
**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, 2019

OR

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER 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)

(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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **Yes** **No**

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

Large accelerated filer **Accelerated filer**
Non-accelerated filer **Smaller reporting company**
Emerging growth company

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001	EYPT	The Nasdaq Stock Market LLC

There were 106,105,728 shares of the registrant's common stock, \$0.001 par value, outstanding as of May 6, 2019.

EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES
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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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 43,379	\$ 45,261
Accounts and other receivables	2,258	627
Prepaid expenses and other current assets	1,849	1,434
Inventory	886	279
Total current assets	48,372	47,601
Property and equipment, net	425	288
Operating lease right-of-use assets	3,393	—
Intangible assets, net	29,514	30,129
Restricted cash	150	150
Total assets	\$ 81,854	\$ 78,168
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,318	\$ 2,640
Accrued expenses	2,924	3,789
Accrued development milestone	15,000	15,000
Deferred revenue	—	30
Operating lease liabilities—current portion	417	—
Total current liabilities	24,659	21,459
Long-term debt	31,952	17,621
Operating lease liabilities—noncurrent	3,266	—
Other long-term liabilities	2,100	1,455
Total liabilities	61,977	40,535
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, \$.001 par value, 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, \$.001 par value, 150,000,000 shares authorized at March 31, 2019 and December 31, 2018; 95,554,228 and 95,372,236 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	96	95
Additional paid-in capital	446,673	445,192
Accumulated deficit	(427,731)	(408,493)
Accumulated other comprehensive income	839	839
Total stockholders' equity	19,877	37,633
Total liabilities and stockholders' equity	\$ 81,854	\$ 78,168

See notes to consolidated financial statements

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

	Three Months Ended	
	March 31,	
	2019	2018
Revenues:		
Product sales, net	\$ 1,227	\$ —
Collaborative research and development	65	524
Royalty income	720	404
Total revenues	<u>2,012</u>	<u>928</u>
Operating expenses:		
Cost of sales, excluding amortization of acquired intangible assets	330	—
Research and development	3,797	3,325
Sales and marketing	7,311	—
General and administrative	4,610	2,281
Amortization of acquired intangible assets	615	—
Total operating expenses	<u>16,663</u>	<u>5,606</u>
Loss from operations	<u>(14,651)</u>	<u>(4,678)</u>
Other income (expense):		
Interest and other income, net	243	25
Interest expense	(1,020)	—
Loss on extinguishment of debt	(3,810)	—
Change in fair value of derivative liability	—	(2,325)
Total other expense, net	<u>(4,587)</u>	<u>(2,300)</u>
Net loss	<u>\$(19,238)</u>	<u>\$(6,978)</u>
Net loss per share—basic and diluted	<u>\$ (0.20)</u>	<u>\$ (0.15)</u>
Weighted average shares outstanding—basic and diluted	95,452	45,644
Net loss	\$(19,238)	\$(6,978)
Foreign currency translation adjustments	—	1
Comprehensive loss	<u>\$(19,238)</u>	<u>\$(6,977)</u>

See notes to consolidated financial statements

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

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Number of Shares	Par Value Amount				
Balance at January 1, 2018	45,256,999	\$ 45	\$331,609	\$ (322,585)	\$ 836	\$ 9,905
Net loss	—	—	—	(6,978)	—	(6,978)
Other comprehensive income	—	—	—	—	1	1
Issuance of stock, net of issue costs	8,606,324	9	4,552	—	—	4,561
Fair value of warrants issued	—	—	268	—	—	268
Vesting of performance stock units	46,594	—	(2)	—	—	(2)
Stock-based compensation	—	—	443	—	—	443
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>
Balance at January 1, 2019	95,372,236	\$ 95	\$445,192	\$ (408,493)	\$ 839	\$ 37,633
Net loss	—	—	—	(19,238)	—	(19,238)
Exercise of stock options	141,760	1	263	—	—	264
Vesting of stock units	40,232	—	(20)	—	—	(20)
Stock-based compensation	—	—	1,238	—	—	1,238
Balance at March 31, 2019	<u>95,554,228</u>	<u>\$ 96</u>	<u>\$446,673</u>	<u>\$ (427,731)</u>	<u>\$ 839</u>	<u>\$ 19,877</u>

See notes to consolidated financial statements

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

	Three Months Ended March 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	\$ (19,238)	\$ (6,978)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Amortization of intangible assets	615	—
Depreciation of property and equipment	44	43
Amortization of debt discount	140	—
Non-cash interest expense	112	—
Loss on extinguishment of debt	3,810	—
Stock-based compensation	1,238	443
Change in fair value of derivative liability	—	2,325
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	(2,046)	(249)
Inventory	(607)	—
Accounts payable and accrued expenses	2,593	(134)
Right-of-use assets and operating lease liabilities	35	—
Deferred revenue	(30)	(265)
Deferred rent	—	(4)
Net cash used in operating activities	<u>(13,334)</u>	<u>(4,819)</u>
Cash flows from investing activities:		
Acquisition of Icon Bioscience Inc., net of cash acquired	—	(15,072)
Purchases of property and equipment	(182)	—
Net cash used in investing activities	<u>(182)</u>	<u>(15,072)</u>
Cash flows from financing activities:		
Proceeds from issuance of stock, net of issuance costs	—	9,266
Proceeds from issuance of long-term debt	35,000	15,000
Payment of debt issue costs	(894)	(905)
Payment of long-term debt principal	(20,000)	—
Payment of extinguishment of debt costs	(2,716)	—
Net settlement of stock units to satisfy statutory tax withholding	(20)	—
Proceeds from exercise of stock options	264	—
Net cash provided by financing activities	<u>11,634</u>	<u>23,361</u>
Effect of foreign exchange rate changes on cash and cash equivalents	—	—
Net (decrease) increase in cash, cash equivalents and restricted cash	(1,882)	3,470
Cash, cash equivalents and restricted cash at beginning of period	45,411	13,026
Cash, cash equivalents and restricted cash at end of period	<u>\$ 43,529</u>	<u>\$ 16,496</u>
Supplemental cash flow information:		
Cash interest paid	\$ 1,111	\$ —
Supplemental disclosure of non-cash investing and financing activities:		
Accrued acquisition costs	—	1,737
Accrued development milestone	—	15,000
Stock issuance costs	—	143
Debt issue costs	222	307
Accrued term loan exit fee	2,100	900
Fair value of second tranche purchase liability	—	4,734
Fair value of warrants issued with debt	—	360

See notes to consolidated financial statements

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

1. Operations and Basis of Presentation

Overview

The accompanying condensed consolidated financial statements of EyePoint Pharmaceuticals, Inc. and subsidiaries (collectively, the “Company”) as of March 31, 2019 and for the three months ended March 31, 2019 and 2018 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 the Company’s Transition Report on Form 10-K for the six months ended December 31, 2018. 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 six months ended December 31, 2018, 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 United States (“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 months ended March 31, 2019 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 has two products, YUTIQ™ and DEXYCU™, which were approved by the U.S. Food and Drug Administration (“FDA”) in October 2018 and February 2018, respectively.

YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg for intravitreal injection, was launched directly in the U.S. in February 2019. YUTIQ is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, which affects between 55,000 to 120,000 people in the U.S. each year and causes approximately 30,000 new cases of blindness every year, making it the third leading cause of blindness. Injected into the eye in an office visit, YUTIQ is a 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 up to 36 months. 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.

DEXYCU (dexamethasone intraocular suspension) 9%, for intraocular administration, was launched directly in the U.S. in March 2019. Indicated for the treatment of post-operative ocular 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 this indication. DEXYCU utilizes the Company’s proprietary Verisome® drug-delivery platform, which allows for a single intraocular injection that releases dexamethasone, a corticosteroid, over time. There were approximately 4.8 million cataract surgeries performed during 2018 in the U.S., with growth projected at an estimated annual rate of 8%, and the Company launched DEXYCU with a primary focus on its use following cataract surgery. The Company acquired DEXYCU in connection with its acquisition of Icon Bioscience, Inc. (“Icon”) in March 2018.

ILUVIEN® for diabetic macular edema (“DME”), the Company’s lead licensed product, is sold directly in the U.S. and several European Union (“EU”) countries by Alimera Sciences, Inc. (“Alimera”). In July 2017, the Company expanded its license agreement with Alimera to include the uveitis indication utilizing the Durasert technology in Europe, the Middle East and Africa (“EMEA”), which received European regulatory approval in March 2019 and, subject to obtaining pricing and reimbursement in each applicable country, will be marketed as ILUVIEN. Retisert®, one of the Company’s earlier generation products, was approved in 2005 by the FDA for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye and is sold in the U.S. by Bausch & Lomb Incorporated (“Bausch & Lomb”). The Company’s development programs are focused primarily on developing sustained release products that utilize its Durasert and Verisome technology platforms to deliver approved drugs to treat chronic diseases. The Company’s strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements.

Liquidity

The Company has a history of operating losses and has not had significant recurring cash inflows from revenue. The Company's operations have been financed primarily from sales of its equity securities, issuance of debt and a combination of royalty income and other fees received from collaboration partners. In February 2019, the Company refinanced its then existing \$20.0 million term loan and made an initial draw of \$35.0 million from a new term loan agreement (the "CRG Loan Agreement") with CRG Servicing LLC ("CRG") (see Note 9), resulting in incremental net proceeds of approximately \$11.4 million. In addition to total cash and cash equivalents of \$43.4 million at March 31, 2019, the Company received net proceeds of \$18.6 million on April 1, 2019 from the issuance of common stock ("Common Stock") (excluding approximately \$300,000 of additional unpaid share issue costs) (see Note 15). During April 2019, the Company exercised its option to draw an additional \$15.0 million under the CRG Loan Agreement and paid a \$15.0 million development milestone that was due to the former Icon security holders following the first commercial sale of DEXYCU (see Note 3). At April 30, 2019, the Company had \$56.9 million of cash and cash equivalents.

During the three months ended March 31, 2019, the Company commenced the U.S. launch of its first two commercial products, YUTIQ and DEXYCU. Executing a phased launch approach specifically for DEXYCU, many early patients have been injected at the end of cataract surgery through the Company's non-revenue samples program that has facilitated physician training. Overall, early sales of these products have been encouraging, and the Company is optimistic that existing cash and cash equivalents at April 30, 2019 and cash inflows from anticipated YUTIQ and DEXYCU product sales will be sufficient to fund the Company's current and planned operations through to the generation of positive cash flow in 2020.

The Company, however, has no history of direct commercialization of its products and management does not yet have sufficient historical evidence to assert that it is probable that the Company will receive sufficient revenues from its sales of YUTIQ and DEXYCU to fund operations. Actual cash requirements could differ from management's projections due to many factors, including the success of commercialization for YUTIQ and DEXYCU, the actual costs of these commercialization efforts, additional investments in research and development programs, competing technological and market developments and the costs of any strategic acquisitions and/or development of complementary business opportunities. Accordingly, the foregoing conditions, taken together, continue to raise substantial doubt about the Company's ability to continue as a going concern for one year from the issuance of these financial statements.

Recently Adopted and Recently Issued Accounting Pronouncements

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 accounting 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 February 2016, the FASB issued Accounting Standards Update ("ASU") No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842), Targeted Improvements*, which contains certain amendments to ASU 2016-02 intended to provide relief in implementing the new standard. 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 operating leases, with an exception provided for leases with a duration of one year or less. The Company adopted ASU 2016-02 on January 1, 2019 using the modified retrospective transition approach which, pursuant to ASU 2018-11, allows companies to recognize existing leases at the adoption date without requiring comparable period presentation. Comparative periods are presented in accordance with the previous guidance in Accounting Standards Codification ("ASC") 840, *Leases*.

In adopting the new standard, the Company elected to utilize the available package of practical expedients permitted under the transition guidance within the new standard, which does not require the reassessment of the following: (i) whether existing or expired arrangements are or contain a lease, (ii) the lease classification of existing or expired leases, and (iii) whether previous initial direct costs would qualify for capitalization under the new lease standard. Additionally, the Company elected to combine lease and non-lease components and to exclude leases with a term of 12 months or less. The adoption of this accounting standard resulted in recording operating lease ROU assets for three real estate operating lease arrangements and corresponding operating lease liabilities of \$3.5 million and \$3.7 million, respectively, as of January 1, 2019. The operating lease assets at adoption were lower than the operating lease liabilities because the balance of the Company's deferred rent liabilities at December 31, 2018, which represented lease incentives, was reclassified into operating lease assets. The adoption of the standard did not have a material effect on the Company's consolidated statements of operations or consolidated statements of cash flows.

Under Topic 842, the Company determines whether the arrangement is or contains a lease at inception. Operating leases are recognized on the consolidated balance sheets as ROU assets, current portion of lease liabilities and long-term lease liabilities. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected remaining lease term. For this purpose, the Company considers only payments that are fixed and determinable at the time of commencement. The operating lease ROU assets also include any lease payments made and adjustments for prepayments and lease incentives. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilized its incremental borrowing rate, which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2 to our audited financial statements included in the Company's Transition Report on Form 10-K for the six-month transition period ended December 31, 2018. There have been no subsequent changes to the Company's significant accounting policies except for the policies discussed below related to revenue and cost of goods sold for commercial product sales and for the adoption of the new accounting standard for lessee operating leases (see Note 1).

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Sales, value add, and other taxes collected on behalf of third parties are excluded from revenue.

Product sales, net — The Company began selling YUTIQ and DEXYCU in February and March 2019, respectively. The Company is currently selling YUTIQ and DEXYCU in the U.S. through a single third-party logistics provider (the "3PL"), which takes title to the goods. The 3PL distributes the products through a limited number of specialty distributors and specialty pharmacies (collectively the "Distributors"), with whom the Company has entered into formal agreements, for delivery to physician practices for YUTIQ and to hospital outpatient departments and ambulatory surgical centers for DEXYCU. The Company recognizes revenue on sales of products when the 3PL obtains control of the products, which occurs at a point in time, typically upon delivery. The Company expects to enter into arrangements with healthcare providers and payors that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's products.

Reserves for variable consideration — Product sales are recorded at the wholesale acquisition costs, net of applicable reserves for variable consideration. Components of variable consideration include trade discounts and allowances, provider chargebacks and discounts, payor rebates, product returns, and other allowances that are offered within contracts between the Company and its Distributors, payors, and other contracted purchasers relating to the Company's product sales. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified either as reductions of accounts receivable or as a current liability, depending on how the amount is to be settled. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, the Company adjusts these estimates, which would affect product revenue and earnings in the period such variances become known.

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Distribution fees — The Company compensates its Distributors for services explicitly stated in the Company's contracts and are recorded as a reduction of revenue in the period the related product sale is recognized.

Provider chargebacks and discounts — Chargebacks are discounts that represent the estimated obligations resulting from contractual commitments to sell products at prices lower than the list prices charged to our Distributors. These Distributors charge us for the difference between what they pay for the product and our contracted selling price. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability. Reserves for chargebacks consist of amounts that the Company expects to pay for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold under a contracted selling price, and chargebacks that Distributors have claimed, but for which the Company has not yet settled.

Government rebates — The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses on the condensed consolidated balance sheets. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Payor rebates — The Company expects to contract with certain private payor organizations, primarily insurance companies, for the payment of rebates with respect to utilization of its products. The Company estimates these rebates and records such estimates in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability.

Co-Payment Assistance: We offer co-payment assistance to commercially insured patients meeting certain eligibility requirements. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that we expect to receive associated with product that has been recognized as revenue.

Product returns — The Company generally offers a limited right of return based on its returned goods policy, which includes damaged product and remaining shelf life. The Company estimates the amount of its product sales that may be returned and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as reductions to trade receivables, net on the condensed consolidated balance sheets. The Company has not received any returns to date and believes that returns of its products will be minimal.

Cost of sales, excluding amortization of acquired intangible assets — Cost of sales, excluding amortization of acquired intangible assets, consist of costs associated with the manufacture of YUTIQ and DEXYCU, certain period costs, product shipping and, as applicable, royalty expense. The inventory costs for YUTIQ include purchases of various components, the active pharmaceutical ingredient (“API”) and internal labor and overhead for the product manufactured in the Company’s Watertown, MA facility. The inventory costs for DEXYCU include purchased components, the API and third-party manufacturing and assembly. Capitalization of inventory costs begins after FDA approval of the product. Prior thereto, inventory costs of products and product candidates are recorded as research and development expense, even if this inventory may later be sold as commercial product.

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 was 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 a debt financing and an equity financing, both of which closed concurrently with the Icon Acquisition (see Notes 9 and 10).

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 U.S., (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 (“CMS”) 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 DEXYCU consideration 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 U.S., 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, comprising 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 determined these payments did 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 purchase price was allocated to a single finite-lived intangible asset with an expected amortization life of approximately 13 years. The intangible asset is being amortized on a straight-line basis over that period. The acquisition did not have a net tax impact due to a full valuation allowance against the acquired net deferred tax assets.

Following the first commercial sale of DEXYCU, in April 2019 the Company paid the \$15.0 million development milestone to SRS. For the three months ended March 31, 2019, the Company accrued sales-based royalty expense of \$99,000 as a component of cost of sales.

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 DME, and Alimera assumed all financial responsibility for the development of the licensed products.

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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.

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 then Durasert three-year uveitis product candidate (currently marketed by the Company as YUTIQ in the U.S.) to Alimera for regulatory approval and distribution under its ILUVIEN trade name in Europe, the Middle East and Africa ("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.

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 YUTIQ, and Alimera filed a Type II variation in December 2017 for ILUVIEN for the treatment of non-infectious uveitis affecting the posterior segment of the eye in all seventeen European countries in which it previously received regulatory approval for ILUVIEN for DME. In March 2019, Alimera received regulatory approval for the uveitis indication. After the label for this new indication is finalized consistent with each such country's local requirements, Alimera has indicated that it plans to commercialize the product for this indication under its ILUVIEN trademark.

Under the Amended Alimera Agreement, sales-based royalties started at the rate of 2%. Commencing December 12, 2018, the sales-based royalty increased to 6% on aggregate calendar year net sales up to \$75 million and to 8% on any calendar year net sales 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 being 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) commencing from December 12, 2018 and 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) in March 2019, another \$5 million was cancelled upon Alimera's receipt of regulatory approval for ILUVIEN for the uveitis indication; 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. At March 31, 2019, the remaining recoverable balance of these commercialization losses was approximately \$9.7 million.

Revenue under the Amended Alimera Agreement totaled \$551,000 and \$234,000 for the three months ended March 31, 2019 and 2018, respectively. In addition to patent fee reimbursements in both periods, the Company recorded \$516,000 and \$183,000 of sales-based royalty income for the three months ended March 31, 2019 and 2018, respectively.

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 \$204,000 and \$221,000 for the three months ended March 31, 2019 and 2018, respectively. Accounts receivable from Bausch & Lomb totaled \$216,000 at March 31, 2019 and \$253,000 at December 31, 2018.

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 previous 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 2018. For each

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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, 2019, OncoSil has not received regulatory approval in any jurisdiction. In March 2019 the British Standards Institute's Clinical Oversight Committee advised OncoSil that insufficient clinical benefit had been demonstrated to recommend approval of its longstanding CE Mark application. OncoSil is awaiting confirmation of a follow-up meeting to discuss next steps. 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. No revenue was recognized related to the OncoSil agreement for each of the three months ended March 31, 2019 and 2018. As of March 31, 2019, no deferred revenue was recorded for this agreement.

Ocumenion Therapeutics

In November 2018, the Company entered into an exclusive license agreement with Ocumenion Therapeutics ("Ocumenion") for the development and commercialization of its three-year micro insert using the Durasert technology for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye in the greater China territory, which is comprised of China, Hong Kong, Macau and Taiwan. The Company received a one-time upfront payment of \$1.75 million from Ocumenion and is eligible to receive up to approximately \$10 million upon the achievement by Ocumenion of certain prescribed development, regulatory and commercial sales-based milestones. In addition, the Company is entitled to receive mid-single digit sales-based royalties.

Other than a fixed number of hours of technical assistance support to be provided at no cost by the Company, Ocumenion is responsible for all development, regulatory and commercial costs, including any additional technical assistance requested. Ocumenion has a first right of negotiation for an additional exclusive license to the Company's shorter-duration line extension candidate for this indication.

During the three months ended March 31, 2019, the remaining balance of \$30,000 attributable to the Company's technical assistance obligation was recognized as revenue.

Feasibility Study 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 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 feasibility study agreement. Revenues under feasibility study agreements totaled \$0 and \$470,000 for the three months ended March 31, 2019 and 2018, respectively. At March 31, 2019, no deferred revenue was recorded for any such agreements.

5. Intangible Assets

The reconciliation of intangible assets for the three months ended March 31, 2019 and 2018 was as follows (in thousands):

	Three Months Ended March 31,	
	2019	2018
Patented Technology		
Gross carrying cost at beginning of period	\$ 68,322	\$ 36,349
Acquisition of Icon Bioscience Inc.	—	31,973
Gross carrying cost at end of period	68,322	68,322
Accumulated amortization at beginning of period	(38,193)	(36,349)
Amortization expense	(615)	—
Accumulated amortization at end of period	(38,808)	(36,349)
Net book value at end of period	\$ 29,514	\$ 31,973

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The Company amortizes intangible assets with finite lives on a straight-line basis over their respective estimated useful lives. Amortization of intangible assets totaled \$615,000 for the three months ended March 31, 2019. The Company's previously acquired finite-lived intangible assets were fully amortized as of December 31, 2017.

In connection with the Icon Acquisition (see Note 3), the initial purchase price was attributed to the DEXYCU product intangible asset. This finite-lived intangible asset is being amortized on a straight-line basis over its expected remaining useful life of 12 years at the rate of approximately \$2.5 million per year. Amortization expense is included as component of cost of sales for the three months ended March 31, 2019.

6. Accrued Expenses

Accrued expenses consisted of the following at March 31, 2019 and December 31, 2018 (in thousands):

	March 31, 2019	December 31, 2018
Personnel costs	\$ 1,324	\$ 1,998
Clinical trial costs	823	798
Professional fees	372	571
Interest	—	343
Other	405	79
	<u>\$ 2,924</u>	<u>\$ 3,789</u>

7. Leases

On May 17, 2018, the Company amended the lease for its headquarters in Watertown, Massachusetts. The original five-year lease for approximately 13,650 square feet of combined office and laboratory space was set to expire in April 2019. Under the amendment, the Company leased an additional 6,590 square feet of rentable area of the building, with a commencement date of September 10, 2018. The amendment extended the term of the lease for the combined space through May 31, 2025. The landlord agreed to provide the Company a construction allowance of up to \$670,750 to be applied toward the aggregate work completed on the total space. The Company has an option to further extend the term of the lease for one additional five-year period. Per the terms of the lease agreement, the Company does not have a residual value guarantee. The Company previously provided a cash-collateralized \$150,000 irrevocable standby letter of credit as security for the Company's obligations under the lease, which was extended through the period that is four months beyond the expiration date of the amended lease. The Company will also be required to pay its proportionate share of certain operating costs and property taxes applicable to the leased premises in excess of new base year amounts.

In July 2017, the Company leased 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. In June 2018, the Company subleased an additional 1,381 square feet of adjoining space from Caladrius Biosciences, Inc. ("Caladrius") through May 2022. The Chief Executive Officer of Caladrius is a director of the Company. Per the terms of the lease and sublease agreements, the Company does not have any residual value guarantees.

The Company identified and assessed the following significant assumptions in recognizing its ROU assets and corresponding lease liabilities:

- As the Company's leases do not provide an implicit rate, the Company estimated the incremental borrowing rate in calculating the present value of the lease payments. The Company utilized the borrowing rate under its existing 5-year term loan facility (see Note 9) as the discount rate.
- Since the Company elected to account for each lease component and its associated non-lease components as a single combined component, all contract consideration was allocated to the combined lease component.

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- The expected lease terms include noncancelable lease periods. Renewal option periods have not been included in the determination of the lease terms as they are not deemed reasonably certain of exercise.
- Variable lease payments, such as common area maintenance, real estate taxes and property insurance are not included in the determination of the lease's ROU asset or lease liability.

As of March 31, 2019, the weighted average remaining term of the Company's operating leases was 5.9 years and the lease liabilities arising from obtaining ROU assets reflect a weighted average discount rate of 12.5%. Maturities of lease liabilities due under these operating lease agreements as of March 31, 2019 are as follows (in thousands):

Remainder of 2019	\$ 630
2020	867
2021	889
2022	849
2023	815
Thereafter	1,176
Total lease payments	5,226
Less imputed interest	(1,543)
Total operating lease liabilities	3,683
Less: current portion	417
Non-current portion	<u>\$ 3,266</u>

Operating lease expense recognized during the three months ended March 31, 2019 related to ROU assets was \$213,000, excluding \$9,000 of variable lease costs, and was included in general and administrative expense in the Company's statement of comprehensive loss. Cash paid for amounts included in the measurement of operating lease liabilities was \$178,000 for the three months ended March 31, 2019.

As previously disclosed in the Company's Transition Report on Form 10-K for the six months ended December 31, 2018, and, under the previous lease accounting standard, ASC 840, *Leases*, the Company's total future minimum lease payments under non-cancellable operating leases at December 31, 2018 were as follows (in thousands):

2019	\$ 826
2020	879
2021	895
2022	849
2023 and beyond	1,990
	<u>\$5,439</u>

8. Product Revenue Reserves and Allowances

To date, the Company's only source of product revenues has been from sales of YUTIQ and DEXYCU in the U.S., which it began shipping to its 3PL in February 2019 and March 2019, respectively.

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Net product revenues by product for the three months ended March 31, 2019 were as follows (in thousands):

	Three Months Ended March 31, 2019
YUTIQ	\$ 543
DEXYCU	684
Total product sales, net	<u>\$ 1,227</u>

The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2019 (in thousands):

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Beginning balance at December 31, 2018	\$ —	\$ —	\$ —	\$ —
Provision related to sales in the current period	189	76	—	265
Adjustments related to prior period sales	—	—	—	—
Credits and payments made	(8)	—	—	(8)
Ending balance at March 31, 2019	<u>\$ 181</u>	<u>\$ 76</u>	<u>\$ —</u>	<u>\$ 257</u>

All product revenue allowances and reserves at March 31, 2019 are recorded as a component of accrued expenses on the consolidated balance sheet.

9. Term Loan Agreements

SWK Credit Agreement

On March 28, 2018 (the “SWK Closing Date”), the Company entered into a Credit Agreement (the “SWK Credit Agreement”) among the Company, as borrower, SWK Funding LLC, as agent, and the lenders party thereto from time to time, providing for a senior secured term loan of up to \$20 million (the “SWK Loan”). On the SWK Closing Date, \$15 million of the SWK Loan was advanced (the “SWK Initial Advance”). The remaining \$5 million of the SWK Loan was advanced on June 26, 2018 (the “SWK Additional Advance”).

In connection with the SWK Loan, the Company issued a warrant (the “SWK Warrant”) to the Agent to purchase (a) 409,091 shares of Common Stock (the “Initial Advance Warrant Shares”) at an exercise price of \$1.10 per share and (b) 77,721 shares of Common Stock (the “Additional Advance Warrant Shares”) at an exercise price of \$1.93 per share (see Note 10). The SWK Warrant is exercisable (i) with respect to the Initial Advance Warrant Shares, any time on or after the SWK Closing Date until the close of business on the 7-year anniversary of the SWK Initial Advance and (ii) with respect to the Additional Advance Warrant Shares, any time on or after the closing of the SWK Additional Advance until the close of business on the 7-year anniversary of the SWK 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 total debt discount related to the SWK Initial Advance was \$2.1 million and was comprised of (1) \$1.8 million, which included a 1.5% upfront fee, a 6% exit fee (the “Exit Fee”) and legal and other transaction costs, which were ratably allocated to each of the two tranches of the SWK Loan based upon the total principal amount available to the Company under each tranche and (2) \$353,000 related to the aggregate fair value of the Initial Advance Warrant Shares and the Additional Advance Warrant Shares. This amount was being amortized as additional interest expense over the term of the SWK Loan using the effective interest rate method.

The total debt issue costs related to the SWK Additional Advance was \$299,000 and was comprised of the allocated portions of the 1.5% upfront fee and the Exit Fee. This amount was recorded as a prepaid expense to be amortized ratably from the SWK Closing Date through December 31, 2018. Through the date of the SWK Additional Advance, \$97,000 was amortized and the remaining balance of \$202,000 was reclassified to debt discount. Together with the 6% Exit Fee on the SWK Additional Advance and other transaction costs, total debt discount of \$652,000 associated with the SWK Additional Advance was to be amortized over the remaining life of the SWK Additional Advance portion of the SWK Loan using the effective interest rate method.

The SWK Loan was originally scheduled to mature on March 27, 2023 and bore interest at a per annum rate of the three-month LIBOR rate (subject to a 1.5% floor) plus 10.50%. On February 13, 2019, the Company repaid the SWK Loan in connection with the consummation of the CRG Loan Agreement (discussed below). In addition to repayment of the \$20 million principal balance, the Company paid (i) a \$1.2 million prepayment penalty, (ii) the \$1.2 million Exit Fee, (iii) accrued and unpaid interest of \$664,000 through that date and (iv) an additional make-whole interest payment of \$306,000 covering the additional period through what would have been the first anniversary of the SWK Loan. In connection with the prepayment of the SWK Loan, the Company recorded a loss on extinguishment of debt of \$3.8 million in the three months ended March 31, 2019. In addition to the prepayment penalty and make-whole interest payment amounts, the loss on extinguishment of debt included the write-off of the remaining balance of unamortized debt discount of approximately \$2.3 million.

CRG Term Loan Agreement

On February 13, 2019 (the “CRG Closing Date”), the Company entered into the CRG Loan Agreement among the Company, as borrower, CRG Servicing LLC, as administrative agent and collateral agent (the “Agent”), and the lenders party thereto from time to time (the “Lenders”), providing for a senior secured term loan of up to \$60 million (the “CRG Loan”). On the CRG Closing Date, \$35 million of the CRG Loan was advanced (the “CRG Initial Advance”). In April 2019, the Company exercised its option to borrow an additional \$15 million of the CRG Loan. The Company may draw up to an additional \$10 million, subject to achievement of prescribed three-month trailing product revenues of YUTIQ and DEXYCU on or before March 31, 2020.

The CRG Loan is due and payable on December 31, 2023 (the “Maturity Date”). The CRG Loan bears interest at a fixed rate of 12.5% per annum payable in arrears on the last business day of each calendar quarter. The Company is required to make quarterly, interest only payments until the Maturity Date. So long as no default has occurred and is continuing, the Company may elect on each applicable interest payment date to pay 2.5% of the 12.5% per annum interest as Paid In-Kind (“PIK”), whereby such PIK amount would be added to the aggregate principal amount and accrue interest at 12.5% per annum. At March 31, 2019, \$112,000 of PIK was added to the principal balance of the CRG Loan. In addition, the Company is required to pay an upfront fee of 1.5% of amounts borrowed under the CRG Loan (excluding any paid-in-kind amounts), which is payable as amounts are advanced under the CRG Loan. The Company will also be required to pay an exit fee equal to 6% of (i) the aggregate principal amount advanced and (ii) PIK amounts issued under the CRG Loan Agreement. In connection with the first draw under the CRG Loan Agreement, a 1.5% financing fee of \$525,000 and an expense reimbursement of \$350,000 were deducted from the net borrowing proceeds.

Upon the occurrence of a bankruptcy-related event of default, all amounts outstanding with respect to the CRG Loan become due and payable immediately, and upon the occurrence of any other Event of Default (as defined in the CRG Loan Agreement), all or any amounts outstanding with respect to the CRG Loan may become due and payable upon request of the Agent or majority Lenders. Subject to certain exceptions, the Company is required to make mandatory prepayments of the CRG Loan with the proceeds of assets sales and in the event of a change of control of the Company. In addition, the Company may make a voluntary prepayment of the CRG Loan, in whole or in part, at any time. All mandatory and voluntary prepayments of the CRG Loan are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs on or prior to December 31, 2019, an amount equal to 10% of the aggregate outstanding principal amount of the CRG Loan being prepaid, (ii) if prepayment occurs after December 31, 2019 and on or prior to December 31, 2020, 5% of the aggregate outstanding principal amount of the CRG Loan being prepaid and (iii) if prepayment occurs after December 31, 2020 and on or prior to December 31, 2021, an amount equal to 3% of the aggregate outstanding principal amount of the Loan being prepaid. No prepayment premium is due on any principal prepaid after December 31, 2021. Certain of the Company’s existing and future subsidiaries are guaranteeing the obligations of the Company under the CRG Loan Agreement. The obligations of the Company under the CRG Loan Agreement and the guarantee of such obligations are secured by a pledge of substantially all of the Company’s and the guarantors’ assets.

The CRG Loan Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on our and our subsidiaries’ abilities, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the CRG Loan Agreement contains the following financial covenants requiring us and the Guarantors to maintain:

- liquidity in an amount which shall exceed the greater of (i) \$5 million and (ii) to the extent we have incurred certain permitted debt, the minimum cash balance, if any, required of the Company by the creditors of such permitted debt; and

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- annual minimum product revenue from YUTIQ and DEXYCU: (i) for the twelve-month period beginning on January 1, 2019 and ending on December 31, 2019, of at least \$15 million, (ii) for the twelve-month period beginning on January 1, 2020 and ending on December 31, 2020, of at least \$45 million, (iii) for the twelve-month period beginning on January 1, 2021 and ending on December 31, 2021, of at least \$80 million and (iv) for the twelve-month period beginning on January 1, 2022 and ending on December 31, 2022, of at least \$90 million.

The total debt discount related to the CRG Initial Advance was approximately \$3.2 million and consisted of (i) the accrual of a \$2.1 million exit fee; (ii) the \$525,000 upfront fee; and (iii) \$591,000 of legal and other transaction costs. This amount is being amortized as additional interest expense over the term of the Loan using the effective interest rate method. For the period from the CRG Closing Date through March 31, 2019, amortization of debt discount totaled \$56,000.

10. Stockholders' Equity

2018 Equity Financing

On the SWK 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 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").

On the SWK 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 certain other accredited investors (collectively, the "Second Tranche Investors"), pursuant to which the Company, subject to the approval of the Company's stockholders, would offer and sell to the Second Tranche Investors an aggregate of approximately \$25.5 million of Units, with each Unit consisting of (a) one share of Common Stock and (b) one warrant to purchase a share of Common Stock (the "Second Tranche Transaction" and together with the First Tranche Transaction, the "Equity Transactions").

At a special meeting of stockholders held on June 22, 2018, the Company's stockholders approved the Second Tranche Transaction, following which, on June 25, 2018, the Company sold to the Second Tranche Investors an aggregate of 20,184,224 Units at a purchase price of \$1.265 per Unit for gross proceeds of approximately \$25.5 million, not including any proceeds that would be received from an exercise of the warrants (each a "Second Tranche Warrant", and collectively, the "Second Tranche Warrants"). In addition, the stockholders approved the adoption of an amendment to the Company's Certificate of Incorporation, as amended, to increase the number of authorized shares of Common Stock from 120,000,000 shares to 150,000,000 shares.

The Company determined that the shares of Common Stock issued in the First Tranche Transaction and the future obligation to issue Units in the Second Tranche Transaction were freestanding instruments. The Common Stock issued in the First Tranche Transaction was recorded as equity on the Company's balance sheet. The future obligation to issue Units in the Second Tranche Transaction was recorded as a liability on the Company's balance sheet, subject to remeasurement at fair value at each reporting period until settled.

The Company 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 SWK Closing 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 SWK Closing Date, with the residual amount allocated to the 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 each of the Common Stock issued in the First Tranche Transaction and the future obligation to issue Units in the Second Tranche Transaction, respectively, as of the SWK Closing Date. As of March 31, 2018, the fair value of the Second Tranche Transaction derivative liability was approximately \$6.9 million, and the Company recorded the \$2.2 million change in fair value for the quarter ended March 31, 2018.

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The future obligation to issue Units in the second tranche transaction was revalued immediately prior to the Second Tranche Transaction on June 25, 2018 and resulted in a change in fair value of approximately \$22.2 million. Upon consummation of the Second Tranche Transaction, the resulting derivative liability balance of approximately \$29.1 million was reclassified to equity.

The Company determined that the Second Tranche Warrants were considered puttable warrants that represented an obligation that was indexed to the repurchase of the Company's shares and could require a transfer of assets that required classification as derivative liabilities. The initial valuation of the Second Tranche Warrants on June 25, 2018 of approximately \$18.2 million was revalued at June 30, 2018 and then immediately prior to exercise and resulted in a change in fair value of \$1.6 million and \$18.9 million, respectively. The change in fair value immediately prior to exercise was determined as the excess of the closing share price of the Company's Common Stock on the respective dates on which exercise notices were submitted by each of the Second Tranche Investors over the \$1.43 exercise price. Upon exercise of the Second Tranche Warrants, the resulting derivative liability balance of \$38.7 million was reclassified to equity.

ATM Facility

In January 2019, the Company entered into an at-the-market ("ATM") program (the "ATM Program"). Pursuant to the ATM Program, under a Form S-3 shelf registration statement that was declared effective by the SEC in December 2018, 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 any future sales of such shares.

The Company did not sell any shares of its Common Stock pursuant to the ATM program during the three months ended March 31, 2019.

Warrants to Purchase Common Shares

The following table provides a reconciliation of warrants to purchase shares of the Company's Common Stock for the three months ended March 31, 2019 and 2018:

	Three Months Ended March 31,			
	2019		2018	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of period	486,812	\$ 1.23	—	\$ —
Issued	—	—	409,091	1.10
Expired	—	—	—	—
Balance and exercisable at end of period	<u>486,812</u>	<u>\$ 1.23</u>	<u>409,091</u>	<u>\$ 1.10</u>

In connection with the SWK Credit Agreement (see Note 9), the Company issued the SWK Warrant to purchase (i) 409,091 Initial Advance Warrant Shares on March 28, 2018 at an exercise price of \$1.10 per share with a seven-year term and (ii) 77,721 Additional Advance Warrant Shares on June 26, 2018 at an exercise price of \$1.93 per share with a seven-year term. At March 31, 2019 the weighted average remaining life of the warrants was approximately 6 years.

11. Share-Based Payment Awards

Equity Incentive Plan

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, 2019, a total of 170,996 shares were available for new awards.

Certain inducement awards, although not awarded under the 2016 Plan or the 2008 Plan, are subject to and governed by the terms and conditions of the 2016 Plan or 2008 Plan, as applicable.

Stock Options

The following table provides a reconciliation of stock option activity under the Company’s equity incentive plans and for inducement awards for the three months ended March 31, 2019:

	Number of options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2019	8,139,377	\$ 2.83		
Granted	973,744	2.62		
Exercised	(141,760)	1.86		
Forfeited	(6,800)	2.09		
Expired	(7,600)	3.73		
Outstanding at March 31, 2019	<u>8,956,961</u>	<u>\$ 2.82</u>	<u>7.59</u>	<u>\$ 78</u>
Exercisable at March 31, 2019	<u>3,262,457</u>	<u>\$ 3.55</u>	<u>5.19</u>	<u>\$ 16</u>

During the three months ended March 31, 2019, the Company granted 817,060 options to employees with ratable monthly vesting over four years, 43,000 options to employees with 25% vesting after one year followed by ratable monthly vesting over three years, 80,000 options to a newly appointed non-executive director with ratable annual vesting over three years, 13,500 options to employees with ratable annual vesting over three years and 20,184 options to one external consultant with 1-year cliff vesting. All option grants have a 10-year term. Options to purchase a total of 27,342 shares of the Company’s Common Stock vested during the three months ended March 31, 2019.

In determining the grant date fair value of option awards during the three months ended March 31, 2019, the Company applied the Black-Scholes option pricing model based on the following key assumptions:

Option life (in years)	5.50 - 6.08
Stock volatility	62% - 63%
Risk-free interest rate	2.47% - 2.63%
Expected dividends	0.0%

The following table summarizes information about employee, non-executive director and external consultant stock options for the three months ended March 31, 2019 (in thousands, except per share amount):

	Three Months Ended March 31, 2019
Weighted-average grant date fair value per share	\$ 1.54
Total cash received from exercise of stock options	264
Total intrinsic value of stock options exercised	62

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.

The following table provides a reconciliation of RSU activity under the 2016 Plan for the three months ended March 31, 2019:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2019	590,213	\$ 1.86
Granted	176,238	2.65
Forfeited	(1,300)	2.04
Nonvested at March 31, 2019	<u>765,151</u>	<u>\$ 2.04</u>

At March 31, 2019, the weighted average remaining vesting term of the RSUs was 1.24 years.

Performance-Based Stock Units

Performance Stock Units (“PSUs”) were previously awarded under the 2016 Plan to certain employees. The performance conditions associated with the PSU awards were 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 achieved, 50% of the PSUs associated with that performance condition vest at the achievement date and 50% 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 48,334 PSUs became subject only to a service-based condition with a vesting date of March 19, 2019. As a result of the achievement of the second performance condition on October 12, 2018, 96,668 PSUs vested at that date and the other 96,666 PSUs became subject only to a service-based condition with a vesting date of October 12, 2019.

In addition, there were 225,000 outstanding PSUs at March 31, 2019 and December 31, 2018 that were granted as inducement awards to the Company’s Chief Financial Officer in connection with his hire at August 1, 2018. The PSUs are subject to proportional vesting based on cumulative measurement over a 3-year period, with two-thirds of the award based upon the achievement of defined amounts of the Company’s product revenues through June 30, 2021 and one-third of the award based upon the net present value of each applicable business development transaction, as defined, through August 1, 2021 measured as of the date that each such transaction is consummated by the Company. The performance conditions of the PSUs were not deemed to be probable of occurrence at March 31, 2019 and, accordingly, no stock-based compensation has been recorded for the three months ended March 31, 2019.

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The following table provides a reconciliation of PSU activity for the three months ended March 31, 2019:

	Number of Performance Stock Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2019	370,000	\$ 2.01
Vested	(48,334)	1.52
Nonvested at March 31, 2019	<u>321,666</u>	<u>\$ 2.08</u>

The weighted-average remaining vesting term of the outstanding PSUs at March 31, 2019 under the 2016 Plan was approximately 6.4 months.

Deferred Stock Units

There were 35,418 non-vested deferred stock units (“DSUs”) issued and outstanding to the Company’s non-executive directors at each of March 31, 2019 and December 31, 2018. Each DSU vests one year from the date of grant. 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. At March 31, 2019, there were 55,000 vested DSUs that have not been settled in shares of the Company’s Common Stock.

At March 31, 2019, the weighted average remaining vesting term of the DSUs was approximately 2.75 months.

Market-Based Restricted Stock Units

At March 31, 2019 and December 31, 2018, there were 500,000 market-based RSUs (“market-based RSUs”) outstanding that were issued on September 15, 2016 as an inducement award to the Company’s President and CEO in connection with her hire. Subject to a service condition through September 15, 2019, the number of shares underlying the market-based RSUs that will vest will be based upon the determination of the 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 over that same 3-year period. The weighted average grant date fair value of the market-based RSUs of \$1.45 per share was determined using a Monte Carlo valuation model at the date of grant. Stock-based compensation has been recorded from the grant date on a straight-line basis.

Stock-Based Compensation Expense

The Company’s consolidated statements of comprehensive loss included total compensation expense from stock-based payment awards for the three months ended March 31, 2019 and 2018, as follows (in thousands):

	<u>Three Months Ended March 31,</u>	
	<u>2019</u>	<u>2018</u>
Compensation expense included in:		
Research and development	\$ 396	\$ 315
Sales and marketing	144	—
General and administrative	698	128
	<u>\$ 1,238</u>	<u>\$ 443</u>

At March 31, 2019, there was approximately \$5.1 million of unrecognized compensation expense related to outstanding equity awards under the 2016 Plan, the 2008 Plan and the inducement awards that is expected to be recognized as expense over a weighted-average period of approximately 1.60 years.

12. Fair Value Measurements

Assets

The following tables summarize the Company's assets carried at fair value measured on a recurring basis at March 31, 2019 and December 31, 2018 by valuation hierarchy (in thousands):

Description	March 31, 2019			
	Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 42,438	\$ 42,438	\$ —	\$ —
	<u>\$ 42,438</u>	<u>\$ 42,438</u>	<u>\$ —</u>	<u>\$ —</u>
Description	December 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	\$ 43,194	\$ 43,194	\$ —	\$ —
	<u>\$ 43,194</u>	<u>\$ 43,194</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, 2019 and December 31, 2018, substantially all of the Company's interest-bearing cash equivalent balances were concentrated in one U.S. Government institutional 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.

Derivative Liabilities

The Second Tranche Transaction was determined to be liability classified (see Note 10), which required 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 statement of operations. The purchase price for each share of Common Stock issuable in the Second Tranche Transaction was defined as the lower of (a) \$1.265 (which was 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 Common Stock on the Nasdaq Stock Market for the 20 trading days immediately prior to the closing of the Second Tranche Transaction; provided, however, that the purchase price could not be lower than \$0.88, which was a 20% discount to the First Tranche Purchase Price. The Second Tranche Warrants were 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 received written notice from the Company that CMS had announced that a new C-code had been established for DEXYCU. The exercise price of each Second Tranche Warrant was 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 could not be lower than \$0.88, which was a 20% discount to the First Tranche Purchase Price. Following written notice of CMS approval to the holders of the Second Tranche Warrants, the Second Tranche Warrants were exercised in September 2018 at a purchase price of \$1.43 per share for gross proceeds of \$28.9 million.

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This valuation was determined to be a level 3 valuation because it included 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 in a material increase or decrease in the fair value of the Second Tranche liability. Significant assumptions used to value this liability were 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 Warrant Shares (see Note 9) were determined to be liability classified, which required that the liability be measured at fair value each period with changes in fair value recorded as a component of other income (expense) in the condensed consolidated statement of comprehensive loss. The Additional Advance Warrant Shares were recorded as a liability at the SWK Closing Date and were remeasured at fair value at each reporting period until the date of the SWK Additional Advance. The aggregate fair value of the Additional Advance Warrant Shares at the SWK Closing Date was \$69,000. The Initial Advance Warrant Shares were recorded as equity on the Company's balance sheet at their relative fair value of \$284,000. Upon the closing of the SWK Additional Advance, the Additional Advance Warrant Shares were re-valued at \$87,000 and reclassified to equity.

This valuation was determined to be a level 3 valuation because it included 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 were 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 was determined by Level 3 inputs (in thousands):

Balance at December 31, 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>

Also included in the change in fair value was \$171,000 of transaction costs that were expensed in connection with the issuance of the derivative liabilities.

13. Contingencies

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.

14. 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 months ended March 31, 2019 and 2018 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:

	Three Months Ended March 31,	
	2019	2018
Stock options	8,956,961	5,955,155
Warrants	486,812	409,091
Restricted stock units	1,265,151	1,129,116
Performance stock units	321,666	241,668
Deferred stock units	35,418	67,500
	<u>11,066,008</u>	<u>7,802,530</u>

15. Subsequent Event

On April 1, 2019, the Company sold 10,526,500 shares of Common Stock in an underwritten public offering at a price of \$1.90 per share for gross proceeds of \$20.0 million. Underwriter discounts and other share issue costs are estimated to total approximately \$1.7 million.

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, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 potential advantages of DEXYCU™ and YUTIQ™ for the treatment of eye diseases;
- our ability to manufacture DEXYCU and YUTIQ, or any future products or product candidates in sufficient quantities and quality;
- our commercialization of DEXYCU and YUTIQ;
- our expectations regarding the timing of a line extension application for approval of our YUTIQ next-generation, shorter-duration treatment for non-infectious posterior segment uveitis;
- our ability to further develop sales and marketing capabilities, whether alone or with potential future collaborators;
- our optimism that existing cash and cash equivalents at April 30, 2019 and cash inflows from anticipated YUTIQ and DEXYCU product sales will be sufficient to fund our current and planned operations through to the generation of positive cash flow in 2020;
- 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., or Alimera, to commercialize ILUVIEN® for the treatment of non-infectious posterior uveitis in Europe, the Middle East and Africa;
- 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™ and Verisome® technology platforms;
- 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;
- 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; our ability to successfully produce sufficient commercial quantities of YUTIQ and DEXYCU and to successfully commercialize YUTIQ and DEXYCU in the U.S.; our ability to sustain and enhance an effective commercial infrastructure and enter into and maintain commercial agreements for the commercialization of YUTIQ and DEXYCU; the regulatory approval and successful release of our YUTIQ line extension shorter-duration treatment for non-infectious uveitis affecting the posterior segment of the eye; potential off-label sales of ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye; consequences of fluocinolone acetonide side effects for YUTIQ; consequences of dexamethasone side effects for DEXYCU; successful commercialization of,

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and receipt of revenues from, ILUVIEN for diabetic macular edema (“DME”); Alimera’s ability to obtain additional marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; Alimera’s ability to commercialize ILUVIEN for non-infectious uveitis affecting the posterior segment of the eye in its licensed territory; potential declines in Retisert® royalties; our ability to market and sell products; the success of current and future license agreements; termination or breach of current license agreements; our dependence on contract research organizations, contract sales 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; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission, or the SEC. 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 our Transition Report on Form 10-K for the six months ended December 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

Overview

We are a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products for the treatment of eye diseases. We have two products, YUTIQ™ and DEXYCU™, which were approved by the United States (“U.S.”) Food and Drug Administration (“FDA”) in October 2018 and February 2018, respectively. During the three months ended March 31, 2019, we launched both products directly in the U.S.

YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg for intravitreal injection, was launched directly in the U.S. in February 2019. YUTIQ is indicated for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, which affects between 55,000 to 120,000 people in the U.S. each year and causes approximately 30,000 new cases of blindness every year, making it the third leading cause of blindness. Injected into the eye in an office visit, YUTIQ is a micro-insert that delivers a corticosteroid to the back of the eye on a sustained constant (zero order release) basis for up to 36 months. 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.

DEXYCU (dexamethasone intraocular suspension) 9%, for intraocular administration, was launched directly in the U.S. in March 2019. Indicated for the treatment of post-operative ocular 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 this indication. DEXYCU utilizes our proprietary Verisome® drug-delivery platform, which allows for a single intraocular injection that releases dexamethasone, a corticosteroid, over time. There were approximately 4.8 million cataract surgeries performed during 2018 in the U.S., with growth projected at an estimated annual rate of 8%, and we launched DEXYCU with a primary focus on its use following cataract surgery. We acquired DEXYCU in connection with its acquisition of Icon Bioscience, Inc. (“Icon”) in March 2018.

ILUVIEN® for diabetic macular edema (“DME”), our lead licensed product, is sold directly in the U.S. and several European Union (“EU”) countries by Alimera Sciences, Inc. (“Alimera”). In July 2017, we expanded our license agreement with Alimera to include the uveitis indication utilizing the Durasert technology in Europe, the Middle East and Africa (“EMEA”), which received European regulatory approval in March 2019 and, subject to obtaining pricing and reimbursement in each applicable country, will be marketed as ILUVIEN. Retisert®, one of our earlier generation products, was approved in 2005 by the FDA for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye and is sold in the U.S. by Bausch & Lomb Incorporated (“Bausch &

Lomb”). Our development programs are focused primarily on developing sustained release products that utilize its Durasert and Verisome technology platforms to deliver approved drugs to treat chronic diseases. Our strategy includes developing products independently while continuing to leverage its technology platforms through collaborations and license agreements.

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

Recent Developments

Recent developments and ongoing activities regarding the commercialization of YUTIQ include:

- YUTIQ received a preliminary recommendation from the Centers for Medicare & Medicaid Services (CMS) for a specific J-code through the Healthcare Common Procedure Coding System (HCPCS) which would become effective January 1, 2020.
- Ten Key Account Managers (KAMs) have been engaged, who are dedicated to calling predominantly on uveitis specialists across the U.S.
- Since the February 2019 launch of YUTIQ, approximately 95% of the top decile of uveitis specialists have been visited by the ten KAMs, and over 100 YUTIQ orders have been shipped for use in patients.
- Over 300 benefit investigations for YUTIQ procedures have been received.
- As of April 30, 2019, YUTIQ has been included in nine academic formularies and is pending inclusion for an additional eleven.
- As of April 30, 2019, our market access initiatives have resulted in over 93% of commercial lives covered, over 75% of Medicare Advantage lives covered and 95% of Medicare Fee-For-Service lives covered.

Recent developments and ongoing activities regarding the commercialization of DEXYCU include:

- 34 KAMs have been engaged, who are dedicated to the promotion of DEXYCU, and have focused on a phased launch program to ensure proper physician training for the preparation, application and administration of DEXYCU.
- Since the March 2019 launch of DEXYCU, nearly 200 surgeons in more than 150 ambulatory surgical centers (ASCs) have completed the training/certification program and are now able to purchase DEXYCU.
- As of April 30, 2019, over 1,200 patients have been injected with DEXYCU, primarily via our sampling program.
- As of April 30, 2019, over 2,000 medical professionals and office staff have been called on to discuss DEXYCU.
- As of April 30, 2019, our market access initiatives have resulted in over 90% of commercial lives covered, over 75% of Medicare Advantage lives covered and 100% of Medicare Fee-For-Service lives covered.

At the 2019 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in Vancouver, British Columbia, 36-month efficacy and safety data supporting YUTIQ was presented in an oral session entitled, “Treatment of Non-infectious Uveitis that Affects the Posterior Segment with a Single Intravitreal Fluocinolone Acetonide Insert (FAi) – 3-year Results.” The 36-month follow up data of the Phase 3 clinical trial of YUTIQ showed a 56.3% recurrence rate of uveitis eye flares, significantly lower than eyes treated with sham (92.9%). The p-value was <0.001. 19.5% of YUTIQ treated eyes needed the assistance of adjunctive intraocular/periocular injection medication for uveitic inflammation compared to 69.0% for sham treated eyes. 34.5% of YUTIQ treated eyes needed the assistance of an adjunctive systemic steroid or immunosuppressant compared to 50.0% for sham treated eyes. Intraocular pressure (IOP) lowering drops were used in 42% of YUTIQ treated eyes and 33% of sham treated eyes with IOP lowering surgeries performed in 6% of YUTIQ treated eyes and 12% of sham treated eyes. Safety and side effects were consistent with those reported for previous analyses of earlier timepoints. These durable 36-month results continue to reinforce the potential of YUTIQ as a long-acting treatment option for patients suffering from this chronic disease.

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At the 2019 American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Administrators (ASOA) Annual Meeting in San Diego, California, data supporting DEXYCU was presented in a paper session entitled, “Effect of Dexamethasone Intraocular Suspension 9% on IOP after Cataract Surgery: Results of Two Phase 3 Studies.” An analysis of the IOP data from two Phase 3 studies of DEXYCU showed that the IOP effect of DEXYCU was comparable to short-term topically administered prednisolone acetate or placebo in cataract surgery patients. Mean IOP was only slightly elevated, to approximately 19 and 18 mmHg at postoperative Day 1 in the DEXYCU and prednisolone acetate arms, respectively, and it returned to baseline in both arms by Day 3. The proportion of patients at each measured IOP category in both studies were similar between the DEXYCU and control group cohorts. These data further support DEXYCU’s safety profile for the treatment of post-operative inflammation.

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 Transition Report on Form 10-K for the six months ended December 31, 2018, we set forth our critical accounting policies and estimates, which included revenue recognition and recognition of expense in outsourced clinical trial agreements. During the three months ended March 31, 2019, we began selling commercial products and consider reserves for variable consideration related to product sales to be a critical accounting estimate. See Note 2 of the notes to our unaudited condensed consolidated financial statements contained in this quarterly report on Form 10-Q for a description of our accounting policies and estimates for reserves for variable consideration related to product sales.

Results of Operations

Three Months Ended March 31, 2019 Compared to Three Months Ended March 31, 2018:

	Three Months Ended March 31,		Change	
	2019	2018	Amounts	%
(In thousands except percentages)				
Revenues:				
Product sales, net	\$ 1,227	\$ —	\$ 1,227	na
Collaborative research and development	65	524	(459)	(88)%
Royalty income	720	404	316	78%
Total revenues	<u>2,012</u>	<u>928</u>	<u>1,084</u>	<u>117%</u>
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	330	—	330	na
Research and development	3,797	3,325	472	14%
Sales and marketing	7,311	—	7,311	na
General and administrative	4,610	2,281	2,329	102%
Amortization of acquired intangible assets	615	—	615	na
Total operating expenses	<u>16,663</u>	<u>5,606</u>	<u>10,727</u>	<u>197%</u>
Loss from operations	<u>(14,651)</u>	<u>(4,678)</u>	<u>(9,973)</u>	<u>(213)%</u>
Other income (expense):				
Interest and other income	243	25	218	872%
Interest expense	(1,020)	—	(1,020)	na
Loss on extinguishment of debt	(3,810)	—	(3,810)	na
Change in fair value of derivative liability	—	(2,325)	2,325	na
Other expense, net	<u>(4,587)</u>	<u>(2,300)</u>	<u>(2,287)</u>	<u>(99)%</u>
Net loss	<u>\$ (19,238)</u>	<u>\$ (6,978)</u>	<u>\$ (12,260)</u>	<u>(176)%</u>

Product Sales, net

Product sales, net represents the gross sales of DEXYCU and YUTIQ less provisions for product sales allowances and accruals. We commenced U.S. commercial sales of YUTIQ in February 2019 and net sales totaled \$543,000 for the quarter ended March 31, 2019. We commenced commercial sales of DEXYCU in March 2019 and net sales totaled \$684,000 for the quarter ended March 31, 2019. We had no product revenue during the three months ended March 31, 2018. We expect significant increases in product sales by quarter during the remainder of fiscal 2019.

Collaborative Research and Development

Collaborative research and development revenues decreased by 88%, or \$459,000 to \$65,000 for the three months ended March 31, 2019 compared to \$524,000 for the three months ended March 31, 2018. This decrease was attributable primarily to the absence in the current period of \$465,000 in revenues recognized from a feasibility study agreement, partially offset by recognition of the remaining \$30,000 of deferred revenue associated with the upfront Ocumension license fee.

Royalty Income

Royalty income increased by \$316,000, or 78%, to \$720,000 for the three months ended March 31, 2019 compared to \$404,000 for the three months ended March 31, 2018. The increase was attributable primarily to a combination of an increase in the net sales-based royalty rate from 2% to 4% and higher ILUVIEN net sales under the Amended Alimera Agreement. We expect Retisert royalty income to decline.

Cost of Sales, Excluding Amortization of Acquired Intangible Assets

Cost of sales, excluding amortization of acquired intangible assets, of approximately \$330,000 for the three months ended March 31, 2019 consisted of (i) costs associated with the manufacturing of YUTIQ and DEXYCU, certain period costs and product shipping costs and (ii) accrued royalty expense on DEXYCU net sales payable to the former Icon security holders. We expensed manufacturing costs as research and development expenses in the periods prior to FDA approval of the products. In the fourth quarter of 2018, we began capitalizing inventory costs for YUTIQ and DEXYCU manufactured in preparation for our launch in the United States. We had no cost of sales for the three months ended March 31, 2018.

Research and Development

Research and development expenses increased by \$472,000, or 14%, to \$3.8 million for the three months ended March 31, 2019 from \$3.3 million for the same period in the prior year. This increase was attributable primarily to (i) a \$768,000 increase in personnel and related expenses for the build-out of our medical affairs group and expansion of regulatory and quality staffing, including \$81,000 of stock-based compensation, and (ii) a \$263,000 increase for medical affairs program expenses, including advisory board meetings and pharmacovigilance, partially offset by decreases of (i) \$494,000 of contract research organization costs for our YUTIQ Phase 3 clinical development program and (ii) \$196,000 of consulting fees, attributable primarily to our prior year YUTIQ NDA submission.

Sales and Marketing

With the commercial launch of DEXYCU and YUTIQ, we continued the build-out of our commercial infrastructure and marketing activities during the first quarter of fiscal 2019. Sales and marketing expense, which totaled \$7.3 million in the three months ended March 31, 2019, consisted primarily of (i) \$3.0 million related to our contract sales organization which includes 10 YUTIQ and 34 DEXYCU key account managers, (ii) \$2.0 million of marketing program and agency costs, (iii) approximately \$1.5 million of personnel and related costs, and (iv) \$258,000 of professional services primarily related to development of our distribution channel and market access.

General and Administrative

General and administrative expenses increased by \$2.3 million, or 102%, to \$4.6 million for the three months ended March 31, 2019 from \$2.3 million for the same period in the prior year. This increase was attributable primarily to (i) a \$1.3 million increase in personnel and related expenses related senior management additions in finance, legal, human resources, information technology and business development, as well as other new hires, including \$570,000 of stock-based compensation, (ii) a \$417,000 increase in consulting services, primarily for corporate compliance and business development, and (iii) a \$218,000 increase in legal, audit and other professional fees.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets totaled \$615,000 for the three months ended March 31, 2019. This amount was attributable to the DEXYCU product intangible asset that resulted from the Icon Acquisition (see Note 3).

Interest (Expense) Income

Interest expense totaled \$1.0 million for the three months ended March 31, 2019, which included \$140,000 of amortization of debt discount and \$112,000 of non-cash payment-in-kind interest expense. During the period, we extinguished the SWK Loan and established a new term loan facility with CRG (see Note 9). There was no interest expense in the three months ended March 31, 2018.

Interest income from amounts invested in an institutional money market fund increased to \$243,000 for the three months ended March 31, 2019 compared to \$25,000 in the prior year quarter, due primarily to significantly higher interest-bearing assets and higher money market interest rates.

Loss on Extinguishment of Debt

Repayment of the SWK Loan in February 2019 resulted in a \$3.8 million loss on extinguishment of debt, which consisted of (i) a \$2.3 million write-off of the remaining balance of unamortized debt discount; (ii) a \$1.2 million prepayment penalty; and (iii) a \$306,000 make-whole interest payment covering the period from the date of the loan repayment to what would have been the first anniversary of the original loan closing date, or March 28, 2019.

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 on March 28, 2018, subject to remeasurement 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.

Liquidity and Capital Resources

We have had a history of operating losses and an absence of significant recurring cash inflows from revenue, and at March 31, 2019 we had a total accumulated deficit of \$427.7 million. Our operations have been financed primarily from sales of our equity securities, issuance of debt and a combination of royalty income and other fees received from collaboration partners.

Financing Activities

In February 2019, we refinanced our then existing \$20.0 million term loan with SWK Funding LLC (“SWK Loan”) and made an initial draw of \$35.0 million from a new term loan agreement (the “CRG Loan Agreement”) with CRG Servicing LLC (“CRG”) (see Note 9), resulting in incremental net proceeds of approximately \$11.4 million. In addition to total cash and cash equivalents of \$43.4 million at March 31, 2019, we received net proceeds of \$18.6 million on April 1, 2019 from the issuance of 10,526,500 shares of our common stock (“Common Stock”) (excluding approximately \$300,000 of additional unpaid share issue costs) (see Note 15). During April 2019, we exercised an option to draw an additional \$15.0 million under the CRG Loan Agreement and paid a \$15.0 million development milestone that was due to the former Icon security holders following the first commercial sale of DEXYCU. At April 30, 2019, the Company had \$56.9 million of cash and cash equivalents.

Pursuant to the terms of the CRG Loan Agreement, subject to achieving product net revenue from YUTIQ and DEXYCU of at least \$25.0 million during any three-month period ending on or before March 31, 2020, we are entitled to borrow up to an additional \$10.0 million.

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The CRG Loan is due and payable on December 31, 2023 (the “Maturity Date”). The CRG Loan bears interest at a per annum rate (subject to increase during an event of default) equal to 12.5%, of which 2.5% may be paid in-kind at the election of the Company, so long as no default or event of default under the CRG Loan Agreement has occurred and is continuing. The Company is required to make interest only payments on a quarterly basis until the Maturity Date. The Company will also be required to pay an exit fee equal to 6% of the aggregate principal amounts advanced (including any paid-in-kind amounts) under the CRG Loan Agreement.

Subject to certain exceptions, we are required to make mandatory prepayments of the CRG Loan with the proceeds of assets sales and in the event of a change of control of our Company. In addition, we may make a voluntary prepayment of the CRG Loan, in whole or in part, at any time. All mandatory and voluntary prepayments of the CRG Loan are subject to the payment of prepayment premiums as follows: (i) if prepayment occurs on or prior to December 31, 2019, an amount equal to 10% of the aggregate outstanding principal amount of the CRG Loan being prepaid, (ii) if prepayment occurs after December 31, 2019 and on or prior to December 31, 2020, 5% of the aggregate outstanding principal amount of the CRG Loan being prepaid and (iii) if prepayment occurs after December 31, 2020 and on or prior to December 31, 2021, an amount equal to 3% of the aggregate outstanding principal amount of the CRG Loan being prepaid. No prepayment premium is due on any principal prepaid after December 31, 2021.

Certain of the Company’s existing and future subsidiaries, including the Guarantors, are guaranteeing the obligations of us under the CRG Loan Agreement. Our obligations under the CRG Loan Agreement and the guarantee of such obligations are secured by a pledge of substantially all of our and the Guarantors’ assets.

The CRG Loan Agreement contains affirmative and negative covenants customary for financings of this type, including limitations on our and our subsidiaries’ abilities, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions and enter into affiliate transactions, in each case, subject to certain exceptions. In addition, the CRG Loan Agreement contains the following financial covenants requiring us and the Guarantors to maintain:

- liquidity in an amount which shall exceed the greater of (i) \$5 million and (ii) to the extent we have incurred certain permitted debt, the minimum cash balance, if any, required of the Company by the creditors of such permitted debt; and
- annual minimum product revenue from YUTIQ and DEXYCU: (i) for the twelve-month period beginning on January 1, 2019 and ending on December 31, 2019, of at least \$15 million, (ii) for the twelve-month period beginning on January 1, 2020 and ending on December 31, 2020, of at least \$45 million, (iii) for the twelve-month period beginning on January 1, 2021 and ending on December 31, 2021, of at least \$80 million and (iv) for the twelve-month period beginning on January 1, 2022 and ending on December 31, 2022, of at least \$90 million.

Future Funding Requirements

During the three months ended March 31, 2019, we commenced the U.S. launch of our first two commercial products, YUTIQ and DEXYCU. Executing a phased launch approach specifically for DEXYCU, many early patients have been injected at the end of cataract surgery through the Company’s non-revenue samples program that has facilitated physician training. Overall, early sales of these products have been encouraging, and we are optimistic that existing cash and cash equivalents at April 30, 2019 and cash inflows from anticipated YUTIQ and DEXYCU product sales will be sufficient to fund our current and planned operations through to the generation of positive cash flow in 2020.

While we are optimistic that we will have enough capital to sustain operations through to the generation of positive cash flow in 2020, actual cash requirements may differ from projections and will depend on many factors, including, but not limited to:

- the success of our U.S. direct commercialization of DEXYCU for the treatment of postoperative ocular inflammation including, among other things, patient and physician acceptance of DEXYCU and our ability to obtain adequate coverage and reimbursement for DEXYCU;
- the success of our U.S. direct commercialization of YUTIQ for the treatment of non-infectious uveitis affecting the posterior segment of the eye including, among other things, patient and physician acceptance of YUTIQ and our ability to obtain adequate coverage and reimbursement for YUTIQ;

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- the cost of commercialization activities for DEXYCU and YUTIQ, including product manufacturing, marketing, sales and distribution;
- whether and to what extent we internally fund, whether and when we initiate, and how we conduct other product development programs;
- payments we receive under any new 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;
- whether and when we acquire new technologies, products or businesses;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing any patent claims; and
- changes in our operating plan, resulting in increases or decreases in our need for capital.

In addition, we have no history of direct commercialization of any products and management does not yet have sufficient historical evidence to assert that it is probable that we will receive sufficient revenues from sales of YUTIQ and DEXYCU to fund operations. Accordingly, the foregoing conditions, taken together, continue to raise substantial doubt about our ability to continue as a going concern for one year from the issuance of these financial statements.

We do not know whether additional capital will be available if and 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 not know the extent to which we will receive funds from the commercialization of YUTIQ or DEXYCU. If we seek to sell our equity securities 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. 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, independent commercialization of YUTIQ and DEXYCU, 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. Additionally, we may never become profitable, or if we do, we may not be able to sustain profitability on a recurring basis.

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

	Three Months Ended		Change
	March 31,		
	2019	2018	
Net loss:	<u>\$ (19,238)</u>	<u>\$ (6,978)</u>	<u>\$ (12,260)</u>
Changes in operating assets and liabilities	(55)	(652)	597
Other adjustments to reconcile net loss to cash flows from operating activities	5,959	2,811	3,148
Net cash used in operating activities	<u>\$ (13,334)</u>	<u>\$ (4,819)</u>	<u>\$ (8,515)</u>
Net cash used in investing activities	<u>\$ (182)</u>	<u>\$ (15,072)</u>	<u>\$ 14,890</u>
Net cash provided by financing activities	<u>\$ 11,634</u>	<u>\$ 23,361</u>	<u>\$ (11,727)</u>

Operating cash outflows for the three months ended March 31, 2019 totaled \$13.3 million, primarily due to our net loss of \$19.2 million, reduced by \$6.0 million of non-cash expenses, which included a \$3.8 million loss on extinguishment of our SWK Loan, \$1.2 million of stock-based compensation and \$615,000 of amortization of the DEXYCU finite-lived intangible asset.

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Operating cash outflows for the three months ended March 31, 2018 totaled \$4.8 million, primarily due to our net loss of \$7.0 million, reduced by \$2.8 million of non-cash expenses, which included a \$2.3 million change in fair value of derivative liability and \$443,000 of stock-based compensation

Net cash used in investing activities for the three months ended March 31, 2019 consisted of \$182,000 of purchases of property and equipment. Net cash used in investing activities for the three months ended March 31, 2018 consisted 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 financing activities for the three months ended March 31, 2019 totaled \$11.6 million and consisted of the following:

- (i) \$34.1 million of net proceeds from the initial drawdown under the CRG Loan Agreement, net of debt issue costs; and
- (ii) \$264,000 of proceeds from the exercise of stock options; partially offset by
- (iii) \$22.7 million repayment of the SWK Loan, which included principal of \$20.0 million, a \$1.2 million prepayment penalty, a \$1.2 million exit fee and \$306,000 of make-whole interest.

Net cash provided by financing activities for the three months ended March 31, 2018 totaled \$23.4 million and 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; and
- (ii) \$14.1 million of net proceeds from the initial drawdown under SWK Loan, net of issue costs.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of March 31, 2019 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, 2019, we had cash and cash equivalents of \$43.4 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.

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, 2019. 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

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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, 2019, 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, 2019, 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

There have been no material changes to the risk factors previously disclosed in Part I, “Item 1A, Risk Factors” of our Transition Report on Form 10-K for the six months ended December 31, 2018, which was filed with the SEC on March 18, 2019.

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

None

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

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Item 6. Exhibits

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
1.1	Underwriting Agreement, dated March 28, 2019, by and between EyePoint Pharmaceuticals, Inc. and Guggenheim Securities, LLC	8-K	04/01/19	1.1
3.1	Certificate of Incorporation of pSivida Corp.	8-K12G3	06/19/08	3.1
3.2	Certificate of Amendment of the Certificate of Incorporation of pSivida Corp.	10-K	09/13/17	3.2
3.3	Certificate of Amendment of the Certificate of Incorporation of pSivida Corp.	8-K	04/02/18	3.1
3.4	Certificate of Amendment of Certificate of Incorporation, as amended, of EyePoint Pharmaceuticals, Inc.	8-K	06/27/18	3.1
3.5	By-Laws of EyePoint Pharmaceuticals, Inc.	10-K	09/18/18	3.5
3.6	Amendment No. 1 to the By-Laws of EyePoint Pharmaceuticals, Inc.	8-K	11/06/18	3.1
10.1	At Market Issuance Sales Agreement, dated January 18, 2019, by and between EyePoint Pharmaceuticals, Inc. and B. Riley FBR, Inc.	8-K	01/18/19	10.1
10.2	Term Loan Agreement, dated February 13, 2019, among EyePoint Pharmaceuticals, Inc., as Borrower, EyePoint Pharmaceuticals US, Inc. and Icon Bioscience, Inc., as Subsidiary Guarantors, and CRG Servicing LLC, as Administrative Agent and Collateral Agent	8-K	02/19/19	10.1
10.3	Fee Letter, dated February 13, 2019, by and between EyePoint Pharmaceuticals, Inc. and CRG Servicing LLC	8-K	02/19/19	10.2
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) of the Securities Exchange Act, as amended, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
32.1**	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
32.2**	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
101	The following materials from EyePoint Pharmaceuticals' Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Comprehensive Loss; (iii) Consolidated Statements of Stockholders' Equity; (iv) Consolidated Statements of Cash Flows; and (v) Notes to Condensed Consolidated Financial Statements.			

* Filed herewith

** Furnished herewith

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.

Date: May 10, 2019

EyePoint Pharmaceuticals, Inc.

By: /s/ Nancy Lurker

Name: Nancy Lurker

Title: President and Chief Executive Officer

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, 2019

/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, David Price, 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, 2019

/s/ David Price

Name: David Price

Title: Chief Financial 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, 2019, 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, 2019

/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, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, David Price, Chief Financial 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, 2019

/s/ David Price

Name: David Price

Title: Chief Financial Officer
(Principal Financial Officer)