXYCU and if approved, YUTIQ, in the United States, restrict or regulate post-approval activities and affect our ability to profitably sell DEXYCU and, if approved, YUTIQ. The United States government and state legislatures also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the “Affordable Care Act”) was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the Affordable Care Act that have been implemented since enactment and are of importance to the commercialization of DEXYCU and, if approved, YUTIQ, in the United States are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs or 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 U.S. civil False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer’s outpatient drugs to be covered under Medicare Part D (such manufacturer discounts will increase from 50% to 70% beginning in 2019 as required by the Bipartisan Budget Act of 2018);
- extension of manufacturers’ Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- price reporting requirements for drugs that are inhaled, infused, instilled, implanted, or injected;
- expansion of eligibility criteria for Medicaid programs;
- addition of entity types eligible for participation in the Public Health Service’s 340B drug pricing program;
- a requirement to annually report certain information regarding drug samples that manufacturers and distributors provide to physicians; and
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Certain legislative changes to and regulatory changes under the Affordable Care Act have occurred in the 115th U.S. Congress and under the Trump Administration. For example, the U.S. Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additional legislative changes to and regulatory changes under the Affordable Care Act remain possible. We expect that the Affordable Care Act, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of DEXYCU and, if approved, YUTIQ, in the United States or to successfully commercialize either in the United States.

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We expect that the Affordable Care Act, as well as other healthcare reform measures that have and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for DEXYCU and, if approved, YUTIQ, in the United States, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare, Medicaid, or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenues, attain profitability or commercialize DEXYCU and, if approved, YUTIQ in the United States.

If competitive products receive regulatory approval or reach the market earlier, are more effective, have fewer side effects, are more effectively marketed and/or cost less than our products or product candidates, our products or product candidates may not be approved, our products or product candidates may not achieve the sales we anticipate and could be rendered noncompetitive or obsolete.

We believe that pharmaceutical, drug delivery and biotechnology companies, research organizations, governmental entities, universities, hospitals, other nonprofit organizations and individual scientists are seeking to develop drugs, therapies, products, approaches or methods to treat our targeted diseases or their underlying causes. For our targeted diseases, competitors have alternate therapies that are already commercialized or are in various stages of development, ranging from discovery to advanced clinical trials. Any of these drugs, therapies, products, approaches or methods may receive government approval or gain market acceptance more rapidly than our products and product candidates, may offer therapeutic or cost advantages, or may more effectively treat our targeted diseases or their underlying causes, which could result in our product candidates not being approved, reduce demand for our products and product candidates or render them noncompetitive or obsolete.

Many of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing and personnel resources than we do. Our competitors may succeed in developing alternate technologies and products that, in comparison to the products or product candidates we have and are seeking to develop:

- are more effective and easier to use;
- are more economical;
- have fewer side effects;
- offer other benefits; or
- may otherwise render our products less competitive or obsolete.

Many of these competitors have greater experience in developing products, conducting clinical trials, obtaining regulatory approvals or clearances and manufacturing and marketing products than we do.

Guidelines, recommendations and studies published by various organizations could reduce the use of our products and potential use of product candidates.

Government agencies, professional societies, practice management groups, private health and science foundations and organizations focused on various diseases may publish guidelines, recommendations or studies that affect our or our competitors' products and product candidates. Any such guidelines, recommendations or studies that reflect negatively on our products or product candidates, either directly or relative to our competitive products, could result in current or potential decreased use, sales of, and revenues from one or more of our products and product candidates. Furthermore, our success depends in part on our and our partners' ability to educate healthcare providers and patients about our products and product candidates, and these education efforts could be rendered ineffective by, among other things, third-parties' guidelines, recommendations or studies.

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The micro-insert for ILUVIEN and YUTIQ delivers FA, a corticosteroid that is associated with certain adverse side effects in the eye, which may affect the success of this micro-insert for treatment of DME and posterior segment uveitis.

The micro-insert for both ILUVIEN and YUTIQ delivers the non-proprietary corticosteroid FA, which is associated with cataract formation and elevated intraocular pressure and may increase the risk of glaucoma and related surgery to manage those side effects. These side effects shown in the Phase 3 trials for ILUVIEN resulted in limitations to the approved indications of ILUVIEN, and sales of ILUVIEN may be adversely affected by the potential side effects from FA relative to other treatments for DME. The extent of ILUVIEN's long-term side-effect profile beyond month 36 is not yet known. Alimera is conducting a five-year post-authorization, open label registry study of the safety of ILUVIEN in 800 patients treated with the European labeled indication, which was a condition of European approval. In July 2017, Alimera announced that the Medicines and Healthcare Products Regulatory Agency gave final approval for Alimera to cap total enrollment at 550 patients, with the last three-year patient follow-up visit anticipated in January 2020. Data from this study or other commercial experience could result in the withdrawal of ILUVIEN's marketing approval in one or more jurisdictions. Further, delay in the commercial launch of ILUVIEN could result in the withdrawal of marketing or regulatory authorization for ILUVIEN in jurisdictions where ILUVIEN has already received marketing authorization. In addition, the perception by physicians of this benefit of efficacy versus the side-effect profile could adversely affect sales of ILUVIEN.

YUTIQ achieved encouraging safety results through the last follow-up visit in each of its two Phase 3 trials. However, there is no assurance that encouraging safety results will continue in these trials. There is also no assurance that the overall risk-benefit profile for YUTIQ will be favorable or that it will be determined to be safe for the treatment of posterior segment uveitis in light of potential side effects from FA. These side effects may limit the population for which marketing authorization is granted or for which reimbursement is provided in one or more jurisdictions and/or adversely affect sales of YUTIQ, if approved. In addition, because the micro-insert for ILUVIEN and YUTIQ are substantially the same, any safety issues that arise with respect to the ILUVIEN micro-insert could raise concerns about the YUTIQ micro-insert, which could result in delays in the approval process, prevent the FDA from approving YUTIQ and, even if approved, cause us to suspend marketing of YUTIQ or subject us to substantial liability, which would adversely affect our financial condition and business.

DEXYCU is an intraocular suspension that delivers dexamethasone, a corticosteroid that is associated with certain adverse side effects in the eye, which may affect the success of DEXYCU for the treatment of post-operative inflammation.

DEXYCU is an intraocular suspension that delivers dexamethasone, a corticosteroid, which is associated with certain adverse side effects in the eye. The safety analyses from DEXYCU's clinical trials revealed that the most commonly reported adverse reactions were increases in intraocular pressure, corneal edema and iritis, a type of uveitis affecting the front of the eye. These side effects may limit commercial use in the population for which marketing authorization was granted or for which reimbursement is provided in one or more jurisdictions and/or adversely affect sales of DEXYCU.

If the FDA or other applicable regulatory authorities approve generic products that compete with any of our products or product candidates, it could reduce our sales of those products or product candidates.

In the United States, after an NDA is approved, the product generally becomes a "listed drug" which can, in turn, be relied upon by potential competitors in support of approval of an ANDA. The Federal Food, Drug, and Cosmetic Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create generic, non-infringing versions of a drug to facilitate the approval of an ANDA. These manufacturers might show that their product has the same active ingredients, dosage form, strength, route of administration, conditions of use, and labeling as our product candidate and to conduct a relatively inexpensive study to demonstrate that the generic product is absorbed in the body at the same rate and to the same extent as, or is bioequivalent to, our product. These generic equivalents would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product are typically lost to the generic product. Accordingly, competition from generic equivalents to our products would substantially limit our ability to generate revenues and therefore to obtain a return on the investments we have made in our products.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of DEXYCU and, if approved, YUTIQ, and any other product candidates that we may develop and commercialize.

We currently face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and this risk will increase significantly as we commercialize DEXYCU and, if approved, YUTIQ, and other product candidates that we may develop and commercialize. We may face product liability claims, regardless of FDA approval for commercial manufacturing and sale as product liability claims may be brought against us by patients who have used these products and product candidates in any of our clinical trials, future patients, healthcare providers or others using, administering or selling our products, if and when approved. If we cannot successfully defend ourselves against claims that our products or product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation and significant negative media attention;
- termination of clinical trial sites or entire trial programs that we conduct in the future relating to DEXYCU, YUTIQ or our other product candidates;

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- withdrawal of clinical trial participants from any future clinical trial relating to DEXYCU, YUTIQ or our other product candidates;
- significant costs to defend the related litigation;
- substantial money awards to patients;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- an increase in product liability insurance premiums or an inability to maintain product liability insurance coverage.

We currently carry product liability insurance with coverage up to \$10.0 million in the aggregate, with a per incident limit of \$5.0 million, which may not be adequate to cover all liabilities that we may incur. Further, 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. Our inability to maintain sufficient product liability insurance at an acceptable cost could prevent or inhibit the commercialization of DEXYCU and, if approved, YUTIQ, or the development and commercialization of our other product candidates.

Additionally, any agreements we may enter into in the future with collaborators in connection with the development or commercialization of DEXYCU, YUTIQ or any of our other product candidates may entitle us to indemnification against product liability losses, but such indemnification may not be available or adequate should any claim arise. In addition, several of our agreements require us to indemnify third parties and these indemnifications obligations may exceed the coverage under our product liability insurance policy.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Our promotional materials, statements and training methods must comply with applicable laws and regulations, including FDA's prohibition of the promotion of unapproved, or off-label, use. Physicians may use our products off-label, as the FDA does not restrict or regulate a physician's independent choice of treatment within the practice of medicine. If the FDA determines that our promotional materials, statements or activities constitute promotion of an off-label use, we could be required to modify our promotional materials, statements or training methods or subject us to regulatory or enforcement actions, such as the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine, disgorgement of money, operating restrictions or criminal penalties. We may also be subject to actions by other governmental entities or private parties, such as the U.S. civil False Claims Act, civil whistleblower or "qui tam" actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our promotional, materials or activities to constitute promotion of an off-label use, which could result in significant fines or penalties under other statutory authorities. In that event, our reputation could be damaged and market adoption of our approved products could be impaired.

Even though FDA approval for DEXYCU has been obtained in the United States, we may never obtain approval for or successfully commercialize it outside of the United States, which would limit our ability to realize its full market potential.

In order to market DEXYCU outside of the United States, we must obtain marketing authorizations and comply with numerous and varying regulatory requirements of other countries regarding quality, safety and efficacy. Clinical trials conducted in one country may not be accepted by foreign regulatory authorities, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials, which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of DEXYCU in those countries. While our management team has experience in obtaining foreign regulatory approvals at other companies, we, as a company, do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, we would not be able to realize the full market potential of DEXYCU.

RISKS RELATED TO THE REGULATORY APPROVAL AND CLINICAL DEVELOPMENT OF OUR PRODUCT CANDIDATES

We are substantially dependent on the success of our lead product candidate, YUTIQ, which is in a later stage of development than our other product candidates. To the extent regulatory approval of YUTIQ is delayed or not granted, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock may decline.

We are focusing a significant portion of our activities and resources on our lead product candidate, YUTIQ, and we believe our prospects are highly dependent on, and a significant portion of the value of our company relates to, our ability to successfully develop, obtain regulatory approval for, and commercialize YUTIQ in the U.S. The U.S. regulatory approval of YUTIQ is subject to many risks, including the risks discussed in other risk factors set forth in this report, and YUTIQ may not receive marketing approval from the FDA or such marketing approval may be delayed. If the results or timing of the regulatory process, regulatory developments, any additional clinical trials or pre-clinical studies, or other activities, actions or decisions related to YUTIQ do not meet our or others' expectations, the market price of our common stock could decline significantly.

We submitted an NDA for YUTIQ in January 2018 and have a Prescription Drug User Fee Act action date of November 5, 2018. Although we have discussed our clinical development plans with the FDA, the agency may ultimately determine that our Phase 3 clinical trials or other aspects of our NDA are not sufficient for regulatory approval and may issue a complete response letter ("CRL") instead of approval. If we receive a CRL, the FDA would outline deficiencies in our NDA and may request the submission of additional information, including clinical data. The FDA will also inspect our facilities, the facilities of our third-party manufacturers, and may also inspect one or more of our clinical trial sites. If any facility or site reveals anomalies or does not otherwise have a satisfactory inspection, the FDA could delay or preclude approval of our NDA. In either case, our commercialization of YUTIQ in the U.S. may be delayed and we may incur additional costs and be required to devote additional resources to address the FDA's concerns. If the FDA requires us to conduct additional clinical trials or studies, or requires our manufacturers to improve or change their practices, our timeline for commercialization of YUTIQ in the U.S. will be delayed and we will incur additional costs. Further, there can be no assurance that we will complete such studies or clinical trials or address manufacturing issues in a manner that is acceptable to the FDA.

In addition, one of our collaborators, Alimera, holds an exclusive license to YUTIQ in the EMEA under the ILUVIEN trademark. Alimera was responsible for filing a Type II variation for ILUVIEN for the treatment of three-year uveitis. In January 2018, Alimera received validation of a Type II variation submitted in December 2017 in all seventeen European countries in which it previously received regulatory approval for ILUVIEN for DME. Obtaining regulatory approval for such a variation is uncertain and Alimera may fail to obtain the approval. The MAA variation review processes and the processes of other regulatory authorities, are extensive, lengthy, expensive, and uncertain, and such regulatory authorities may delay, limit, or deny approval of ILUVIEN for posterior segment uveitis.

Any delay or setback in the development or regulatory approval of YUTIQ will adversely affect our business and could cause our stock price to decline.

The regulatory approval processes of the FDA or other foreign regulatory authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business may be substantially harmed.

The time required to obtain approval by the FDA or other foreign regulatory authorities is unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory agency. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the regulatory authority may not accept our application for filing;
- the regulatory authority may disagree with the design, scope or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the regulatory authority that a product candidate is safe and effective for its proposed indication and/or that its clinical and other benefits outweigh its safety risks;

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- the regulatory authority may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the approval of a drug application or marketing authorization application;
- the regulatory authority may fail to approve our or our third-party manufacturers' manufacturing processes or facilities for clinical and commercial supplies; and
- the approval policies or regulations of the regulatory authority may change in a manner rendering our clinical data insufficient for approval.

We cannot be certain that any of our current product candidates will receive regulatory approval. If we do not receive regulatory approval for our product candidates, our business may be substantially harmed.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval and commence product sales.

Other than YUTIQ, all of our product development is at earlier stages. Product development at all stages involves a high degree of risk, and only a small proportion of research and development programs result in product candidates that advance to pivotal clinical trials or result in approved products. There is no assurance that any feasibility study agreements we have, or enter into, with third parties, or our own research and development programs and collaborations will result in any new product candidates, or that we or any licensees will commence clinical trials for any new product candidates or continue clinical trials once commenced. If clinical trials conducted by or for us or any licensees for any product candidates do not provide the necessary evidence of safety and efficacy, those product candidates will not receive the necessary regulatory approvals, cannot be sold, and will not generate revenues for us.

We may also experience delays in clinical trials of our product candidates or the time required to complete clinical trials for our product candidates may be longer than anticipated. Our future clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients, or be completed on schedule, if at all. Our clinical trials can be delayed, or even terminated, for a variety of reasons, including, but not limited to:

- decisions not to pursue development of product candidates due to pre-clinical or clinical trial results or market factors;
- lack of sufficient funding;
- inability to attract clinical investigators for trials;
- inability to recruit patients in sufficient numbers or at the expected rate;
- decisions by licensees not to exercise options for products or not to pursue or promote products licensed to them;
- adverse side effects;
- failure of trials to demonstrate safety and efficacy;
- failure to meet FDA or other regulatory agency requirements for clinical trial design, or inadequate clinical trial design;
- inability to follow patients adequately after treatment;
- changes in the design or manufacture of a product candidate;
- failures by, changes in our (or our licensees') relationship with, or other issues at, CROs, vendors and investigators responsible for pre-clinical testing and clinical trials;
- imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or foreign regulatory authorities;

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- inability to obtain supplies and/or to manufacture sufficient quantities of materials for use in clinical trials;
- stability issues with clinical materials;
- failure to comply with good laboratory practices, good clinical practices, current good manufacturing practices or similar foreign regulatory requirements that affect the conduct of pre-clinical and clinical studies and the manufacturing of product candidates;
- requests by regulatory authorities for additional data or clinical trials;
- governmental or regulatory agency assessments of pre-clinical or clinical testing that differ from our (or our licensees') interpretations or conclusions;
- governmental or regulatory delays, or changes in approval policies or regulations; and
- developments, clinical trial results and other factors with respect to competitive products and treatments.

If clinical trials for our product candidates are delayed or terminated for any of the above reasons or other reasons, our development costs may increase, our approval process could be delayed and our ability to commercialize our product candidates could be materially harmed.

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

Because we have limited financial and managerial resources, we focus on research programs and product candidates for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products.

We have historically based our research and development efforts primarily on our Durasert technology platform to develop proprietary sustained-release pharmaceutical products for the treatment of posterior uveitis and other chronic eye diseases. As a result of pursuing the development of product candidates using our proprietary technologies, we may fail to develop product candidates or address indications based on other scientific approaches that may offer greater commercial potential or for which there is a greater likelihood of success. Research programs to identify new product candidates require substantial technical, financial and human resources. These research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development.

Initial results from a clinical trial do not ensure that the trial will be successful and success in early stage clinical trials does not ensure success in later-stage clinical trials.

Results from pre-clinical testing, early clinical trials, investigator-sponsored studies and other data and information often do not accurately predict final pivotal clinical trial results. In addition, data from one pivotal clinical trial may not be predictive of the results of other pivotal clinical trials for the same product candidate, even if the trial designs are the same or similar. Data obtained from pre-clinical studies and clinical trials are susceptible to varying interpretations, which may delay, limit or prevent regulatory approval. Adverse side effects may be observed in clinical trials that delay, limit or prevent the regulatory approval, and even after a product candidate has received marketing approval, the emergence of adverse side effects in more widespread clinical practice may cause the product's regulatory approval to be limited or even rescinded. Additional trials necessary for approval may not be undertaken or may ultimately fail to establish the safety and efficacy of our product candidates.

In addition, while the clinical trials of our product candidates are designed based on the available relevant information, in view of the uncertainties inherent in drug development, such clinical trials may not be designed with a focus on indications, patient populations, dosing regimens, safety or efficacy parameters or other variables that will provide the necessary safety and efficacy data to support regulatory approval to commercialize the product. In addition, the methods we select to assess particular safety or efficacy parameters may not yield statistically significant results regarding our product candidates' effects on patients. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Pre-clinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent regulatory approval.

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Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols submitted to applicable regulatory authorities to reflect these changes. Amendments may require us to resubmit clinical trial protocols to institutional review boards or ethics committees for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are required to conduct additional clinical trials or other studies with respect to our product candidates beyond those that we currently contemplate, or if we are unable to successfully complete our clinical trials or other studies, we may be delayed in obtaining regulatory approval of any of our product candidates, we may not be able to obtain regulatory approval at all or we may obtain approval of indications that are not as broad as intended. Our product development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for our product candidates. Significant clinical trial delays could allow our competitors to bring products to market before we do and impair our ability to commercialize our products if and when approved. If any of this occurs, our business would be harmed.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate to protect our product candidates, our competitors could develop and commercialize technology and products similar to ours, and our competitive position could be harmed.

Our commercial success will depend in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We rely on trade secret, patent, copyright and trademark laws, and confidentiality and other agreements with employees and third parties, all of which offer only limited protection. We seek patent protection for many different aspects of our product candidates, including their compositions, their methods of use, processes for their manufacture, and any other aspects that we deem to be commercially important to the development of our business.

The patent prosecution process is expensive and time-consuming, and we and any licensors and licensees may not be able to apply for or prosecute patents on certain aspects of our product candidates or delivery technologies at a reasonable cost, in a timely fashion, or at all. For technology licensed to third parties, we may not have the right to control the preparation, filing and/or prosecution of the corresponding patent applications, or to maintain patent rights corresponding to such technology. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is also possible that we or any licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If any licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised and we might not be able to prevent third parties from making, using, and selling competing products. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid or unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business, financial condition, and operating results.

The patent positions of pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of any patents that issue, are highly uncertain. For example, recent changes to the patent laws of the United States provide additional procedures for third parties to challenge the validity of issued patents. Under the Leahy-Smith America Invents Act ("AIA"), which was signed into law on September 16, 2011, patents issued from applications with an effective filing date after March 15, 2013 may be challenged by third parties using the post-grant review procedure which allows challenges for a number of reasons,

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including prior art, sufficiency of disclosure, and subject matter eligibility. Under the AIA, patents may also be challenged under the *inter partes* review procedure. *Inter partes* review provides a mechanism by which any third party may challenge the validity of any issued U.S. Patent in the United States Patent and Trademark Office (“USPTO”) on the basis of prior art. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings as compared to the evidentiary standard relied on in U.S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

With respect to foreign jurisdictions, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Also, patents granted by the European Patent Office may be opposed by any person within nine months from the publication of their grant.

Our patents and patent applications, even if unchallenged by a third party, may not adequately protect our intellectual property or prevent others from designing around our claims. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the United States. Further, the examination process may require us to narrow the claims of pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The rights that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be impaired.

As of March 31, 2018, we had 243 patents or granted applications and 69 pending patent applications, including patents and pending applications covering our Durasert, DEXYCU, Tethadur and other technologies. With respect to these patent rights, we do not know whether any of our patent applications will result in issued patents or, if any of our patent applications do issue, whether such patents will protect our technology in whole or in part, or whether such patents will effectively prevent others from commercializing competitive technologies and products. There is no guarantee that any of our issued or granted patents will not later be found invalid or unenforceable. Furthermore, since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications. For applications with an effective filing date before March 16, 2013, or patents issuing from such applications, an interference proceeding can be provoked by a third party, or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the United States resulting from the AIA.

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, until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, that we were the first to file for patent protection of such inventions, or that we have found all of the potentially relevant prior art relating to our patents and patent applications that could invalidate one or more of our patents or prevent one or more of our patent applications from issuing. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate oppositions, interferences, re-examinations, post-grant reviews, *inter partes* reviews, nullification or derivation actions in court or before patent offices or similar proceedings challenging the validity, enforceability, or scope of such patents, which may result in the patent claims being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, or prevent others from designing around our claims. Any of these outcomes could impair our ability to prevent competition from third parties.

Furthermore, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and

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abroad. Such challenges may result in loss of exclusivity or freedom to operate 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 product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of any party from whom we may license patents from in the future. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In a patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. A court may decide that a patent of ours or of any of our future licensors is not valid or is unenforceable, or may 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. In addition, to the extent that we have to file patent litigation in a federal court against a U.S. patent holder, we would be required to initiate the proceeding in the state of incorporation or residency of such entity. With respect to the validity question, for example, we cannot be certain that no invalidating prior art exists. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, found unenforceable, or interpreted narrowly, and it could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our products. Such a loss of patent protection could compromise our ability to pursue our business strategy.

As noted above, interference proceedings brought by the USPTO for applications with an effective filing date before March 16, 2013, or for patents issuing from such applications may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with any of our future licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. 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. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. 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.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO or other foreign patent offices, or become involved in 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 invalidate or reduce the scope of, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs 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 product candidates.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws and practices of some foreign countries do not protect intellectual property rights, especially those relating to life sciences, to the same extent as federal and state laws in

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the United States. For example, novel formulations of drugs and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries, particularly developing countries. Also, some foreign countries, including European Union (“EU”) countries, India, Japan and China, have compulsory licensing laws under which a patent owner may be compelled under certain circumstances to grant licenses to third parties. Consequently, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, and we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions into or within the United States or other jurisdictions. This could limit our potential revenue opportunities. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us in these jurisdictions. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from our intellectual property. We may not prevail in any lawsuits that we initiate in these foreign countries and the damages or other remedies awarded, if any, may not be commercially meaningful.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and applications are required to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and applications. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has issued. There are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which could be uncertain and could harm our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without infringing the proprietary rights of third parties. While many of our product candidates are in pre-clinical studies and clinical trials, we believe that the use of our product candidates in these pre-clinical studies and clinical trials falls within the scope of the exemptions provided by 35 U.S.C. Section 271(e) in the United States, which exempts from patent infringement liability activities reasonably related to the development and submission of information to the FDA. As our other product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and expensive and time-consuming patent litigation before our product candidates may be commercialized. There can be no assurance that our product candidates do not infringe other parties’ patents or other proprietary rights, and competitors or other parties may assert that we infringe their proprietary rights in any event.

There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including interference or derivation proceedings before the USPTO. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future.

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 commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenues or achieve profitability and possibly prevent us from generating revenues sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court order, to cease commercializing

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our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our commercialization efforts, delay our research and development efforts and limit our ability to continue our operations. There could also be public announcements of the results of the hearing, motions, or other interim proceedings or developments. If securities analysts or investors perceive those results to be negative, it could cause the price of shares of our common stock to decline.

Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner.

Our competitors may seek approval to market their own products that are the same as, similar to or otherwise competitive with our product candidates. In these circumstances, we may need to defend or assert our patents by various means, including filing lawsuits alleging patent infringement requiring us to engage in complex, lengthy and costly litigation or other proceedings. In any of these types of proceedings, a court or government agency with jurisdiction may find our patents invalid, unenforceable or not infringed. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Changes in either U.S. or foreign patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve both technological and legal complexity, and it therefore is costly, time-consuming and inherently uncertain. As noted above, the AIA has significantly changed U.S. patent law. In addition to transitioning from a "first-to-invent" to "first-to-file" system, the AIA also limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge issued patents in the USPTO via post-grant review or *inter partes* review, for example. All of our U.S. patents, even those issued before March 16, 2013, may be challenged by a third party seeking to institute *inter partes* review.

Depending on decisions by the U.S. Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

We may be subject to claims asserting that our employees, consultants, independent contractors and advisors have wrongfully used or disclosed confidential information and/or alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees, consultants, independent contractors and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have inadvertently or otherwise used or disclosed confidential information and/or intellectual property, including trade secrets or other proprietary information, of the companies that any such individual currently or formerly worked for or provided services to. Litigation may be necessary to defend against these claims. If we fail in 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 defending against such claims, litigation could result in substantial costs and be a distraction to our business.

In addition, while we require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

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Intellectual property rights do not prevent all potential threats to competitive advantages we may have.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and intellectual property rights may not adequately protect our business or permit us to maintain our competitive advantage.

The following examples are illustrative:

- others may be able to make drug and device components that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or any of our licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or any of our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- the prosecution of our pending patent applications may not result in granted patents;
- granted patents that we own or have licensed may not cover our products or may be held not infringed, invalid or unenforceable, as a result of legal challenges by our competitors;
- with respect to granted patents that we own or have licensed, especially patents that we either acquire or in-license, if certain information was withheld from or misrepresented to the patent examiner, such patents might be held to be unenforceable;
- patent protection on our product candidates may expire before we are able to develop and commercialize the product, or before we are able to recover our investment in the product;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for such activities, as well as in countries in which we do not have patent rights, and may then use the information learned from such activities to develop competitive products for sale in markets where we intend to market our product candidates;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent application for certain technologies, trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

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

In addition to seeking patent protection for certain aspects of our product candidates and technologies, we also consider trade secrets, including confidential and unpatented know-how important to the maintenance of our competitive position. We protect trade secrets and confidential and unpatented know-how, in part, by customarily entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, outside scientific and commercial collaborators, CROs, CMOs, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. 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. In addition, our trade secrets may otherwise become known, including through a potential cybersecurity breach, or may be independently developed by competitors.

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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 in the United States and certain foreign jurisdictions 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 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.

If our trademarks are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We expect to rely on trademarks as one means to distinguish any of our approved products from the products of our competitors. We have received Notices of Allowance for DEXYCU™, YUTIQ™, DELIVERING INNOVATION TO THE EYE™ and Durasert™. ILUVIEN® is Alimera's trademark. Retisert® and Vitrasert® are Bausch & Lomb's trademarks. Our and our licensees' trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. For instance, Sun Pharma has filed an extension of time to file an opposition to our trademark application for Durasert. We are currently negotiating a co-existence agreement with Sun Pharma. If we are unable to reach an agreement and our Durasert trademark is successfully challenged, we could be forced to rebrand our Durasert technology, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing a new brand. In addition, we may not be able to protect our or our licensees' rights to these trademarks or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks, we may not be able to compete effectively.

RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES

We do not control the development or commercialization of YUTIQ in the EMEA, which is licensed to Alimera, and as a result we may not realize the full market potential of YUTIQ.

Under the amended and restated collaboration agreement, dated July 10, 2017, we granted Alimera rights to YUTIQ in the EMEA (under the ILUVIEN trademark) and subsequently withdrew our YUTIQ MAA and orphan drug designation for posterior segment uveitis. Alimera is now responsible for obtaining all regulatory approvals in the EMEA. Under this agreement, we have no control over Alimera's regulatory activities in the EMEA (with the exception of the completion of our ongoing Phase 3 uveitis clinical trials), including regulatory approvals, and no direct control over commercialization efforts for YUTIQ in the EMEA. Alimera has only limited experience in filing and supporting the applications necessary to obtain marketing approvals for product candidates. Obtaining approval of an MAA by the EMA is uncertain and Alimera may fail to obtain the approval. The MAA review processes, and the processes of other regulatory authorities, are extensive, lengthy, expensive, and uncertain, and such regulatory authorities may delay, limit, or deny approval of YUTIQ. Further, Alimera may abandon further development of YUTIQ in the EMEA. Because the full market potential of YUTIQ is contingent upon the successful development and commercialization of YUTIQ in the EMEA, we will be dependent on Alimera to achieve the full market potential of YUTIQ. If Alimera does not succeed in obtaining regulatory approval of YUTIQ in the EMEA for any reason, or does not succeed in securing market acceptance of YUTIQ in the EMEA, or elects for any reason to discontinue development of YUTIQ, we will be unable to realize the full market potential of YUTIQ.

If our CROs, vendors and investigators do not successfully carry out their responsibilities or if we lose our relationships with them, our development efforts with respect to our product candidates could be delayed.

We are dependent on CROs, vendors and investigators for pre-clinical testing and clinical trials related to our product development programs. These parties are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If they do not timely fulfill their responsibilities or if their performance is inadequate, the development and commercialization of our product candidates could be delayed. The parties with which we contract for execution of clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Their failure to meet their obligations could adversely affect clinical development of our product candidates. In addition, if we or our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with cGCPs.

Switching or adding additional CROs involves additional cost and requires management time and focus. Identifying, qualifying and managing performance of third-party service providers can be difficult, time-consuming

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and cause delays in our development programs. In addition, there is a natural transition period when a new CRO commences work and the new CRO may not provide the same type or level of services as the original provider. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. If any of our relationships with our CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

Because we have relied on third parties, our internal capacity to perform these functions is limited. Outsourcing these functions involves risks that third parties may not perform to our standards, may not produce results in a timely manner or may fail to perform at all. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated. We currently have a small number of employees, which limits the internal resources we have available to identify and monitor our third-party providers. To the extent we are unable to identify and successfully manage the performance of third-party service providers in the future, our ability to advance our product candidates through clinical trials will be compromised. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

If we encounter difficulties in negotiating commercial manufacturing and supply agreements with our third-party manufacturers and suppliers of DEXYCU, our ability to commercialize DEXYCU would be impaired.

We currently rely, and expect to continue to rely, on a limited number of CMOs and suppliers who assist in the production, assembly, test, supply, storage and distribution of DEXYCU in our FDA registration, and we control only some of the aspects of their activities. We may not be able to obtain terms that are favorable to us or enter into commercial manufacturing and supply agreements at all with each of the necessary third parties. If we are unable to enter into such agreements on commercially reasonable terms, our ability to commercialize DEXYCU would be impaired, and our business, financial condition and results of operations would be materially adversely affected.

If we encounter issues with our contract manufacturers or suppliers, we may need to qualify alternative manufacturers or suppliers, which could impair our ability to sufficiently and timely manufacture and supply DEXYCU.

We currently depend on contract manufacturers and suppliers for DEXYCU. We expect to obtain the drug product for commercial supply of DEXYCU from one CMO. Although we could obtain the drug product for DEXYCU from other third-party suppliers, we would need to qualify and obtain FDA approval for another contract manufacturer or supplier as an alternative source for the drug product, which could be costly and cause significant delays. In addition, the manufacturer of the drug product in DEXYCU conducts its manufacturing operations for us at a single facility. Unless and until we qualify additional facilities, we may face limitations in our ability to respond to manufacturing and supply issues. For example, if regulatory, manufacturing or other problems require this manufacturer to discontinue production at its facility, or if the equipment used for the production of the drug product in this facility is significantly damaged or destroyed by fire, flood, earthquake, power loss or similar events, the ability of such manufacturer to manufacture DEXYCU may be significantly impaired. In the event that this party suffers a temporary or protracted loss of its materials, facility or equipment, we would still be required to obtain FDA approval to qualify a new manufacturer or supplier, as applicable, as an alternate manufacturer or source for the drug product before any drug product manufactured by such manufacturer or by such supplier could be sold or used.

Any production shortfall that impairs the supply of DEXYCU could have a material adverse effect on our business, financial condition and results of operations and adversely affect our ability to satisfy demand for DEXYCU, which could adversely affect our product sales and operating results materially.

If we or our licensees encounter problems with product manufacturing, there could be delays in product development or commercialization, which would adversely affect our future profitability.

Our ability and that of our licensees to conduct timely pre-clinical and clinical research and development programs, obtain regulatory approvals, and develop and commercialize our product candidates will depend, in part, upon our and our licensees' ability to manufacture our products and product candidates, either directly or through third parties, in accordance with FDA and other regulatory requirements. The manufacture, packaging and testing of our products and product candidates are regulated by the FDA and similar foreign regulatory entities and must be conducted in accordance with applicable cGMP and comparable foreign requirements. Any change in a manufacturing process or procedure used for one of our products or product candidates, including a change in the location at which a product or product candidate is being manufactured or in the third-party manufacturer being used, may require the FDA's and similar foreign regulatory entities' prior review and/or approval in accordance with applicable cGMP or other regulations. Additionally, the FDA and similar foreign regulatory entities may implement new standards, or change their interpretation and enforcement of existing standards, for the manufacture, packaging and testing of products at any time.

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There are a limited number of manufacturers that operate under cGMP and other foreign regulations that are both capable of manufacturing our products and product candidates and are willing to do so. Alimera has contracted with individual third-party manufacturers for the manufacture of ILUVIEN and its components. If any of Alimera's third-party manufacturers breach their agreements or are unable or unwilling to perform for any reason or fail to comply with cGMP and comparable foreign requirements, Alimera may not be able to locate alternative acceptable manufacturers, enter into favorable agreements with them or get them approved by the applicable regulatory authorities in a timely manner. Delays in the commercial production of ILUVIEN could delay or impair Alimera's marketing of ILUVIEN, which, in turn, could adversely affect Alimera's generation of sales-based royalties to us. Failure by us, our collaborative partners, or our or their third-party manufacturers, to comply with applicable manufacturing requirements could result in sanctions being imposed on us or our collaborative partners, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product, operating restrictions and criminal prosecutions. If we or our collaborative partners are unable to develop our own manufacturing facilities or to obtain or retain third-party manufacturing on acceptable terms, we may not be able to conduct certain future pre-clinical and clinical testing of our product candidates and our collaborative partners may not be able to conduct certain future pre-clinical and clinical testing or to supply commercial quantities of our products. We manufacture supplies in connection with pre-clinical or clinical studies conducted by us and our licensees. Our licensees have the exclusive rights to manufacture commercial quantities of products, once approved for marketing. Our licensees' reliance on third-party manufacturers entails risks, including:

- failure of third parties to comply with cGMP and other applicable U.S. and foreign regulations and to employ adequate quality assurance practices;
- inability to obtain the materials necessary to produce a product or to formulate the active pharmaceutical ingredient on commercially reasonable terms, if at all;
- supply disruption, deterioration in product quality or breach of a manufacturing or license agreement by the third party because of factors beyond our or our licensees' control;
- termination or non-renewal of a manufacturing or licensing agreement with a third party at a time that is costly or difficult; and
- inability to identify or qualify an alternative manufacturer in a timely manner, even if contractually permitted to do so.

If third-party manufacturers, wholesalers and distributors fail to devote sufficient time and resources to DEXYCU or their performance is substandard, our product supply may be impacted.

Our reliance on a limited number of manufacturers, wholesalers and distributors exposes us to the following risks, any of which could limit commercial supply of our products, result in higher costs, or deprive us of potential product revenues:

- our CMOs, or other third parties we rely on, may encounter difficulties in achieving the volume of production needed to satisfy commercial demand, may experience technical issues that impact quality or compliance with applicable and strictly enforced regulations governing the manufacture of pharmaceutical products, and may experience shortages of qualified personnel to adequately staff production operations;
- our wholesalers and distributors could become unable to sell and deliver DEXYCU for regulatory, compliance and other reasons;
- our CMOs, wholesalers and distributors could default on their agreements with us to meet our requirements for commercial supply of DEXYCU;
- our CMOs, wholesalers and distributors may not perform as agreed or may not remain in business for the time required to successfully produce, store, sell and distribute DEXYCU and we may incur additional cost; and

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- if our CMOs, wholesalers and distributors were to terminate our arrangements or fail to meet their contractual obligations, we may be forced to delay the commercialization of DEXYCU.

Our reliance on third parties reduces our control over our development and commercialization activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards. For example, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP and similar foreign standards. Any failure by our third-party manufacturers to comply with cGMP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates or supply our commercial volume of DEXYCU. In addition, such failure could be the basis for the FDA to issue a warning or untitled letter, withdraw approvals for products previously granted to us, or take other regulatory or legal action, including recall or seizure, total or partial suspension of production, suspension of ongoing clinical trials, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction, imposing civil penalties or pursuing criminal prosecution.

Manufacturing issues may arise that could result in delays or suspension of the commercialization of DEXYCU.

As we further scale up manufacturing of DEXYCU and conduct required stability testing, issues may arise involving product-packaging and third-party equipment malfunctions. These issues may require refinement or resolution in order to initiate or continue the commercial marketing of DEXYCU. In addition, quality issues may arise during scale-up and of commercial manufacturing processes. Any issues in our product or delivery devices could result in delays in the commercialization of DEXYCU or the suspension of commercialization of DEXYCU.

We intend to use our own facility for the manufacturing of YUTIQ, which will require significant resources, which could adversely affect its commercial viability.

If approved by the FDA, we plan to manufacture commercial supplies of YUTIQ ourselves at our Watertown facility. We currently manufacture products only for clinical and testing purposes in this facility and we do not manufacture products for commercial use. We must obtain FDA approval of our manufacturing process before we can commercially manufacture YUTIQ in the United States. In addition, we must pass a pre-approval inspection of our manufacturing facility before we can obtain marketing approval for YUTIQ. In order to obtain approval, all of our manufacturing methods, equipment and processes must comply with the FDA's cGMP requirements. We will also need to perform extensive audits of our suppliers, vendors and contract laboratories. The cGMP requirements govern, among other things, recordkeeping, production processes and controls, personnel and quality control. To ensure that we meet these requirements, we will expend significant time, money and effort. Due to the unique nature of our Durasert technology platform, we cannot predict the likelihood that the FDA will approve our facility as compliant with cGMP requirements even if we believe that we have taken the steps necessary to achieve compliance.

The FDA, in its regulatory discretion, may require us to undergo additional clinical trials with respect to any new or improved manufacturing process we may develop or utilize in the future. This could delay or prevent approval of YUTIQ or any of our other product candidates. If we fail to comply with cGMP requirements, pass an FDA pre-approval inspection or obtain FDA approval of our manufacturing process, we would not receive FDA approval and would be subject to possible regulatory action, including recall or withdrawal of the product from the market or suspension of manufacturing. The failure to successfully implement our manufacturing process may delay or prevent our ability to commercialize YUTIQ.

If we do obtain FDA approval for YUTIQ, including satisfying the FDA with regard to a validated manufacturing process, we may still be unable to commercially manufacture YUTIQ. The commercial manufacture of medical products is complex and requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of medical products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. We cannot assure you that any stability or other issues relating to the manufacture of YUTIQ, if approved, will not occur in the future.

The FDA also may, at any time following approval of a product for sale, audit our manufacturing facilities. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product

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specifications or applicable regulation occurs independent of such an inspection or audit, FDA may issue a Form FDA-483 and/or an untitled or warning letter, or we or the FDA may require remedial measures that may be costly and/or time consuming for us to implement and that may include the temporary or permanent suspension of commercial sales, recalls, market withdrawals, seizures or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us could materially harm our business.

Our employees, collaborators, service providers, independent contractors, principal investigators, consultants, CSOs, vendors and CROs may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, collaborators, independent contractors, principal investigators, consultants, CSOs, vendors and CROs may engage in fraudulent or other illegal activity with respect to our business. Misconduct by these employees could include intentional, reckless and/or negligent conduct or unauthorized activity that violates:

- FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA;
- manufacturing standards;
- federal and state healthcare fraud and abuse laws and regulations; or
- laws that require the true, complete and accurate reporting of financial information or data.

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. Misconduct by these parties could also involve individually identifiable information, including, without limitation, the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and serious harm to our reputation. Any incidents or any other conduct that leads to an employee receiving an FDA debarment could result in a loss of business from third parties and severe reputational harm.

Although we have adopted a Code of Business Conduct to govern and deter such behaviors, 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 civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations.

The success of our current and possible future collaborative and licensing arrangements depends and will depend heavily on the experience, resources, efforts and activities of our licensees, and if they are not successful in developing and marketing our products or product candidates, as applicable, it will adversely affect our revenues, if any, from those products.

Our business strategy includes continuing to leverage our technology platform by entering into collaborative and licensing arrangements for the development and commercialization of our products and product candidates, where appropriate. The success of current and future collaborative and licensing arrangements do and will depend heavily on the experience, resources, skill, efforts and activities of our licensees. Our licensees have had, and are expected to have, significant discretion in making decisions related to the development of product candidates and the commercialization of products under these collaboration agreements. Risks that we face in connection with our collaboration and licensing strategy include the following:

- our collaborative and licensing arrangements are, and are expected to be, subject to termination under various circumstances, including on short notice and without cause;

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- we are required, and expect to be required, under our collaborative and licensing arrangements, not to conduct specified types of research and development in the field that is the subject of the arrangement or not to sell products in such field, limiting the areas of research, development and commercialization that we can pursue;
- our licensees may develop and commercialize, either alone or with others, products that are similar to or competitive with our products;
- our licensees may change the focus of their development and commercialization efforts or decrease or fail to increase spending related to our products or product candidates, thereby limiting the ability of these products to reach their potential;
- our licensees may lack the funding, personnel or experience to develop and commercialize our products successfully or may otherwise fail to do so; and
- our licensees may not perform their obligations, in whole or in part.

We currently have collaboration and licensing arrangements with various companies, most significantly Alimera and Bausch & Lomb. While Bausch & Lomb has significant experience in the ophthalmic field and substantial resources, there is no assurance whether, and to what extent, that experience and those resources will be devoted to Retisert, and we do not expect revenues from Retisert to increase, and they may decline further. Although we believe potential revenues from ILUVIEN are important to our future results of operations and financial condition, Alimera has limited experience and limited financial resources, and ILUVIEN for DME is currently Alimera's first and only commercial product. Alimera has reported that its negative cash flows from operations and accumulated deficit may raise substantial doubt about its ability to continue as a going concern. Further, due to the limited revenue generated by Alimera to date, Alimera may not be able to maintain compliance with covenants under its loan agreement and, in the event of a default, we do not know whether Alimera will be able to obtain amendments or waivers of those covenants. We do not know if Alimera will be able to raise additional financing if and when required.

If our current and future licensees are not successful in developing and marketing our products, it will adversely affect our revenues, if any, from those products.

Our current licensees may terminate their agreements with us at any time or fail to fulfill their obligations under those agreements, and, if they do, we will lose the benefits of those agreements.

Our licensees have rights of termination under our agreements with them and could terminate those agreements without cause on short notice. Further, our licensees may fail to fulfill their obligations under their agreements, or we may disagree with them over the rights and obligations under those agreements, which could result in breach of the agreements and/or termination. Exercise of termination rights by one or more of our licensees or by us may leave us without the financial benefits and development, marketing or sales resources provided under the terminated agreement. It could be necessary for us to replace, or seek to provide ourselves, the services provided by the licensee, and there is no assurance we would be successful in doing so. It could delay, impair or stop the development or commercialization of products or product candidates licensed to them or require significant additional capital investment by us, which we may not have the resources to fund. If any of our licensees do not perform their obligations under our agreements or if any of those agreements are terminated, it could have an adverse effect on our business, financial condition and results of operations.

Off-label sales of ILUVIEN to treat posterior segment uveitis may adversely affect sales of YUTIQ, if approved.

The micro-inserts that comprise ILUVIEN and YUTIQ have substantially the same design, polymers and release rate, and both deliver the corticosteroid FA. Although YUTIQ delivers a somewhat lower dose of FA than ILUVIEN, ILUVIEN is already approved and marketed. It is possible that physicians will prescribe ILUVIEN for the treatment of posterior segment uveitis on an off-label basis, which could adversely affect the sales of YUTIQ, if approved.

There is no assurance that Alimera will successfully commercialize ILUVIEN for DME or that we will receive significant revenues from the commercialization of ILUVIEN.

We are entitled to royalties on a country-by-country and quarter-by-quarter basis on net sales of ILUVIEN where Alimera markets ILUVIEN directly and to a percentage of product revenues, royalties and non-royalty consideration where Alimera sublicenses the marketing of ILUVIEN. The commercialization of ILUVIEN for DME is a significant undertaking by Alimera, and ILUVIEN for DME is Alimera's first and only commercial product.

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Alimera's sales of ILUVIEN have not been significant to date, Alimera has continued to incur operating losses, and it has violated and in the future may violate the financial covenants of its loan agreement. We do not know if, when, or to what extent Alimera's ILUVIEN net revenues will increase significantly, which would generate royalties to us from the commercialization of ILUVIEN for DME. The amount and timing of any revenues we receive will be affected by many factors including:

- Alimera's and its distributors' and sublicensees' ability to effectively market and sell ILUVIEN in each country where sold;
- the manner of sale, whether directly by Alimera or by sublicensees or distributors, and the terms of sublicensing and distribution agreements;
- the amount and timing of sales of ILUVIEN in each country;
- regulatory approvals, appropriate labeling, and desirable pricing, insurance coverage and reimbursement;
- competition;
- commencement of marketing in additional countries; and
- Alimera's ability to raise adequate capital as needed to fund its operations, to maintain compliance with its loan agreement and to achieve profitability from its operations.

If Alimera is not successful in commercializing ILUVIEN for DME, it would adversely affect our business, operating results and financial condition.

Alimera may need alternative financing to replace its \$40.0 million debt facility or additional capital to maintain compliance with the financial covenants under its loan agreement, which Alimera may be unable to obtain, and Alimera's continued losses and financial condition may cast doubt on its ability to continue to operate as a going concern.

Although Alimera commercially markets ILUVIEN for DME in the United States and in certain countries in Europe, Alimera had a net loss from operations of \$16.5 million for the fiscal year ended December 31, 2017 and an accumulated deficit of \$399.1 million as of December 31, 2017. Alimera has not generated revenues that cover its actual or anticipated expenses and cannot project the extent of its future losses. Alimera may continue to incur operating losses, and as a result, it is uncertain when or if it will achieve or sustain profitability. Alimera's ability to generate royalty payments to us is dependent on its ability to successfully market and sell ILUVIEN for DME and, if approved, ILUVIEN for non-infectious posterior uveitis.

Alimera failed to meet a revenue threshold in January 2016 and a liquidity threshold as of June 30, 2016 under the financial covenants of its former loan agreement. While these failures were subsequently waived by its former lender, Alimera was required to pay substantial amounts and grant concessions in connection with these waivers. In January 2018, Alimera refinanced its debt with a \$40 million loan agreement with a new lender. If Alimera defaults on its obligations under its new loan agreement, its new lender may call the loan, which could require Alimera to pay back the entire amount owed and pay an early termination fee, or if the lender does not call the loan, Alimera may have to pay an increased rate of interest, pay additional monetary amounts in exchange for a waiver or modification of the loan agreement, or grant equity or warrant coverage and agree to further restrictions on its operations that could hinder it in the future. Alimera's failure to comply with the covenants under its new loan agreement could create substantial doubt about Alimera's ability to continue as a going concern and to market and sell ILUVIEN. The termination provisions of our agreement with Alimera include various bankruptcy events.

Further, due to the limited revenue generated by ILUVIEN to date, even if Alimera is able to maintain compliance with its debt covenants, Alimera may need to raise additional capital to fund the continued commercialization of ILUVIEN. If Alimera is unable to raise sufficient additional financing, it may need to adjust its commercial plans, which likely would adversely affect Alimera's ability to market ILUVIEN and make any potential royalty payments to us.

There is no assurance our Retisert royalty income will continue at current levels or at all.

Our Retisert royalty income, which had ranged between \$1.2 million and \$1.4 million from fiscal 2012 through fiscal 2016, decreased to \$970,000 for fiscal 2017 and was \$742,000 for the nine months ended March 31, 2018. We do not expect Retisert royalty income to increase materially, if at all, and it may decline further or cease. Bausch & Lomb's obligation to pay a royalty terminates on a licensed product by licensed product basis and country by country basis upon the date that the last to expire patent expires. The patent with which Retisert is marketed expires in March 2019. The latest patent covering Retisert expires in April 2020, and we will not receive any Retisert royalty income after that time. Bausch & Lomb previously ceased selling Vitrasert, our product previously licensed to Bausch & Lomb, on its patent expiration.

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Sales of ILUVIEN for DME may be materially adversely affected by pricing and reimbursement decisions of regulatory bodies, insurers and others.

Prices, coverage and reimbursement to consumers of ILUVIEN for DME, like other drugs, are generally regulated by third-party payors, such as government health administration authorities and plans, private health insurers and other organizations and affect ILUVIEN's sales. The timing and complexity of those reimbursements also affect sales. Prices in the EU are generally lower and coverage and access to drugs more limited than in the U.S. For example, in the U.K. and Scotland, National Health Service coverage is limited to the treatment of the eyes of chronic DME patients unresponsive to existing therapies that have undergone cataract surgery, subject to simple patient access schemes. Alimera may not achieve satisfactory agreements with statutory or other insurers. We do not know what levels of pricing will be approved or reimbursed for ILUVIEN, or what restrictions will be placed on its use or reuse in countries where ILUVIEN is not currently sold. In the U.S., Alimera has offered extended customer payment terms. Future net sales of ILUVIEN and, accordingly, the amount of royalties that we may receive from such net sales, may be adversely affected by pricing and reimbursement decisions, and such effects may be material.

If we or our licensees fail to comply with environmental laws and regulations, our or their ability to manufacture and commercialize products may be adversely affected.

Medical and biopharmaceutical research and development involves the controlled use of hazardous materials, such as radioactive compounds and chemical solvents. We and our licensees are subject to federal, state and local laws and regulations in the U.S. and abroad governing the use, manufacture, storage, handling and disposal of such materials and waste products. We and they could be subject to both criminal liability and civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. In addition, claimants may sue us or them for resulting injury or contamination, and the liability may exceed our or their ability to pay. Compliance with environmental laws and regulations is expensive, and current or future environmental regulations may impair the research, development or production efforts of our company or our licensees and harm our operating results.

RISKS RELATED TO OUR INDUSTRY, STRATEGY AND OPERATIONS

If we fail to retain key personnel, our business could suffer.

We are dependent upon the principal members of our management and scientific staff. In addition, we believe that our future success in developing and marketing our products will depend on whether we can attract and retain additional qualified management and scientific personnel as well as a sales and marketing staff. There is strong competition for qualified personnel within the industry in which we operate, and we may not be able to attract and retain such personnel. As we have a small number of employees and we believe our products and product candidates are unique and highly specialized, the loss of the services of one or more of the principal members of our management or scientific staff, or the inability to attract and retain additional personnel and develop expertise as needed, could have a material adverse effect on our results of operations and financial condition.

We will need to grow the size of our organization, and we may experience difficulties in managing this growth.

Implementation of our development and commercialization strategies will require additional managerial, operational, sales, marketing, financial and other resources. Our current management, personnel and systems may not be adequate to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, employee turnover and reduced productivity. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. Future growth would impose significant added responsibilities on members of management, including:

- managing the commercialization of DEXYCU and, if approved, YUTIQ;
- overseeing our pre-clinical studies and clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees, including any sales and marketing personnel engaged in connection with the commercialization of DEXYCU and, if approved, YUTIQ;

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- engaging and managing our relationship with any contract sales organizations; and
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties; and improving our managerial, development, operational and financial systems and procedures.

As our operations expand, we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and sales and marketing personnel. Failure to accomplish any of these activities could prevent us from successfully growing our company.

Consolidation in the pharmaceutical and biotechnology industries may adversely affect us.

There has been consolidation in the pharmaceutical and biotechnology industries. Consolidation could result in the remaining companies having greater financial resources and technological capabilities, thus intensifying competition, and fewer potential collaboration partners or licensees for our product candidates. In addition, if a consolidating company is already doing business with any of our competitors, we could lose existing or potential future licensees or collaboration partners as a result of such consolidation.

Economic conditions and regulatory changes leading up to and following the U.K.'s likely exit from the EU could have a material adverse effect on our business and results of operations.

The U.K. held a referendum on June 23, 2016 in which a majority voted for the U.K.'s withdrawal from the EU (referred to as "Brexit"). As a result of this vote, negotiations have commenced to determine the terms of the U.K.'s withdrawal from the EU as well as its relationship with the EU going forward, including the terms of trade between the U.K. and the EU. The effects of Brexit have been and are expected to continue to be far-reaching. Brexit and the perceptions as to its impact may adversely affect business activity and economic conditions in Europe and globally and could continue to contribute to instability in global financial and foreign exchange markets. Brexit could also have the effect of disrupting the free movement of goods, services and people between the U.K. and the EU; however, the full effects of Brexit are uncertain and will depend on any agreements the U.K. may make to retain access to EU markets.

In addition, we expect that Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the U.K. determines which EU laws to replicate or replace. If the U.K. were to significantly alter its regulations affecting our industry, we could face significant new costs. It may also be time-consuming and expensive for us to alter our internal operations in order to comply with new regulations. Altered regulations could also add time and expense to the process by which our products or product candidates or those of our licensees or collaborators receive regulatory approval in the U.K. and EU. Similarly, it is unclear at this time what Brexit's impact will have on our intellectual property rights and the process for obtaining, maintaining and defending such rights. It is possible that certain intellectual property rights, such as trademarks, granted by the EU will cease being enforceable in the U.K. absent special arrangements to the contrary, and we are required to refile our trademarks and other intellectual property applications domestically in the U.K.

Lastly, as a result of the Brexit, other European countries may seek to conduct referenda with respect to their continuing membership in the EU. Given these possibilities and others we may not anticipate, as well as the lack of comparable precedent, the full extent to which our business, results of operations and financial condition could be adversely affected by Brexit is uncertain.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures, cyberattacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of

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attempted attacks and intrusions from around the world have increased. Such an event could cause interruption of our operations. As part of our business, we and our vendors maintain large amounts of confidential information, including non-public personal information on patients and our employees. Breaches in security could result in the loss or misuse of this information, which could, in turn, result in potential regulatory actions or litigation, including material claims for damages, interruption to our operations, damage to our reputation or otherwise have a material adverse effect on our business, financial condition and operating results. We expect to have appropriate information security policies and systems in place in order to prevent unauthorized use or disclosure of confidential information, including non-public personal information, there can be no assurance that such use or disclosure will not occur.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions, which could include civil or criminal penalties, as well as private litigation and/or adverse publicity, any of which could negatively affect our operating results and business.

We may be subject to laws and regulations that address privacy and data security of patients who use our products or product candidates in the United States and in states in which we conduct our business. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act) govern the collection, use, disclosure, and protection of health-related and other personal information. For instance, HIPAA imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information and imposes notification obligations in the event of a breach of the privacy or security of individually identifiable health information on entities subject to HIPAA and their business associates that perform certain activities that involve the use or disclosure of protected health information on their behalf. Failure to comply with applicable data protection laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, as well as private litigation and/or adverse publicity that could negatively affect our operating results and business.

We may be exposed to liabilities under the U.S. Foreign Corrupt Practices Act and other U.S. and foreign anti-corruption anti-money laundering, export control, sanctions, and other trade laws and regulations, and any determination that we violated these laws could have a material adverse effect on our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control. We are also subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, and possibly other anti-bribery and anti-money laundering laws in countries outside of the United States in which we conduct our activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees and third-party intermediaries from authorizing, promising, offering, providing, soliciting, or accepting, directly or indirectly, improper payments or benefits to or from any person whether in the public or private sector. As we commercialize DEXYCU, if approved, YUTIQ, and any of other product candidates that we may develop, we may engage with third-party manufacturers and collaborators who operate abroad and are required to obtain certain necessary permits, licenses and other regulatory approvals with respect to our business. Our activities abroad create the risk of unauthorized payments or offers of payments by employees, consultants, sales agents or distributors, even though they may not always be subject to our control. It is our policy to implement safeguards to discourage these practices by our employees, consultants, sales agents and distributors. However, our existing safeguards and any future improvements may prove to be less than effective, and the employees, consultants, sales agents, or distributors of our company may engage in conduct for which we might be held responsible, even if we do not explicitly authorize such activities.

Noncompliance with anti-corruption, anti-money laundering, export control, sanctions, and other trade laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas or investigations are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. Responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In addition, the U.S. government may seek to hold us liable for successor liability FCPA violations committed by companies in which we invest or that we acquire. As a general matter, enforcement actions and sanctions could harm our business, results of operations, and financial condition.

RISKS RELATED TO OWNERSHIP OF OUR COMMON STOCK

The trading price of the shares of our common stock has been highly volatile, and purchasers of our common stock could incur substantial losses.

The price of our common stock is highly volatile and may be affected by developments directly affecting our business, as well as by developments out of our control or not specific to us. The pharmaceutical and biotechnology industries, in particular, and the stock market generally, are vulnerable to abrupt changes in investor sentiment. Prices of securities and trading volumes of companies in the pharmaceutical and biotechnology industries, including ours, can swing dramatically in ways unrelated to, or that bear a disproportionate relationship to, our performance. The price of our common stock and their trading volumes may fluctuate based on a number of factors including, but not limited to:

- the timing, costs and progress of our commercialization efforts;
- clinical trials and their results, and other product and technological developments and innovations;
- FDA and other domestic and international governmental regulatory actions, receipt and timing of approvals of our product candidates, and any denials and withdrawal of approvals;
- competitive factors, including the commercialization of new products in our markets by our competitors;
- advancements with respect to treatment of the diseases targeted by our products or product candidates;
- developments relating to, and actions by, our collaborative partners, including execution, amendment and termination of agreements, achievement of milestones and receipt of payments;
- the success of our collaborative partners in marketing any approved products and the amount and timing of payments to us;
- availability and cost of capital and our financial and operating results;
- actions with respect to pricing, reimbursement and coverage, and changes in reimbursement policies or other practices relating to our products or the pharmaceutical or biotechnology industries generally;
- meeting, exceeding or failing to meet analysts' or investors' expectations, and changes in evaluations and recommendations by securities analysts;
- economic, industry and market conditions, changes or trends; and
- other factors unrelated to us or the pharmaceutical and biotechnology industries.

In addition, low trading volume in our common stock may increase their price volatility. Holders of our common stock may not be able to liquidate their positions at the desired time or price. Finally, we will need to continue to meet the listing requirements of Nasdaq including the minimum stock price, for our stock to continue to be traded on Nasdaq.

Additional shares that may be issued upon the exercise of currently outstanding options or warrants or upon the settlement of restricted, performance or deferred stock units would dilute the voting power of our currently outstanding common stock and could cause our stock price to decline.

As of May 10, 2018, we had outstanding options to acquire approximately 5.8 million shares of our common stock, outstanding restricted stock units to acquire 629,116 shares of our common stock, outstanding performance stock units to acquire 741,668 shares of our common stock, outstanding deferred stock units to acquire 67,500 shares of our common stock and warrants to acquire 409,091 shares of our common stock at an exercise price of \$1.10, or approximately 12.4% of our shares on a fully diluted basis. The issuance of shares of our common stock upon exercise of the stock options or warrants or settlement of the restricted, performance or deferred stock units could result in dilution to the interests of other holders of our common stock and could adversely affect our stock price.

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If four stockholders approve the Second Tranche Transaction, then existing stockholders will suffer additional dilution in voting rights and in ownership interests.

On the Closing Date, concurrently with the closing of the Icon Acquisition, we entered into (i) a Securities Purchase Agreement (the “First Tranche Securities Purchase Agreement”) with EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. (collectively, “EW Healthcare”), pursuant to which we offered and sold to such investors an aggregate of 8,606,324 shares of our common stock at a purchase price of \$1.10 per share, which was the consolidated closing bid price of our common stock on Nasdaq immediately preceding the execution of the First Tranche Securities Purchase Agreement and (ii) the Second Securities Purchase Agreement with EW Healthcare and another accredited investor (collectively, the “Second Tranche Investors”), pursuant to which we agreed to sell to the Second Tranche Investors, subject to the approval of our stockholders, an aggregate of up to approximately \$25.5 million of units (each, a “Unit”), with each Unit consisting of (a) one share of our common stock (the “Second Tranche Common Shares”) and (b) one warrant (the “Second Tranche Warrants”) to purchase a share of our common stock (collectively, the “Second Tranche Transaction”).

If the Second Tranche Transaction is approved by our stockholders, existing stockholders will suffer additional dilution in voting rights and in ownership interests upon the issuance of the Second Tranche Common Shares and the shares of common stock issued upon the exercise, if any, of the Second Tranche Warrants. The maximum number of each of Second Tranche Common Shares and Second Tranche Warrant shares that may be issued at the closing of the Second Tranche Transaction, assuming a per Unit price of \$0.88 (which represents the lowest per Unit sale price permitted under the terms of the Second Securities Purchase Agreement), is 27,250,000. In addition, in connection with the Loan, we will issue a warrant to the Agent to purchase an aggregate number of shares of our common stock determined by multiplying \$5.0 million by 3% and then dividing such number by the consolidated closing bid price of a share of our common stock on Nasdaq immediately preceding the closing of the \$5.0 million advance (the “Additional Advance Warrants”). The Additional Advance Warrants shall become exercisable if and when we draw down the \$5.0 million Additional Advance and the exercise price for the Additional Advance Warrants shall be equal to the consolidated closing bid price of our common stock on Nasdaq immediately preceding the closing of the \$5.0 million advance.

The sale into the public market of the Second Tranche Common Shares and the shares of our common stock underlying the Second Tranche Warrants (if exercised) and Additional Advance Warrants (if exercised), also could materially and adversely affect the market price of our common stock.

Following the closing of the Second Tranche Transaction, EW Healthcare will own a substantial amount of our common stock and would be able to exert significant control over matters subject to stockholder approval, which would prevent new investors from influencing significant corporate decisions.

EW Healthcare, our largest stockholder, beneficially owns approximately 16.0% of our outstanding common stock. If the Second Tranche Transaction is approved by our stockholders and assuming a per Unit price of \$0.88 (which represents the lowest per Unit sale price permitted under the terms of the Second Securities Purchase Agreement), EW Healthcare would beneficially own approximately 40.0% of our common stock, which will increase to approximately 52.0% of our common stock if the Second Tranche Warrants are exercised in full. Upon the closing of the Second Tranche Transaction, EW Healthcare will have the ability to significantly influence the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, this concentration of voting power in EW Healthcare may: (i) delay, defer or prevent a change in control; (ii) entrench our management and Board; or (iii) delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the U.S. government signed into law comprehensive tax legislation, referred to as the Tax Cuts and Jobs Act (the “Tax Act”). The Tax Act introduced significant changes to the U.S. tax laws. The Tax Act, among other things, contains significant changes to corporate taxation, including but not limited to the reduction of the corporate tax rate from a top rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income in respect of losses arising in taxable years beginning after 2017 and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as “orphan drugs”). Any federal net operating loss carryovers for taxable years beginning after 2017 will be carried forward indefinitely pursuant to the Tax Act. The Tax Act also limits deductions for compensation in excess of \$1 million, which could impact our ability to deduct such corporate expenses. We continue to examine the impact the Tax Act may have on our business. Notwithstanding the reduction in the federal corporate income tax rate, the overall impact of the Tax Act is uncertain and our business and financial condition could be adversely affected.

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Future sales of our common stock may depress our stock price.

The market price of our common stock could decline as a result of sales of substantial amounts of our common stock in the public market, or as a result of the perception that these sales could occur, which could occur if we issue a large number of shares of common stock (or securities convertible into our common stock) in connection with a future financing, as our common stock is trading at low levels. These factors could make it more difficult for us to raise funds through future offerings of common stock or other equity securities.

Provisions in our charter documents could prevent or delay stockholders' attempts takeover our company.

Our board of directors is authorized to issue "blank check" preferred stock, with designations, rights and preferences as they may determine. Accordingly, our board of directors may in the future, without stockholder approval, issue shares of preferred stock with dividend, liquidation, conversion, voting or other rights that could adversely affect the voting power or other rights of the holders of our common stock. This type of preferred stock could also be issued to discourage, delay or prevent a change in our control. The ability to issue "blank check" preferred stock is a traditional anti-takeover measure. This provision in our charter documents makes it difficult for a majority stockholder to gain control of our company. Provisions like this may be beneficial to our management and our board of directors in a hostile tender offer and may have an adverse impact on stockholders who may want to participate in such a tender offer.

Provisions in our bylaws provide for indemnification of officers and directors, which could require us to direct funds away from our business and the development of our product candidates.

Our bylaws provide for the indemnification of our officers and directors. We may in the future be required to advance costs incurred by an officer or director and to pay judgments, fines and expenses incurred by an officer or director, including reasonable attorneys' fees, as a result of actions or proceedings in which our officers and directors are involved by reason of being or having been an officer or director of our company. Funds paid in satisfaction of judgments, fines and expenses may be funds we need for the operation of our business and the development of our product candidates, thereby affecting our ability to attain profitability.

We do not currently intend to pay dividends on our common stock, and any return to investors is expected to come, if at all, only from potential increases in the price of our common stock.

We have never declared or paid cash dividends on our capital stock, and you should not rely on an investment in our common stock to provide dividend income. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may be subject to securities litigation, which is expensive and could divert our management's attention.

As we operate in the pharmaceutical and biotechnology industries, we may be especially vulnerable to volatility in the market price of our common stock, especially to the extent that various factors affect the common stock of companies in our industry. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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Item 6. Exhibits

The following exhibits are being filed herewith:

- 3.1 [Certificate of Amendment of Certificate of Incorporation \(incorporated herein by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on April 2, 2018\).](#)
- 4.1 [Warrant to Purchase Common Stock of pSivida Corp., issued March 28, 2018, to SWK Funding, LLC \(incorporated herein by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on March 29, 2018\).](#)
- 10.1 [Securities Purchase Agreement, dated as of March 28, 2018, by and among pSivida Corp. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. \(incorporated herein by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 29, 2018\)](#)
- 10.2 [Second Securities Purchase Agreement, dated as of March 28, 2018, by and among pSivida Corp. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. and each other person identified on the signature pages thereto \(incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on March 29, 2018\)](#)
- 10.3 [Registration Rights Agreement, dated as of March 28, 2018, by and among pSivida Corp. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. \(incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on March 29, 2018\)](#)
- 10.4 [Credit Agreement, dated as of March 28, 2018, among pSivida Corp., SWK Funding LLC and the financial institutions party thereto from time to time as lenders \(incorporated herein by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on March 29, 2018\)](#)
- 10.5 [Agreement and Plan of Merger, dated March 28, 2018, by and among pSivida Corp., Oculus Merger Sub, Inc., Icon Bioscience, Inc. and Shareholder Representative Services LLC \(incorporated herein by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K filed on March 29, 2018\)](#)
- *10.6+ [Short Term Incentive Plan](#)
- *10.7+ [Employment Agreement, dated March 27, 2018, by and between Dario Paggiarino and EyePoint Pharmaceuticals, Inc.](#)
- 31.1 [Certification of Principal Executive Officer required by Rule 13a-14\(a\) and Rule 15d-14\(a\) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](#)
- 31.2 [Certification of Principal Financial Officer required by Rule 13a-14\(a\) and Rule 15d-14\(a\) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002](#)
- 32.1 [Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](#)
- 32.2 [Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002](#)
- 101 The following materials from EyePoint Pharmaceutical's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Comprehensive Loss; (iii) Condensed Consolidated Statement of Stockholders' Equity; (iv) Condensed Consolidated Statements of Cash Flows; and (v) Notes to Condensed Consolidated Financial Statements

* Filed herewith.

+ Indicates management contract or compensatory plan.

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.

EyePoint Pharmaceuticals, Inc.

Date: May 10, 2018

By: /s/ Nancy Lurker

Name: Nancy Lurker

Title: President and Chief Executive Officer

pSivida Short Term Incentive Plan

Purpose

pSivida’s Short Term Incentive (STI) Plan (the “Plan”) is designed to drive the achievement of Corporate Performance by providing employees the opportunity to receive discretionary Short Term Incentive Awards at the Compensation Committee’s discretion, including a variety of compensation vehicles such as Cash Bonuses based on Corporate Performance and Individual Performance each budget/performance year. The Plan replaces the “pSivida Compensation Guidelines for Key Employees.” The Plan runs concurrent with the 2016 pSivida Long Term Incentive Plan.

Effective Date

The Plan is effective July 1, 2017, unless otherwise terminated or amended as set forth below.

Eligibility

Active Regular, Full Time pSivida US, Inc employees are eligible to participate in the Plan. Regular, Full Time employees are defined as continuously scheduled for thirty (30) or more hours per week. New Hires with six (6) months or more of continuous service through the end of each budget/performance year are eligible to participate. Employees must be in good standing and maintain satisfactory performance.

Corporate Goal Setting

pSivida’s CEO proposes annual Corporate Goals, subject to review and approval by the Board’s Compensation Committee for the upcoming budget/performance year.

The Corporate Goals focus on both short term and long term strategic growth and development priorities to best yield results for pSivida and its various stakeholder groups, in accordance with pSivida’s Values.

Each Corporate Goal is assigned a weighted factor, reflective of the perceived relative importance of each Corporate Goal to the Company, with the total to equal 100%.

Corporate Performance Score

At the end of the budget/performance year, the CEO will recommend to the Compensation Committee a Corporate Performance Score for each Corporate Goal, using the following scale 1 – 5 (low – high) to describe Achievement of the Corporate Goal:

Corporate Performance Score

<u>Achievement Level</u> Achievement Score	<u>Minimum Achievement</u> 1	<u>Target Achievement</u> 3	<u>Exceeds Achievement</u> 5
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The Compensation Committee reviews the proposed Individual Performance and Overall Corporate Performance Scores. The Compensation Committee has the authority to exercise discretion and take into account mitigating circumstances and may adjust the Scores. The Committee will finalize the Corporate Performance Score for each Corporate Goal. The Overall Corporate Performance Score is the sum of weighted Achievement Scores for each Corporate Goal.

The Overall Corporate Performance Score is one of the factors used to calculate corporate Merit Increases and the pool for STI Awards for the annual compensation cycle.

Rev. June 22, 2017
Approved June 27, 2017

pSivida Short Term Incentive Plan

Individual Performance Score

In FY 2017, pSivida implemented a Performance Management Process for Individual Goal Setting and Performance Scores. At the beginning of each budget/performance year, the CEO communicates pSivida's weighted Corporate Goals to all employees. Employees work with their management to set their Individual Goals. Once the Goals are approved, they are used to track Individual Performance and guide periodic one on one meetings between manager and employee.

At the end of the budget /performance year, each employee receives an Individual Performance Results Summary Score of 1 – 5 (low to high). This Individual Performance Score is a factor used to calculate a Salary Merit Increase and an STI Award.

Short Term Incentive Award Weighting and Governance

Short Term Incentive Awards are “at-risk” variable compensation for each budget/performance year and are reflective of Corporate Performance and Individual Performance. They are earned each year, and are not a permanent component of any employee's direct compensation. The weighting of Corporate and Individual Performance, and the governance decisions for STI Awards, are as follows:

<u>Organization Level/Title</u>	<u>% Corporate Performance Score Weighting</u>	<u>% Individual Performance Score Weighting</u>	<u>Determined by:</u>
President and CEO	100	0	Compensation Committee
Direct report of CEO (independent of title, but excluding administrative assistant) [defined as 'executives' in the context of this document]	75	25	Compensation Committee & CEO
VP	60	40	Senior Staff & CEO
Exec./Sr./Director	50	50	Senior Staff & CEO
Assoc. Director/Sr./Manager	40	60	Senior Staff & CEO
Associate Manager/Supervisor	35	65	Manager
All Others	25	75	Manager

Target Short Term Incentive Percentage

The Short Term Incentive Target is based on factors outlined above, as well as each employee's role and its relative impact based on job responsibilities and accountabilities.

Overview of pSivida's Short Term Incentive Plan Factors

To best illustrate how the STI Plan works, below is a snapshot of how STI Awards are calculated:

Corporate Goals	% Weighting	Corporate Performance Score	Overall Individual Performance Score	Payout Level (Percent of Target Amount)
	100%	1 – 5 (Low to High)	1 – 5 (Low to High)	0 = 0%
		Weighting per Level/Title	Sum Weighted Total Average of Each Individual Goal Achievement Score	1 = 0%
			Weighting per Level/Title	2 = 50%
				3 = 100%
				4 = 110%
				5 = 120%

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pSivida Short Term Incentive Plan

STI Award Payouts

Short Term Incentive Awards are calculated using the factors described above. The STI Award value is paid as a Cash Lump Sum Bonus subject to discretion by the Compensation Committee.

The Cash Lump Sum Bonus is generally paid (less applicable withholding and payroll taxes) within the last payroll cycle of the quarter following the close of the budget/performance year, provided all eligibility requirements are met.

Changes in Employment

Employees who change roles within the budget /performance year, will receive a pro-rated portion of STI Target Percentage reflective to the time in the role.

Eligible employees on paid Leave of Absence are eligible for STI Awards on a pro-rated basis to include active status of Individual and Corporate Performance for the budget/performance year, and it will be paid in the same payroll processing schedule as the Active eligible employees

Employees on paid Leave of Absence are eligible to participate in the STI Plan, upon Return to Work status. STI Awards will be pro-rated to reflect Corporate and Individual Performance achieved during active status.

Administration

The Compensation Committee, the retained Compensation Consultant and assigned Management Liaison to the Compensation Committee are collectively responsible for the administration and compliance of the Plan.

Rev. June 22, 2017
Approved June 27, 2017



March 27, 2018

Dario Paggiarino
26 Beacon Street
Apt 67E
Burlington, MA 01803

Dear Mr. Paggiarino:

This letter (the "Agreement") will confirm our offer to you of employment with pSivida Corp. (the "Company"), under the terms and conditions that follow.

1. Position and Duties.

(a) Your employment commenced on August 1, 2016, or such other date as the Company and you may have agreed, (the "Start Date") on a full-time basis, as its Chief Medical Officer, reporting to the Chief Executive Officer of the Company. During your employment, you may be asked from time to time to serve as a director or officer of one or more of the Company's subsidiaries, in each case, without further compensation. If your employment with the Company terminates for any reason, then concurrently with such termination, you will be deemed to have resigned from any director, officer, trustee, or other positions you may hold with the Company, the Company's subsidiaries, or any of their respective related committees, trusts, or other similar entities, in each case unless otherwise agreed in writing by the Company and you.

(b) You agree to perform the duties of your position and such other duties as may reasonably be assigned to you consistent therewith from time to time. You also agree that, while employed by the Company, you will devote your full business time and your best efforts, business judgment, skill and knowledge exclusively to the advancement of the business interests of the Company and its subsidiaries and to the discharge of your duties and responsibilities for them.

(c) You agree that, while employed by the Company, you will comply with all Company policies, practices and procedures and all codes of ethics or business conduct applicable to your position, as in effect from time to time.

2. Compensation and Benefits. During your employment, as compensation for all services performed by you for the Company and its subsidiaries and subject to your full performance of your obligations hereunder, the Company will provide you the following pay and benefits:

(a) Base Salary. The Company will pay you a base salary at the rate of \$396,550 per year, payable in accordance with the regular payroll practices of the Company (as may be adjusted, from time to time, the "Base Salary").

(b) Bonus Compensation. For each fiscal year completed during your employment under this Agreement, you will be eligible to earn an annual cash bonus. Your target bonus will be 35.0% of the Base Salary (the "Target Bonus"), with the actual amount of any such bonus being determined by the Board of Directors of the Company (the "Board") in its discretion, based on your performance and that of the Company against goals established by the Board. Except as otherwise expressly provided in Section 5 hereof, you must be employed through the date a bonus is paid in order to be eligible for the bonus.

(c) Participation in Employee Benefit Plans. You will be entitled to participate in all employee benefit plans from time to time in effect for employees of the Company generally, except to the extent such plans are duplicative of benefits otherwise provided you under this Agreement (e.g., a severance pay plan). Your participation will be subject to the terms of the applicable plan documents and generally applicable Company policies, as the same may be in effect from time to time, and any other restrictions or limitations imposed by law.

(d) Vacations. You will be entitled to earn four (4) weeks of vacation per year, in addition to holidays observed by the Company. Vacation may be taken at such times and intervals as you shall determine, subject to the business needs of the Company. Vacation shall otherwise be subject to the policies of the Company, as in effect from time to time.

(e) Business Expenses. The Company will pay or reimburse you for all reasonable business expenses incurred or paid by you in the performance of your duties and responsibilities for the Company, subject to any maximum annual limit and other restrictions on such expenses set by the Company and to such reasonable substantiation and documentation as may be specified from time to time. Your right to payment or reimbursement for business expenses hereunder shall be subject to the following additional rules: (i) the amount of expenses eligible for payment or reimbursement during any calendar year shall not affect the expenses eligible for payment or reimbursement in any other calendar year, (ii) payment or reimbursement shall be made not later than December 31 of the calendar year following the calendar year in which the expense or payment was incurred, and (iii) the right to payment or reimbursement is not subject to liquidation or exchange for any other benefit.

3. Confidential Information and Restricted Activities.

(a) Confidential Information. During the course of your employment with the Company, you will learn of Confidential Information, as defined below, and you may develop Confidential Information on behalf of the Company and its subsidiaries. You agree that you will not use or disclose to any Person (except as required by applicable law or for the proper performance of your regular duties and responsibilities for the Company) any Confidential Information obtained by you incident to your employment or any other association with the Company or any of its subsidiaries. You agree that this restriction shall continue to apply after your employment terminates, regardless of the reason for such termination. Nothing in this Agreement limits, restricts or in any other way affects your communicating with any governmental agency or entity, or communicating with any official or staff person of a governmental agency or entity, concerning matters relevant to the governmental agency or entity.

You cannot be held criminally or civilly liable under any federal or state trade secret law for disclosing a trade secret (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, solely for the purpose of reporting or investigating a suspected violation of law, or (ii) in a complaint or other document filed under seal in a lawsuit or other proceeding. Notwithstanding this immunity from liability, you may be held liable if you unlawfully access trade secrets by unauthorized means.

(b) Protection of Documents. All documents, records and files, in any media of whatever kind and description, relating to the business, present or otherwise, of the Company or any of its subsidiaries, and any copies, in whole or in part, thereof, other than your rolodex (or electronic equivalent), which we agree is your property, (the "Documents"), whether or not prepared by you, shall be the sole and exclusive property of the Company. You agree to safeguard all Documents and to surrender to the Company, at the time your employment terminates or at such earlier time or times as the Board or its designee may specify, all Documents then in your possession or control. You also agree to disclose to the Company, at the time your employment terminates or at such earlier time or times as the Board or its designee may specify, all passwords necessary or desirable to obtain access to, or that would assist in obtaining access to, any information which you have password-protected on any computer equipment, network or system of the Company or any of its subsidiaries.

(c) Assignment of Rights to Intellectual Property. You shall promptly and fully disclose all Intellectual Property to the Company. You hereby assign and agree to assign to the Company (or as otherwise directed by the Company) your full right, title and interest in and to all Intellectual Property. You agree to execute any and all applications for domestic and foreign patents, copyrights or other proprietary rights and to do such other acts (including without limitation the execution and delivery of instruments of further assurance or confirmation) requested by the Company to assign the Intellectual Property to the Company (or as otherwise directed by the Company) and to permit the Company to enforce any patents, copyrights or other proprietary rights to the Intellectual Property. You will not charge the Company for time spent in complying with these obligations. All copyrightable works that you create during your employment shall be considered "work made for hire" and shall, upon creation, be owned exclusively by the Company.

(d) Restricted Activities. You agree that the following restrictions on your activities during and after your employment are necessary to protect the good will, Confidential Information, trade secrets and other legitimate interests of the Company and its subsidiaries:

(i) While you are employed by the Company and during the twelve (12)-month period immediately following termination of your employment, regardless of the reason therefor (in the aggregate, the "Restricted Period"), you shall not, directly or indirectly, whether as owner, partner, investor, consultant, agent, employee, co-venturer or otherwise, compete with the Company or any of its subsidiaries in any geographic area in which the Company does business or is actively planning to do business during your employment or, with respect to the portion of the Restricted Period that follows the termination of your employment, at the time your employment terminates (the "Restricted Area") or undertake any planning for any business competitive with the Company or any of its subsidiaries in the Restricted Area. Specifically, but without limiting the foregoing, you agree not to work or provide services, in any capacity, anywhere in the Restricted Area, whether as an employee, independent contractor or

otherwise, whether with or without compensation, to any Person that is engaged in any business that is specifically engaged in drug delivery ophthalmology for delivery in the anterior or posterior segment, or, with respect to the portion of the Restricted Period that follows the termination of your employment, at the time your employment terminates. Notwithstanding the foregoing, in the event of any termination of your employment pursuant to Section 4(b) or Section 4(c) below that occurs prior to the first anniversary of the Start Date, the Restricted Period shall mean the period that commences on the Start Date and ends on the date that is six (6) months following the date that your employment terminates.

(ii) During the Restricted Period, you will not directly or indirectly (a) solicit or encourage any customer, vendor, supplier or other business partner of the Company or any of its subsidiaries to terminate or diminish its relationship with them; or (b) seek to persuade any such customer, vendor, supplier or other business partner or prospective customer, vendor, supplier or other business partner of the Company or any of its subsidiaries to conduct with anyone else any business or activity which such customer, vendor, supplier or other business partner or prospective customer, vendor, supplier or other business partner conducts or could conduct with the Company or any of its subsidiaries; provided, however, that these restrictions shall apply (y) only with respect to those Persons who are or have been a business partner of the Company or any of its subsidiaries at any time within the immediately preceding two (2)-year period or whose business has been solicited on behalf of the Company or any of the subsidiaries by any of their officers, employees or agents within such two (2) year period, other than by form letter, blanket mailing or published advertisement, and (z) only if you have performed work for such Person during your employment with the Company or one of its subsidiaries or been introduced to, or otherwise had contact with, such Person as a result of your employment or other associations with the Company or one of its subsidiaries or have had access to Confidential Information which would assist in your solicitation of such Person.

(iii) During the Restricted Period, you will not, and will not assist any other Person to, (a) hire or engage, or solicit for hiring or engagement, any employee of the Company or any of its subsidiaries or seek to persuade any employee of the Company or any of its subsidiaries to discontinue employment or (b) solicit or encourage any independent contractor providing services to the Company or any of its subsidiaries to terminate or diminish his, her or its relationship with them. For the purposes of this Agreement, an “employee” or an “independent contractor” of the Company or any of its subsidiaries is any person who was such at any time within the preceding eighteen (18) months.

(e) In signing this Agreement, you give the Company assurance that you have carefully read and considered all the terms and conditions of this Agreement, including the restraints imposed on you under this Section 3. You agree without reservation that these restraints are necessary for the reasonable and proper protection of the Company and its subsidiaries, and that each and every one of the restraints is reasonable in respect to subject matter, length of time and geographic area. You further agree that, were you to breach any of the covenants contained in this Section 3, the damage to the Company and its subsidiaries would be irreparable. You therefore agree that the Company, in addition and not in the alternative to any

other remedies available to it, shall be entitled to preliminary and permanent injunctive relief against any breach or threatened breach by you of any of those covenants, without having to post bond, together with an award of its reasonable attorney's fees incurred in enforcing its rights hereunder. So that the Company may enjoy the full benefit of the covenants contained in this Section 3, you further agree that the Restricted Period shall be tolled, and shall not run, during the period of any breach by you of any of the covenants contained in this Section 3. You and the Company further agree that, in the event that any provision of this Section 3 is determined by any court of competent jurisdiction to be unenforceable by reason of its being extended over too great a time, too large a geographic area or too great a range of activities, that provision shall be deemed to be modified to permit its enforcement to the maximum extent permitted by law. It is also agreed that each of the Company's subsidiaries shall have the right to enforce all of your obligations to that subsidiary under this Agreement, including without limitation pursuant to this Section 3. Finally, no claimed breach of this Agreement or other violation of law attributed to the Company, or change in the nature or scope of your employment or other relationship with the Company or any of its subsidiaries, shall operate to excuse you from the performance of your obligations under this Section 3.

4. Termination of Employment. Your employment under this Agreement shall continue until terminated pursuant to this Section 4.

(a) By the Company for Cause. The Company may terminate your employment for Cause upon notice to you setting forth in reasonable detail the nature of the Cause. The following, as determined by the Board in its reasonable, good faith judgment, shall constitute "Cause" for termination: (i) your substantial failure to perform (other than by reason of disability), or gross negligence in the performance of, your duties and responsibilities to the Company or any of its subsidiaries; (ii) your material breach of this Agreement or any other agreement between you and the Company or any of its subsidiaries; (iii) your commission of, or plea of nolo contendere to, a felony or other crime involving moral turpitude; or (iv) other conduct by you that is or could reasonably be expected to be harmful to the interests or reputation of the Company or any of its subsidiaries, in each such case, you shall have a one-time 30-day period to cure such Cause.

(b) By the Company Without Cause. The Company may terminate your employment at any time other than for Cause upon notice to you.

(c) By You for Good Cause. You may terminate your employment for Good Cause by (A) providing notice to the Company specifying in reasonable detail the condition giving rise to the Good Cause no later than the thirtieth (30th) day following your first becoming aware of such event or condition; (B) providing the Company a period of (30) days to remedy the event or condition; and (C) terminating your employment for Good Cause within fifteen (15) days following the expiration of the period to remedy if the Company fails to remedy the condition. The following, if occurring without your consent, shall constitute "Good Cause" for termination by you: (i) a material diminution in the nature or scope of your position, duties, or authority (other than temporarily while you are physically or mentally incapacitated to such a degree that you would be eligible for disability benefits under the Company's disability income plan or as required by applicable law); (ii) a material reduction in the Base Salary or the Target Bonus opportunity; (iii) a material breach by the Company of this Agreement; (iv) a requirement by the Company that you relocate to a location more than thirty (30) miles from Watertown, Massachusetts.

(d) By You Without Good Cause. You may terminate your employment at any time without Good Cause upon sixty (60) days' notice to the Company. The Board may elect to waive such notice period or any portion thereof; but in that event, the Company shall pay you the Base Salary for that portion of the notice period so waived.

(e) Death and Disability. Your employment hereunder shall automatically terminate in the event of your death during employment. In the event you become disabled during employment and, as a result, are unable to continue to perform substantially all of your duties and responsibilities under this Agreement, either with or without reasonable accommodation, the Company will continue to pay you the Base Salary and to provide you benefits in accordance with Section 2(c) above, to the extent permitted by plan terms, for up to twelve (12) weeks of disability during any period of three hundred sixty-five (365) consecutive calendar days. If you are unable to return to work after twelve (12) weeks of disability, the Company may terminate your employment, upon notice to you. If any question shall arise as to whether you are disabled to the extent that you are unable to perform substantially all of your duties and responsibilities for the Company and its subsidiaries, you shall, at the Company's request, submit to a medical examination by a physician selected by the Company to whom you or your guardian, if any, has no reasonable objection to determine whether you are so disabled, and such determination shall for purposes of this Agreement be conclusive of the issue. If such a question arises and you fail to submit to the requested medical examination, the Company's determination of the issue shall be binding on you.

5. Other Matters Related to Termination.

(a) Final Compensation. In the event of termination of your employment with the Company, howsoever occurring, the Company shall pay you (i) the Base Salary for the final payroll period of your employment, through the date that your employment terminates; (ii) compensation at the rate of the Base Salary for any vacation time earned but not used as of the date your employment terminates; and (iii) reimbursement, in accordance with Section 2(e) hereof, for business expenses incurred by you but not yet paid to you as of the date your employment terminates; provided you submit all expenses and supporting documentation required within sixty (60) days of the date your employment terminates, and provided further that such expenses are reimbursable under Company policies as then in effect (all of the foregoing, "Final Compensation"). Except as otherwise provided in Section 5(a)(iii), Final Compensation will be paid to you within thirty (30) days following the date of termination (or such shorter period required by law).

(b) Severance Payments. In the event of any termination of your employment pursuant to Section 4(b) or Section 4(c) above, the Company will pay you, in addition to Final Compensation, (i) the Base Salary for the period of twelve (12) months from the date of termination, provided, however, that if such termination occurs within twelve (12) months following the Start Date (a "Year One Termination"), the Company will instead pay you, in addition to Final Compensation, the Base Salary for the period of six (6) months from the date of termination; (ii) one times the Target Bonus, or 0.5 times the Target Bonus in the event of a Year One Termination, in either case, payable in equal installments during the period of Base Salary

continuation under clause (i); and (iii) provided you timely elect continuation coverage for yourself and your eligible dependents under the federal law known as "COBRA" or similar state law, a monthly amount that equals the portion of the monthly health premiums paid by the Company on your behalf and that of your eligible dependents immediately preceding the date that your employment terminates until the earlier of (A) the last day of the period of Base Salary continuation under clause (i) and (B) the date that you and your eligible dependents become ineligible for COBRA coverage pursuant to applicable law or plan terms. The severance payments described in clauses (i) through (iii) above are referred to as the "Severance Payments". In the event a Change of Control occurs following the Start Date, and any options to purchase Stock or shares of restricted Stock held by you are assumed or substituted in such Change of Control, all such assumed or substituted options and restricted shares that remain outstanding and are not fully vested at the time of any subsequent termination of your employment pursuant to Section 4(b) or Section 4(c) will accelerate and vest in full upon such termination and the options will remain exercisable until the earlier of the first anniversary of the date of your employment termination (or three (3) months following the date of your employment termination in the case of any incentive stock options) and last day of the option term (the "Equity Acceleration").

(c) Conditions to and Timing of Severance Payments. Any obligation of the Company to provide you the Severance Payments and the Equity Acceleration is conditioned, however, on your signing and returning to the Company a timely and effective separation agreement containing a general release of claims substantially in the form attached hereto as Exhibit A (the "Release of Claims") and other customary terms in the form provided to you by the Company at the time your employment is terminated. The Release of Claims must become effective, if at all, by the sixtieth (60th) calendar day following the date your employment is terminated. Any Severance Payments, to which you are entitled will be provided in the form of salary continuation, payable in accordance with the normal payroll practices of the Company. The first payment will be made on the Company's next regular payday following the expiration of sixty (60) calendar days from the date of termination; but that first payment shall include all amounts accrued retroactive to the day following the date your employment terminated.

(d) Benefits Termination. Except as provided in Section S(b) above or under COBRA, your participation in all employee benefit plans shall terminate in accordance with the terms of the applicable benefit plans based on the date of termination of your employment, without regard to any continuation of the Base Salary or other payment to you following termination and you shall not be eligible to earn vacation or other paid time off following the termination of your employment.

(e) Survival. Provisions of this Agreement shall survive any termination of employment if so provided in this Agreement or if necessary or desirable to accomplish the purposes of other surviving provisions, including without limitation your obligations under Section 3. The obligation of the Company to make payments to you under Section 5(b), and your right to retain the same, are expressly conditioned upon your continued full performance of your obligations under Section 3 hereof. Upon termination by either you or the Company, all rights, duties and obligations of you and the Company to each other shall cease, except as otherwise expressly provided in this Agreement.

6. Timing of Payments and Section 409A.

(a) Notwithstanding anything to the contrary in this Agreement, if at the time your employment terminates, you are a “specified employee,” as defined below, any and all amounts payable under this Agreement on account of such separation from service that would (but for this provision) be payable within six (6) months following the date of termination, shall instead be paid on the next business day following the expiration of such six (6) month period or, if earlier, upon your death; except (A) to the extent of amounts that do not constitute a deferral of compensation within the meaning of Treasury regulation Section 1.409A-1(b) (including without limitation by reason of a short-term deferral or the safe harbor set forth in Section 1.409A-1(b)(9)(iii), as determined by the Company in its reasonable good faith discretion); (B) benefits which qualify as excepted welfare benefits pursuant to Treasury regulation Section 1.409A-1(a)(5); or (C) other amounts or benefits that are not subject to the requirements of, or satisfy an exception from treatment as deferred compensation under, Section 409A of the Internal Revenue Code of 1986, as amended (“Section 409A”).

(b) For purposes of this Agreement, all references to “termination of employment” and correlative phrases shall be construed to require a “separation from service” (as defined in Section 1.409A-1(h) of the Treasury regulations after giving effect to the presumptions contained therein), and the term “specified employee” means an individual determined by the Company to be a specified employee under Treasury regulation Section 1.409A-1(i).

(c) Each payment made under this Agreement shall be treated as a separate payment and the right to a series of installment payments under this Agreement is to be treated as a right to a series of separate payments.

(d) In no event shall the Company have any liability relating to the failure or alleged failure of any payment or benefit under this Agreement to comply with, or be exempt from, the requirements of Section 409A.

7. Definitions. For purposes of this Agreement, the following definitions apply:

“Change of Control” means

(A) The acquisition by any Person (defined for purposes of this definition as any individual, entity or group (within the meaning of Section 13(d)(3) or Section 14(d)(2) of the Securities Exchange Act of 1934, as amended (“Exchange Act”))) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of 35% or more of the common stock of the Company; provided, however, that for purposes of this subsection (A), an acquisition shall not constitute a Change of Control if it is: (i) either by or directly from the Company, or by an entity controlled by the Company, (ii) by any employee benefit plan, including any related trust, sponsored or maintained by the Company or an entity controlled by the Company (“Benefit Plan”), or (iii) by an entity pursuant to a transaction that complies with clauses (i), (ii) and (iii) of subsection (C) below; or

(B) Individuals who, as of the effective date of this Agreement, constitute the Board (together with the individuals identified in the proviso to this subsection (B)), the “Incumbent

Board”) cease for any reason to constitute at least a majority of the Board; provided, however, that any individual becoming a director subsequent to the effective date of this agreement whose election, or nomination for election by the Company’s stockholders, was approved by at least a majority of the directors then comprising the Incumbent Board shall be treated as a member of the Incumbent Board unless he or she assumed office as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board; or

(C) Consummation of a reorganization, merger or consolidation involving the Company, or a sale or other disposition of all or substantially all of the assets of the Company (a “Transaction”), in each case unless, following such Transaction, (i) all or substantially all of the Persons who were the beneficial owners of the common stock of the Company outstanding immediately prior to such Transaction beneficially own, directly or indirectly, more than 50% of the combined voting power of the then outstanding voting securities of the entity resulting from such Transaction (including, without limitation, an entity that as a result of such Transaction owns the Company or all or substantially all of the Company’s assets either directly or through one or more subsidiaries) in substantially the same proportions as their ownership, immediately prior to such Transaction, of the outstanding common stock of the Company, (ii) no Person (excluding any entity or wholly-owned subsidiary of any entity resulting from such Transaction or any Benefit Plan of the Company or such entity or wholly-owned subsidiary of such entity resulting from such Transaction) beneficially owns, directly or indirectly, 35% or more of the combined voting power of the then outstanding voting securities of such entity except to the extent that such ownership existed prior to the transaction and (iii) at least a majority of the members of the board of directors or similar board of the entity resulting from such Transaction were members of the Incumbent Board at the time of the execution of the initial agreement, or of the action of the Board, providing for such Transaction; or

(D) Approval by the stockholders of the Company of a liquidation or dissolution of the Company.

“Confidential Information” means any and all information of the Company and its subsidiaries that is not generally available to the public. Confidential Information also includes any information received by the Company or any of its subsidiaries from any Person with any understanding, express or implied, that it will not be disclosed. Confidential Information does not include information that enters the public domain, other than through your breach of your obligations under this Agreement.

“Intellectual Property” means inventions, discoveries, developments, methods, processes, compositions, works, concepts and ideas (whether or not patentable or copyrightable or constituting trade secrets) conceived, made, created, developed or reduced to practice by you (whether alone or with others, whether or not during normal business hours or on or off Company premises) during your employment and during the period of twelve (12) months immediately following termination of your employment that relate either to the business of the Company or any of its subsidiaries or to any prospective activity of the Company or any of its subsidiaries or that result from any work performed by you for the Company or any of its subsidiaries or that make use of Confidential Information or any of the equipment or facilities of the Company or any of its subsidiaries.

“Person” means an individual, a corporation, a limited liability company, an association, a partnership, an estate, a trust or any other entity or organization, other than the Company or any of its subsidiaries.

8. Conflicting Agreements. You hereby represent and warrant that your signing of this Agreement and the performance of your obligations under it will not breach or be in conflict with any other agreement to which you are a party or are bound, and that you are not now subject to any covenants against competition or similar covenants or any court order that could affect the performance of your obligations under this Agreement. You agree that you will not disclose to or use on behalf of the Company any confidential or proprietary information of a third party without that party’s consent.

9. Withholding. All payments made by the Company under this Agreement shall be reduced by any tax or other amounts required to be withheld by the Company under applicable law.

10. Assignment. Neither you nor the Company may maim any assignment of this Agreement or any interest in it, by operation of law or otherwise, without the prior written consent of the other; provided, however, the Company may assign its rights and obligations under this Agreement without your consent to one of its subsidiaries or to any Person with whom the Company shall hereafter effect a reorganization, consolidate or merge, or to whom the Company shall hereafter transfer all or substantially all of its properties or assets. This Agreement shall inure to the benefit of and be binding upon you and the Company, and each of our respective successors, executors, administrators, heirs and permitted assigns.

11. Severability. If any portion or provision of this Agreement shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

12. Miscellaneous. This Agreement sets forth the entire agreement between you and the Company, and replaces all prior and contemporaneous communications, agreements and understandings, written or oral, with respect to the terms and conditions of your employment. This Agreement may not be modified or amended, and no breach shall be deemed to be waived, unless agreed to in writing by you and an expressly authorized representative of the Board. The headings and captions in this Agreement are for convenience only and in no way define or describe the scope or content of any provision of this Agreement. This Agreement may be executed in two or more counterparts, each of which shall be an original and all of which together shall constitute one and the same instrument. This is a Massachusetts contract and shall be governed and construed in accordance with the laws of the Commonwealth of Massachusetts, without regard to any conflict of laws principles that would result in the application of the laws of any other jurisdiction. You agree to submit to the exclusive jurisdiction of the courts situated in the county in which the Company’s headquarters is located in connection with any dispute arising out of this Agreement.

13. Notices. Any notices provided for in this Agreement shall be in writing and shall be effective when delivered in person or deposited in the United States mail, postage prepaid, and addressed to you at your last known address on the books of the Company or, in the case of the Company, to it at its principal place of business, attention of the Chairman of the Board, or to such other address as either party may specify by notice to the other actually received.

14. Indemnification. During your employment or service as a member of the Board, and for all periods thereafter for which you may be subject to liability for your acts or omissions to act with respect to your duties to the Company as an officer or director, the Company shall indemnify you and provide advancement of expenses in accordance with the terms of the Company's Certificate of Incorporation, as may be amended from time to time, and the indemnification agreement to be entered into between you and the Company substantially in the form attached hereto as Exhibit B.

[Remainder of page intentionally left blank.]

If the foregoing is acceptable to you, please sign this letter in the space provided and return it to me no later than March 23, 2018. At the time you sign and return it, this letter will take effect as a binding agreement between you and the Company on the basis set forth above. The enclosed copy is for your records.

Sincerely yours,

/s/ Nancy Lurker

Nancy Lurker
President & CEO

Accepted and Agreed:

/s/ Dario Paggiarino

Dario Paggiarino

Date: March 27, 2018



EXHIBIT A

General Release and Waiver of Claims

For and in consideration of the severance benefits to be provided to me under the letter between me and pSivida Corp. (the "Company"), dated , 2017 (the "Agreement"), which are conditioned on my signing this General Release and Waiver of Claims (this "Release of Claims"), and to which I am not otherwise entitled, and other good and valuable consideration, the receipt and sufficiency of which I hereby acknowledge, on my own behalf and on behalf of my heirs, executors, administrators, beneficiaries, representatives, successors and assigns, and all others connected with or claiming through me, I hereby release and forever discharge the Company and its Affiliates, and all of their respective past, present and future officers, directors, shareholders, employees, employee benefits plans, administrators, trustees, agents, representatives, consultants, predecessors, successors and assigns, and all those connected with any of them, in their official and individual capacities (collectively, the "Released Parties"), from any and all causes of action, suits, rights and claims, demands, damages and compensation of any kind and nature whatsoever, whether at law or in equity, whether now known or unknown, suspected or unsuspected, contingent or otherwise, which I now have or ever have had against the Released Parties, or any of them, in any way related to, connected with or arising out of my employment and/or other relationship with the Company or any of its Affiliates, or the termination of such employment and/or other relationship, or pursuant to Title VII of the Civil Rights Act, the Americans With Disabilities Act, the Family and Medical Leave Act, the Age Discrimination in Employment Act (as amended by the Older Workers Benefit Protection Act), the Employee Retirement Income Security Act, the wage and hour, wage payment and fair employment practices laws of the state or states in which I have provided services to the Company or any of its Affiliates (each as amended from time to time) and/or any other federal, state or local law, regulation, or other requirement (collectively, the "Claims") through the date that I sign this Release of Claims, and I hereby waive all such Claims. For purposes of this Release of Claims, "Affiliates" means all persons and entities directly or indirectly controlling, controlled by or under common control with the Company, where control may be by management authority, equity interest or otherwise.

I understand that nothing contained in this Release of Claims shall be construed to prohibit me from filing a charge with or participating in any investigation or proceeding conducted by the federal Equal Employment Opportunity Commission or a comparable state or local agency; provided, however, that I hereby agree to waive my right to recover monetary damages or other individual relief in any such charge, investigation or proceeding or any related complaint or lawsuit filed by me or by anyone else on my behalf. I further understand that nothing contained in this Release of Claims shall be construed to limit, restrict or in any other way affect my communicating with any governmental agency or entity, or communicating with any official or staff person of a governmental agency or entity, concerning matters relevant to such governmental agency or entity. Subject to this paragraph, I agree that I will not disparage or criticize the Company, its Affiliates, their business, their management or their products or services. The Company agrees that (i) the Company (via any authorized public statement) and (ii) its officers and members of its Board of Directors as of the date that my employment with the Company terminates will not disparage or criticize me or my reputation.

[I acknowledge and agree I have received any and all compensation and benefits due to me from the Company or any of its Affiliates, whether for services provided to the Company, under the Agreement, or otherwise, through the date that my employment with the Company terminated, except for any accrued, vested benefits that are unpaid as of the date that my employment with the Company terminates and are due in accordance with the terms of the Company's benefit plans as in effect from time to time. I further acknowledge that, except as expressly provided hereunder, no further compensation or benefits are owed or will be provided to me by the Company or any of its Affiliates.]¹

Anything in this Release to the contrary notwithstanding, I am not releasing or discharging any Claim under Section 14 of the Agreement or the Indemnification Agreement between me and the Company, dated September , 2016, or any Claim with respect to any equity in the Company that I hold following the date that my employment with the Company terminates.

I acknowledge that I will continue to be bound by my obligations under the Agreement and under _____² that survive the termination of my employment by the terms thereof (the "Continuing Obligations"). I further acknowledge that the obligation of the Company to make the Severance Payments and provide the Equity Acceleration to me under the Agreement, and my right to retain the same, are expressly conditioned upon my continued full performance of the Continuing Obligations.

I understand that I must sign this Release of Claims, if at all, within [twenty-one (21)/forty-five (45)] days of the date hereof, and in no event prior to the date that my employment with the Company terminates. I acknowledge that this Release of Claims creates legally binding obligations, and that the Company has advised me to consult an attorney before signing it. In signing this Release of Claims, I give the Company assurance that I have signed it voluntarily and with a full understanding of its terms; that I have had sufficient opportunity of not less than [twenty-one (21)/forty-five (45)] days before signing this Release of Claims to consider its terms and to consult with an attorney, if I wished to do so, or to consult with any of the other persons described in the third sentence of the second paragraph hereof; and that I have not relied on any promises or representations, express or implied, that are not set forth expressly in this Release of Claims. I understand that I will have seven (7) days after signing this Release of Claims to revoke my signature, and that, if I intend to revoke my signature, I must do so in writing addressed and delivered to the [Contact Name and Title] prior to the end of the seven (7)-day revocation period. I understand that this Release of Claims will become effective upon the eighth (8th) day following the date that I sign it, provided that I do not revoke my acceptance in accordance with the immediately preceding sentence. This Release constitutes the entire agreement between me and the Company or any of its Affiliates and supersedes all prior and

¹ Note to Draft: To be adjusted depending on when the release is presented to the Executive and whether final compensation has been paid yet.

² Note to Draft: To include any other relevant documents.

contemporaneous communications, agreements and understandings, whether written or oral, with respect to my employment, its termination and all related matters, excluding only (i) the Continuing Obligations, which shall remain in full force and effect in accordance with their terms and (ii) any Claims not released or discharged by me.

Accepted and agreed:

Signature: _____
Dario Paggiarino

Date: _____

EXHIBIT B

Indemnification Agreement

This Indemnification Agreement, made and entered into effective _____, 2017 (“Agreement”), by and between pSivida Corp., a Delaware corporation (“Company”), and Dario Paggiarino (“Indemnitee”)

WHEREAS, it is reasonable, prudent and necessary for the Company to obligate itself to indemnify, and to advance expenses on behalf of, its directors and officers to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified; and

WHEREAS, Indemnitee is willing to serve the Company as an officer and a director and to take on additional service for or on its behalf on the condition that she be so indemnified;

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. Services by Indemnitee. Indemnitee agrees to serve as an officer and a director of the Company. Indemnitee may at any time and for any reason resign from such positions (subject to any other contractual obligation or any obligation imposed by operation of law).

Section 2. Indemnification - General. The Company shall indemnify, and advance Expenses (as hereinafter defined) to, Indemnitee (a) as provided in this Agreement and (b) (subject to the provisions of this Agreement) to the fullest extent permitted by applicable law in effect on the date hereof and as amended from time to time. The rights of Indemnitee provided under the preceding sentence shall include, but shall not be limited to, the rights set forth in the other Sections of this Agreement.

Section 3. Proceedings Other Than Proceedings by or in the Right of the Company. Indemnitee shall be entitled to the rights of indemnification provided in this Section 3 if, by reason of her Corporate Status (as hereinafter defined), she is, or is threatened to be made, a party to or a participant in any threatened, pending or completed Proceeding (as hereinafter defined), other than a Proceeding by or in the right of the Company. Pursuant to this Section 3, Indemnitee shall be indemnified against all Expenses, judgments, penalties, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, penalties, fines and amounts paid in settlement) actually and reasonably incurred by her or on her behalf in connection with such Proceeding or any claim, issue or matter therein, if she acted in good faith and in a manner she reasonably believed to be in or not opposed to the best interests of the Company and, with respect to any criminal Proceeding, had no reasonable cause to believe her conduct was unlawful.

Section 4. Proceedings by or in the Right of the Company. Indemnitee shall be entitled to the rights of indemnification provided in this Section 4 if, by reason of her Corporate Status, she is, or is threatened to be made, a party to or a participant in any threatened, pending or completed Proceeding brought by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section, Indemnitee shall be indemnified against all Expenses (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses) actually and reasonably incurred by her or on her behalf in connection with such Proceeding if she acted in good faith and in a manner she reasonably believed to be in or not opposed to the best interests of the Company; provided, however, that indemnification against such Expenses shall be made in respect of any claim, issue or matter in such Proceeding as to which Indemnitee shall have been adjudged by a court of competent jurisdiction to be liable to the Company if and only to the extent that the Chancery Court of the State of Delaware (the "Delaware Court"), or court in which such Proceeding shall have been brought or is pending, shall determine that despite such adjudication of liability and in light of all circumstances, such indemnification may be made.

Section 5. Partial Indemnification. Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of her Corporate Status, a party to (or a participant in) and is successful, on the merits or otherwise, in defense of any Proceeding, she shall be indemnified to the maximum extent permitted by law against all Expenses actually and reasonably incurred by her or on her behalf in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by her or on her behalf in connection with each successfully resolved claim, issue or matter. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

Section 6. Indemnification for Additional Expenses.

(a) The Company shall indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within thirty (30) days of such request) advance such Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for (i) indemnification or advance payment of Expenses by the Company under this Agreement or any other agreement or by-law of the Company now or hereafter in effect; or (ii) recovery under any directors' and officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advance expense payment or insurance recovery, as the case may be.

(b) Notwithstanding any other provision of this Agreement, to the extent that Indemnitee is, by reason of her Corporate Status, a witness, or is made (or asked) to respond to discovery requests, in any Proceeding to which Indemnitee is not a party, she shall be indemnified against all Expenses actually and reasonably incurred by her or on her behalf in connection therewith.

Section 7. Advancement of Expenses. The Company shall advance all reasonable Expenses incurred by or on behalf of Indemnitee in connection with any Proceeding within thirty (30) days after the receipt by the Company of a statement or statements from Indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by Indemnitee and shall include or be preceded or accompanied by an undertaking by or on behalf of Indemnitee to repay any Expenses advanced if it shall ultimately be determined that Indemnitee is not entitled to be indemnified against such Expenses. Notwithstanding the foregoing, the obligation of the Company to advance Expenses pursuant to this Section 7 shall be subject to the condition that, if, when and to the extent that the Company determines that Indemnitee would not be permitted to be indemnified under applicable law, the Company shall be entitled to be reimbursed, within thirty (30) days of such determination, by Indemnitee (who hereby agrees to reimburse the Company) for all such amounts theretofore paid; provided, however, that if Indemnitee has commenced or thereafter commences legal proceedings in accordance with the terms of this Agreement to secure a determination that Indemnitee should be indemnified under applicable law, any determination made by the Company that Indemnitee would not be permitted to be indemnified under applicable law shall not be binding and Indemnitee shall not be required to reimburse the Company for any advance of Expenses until a final judicial determination is made with respect thereto (as to which all rights of appeal therefrom have been exhausted or lapsed).

Section 8. Procedure for Determination of Entitlement to Indemnification.

(a) To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board of Directors of the Company (the "Board") in writing that Indemnitee has requested indemnification.

(b) Upon written request by Indemnitee for indemnification pursuant to the first sentence of Section 8(a) hereof, a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case by (A) a majority vote of the Disinterested Directors (as hereinafter defined), even though less than a quorum of the Board, or (B) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee, or (C) if contracting an Independent Counsel is impracticable or undesirable and if so directed by the Board, by the stockholders of the Company. If it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within thirty (30) days after such determination. The Company and the Indemnitee shall each cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or expenses (including attorneys' fees and disbursements) incurred by

Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification), and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom.

(c) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 8(b) hereof, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising her of the identity of the Independent Counsel so selected. Indemnitee may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 18 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Delaware Court has determined that such objection is without merit. If, within twenty (20) days after submission by Indemnitee of a written request for indemnification pursuant to Section 8(a) hereof, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Delaware Court for resolution of any objection which shall have been made by the Indemnitee to the selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by the Delaware Court or by such other person as the Delaware Court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 8(b) hereof. The Company shall pay any and all reasonable fees and expenses of Independent Counsel incurred by such Independent Counsel in connection with acting pursuant to Section 8(b) hereof, and the Company shall pay all reasonable fees and expenses incident to the procedures of this Section 8(c), regardless of the manner in which such Independent Counsel was selected or appointed. Upon the due commencement of any judicial proceeding pursuant to Section 10(a)(iii) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

(d) The Company shall not be required to obtain the consent of the Indemnitee to the settlement of any Proceeding which the Company has undertaken to defend if the Company assumes full and sole responsibility for such settlement and the settlement grants the Indemnitee a complete and unqualified release in respect of the potential liability. The Company shall not be liable for any amount paid by the Indemnitee in settlement of any Proceeding that is not defended by the Company, unless the Company has consented to such settlement, which consent shall not be unreasonably withheld.

Section 9. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification or the advancement of expenses hereunder, the person or persons or entity making such determination shall presume that Indemnitee is entitled to indemnification or advancement of expenses under this Agreement if Indemnitee has submitted a request for indemnification or the advancement of

expenses in accordance with Section 8(a) of this Agreement, and the Company shall have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including its board of directors or independent legal counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including its board of directors or independent legal counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) If the person, persons or entity empowered or selected under Section 8 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within ninety (90) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law: provided, however, that such 90-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this Section 9(b) shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 8(b) of this Agreement and if (A) within thirty (30) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within ninety (90) days after such receipt and such determination is made thereat, or (B) a special meeting of stockholders is called within thirty (30) days after such receipt for the purpose of making such determination, such meeting is held for such purpose within ninety (90) days after having been so called and such determination is made thereat, or (ii) if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 8(b) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which she reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that her conduct was unlawful.

(d) Reliance as Safe Harbor. For purposes of any determination of good faith, Indemnitee shall be presumed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Company or relevant enterprise, including financial statements, or on information supplied to Indemnitee by the officers of the Company or relevant

enterprise in the course of their duties, or on the advice of legal counsel for the Company or relevant enterprise or on information or records given in reports made to the Company or relevant enterprise by an independent certified public accountant or by an appraiser or other expert selected with reasonable care by the Company or relevant enterprise. The provisions of this Section 9(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) Actions of Others. The knowledge and/or actions, or failure to act, of any director, officer, agent or employee of the Company or relevant enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

Section 10. Remedies of Indemnitee.

(a) In the event that any of the following occur: (i) a determination is made pursuant to Section 8 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 7 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 8(b) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5 or 6 of this Agreement within thirty (30) days after receipt by the Company of a written request therefor, or (v) payment of indemnification is not made within thirty (30) days after a determination has been made that Indemnitee is entitled to indemnification, Indemnitee shall be entitled to an adjudication by the Delaware Court of her entitlement to such indemnification or advancement of Expenses. Indemnitee shall commence any such proceeding within one hundred eighty (180) days following the date on which Indemnitee first has the right to commence such proceeding pursuant to this Section 10(a).

(b) In the event that a determination shall have been made pursuant to Section 8(b) of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding commenced pursuant to this Section 10 shall be conducted in all respects as a de novo trial on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination.

(c) If a determination shall have been made pursuant to Section 8(b) of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding commenced pursuant to this Section 10, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) In the event that Indemnitee, pursuant to this Section 10, seeks a judicial adjudication of, or to recover damages for breach of, this Agreement, Indemnitee shall be entitled to recover from the Company, and shall be indemnified by the Company against, any and all expenses (of the types described in the definition of Expenses in Section 17 of this Agreement) actually and reasonably incurred by her in such judicial adjudication, but only if she prevails therein. If it shall be determined in said judicial adjudication that Indemnitee is entitled

to receive part but not all of the indemnification or advancement of expenses sought, the expenses incurred by Indemnitee in connection with such judicial adjudication shall be appropriately prorated. The Company shall indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within thirty (30) days after receipt by the Company of a written request therefor) advance such expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' or officers' liability insurance policies maintained by the Company, regardless of whether Indemnitee ultimately is determined to be entitled to such indemnification, advancement of Expenses or insurance recovery, as the case maybe.

(e) The Company shall be precluded from asserting in any judicial proceeding commenced pursuant to this Section 10 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such judicial proceeding that the Company is bound by all the provisions of this Agreement.

Section I 1. Non-Exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the By-Laws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in her Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in the General Corporation Law of the State of Delaware, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Company's By-Laws and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees or agents of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise which such person serves at the request of the Company, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies.

(c) In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit or enforce such rights.

(d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(e) The Company's obligation to indemnify or advance expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, employee or agent of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise.

Section 12. Duration of Agreement.

(a) This Agreement shall continue until and terminate upon the later of: (a) 10 years after the last date that Indemnitee shall have served as a director or an officer of the Company (or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise which Indemnitee served at the request of the Company); or (b) the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of expenses hereunder and of any proceeding commenced by Indemnitee pursuant to Section 10 of this Agreement relating thereto.

(b) This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Company (or any of its subsidiaries) is at will, and the Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Company (or any of its subsidiaries), other applicable formal severance policies duly adopted by the Board or the Company's Certificate of Incorporation, By-Laws or the General Corporation Law of the State of Delaware. The foregoing notwithstanding, this Agreement shall continue in force as provided above after such date as Indemnitee has ceased to serve as a director or an officer of the Company.

(c) This Agreement shall be binding upon the Company and its successors and assigns and shall inure to the benefit of Indemnitee and her heirs, executors and administrators.

Section 13. Severability. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including,

without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

Section 14. Exception to Right of Indemnification or Advancement of Expenses. Except as provided in Section 6(a) of this Agreement, Indemnitee shall not be entitled to indemnification or advancement of Expenses under this Agreement with respect to any Proceeding brought by Indemnitee (other than a Proceeding by Indemnitee to enforce her rights under this Agreement), or any claim therein, unless the bringing of such Proceeding or making of such claim shall have been approved by the Board.

Section 15. Identical Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 16. Headings. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

Section 17. Construction. This Agreement shall not be construed more strictly against one party than another merely by virtue of the fact that it, or any part of it, may have been prepared by one of the parties, it being recognized that this Agreement is the result of arm's-length negotiations among the parties.

Section 18. Definitions. For purposes of this Agreement:

(a) "Corporate Status" describes the status of a person who is or was a director, officer, employee, fiduciary or agent of the Company or of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise which such person is or was serving at the request of the Company.

(b) "Disinterested Director" means a director of the company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(c) "Effective Date" means September 15, 2016.

(d) "Expenses" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness, in, or otherwise participating in, a Proceeding.

(e) "Independent Counsel" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained

to represent: (i) the Company or Indemnitee in any matter material to either such party, or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(f) "Proceeding" includes any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought by or in the right of the Corporation or otherwise and whether civil, criminal, administrative or investigative, in which Indemnitee was, is, may be or will be involved as a party or otherwise, by reason of the fact that Indemnitee is or was a director or officer of the Company, by reason of any action taken by her or of any inaction on her part while acting as director or officer of the Company, or by reason of the fact that she is or was serving at the request of the Company as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise; in each case whether or not she is acting or serving in any such capacity at the time any liability or expense is incurred for which indemnification or advancement of expenses can be provided under this Agreement; except one (i) initiated by an Indemnitee pursuant to Section 10 of this Agreement to enforce her right under this Agreement or (ii) pending on or before the Effective Date.

Section 19. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director and an officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as a director and an officer of the Company.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof.

Section 20. Modification and Waiver. No supplement, modification or amendment of this Agreement shall be binding unless executed in writing by both of the parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar), nor shall such waiver constitute a continuing waiver.

Section 21. Notice by Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so

notify the Company shall not relieve the Company of any obligation which it may have to the Indemnitee under this Agreement or otherwise unless, and to the extent that, such failure actually and materially prejudices the interests of the Company.

Section 22. Notices. All notices, requests, demands or other communications hereunder shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been direct, or (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed:

(a) If to Indemnitee to:

Dario Paggiarino
ADDRESS
ADDRESS

(b) If to the Company to:

pSivida Corp.
480 Pleasant Street
Watertown, Massachusetts 02472

or to such other address as may have been furnished to Indemnitee by the Company or to the Company by Indemnitee, as the case may be.

Section 23. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (a) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (b) the relative fault of the Company (and its directors, officers, employees and agents) and Indemnitee in connection with such event(s) and/or transaction(s).

Section 24. Governing Law; Submission to Jurisdiction; Appointment of Agent for Service of Process. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. The Company and Indemnitee hereby irrevocably and unconditionally (a) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Delaware Court, and not in any other state or federal court in the United States of America or any court in any other country, (b) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, (c) consent to the service of legal process outside the State of Delaware via registered mail or in-person service in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Delaware, (d) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (e) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or otherwise inconvenient forum.

[Remainder of Page Intentionally Blank]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the day and year first above written.

pSivida Corp.

By: _____
Nancy Lurker
President & CEO

INDEMNITEE

By: _____
Name: Dario Paggiarino

Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.**CERTIFICATIONS**

I, Nancy Lurker, certify that:

1. I have reviewed this quarterly report on Form 10-Q of EyePoint Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2018

/s/ Nancy Lurker

Name: Nancy Lurker

Title: President and Chief Executive Officer
(Principal Executive Officer)

Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.**CERTIFICATIONS**

I, Leonard S. Ross, certify that:

1. I have reviewed this quarterly report on Form 10-Q of EyePoint Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 10, 2018

/s/ Leonard S. Ross

Name: Leonard S. Ross
Title: Vice President, Finance and Chief Accounting Officer
(Principal Financial Officer)

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.

In connection with the Quarterly Report of EyePoint Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Nancy Lurker, President and Chief Executive Officer of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2018

/s/ Nancy Lurker

Name: Nancy Lurker

Title: President and Chief Executive Officer
(Principal Executive Officer)

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.

In connection with the Quarterly Report of EyePoint Pharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Leonard S. Ross, Vice President, Finance and Chief Accounting Officer of the Company, certify that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 10, 2018

/s/ Leonard S. Ross

Name: Leonard S. Ross

Title: Vice President, Finance and Chief Accounting Officer
(Principal Financial Officer)

