

**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 June 30, 2020

OR

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

For the transition period from _____ to _____

COMMISSION FILE NUMBER 000-51122

EyePoint Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

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)

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

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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

There were 125,217,066 shares of the registrant's common stock, \$0.001 par value, outstanding as of July 30, 2020.

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Item 1. Unaudited Financial Statements

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

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 22,814	\$ 22,214
Accounts and other receivables, net	7,350	11,368
Prepaid expenses and other current assets	5,895	5,997
Inventory	3,773	2,138
Total current assets	39,832	41,717
Property and equipment, net	412	357
Operating lease right-of-use assets	2,852	3,078
Intangible assets, net	26,439	27,669
Restricted cash	150	150
Total assets	\$ 69,685	\$ 72,971
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 3,882	\$ 4,192
Accrued expenses	5,131	6,832
Deferred revenue	—	15
Other current liabilities	573	481
Total current liabilities	9,586	11,520
Long-term debt	50,259	47,223
Operating lease liabilities - noncurrent	2,626	2,898
Other long-term liabilities	3,026	3,000
Total liabilities	65,497	64,641
Contingencies (Note 14)		
Stockholders' equity:		
Preferred stock, \$.001 par value, 5,000,000 shares authorized, no shares issued and outstanding	—	—
Common stock, \$.001 par value, 300,000,000 and 150,000,000 shares authorized at June 30, 2020 and December 31, 2019, respectively; 125,197,899 and 109,417,322 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	125	109
Additional paid-in capital	494,633	472,667
Accumulated deficit	(491,410)	(465,286)
Accumulated other comprehensive income	840	840
Total stockholders' equity	4,188	8,330
Total liabilities and stockholders' equity	\$ 69,685	\$ 72,971

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Product sales, net	\$ 3,706	\$ 6,705	\$ 8,393	\$ 7,932
License and collaboration agreement	35	5	2,055	70
Royalty income	381	500	1,163	1,220
Total revenues	<u>4,122</u>	<u>7,210</u>	<u>11,611</u>	<u>9,222</u>
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	502	706	1,482	1,035
Research and development	3,276	3,955	8,129	7,753
Sales and marketing	6,089	7,284	14,214	14,595
General and administrative	4,792	4,815	9,152	9,425
Amortization of acquired intangible assets	615	615	1,230	1,230
Total operating expenses	<u>15,274</u>	<u>17,375</u>	<u>34,207</u>	<u>34,038</u>
Loss from operations	<u>(11,152)</u>	<u>(10,165)</u>	<u>(22,596)</u>	<u>(24,816)</u>
Other income (expense):				
Interest and other income, net	8	266	62	509
Interest expense	(1,806)	(1,599)	(3,590)	(2,619)
Loss on extinguishment of debt	—	—	—	(3,810)
Total other expense, net	<u>(1,798)</u>	<u>(1,333)</u>	<u>(3,528)</u>	<u>(5,920)</u>
Net loss	<u>\$ (12,950)</u>	<u>\$ (11,498)</u>	<u>\$ (26,124)</u>	<u>\$ (30,736)</u>
Net loss per share - basic and diluted	<u>\$ (0.10)</u>	<u>\$ (0.11)</u>	<u>\$ (0.22)</u>	<u>\$ (0.30)</u>
Weighted average shares outstanding - basic and diluted	<u>124,771</u>	<u>106,238</u>	<u>120,151</u>	<u>100,847</u>
Net loss	\$ (12,950)	\$ (11,498)	\$ (26,124)	\$ (30,736)
Foreign currency translation adjustments	—	1	—	1
Comprehensive loss	<u>\$ (12,950)</u>	<u>\$ (11,497)</u>	<u>\$ (26,124)</u>	<u>\$ (30,735)</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 March 31, 2019	95,554,228	\$ 96	\$ 446,673	\$ (427,731)	\$ 839	\$ 19,877
Net loss	—	—	—	(11,498)	—	(11,498)
Other comprehensive income	—	—	—	—	1	1
Issuance of stock, net of issue cost	10,526,500	10	18,333	—	—	18,343
Exercise of stock options	25,000	—	44	—	—	44
Vesting of stock units	192,064	—	(53)	—	—	(53)
Stock-based compensation	—	—	1,496	—	—	1,496
Balance at June 30, 2019	<u>106,297,792</u>	<u>\$ 106</u>	<u>\$ 466,493</u>	<u>\$ (439,229)</u>	<u>\$ 840</u>	<u>\$ 28,210</u>
Balance at March 31, 2020	124,741,832	\$ 125	\$ 493,969	\$ (478,460)	\$ 840	\$ 16,474
Net loss	—	—	—	(12,950)	—	(12,950)
Vesting of stock units	456,067	—	(71)	—	—	(71)
Stock-based compensation	—	—	735	—	—	735
Balance at June 30, 2020	<u>125,197,899</u>	<u>\$ 125</u>	<u>\$ 494,633</u>	<u>\$ (491,410)</u>	<u>\$ 840</u>	<u>\$ 4,188</u>

	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, 2019	95,372,236	95	445,192	(408,493)	839	37,633
Net loss	—	—	—	(30,736)	—	(30,736)
Other comprehensive income	—	—	—	—	1	1
Issuance of stock, net of issue cost	10,526,500	10	18,333	—	—	18,343
Exercise of stock options	166,760	1	307	—	—	308
Vesting of stock units	232,296	—	(73)	—	—	(73)
Stock-based compensation	—	—	2,734	—	—	2,734
Balance at June 30, 2019	<u>106,297,792</u>	<u>\$ 106</u>	<u>\$ 466,493</u>	<u>\$ (439,229)</u>	<u>\$ 840</u>	<u>\$ 28,210</u>
Balance at January 1, 2020	109,417,322	\$ 109	\$ 472,667	\$ (465,286)	\$ 840	\$ 8,330
Net loss	—	—	—	(26,124)	—	(26,124)
Issuance of stock, net of issue costs	15,000,000	15	19,975	—	—	19,990
Employee stock purchase plan	161,660	1	186	—	—	187
Vesting of stock units	618,917	—	(90)	—	—	(90)
Stock-based compensation	—	—	1,895	—	—	1,895
Balance at June 30, 2020	<u>125,197,899</u>	<u>\$ 125</u>	<u>\$ 494,633</u>	<u>\$ (491,410)</u>	<u>\$ 840</u>	<u>\$ 4,188</u>

See notes to consolidated financial statements

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

	Six Months Ended	
	June 30	
	2020	2019
Cash flows from operating activities:		
Net loss	\$ (26,124)	\$ (30,736)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Amortization of intangible assets	1,230	1,230
Depreciation of property and equipment	88	78
Amortization of debt discount	348	270
Non-cash interest expense	647	406
Loss on extinguishment of debt	—	3,810
Stock-based compensation	1,895	2,734
Changes in operating assets and liabilities:		
Accounts receivable and other current assets	4,472	(10,681)
Inventory	(1,635)	(1,392)
Accounts payable and accrued expenses	(2,342)	3,826
Right-of-use assets and operating lease liabilities	(30)	44
Deferred revenue	(15)	(30)
Net cash used in operating activities	<u>(21,466)</u>	<u>(30,441)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(42)	(207)
Net cash used in investing activities	<u>(42)</u>	<u>(207)</u>
Cash flows from financing activities:		
Proceeds from issuance of stock, net of issuance costs	19,990	18,343
Proceeds under paycheck protection program loan	2,041	—
Proceeds from issuance of long-term debt	—	50,000
Payment of debt issue costs	—	(1,341)
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	(90)	(46)
Proceeds from exercise of stock options and employee stock purchase plan	187	308
Payment of contingent development milestone	—	(15,000)
Principal payments on finance lease obligations	(20)	—
Net cash provided by financing activities	<u>22,108</u>	<u>29,548</u>
Effect of foreign exchange rate changes on cash and cash equivalents	—	—
Net increase (decrease) in cash, cash equivalents and restricted cash	600	(1,100)
Cash, cash equivalents and restricted cash at beginning of period	22,364	45,411
Cash, cash equivalents and restricted cash at end of period	\$ 22,964	\$ 44,311
Supplemental cash flow information:		
Cash interest paid	\$ 1,299	\$ 1,175
Supplemental disclosure of non-cash investing and financing activities:		
Accrued term loan exit fee	—	3,000

See notes to consolidated financial statements

1. Operations and Basis of Presentation

Overview

The accompanying condensed consolidated financial statements of EyePoint Pharmaceuticals, Inc. and subsidiaries (collectively, the “Company”) as of June 30, 2020 and for the three and six months ended June 30, 2020 and 2019 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 Annual Report on Form 10-K for the year ended December 31, 2019. In the opinion of management, these statements have been prepared on the same basis as the audited consolidated financial statements as of and for the year ended December 31, 2019, 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 and six months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the entire fiscal year or any future period.

The Company is a pharmaceutical company committed to developing and commercializing innovative ophthalmic products for the treatment of serious eye disorders. The Company has two products, YUTIQ® and DEXYCU®, which were approved by the U.S. Food and Drug Administration (“FDA”) in 2018.

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 60,000 to 100,000 people in the U.S. each year and causes approximately 30,000 new cases of blindness annually, making it the third leading cause of blindness. Injected into the vitreous humor during a physician office visit, YUTIQ delivers a micro-dose of a corticosteroid 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 that can deliver drug 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 locally as a single dose at the conclusion 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 technology that allows for a single intraocular injection that releases dexamethasone, a corticosteroid, over time. There were approximately 3.8 million cataract surgeries performed during 2018 in the U.S. 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 (the “Icon Acquisition”).

ILUVIEN® for diabetic macular edema (“DME”), the Company’s 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 is being marketed as ILUVIEN, subject to obtaining pricing and reimbursement in each applicable country.

EYP-1901 is being developed by the Company as a potential single dose, 6-month therapy for the treatment of wet age-related macular degeneration (“wAMD”) with future potential indications in diabetic retinopathy (“DR”) and retinal vein occlusion (“RVO”). EYP-1901 utilizes our bioerodible Durasert technology and vorolanib, an anti-VEGF tyrosine kinase inhibitor (“TKI”). Vorolanib has previously been studied in human clinical trials as an oral therapy and is anticipated to be delivered as an intra-vitreous treatment in EYP-1901. The Company completed initial animal pharmacokinetic and toxicology studies and initiated a GLP toxicology study in March 2020 to support the anticipated filing of an Investigational New Drug (“IND”) application with the FDA by the end of 2020. A Phase 1 clinical trial is expected to follow upon acceptance of the IND by the FDA.

YUTIQ50 is being developed by the Company as a potential 6-month dosing option for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. The Company has consulted with the FDA and identified a clinical pathway for a supplemental new drug application (“sNDA”) filing that involves a clinical trial of a small study, randomized 2:1. The Company is currently evaluating the timeline and investment requirements for the initiation of this trial.

Effects of the COVID-19 Coronavirus Pandemic

The outbreak of the COVID-19 Coronavirus Pandemic (the “Pandemic”) in March 2020 has had and will likely continue to have, a material and adverse impact on the Company’s business, including as a result of measures that the Company, other businesses, and government have and will likely continue to take. This includes a significant impact on cash flows from expected revenues due to the closure of ambulatory surgery centers for DEXYCU and a significant reduction in physician office visits impacting YUTIQ. These closures precipitated the restructuring of the Company’s commercial organization that was announced on April 1, 2020 along with a reduction in planned spending for the calendar year. Due to these impacts and measures, the Company has experienced a material adverse impact on its revenues, financial condition and cash flows in the second quarter of 2020. The Company is currently unable to fully determine its future impact on the Company’s business. The Company expects these factors to continue to adversely impact the Company’s revenues, financial condition and cash flows but the extent and duration of that impact is uncertain at this time. The Company is monitoring the Pandemic and its potential effect on the Company’s financial position, results of operations and cash flows. This uncertainty could have an impact in future periods on certain estimates used in the preparation of the Company’s quarterly financial results, including reserves for variable consideration related to product sales, realizability of certain receivables, assessment for excess or obsolete inventory, and impairment of long-lived assets. Uncertainty around the extent and duration of the Pandemic, and any future related financial impact cannot be reasonably estimated at this time.

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 license fees, milestone payments, royalty income and other fees received from its collaboration partners. In the first quarter of 2019, the Company commenced the U.S. launch of its first two commercial products, YUTIQ and DEXYCU. However, the Company has not received sufficient revenues from its product sales to fund operations and the Company does not expect revenues from its product sales to generate sufficient funding to sustain its operations in the near-term. As of June 30, 2020, the Company has had recurring operating losses since its inception and has an accumulated deficit of approximately \$491.4 million and working capital of \$30.2 million. The Company had cash and cash equivalents of \$22.8 million at June 30, 2020.

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. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

The Company’s plans that are intended to mitigate those conditions include continuing to fulfill its funding needs through cash inflows from revenue of YUTIQ and DEXYCU product sales, licensing and research collaboration transactions, at-the-market program (the “ATM Program”) financing, additional capital raises and other arrangements. The Company’s plans also include the continuation of expense reductions to conserve cash in response to a material adverse impact on the Company’s revenue of YUTIQ and DEXYCU product sales due to a significant decline in product demand associated with shut-downs of customer facilities and postponements of elective surgical procedures and physician office visits in response to the Pandemic. The Company believes that its cash and cash equivalents of \$22.8 million at June 30, 2020 and expected cash inflows from its product sales, and royalty agreements, coupled with cash conservation activities will enable the Company to fund its current and planned operations into 2021. There can be no assurance that the Company will receive the additional funding from any of these potential resources and, even if such cash proceeds are received, that such proceeds would be sufficient to support the Company’s current operating plan for the next twelve months from the date of issuance of these financial statements. 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, the continued effect of the Pandemic on our business and the medical community, 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.

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 December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740) (“ASU 2019-12”): Simplifying the Accounting for Income Taxes*. The amendments simplify the accounting for income taxes by removing certain exceptions for recognizing deferred taxes for investments, performing intraperiod allocation and calculating income taxes in interim periods. The ASU also adds guidance to reduce complexity in certain areas, including recognizing deferred taxes for tax goodwill and allocating taxes to members of a consolidated group. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. Early adoption is permitted, including adoption in interim or annual periods for which financial statements have not yet been issued. This standard will be effective for the Company in the first quarter of its fiscal year ending December 31, 2021. The Company is currently evaluating the impact the adoption of this update will have on its consolidated financial statements.

2. Summary of Significant Accounting Policies

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, Revenue from Contracts with Customers (“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 sells YUTIQ and DEXYCU to a limited number of specialty distributors and specialty pharmacies (collectively the “Distributors”) in the U.S., 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 its products when Distributors obtain control of the products, which occurs at a point in time, typically upon delivery. In addition to agreements with Distributors, the Company also enters into arrangements with healthcare providers, ambulatory surgical centers, and payors that provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts with respect to their purchase of the Company’s products from Distributors.

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 product revenue and accounts receivable or 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 the Company’s estimates. If actual results in the future vary from the estimates, the Company adjusts these estimates, which would affect product revenue and earnings in the period such variances become known.

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 the Company's Distributors. These Distributors charge the Company for the difference between what they pay for the product and the Company's 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 and other current liabilities 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 contracts 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 — The Company offers 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 the Company expects 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.

License and collaboration agreement revenue — The Company analyzes each element of its license and collaboration arrangements to determine the appropriate revenue recognition. The terms of the license agreement may include payment to the Company of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments at a point in time, typically upon fulfilling the delivery of the associated intellectual property to the customer.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price based on the estimated relative standalone selling prices of the promised products or services underlying each performance obligation. The Company determines standalone selling prices based on the price at which the performance obligation is sold separately. If the standalone selling price is not observable through past transactions, the Company estimates the standalone selling price taking into account available information such as market conditions and internally approved pricing guidelines related to the performance obligations.

The Company recognizes sales-based milestone payments as revenue upon the achievement of the cumulative sales amount specified in the contract in accordance with ASC 606-10-55-65. For those milestone payments which are contingent on the occurrence of particular future events, the Company determines that these need to be considered for inclusion in the calculation of total consideration from the contract as a component of variable consideration using the most-likely amount method. As such, the Company assesses each milestone to determine the probability and substance behind achieving each milestone. Given the inherent uncertainty associated with these future events, the Company will not recognize revenue from such milestones until there is a high probability of occurrence, which typically occurs near or upon achievement of the event.

When determining the transaction price of a contract, an adjustment is made if payment from a customer occurs either significantly before or significantly after performance, resulting in a significant financing component. Applying the practical expedient in paragraph 606-10-32-18, the Company does not assess whether a significant financing component exists if the period between when the Company performs its obligations under the contract and when the customer pays is one year or less. None of the Company's contracts contained a significant financing component as of June 30, 2020.

Royalties — The Company recognizes revenue from license arrangements with its commercial partners’ net sales of products. Such revenues are included as royalty income. In accordance with ASC 606-10-55-65, royalties are recognized when the subsequent sale of the commercial partner’s products occurs. The Company’s commercial partners are obligated to report their net product sales and the resulting royalty due to the Company typically within 60 days from the end of each quarter. Based on historical product sales, royalty receipts and other relevant information, the Company recognizes royalty income each quarter and subsequently determines a true-up when it receives royalty reports and payment from its commercial partners. Historically, these true-up adjustments have been immaterial.

Research Collaborations— The Company recognizes revenue over the term of the statements of work under any funded research collaborations (including feasibility study agreements). 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 research collaborations (including feasibility study agreements).

Please refer to Note 3 for further details on the license and collaboration agreements into which the Company has entered and corresponding amounts of revenue recognized during the current and prior year periods.

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 for DEXYCU product revenue, product shipping and, as applicable, royalty expense. The inventory costs for YUTIQ include purchases of various components, the active pharmaceutical ingredient (“API”) and direct 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 a 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.

The Company accrued DEXYCU product revenue-based royalty expense of \$99,000 and \$0 for the three months ended June 30, 2020 and 2019, respectively, and \$616,000 and \$99,000 for the six months ended June 30, 2020 and 2019, respectively, as a component of cost of sales. \$0 and \$400,000 of accrued revenue-based royalty expense during the three and six months ended June 30, 2020 were related to the partnering income in connection with the acquisition of Icon Bioscience, Inc. in March 2018.

3. Revenue

Product Revenue Reserves and Allowances

The Company’s product revenues have been primarily from sales of YUTIQ and DEXYCU in the U.S., which it began shipping to its customers in February 2019 and March 2019, respectively.

Net product revenues by product for each of the three and six months ended June 30, 2020 and 2019, respectively, were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
YUTIQ	\$ 2,879	\$ 6,705	\$ 6,454	\$ 7,248
DEXYCU	827	—	1,939	684
Total product sales, net	\$ 3,706	\$ 6,705	\$ 8,393	\$ 7,932

The following table summarizes activity in each of the product revenue allowance and reserve categories for the six months ended June 30, 2020 and 2019, respectively (in thousands):

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Beginning balance at January 1, 2020	\$ 1,618	\$ 271	\$ 352	\$ 2,241
Provision related to sales in the current year	864	247	436	1,547
Adjustments related to prior period sales	(387)		50	(337)
Deductions applied and payments made	(1,185)	(400)	(324)	(1,909)
Ending balance at June 30, 2020	<u>\$ 910</u>	<u>\$ 118</u>	<u>\$ 514</u>	<u>\$ 1,542</u>

	Chargebacks, Discounts and Fees	Government and Other Rebates	Returns	Total
Beginning balance at January 1, 2019	\$ —	\$ —	\$ —	\$ —
Provision related to sales in the current year	877	76	187	1,140
Adjustments related to prior period sales	—	—	—	—
Deductions applied and payments made	(89)	—	—	(89)
Ending balance at June 30, 2019	<u>\$ 788</u>	<u>\$ 76</u>	<u>\$ 187</u>	<u>\$ 1,051</u>

Returns are recorded as a reduction of accounts receivable on the condensed consolidated balance sheets. Chargebacks, discounts and fees and rebates are recorded as a component of accrued expenses on the condensed consolidated balance sheets (See Note 6).

License and Collaboration Agreements and Royalty Income

Alimera

Pursuant to a licensing and development agreement, as amended, Alimera Sciences, Inc. has a worldwide exclusive license to make and sell ILUVIEN in return for royalties based on sales and patent fee reimbursements. Royalties income was \$381,000 and \$500,000 for the three months ended June 30, 2020 and 2019, respectively, and \$1.2 million and \$1.0 million for the six months ended June 30, 2020 and 2019, respectively.

Total revenue was \$386,000 and \$505,000 for the three months ended June 30, 2020 and 2019, respectively, and \$1.2 million and \$1.1 million for the six months ended June 30, 2020 and 2019, respectively.

Ocumension Therapeutics

In November 2018, the Company entered into an exclusive license agreement with Ocumension Therapeutics (“Ocumension”) 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 (YUTIQ in the U.S.) in Mainland China, Hong Kong, Macau and Taiwan. The Company received a one-time upfront payment of \$1.75 million from Ocumension and is eligible to receive up to (i) \$7.25 million upon the achievement by Ocumension of certain prescribed development and regulatory milestones, and (ii) \$3.0 million commercial sales-based milestones. In addition, the Company is entitled to receive mid-single digit sales-based royalties. Ocumension has also received a special approval by the Hainan Province People's Government to market this product for chronic, non-infectious posterior segment uveitis in the Hainan Bo Ao Lecheng International Medical Tourism Pilot Zone (“Hainan Pilot Zone”). In March 2019, the Company entered into a Memorandum of Understanding (“MOU”), pursuant to which, the Company will supply product for the clinical trials and Hainan Pilot Zone use. Paralleling to Ocumension’s normal registration process of the product with the Chinese Regulatory Authorities, the MOU modified the Company’s entitlement to the development and regulatory milestones of up to \$7.25 million under the license agreement to product supply milestones or development milestones, whichever comes first, totaling up to \$7.25 million. In August 2019, the Company began shipping this product to Ocumension.

The Company was required to provide a fixed number of hours of technical assistance support to Ocumension at no cost, which support has been completed and no future performance obligation exists. Ocumension is responsible for all development, regulatory and commercial costs, including any additional technical assistance requested. Ocumension has a first right of negotiation for an additional exclusive license to the Company’s shorter-duration line extension candidate for this indication.

In August 2019, the Company received a \$1.0 million development milestone payment from Ocumension

triggered by the approval of its Investigational New Drug (“IND”) in China for this program. The IND allows the importation of finished product into China for use in a clinical trial to support regulatory filing.

In January 2020, the Company entered into an exclusive license agreement with Ocumension for the development and commercialization in Mainland China, Hong Kong, Macau and Taiwan of DEXYCU for the treatment of post-operative inflammation following ocular surgery. Pursuant to the terms of the license agreement, the Company received upfront payments of \$2.0 million from Ocumension in February 2020 and will be eligible to receive up to (i) \$6.0 million upon the achievement by Ocumension of certain prescribed development and regulatory milestones, and (ii) \$6.0 million commercial sales-based milestones. In addition, the Company is entitled to receive mid-single digit sales-based royalties. In exchange, Ocumension will receive exclusive rights to develop and commercialize DEXYCU in Mainland China, Hong Kong, Macau and Taiwan, at its own cost and expense with the Company supplying product for clinical trials and commercial sale. In addition, Ocumension will receive a fixed number of hours of technical assistance support from the Company at no cost.

Other than a fixed number of hours of technical assistance support to be provided at no cost by the Company, Ocumension is responsible for all development, regulatory and commercial costs, including any additional technical assistance requested. During the three and six months ended June 30, 2020, the Company recognized \$30,000 and approximately \$2.0 million of license and collaboration revenue, respectively. As of June 30, 2020 and December 31, 2019, no deferred revenue was recorded for this agreement, respectively.

The Company recorded sales-based royalty expense of \$0 and \$400,000, respectively, during the three and six months ended June 30, 2020, with respect to partnering income in connection with the Icon acquisition in March 2018.

Research Collaborations

The Company from time to time enters into funded agreements to evaluate the potential use of its technology for sustained release of third-party drug candidates in the treatment of various diseases or conditions. Consideration received is generally recognized as revenue over the term of the research collaborations (including feasibility study agreements). 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 research collaborations (including feasibility study agreements). Revenue under research collaborations (including feasibility study agreements) was \$0 for each of the three months ended June 30, 2020 and 2019, respectively, and \$0 and \$15,000 for the six months ended June 30, 2020 and 2019, respectively. At June 30, 2020 and December 31, 2019, \$0 and \$15,000 deferred revenue was recorded for the research collaborations (including feasibility study agreements), respectively.

4. Inventory

Inventory consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Raw materials	\$ 1,375	\$ 1,476
Work in process	1,058	346
Finished goods	1,340	316
Total inventory	<u>\$ 3,773</u>	<u>\$ 2,138</u>

5. Intangible Assets

The reconciliation of intangible assets for the six months ended June 30, 2020 and 2019 was as follows (in thousands):

	June 30, 2020	June 30, 2019
Patented technologies		
Gross carrying cost at beginning of period	\$ 68,322	\$ 68,322
Gross carrying cost at end of period	68,322	68,322
Accumulated amortization at beginning of period	(40,653)	(38,193)
Amortization expense	(1,230)	(1,230)
Accumulated amortization at end of period	(41,883)	(39,423)
Net book value at end of period	<u>\$ 26,439</u>	<u>\$ 28,899</u>

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 and \$1.2 million for each of the three and six months ended June 30, 2020 and 2019, respectively.

In connection with the Icon Acquisition in March 2018, 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 10.75 years at the rate of approximately \$2.5 million per year. Amortization expense was reported as a component of cost of sales for the three and six months ended June 30, 2020 and 2019, respectively.

6. Accrued Expenses

Accrued expenses consisted of the following at June 30, 2020 and December 31, 2019 (in thousands):

	June 30, 2020	December 31, 2019
Personnel costs	\$ 2,709	\$ 3,263
Sales chargebacks, rebates and other revenue reserves	1,028	1,889
Professional fees	904	700
Clinical trial costs	—	345
Accrued restructuring charges	326	—
Other	164	635
	<u>\$ 5,131</u>	<u>\$ 6,832</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 Basking Ridge, 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 right-of-use ("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 7) 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.
- 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 June 30, 2020, the weighted average remaining term of the Company's operating leases was 4.7 years and the lease liabilities arising from obtaining ROU assets reflect a weighted average discount rate of 12.5%.

Supplemental balance sheet information related to operating leases as of June 30, 2020 and December 31, 2019 are as follows (in thousands):

	June 30, 2020	December 31, 2019
Other current liabilities - operating lease current portion	\$ 523	\$ 481
Operating lease liabilities – noncurrent portion	2,626	2,898
Total operating lease liabilities	\$ 3,149	\$ 3,379

Operating lease expense recognized was \$213,000 related to ROU assets, excluding \$9,000 of variable lease costs, during each of the three months ended June 30, 2020 and 2019, respectively, and \$427,000 related to ROU assets, excluding \$18,000 of variable lease costs, during each of the six months ended June 30, 2020 and 2019, respectively, and were 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 were \$215,000 and \$205,000 for the three months ended June 30, 2020 and 2019, and \$430,000 and \$383,000 for the six months ended June 30, 2020 and 2019, respectively.

The Company is a party to a finance lease for laboratory equipment. The equipment lease expires on December 18, 2021.

Supplemental balance sheet information related to the finance lease as of June 30, 2020 is as follows (in thousands):

	June 30, 2020	
Property and equipment, at cost	\$	100
Accumulated amortization		(26)
Property and equipment, net	\$	<u>74</u>
Other current liabilities – finance lease current portion	\$	50
Other long-term liabilities		26
Total finance lease liabilities	\$	<u>76</u>

The components of finance lease expense recognized during the three and six months ended June 30, 2020 related to ROU assets were \$13,000 and \$27,000, respectively. Interest on lease liabilities were \$2,000 and \$5,000, respectively, during the three and six months ended June 30, 2020. Cash paid for amounts included in the measurement of finance lease liabilities were operating cash flows of \$2,000 and \$4,000 during the three and six months ended June 30, 2020, and financing cash flows of \$12,000 and \$20,000 during the three and six months ended June 30, 2020. The Company has no finance lease in 2019.

As of June 30, 2020, the weighted average remaining term of the Company's finance lease was 1.5 years and the lease liabilities arising from obtaining ROU assets reflect a weighted average discount rate of 12.5%.

The Company's total future minimum lease payments under non-cancellable leases at June 30, 2020 were as follows (in thousands):

	Operating Leases		Finance Leases	
Remainder of 2020	\$	436	\$	28
2021		889		55
2022		849		—
2023		815		—
2024 and beyond		1,176		—
Total lease payments	\$	4,165	\$	83
Less imputed interest		(1,016)		(7)
Total	\$	<u>3,149</u>	\$	<u>76</u>

8. Term Loan Agreements

Paycheck Protection Program Loan

On April 8, 2020, the Company applied to Silicon Valley Bank (the "SVB") for a Paycheck Protection Program Loan (the "PPP Loan") of \$2.0 million that is administered by the U.S. Small Business Administration (the

“SBA”), under the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”). On April 22, 2020, the PPP Loan was approved and the Company received the PPP Loan proceeds.

The PPP Loan bears interest at a fixed rate of 1.0% per annum and has a two-year term that matures on April 21, 2022. Monthly principal and interest payments will commence on November 21, 2020. The PPP Loan may be forgiven partially or fully if the PPP Loan proceeds are used for covered payroll costs, rent and utility costs and the maintenance of employee and compensation levels.

The Paycheck Protection Program Flexibility Act of 2020 (the “PPP Flexibility Act”), enacted on June 5, 2020, amended the Paycheck Protection Program, among others, as follows: (i) extended the covered period from 8 weeks to the earlier of 24 weeks from the date the PPP Loan is originated and December 31, 2020, during which PPP funds needed to be expended in order to be forgiven. A borrower may submit a loan forgiveness application any time on or before the maturity date of the loan – including before the end of the covered period – if the borrower has used all of the loan proceeds for which the borrower is requesting forgiveness. (ii) at least 60% of PPP funds must be spent on payroll costs, with the remaining 40% available to spend on other eligible expenses. (iii) payments are deferred until the date on which the amount of forgiveness determined is remitted to the lender. If a borrower fails to seek forgiveness within 10 months after the last day of its covered period, then payments will begin on the date that is 10 months after the last day of the covered period. In addition, the PPP Flexibility Act modified the CARES Act by increasing the maturity date for loans made after the effective date from two years to a minimum maturity of five years from the date on which the borrower applies for loan forgiveness. Existing PPP loans made before the new legislation retain their original two-year term, but may be renegotiated between a lender and a borrower to match the 5-year term permitted under the PPP Flexibility Act.

Pursuant to an SVB announcement on June 23, 2020, SVB will inform its PPP borrowers directly when they can request loan forgiveness online. The Company intends to apply for full loan forgiveness when SVB starts to accept applications, subject to its additional guidance and change. No assurance is provided that the Company will obtain forgiveness of the PPP Loan in whole or in part.

The PPP Loan proceeds of \$2.0 million were recorded as a loan in accordance with ASC 470, *Debt*, and included in long-term debt in the Company’s balance sheet as of June 30, 2020. Accrued interest expense based on the stated interest rate of 1% per annum was \$4,000 for the three months ended June 30, 2020.

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”). The Company utilized the proceeds from the CRG Initial Advance for the repayment in full of all outstanding obligations under its prior credit agreement (the “SWK Credit Agreement”) with SWK Funding LLC (“SWK”). In April 2019, the Company exercised its option to borrow an additional \$15 million of the CRG Loan (the “CRG Second Advance”). The Company did not draw any additional funds under the CRG Loan by the final draw deadline of 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. Through June 30, 2020, total PIK amounts of \$647,000 have been 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 amounts advanced and (ii) PIK amounts issued, under the CRG Loan Agreement. In connection with the CRG Initial Advance, a 1.5% financing fee of \$525,000 and an expense reimbursement of \$350,000 were deducted from the net borrowing proceeds. In connection with the CRG Second Advance, a 1.5% financing fee of \$225,000 was 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 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 (ii) 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 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 the Company and the Guarantors to maintain:

- liquidity in an amount which shall exceed the greater of (i) \$5 million and (ii) to the extent the Company has 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.

In November 2019, CRG waived the financial covenant associated with the Company's revenue derived from sales of its products, DEXYCU and YUTIQ, for the twelve-month period ending December 31, 2019.

The total debt discount related to the CRG Loan was approximately \$4.3 million and consisted of (i) the accrual of a \$3.0 million exit fee; (ii) the \$750,000 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 CRG Loan using the effective interest rate method.

Amortization of debt discount under the CRG Loan totaled \$177,000 and \$130,000 for the three months ended June 30, 2020 and 2019, respectively, and \$348,000 and \$185,000 for the six months ended June 30, 2020 and 2019, respectively.

SWK Credit Agreement

On March 28, 2018 (the "SWK Closing Date"), the Company entered into the SWK Credit Agreement among the Company, as borrower, SWK, 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 Additional Advance Warrant Shares were recorded as a liability at the 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 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. The remaining \$14.6 million of the proceeds received were allocated to the SWK Initial Advance term loan. Upon the closing of the SWK Additional Advance in June 2018, the Additional Advance Warrant Shares were re-valued at \$87,000 and reclassified to equity.

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 in June 2018. 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. 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.

Amortization of debt discount under the SWK Loan totaled \$84,000 in the first quarter of 2019 through the SWK loan extinguishment date.

9. Stockholders' Equity

2020 Equity Financing

Share Offering

In February 2020, the Company sold 15,000,000 shares of common stock in an underwritten public offering at a price of \$1.45 per share for gross proceeds of \$21.75 million. Underwriter discounts and commissions and other share issue costs totaled approximately \$1.8 million.

At the Annual Meeting of Stockholders (the "Annual Meeting") held on June 23, 2020, the Company's stockholders approved the adoption of an amendment to the Company's Certificate of Incorporation, to increase the number of authorized shares of its Common Stock from 150,000,000 shares to 300,000,000 shares. The Company filed the Certificate of Amendment on June 23, 2020.

2019 Equity Financing

ATM Facility

In January 2019, the Company entered into an at-the-market program (the "ATM Program") with B. Riley FBR Inc. 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. On July 30, 2020, the Company notified B. Riley FBR Inc. that it was terminating the ATM Program in accordance with its terms, effective as of August 4, 2020.

The Company did not sell any shares of its Common Stock pursuant to the ATM program during each of the three and six months ended June 30, 2020 and 2019, respectively.

Share Offering

In April 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 commissions and other share issue costs totaled approximately \$1.7 million.

Warrants to Purchase Common Shares

The following table provides a reconciliation of fixed price warrants to purchase shares of the Company's Common Stock for the six months ended June 30, 2020 and 2019, respectively:

	Six Months Ended June 30,			
	2020		2019	
	Number of Warrants	Weighted Average Exercise Price	Number of Warrants	Weighted Average Exercise Price
Balance at beginning of period	486,812	\$ 1.23	486,812	\$ 1.23
Expired	—	—	—	—
Balance and exercisable at end of period	486,812	\$ 1.23	486,812	\$ 1.23

Pursuant to a credit agreement, 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 June 30, 2020, the weighted average remaining life of the warrants was approximately 4.79 years.

10. 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 the Company’s Annual Meeting of Stockholders held on June 25, 2019, the Company’s stockholders approved an amendment to the 2016 Plan to increase the number of shares authorized for issuance by 11,000,000 shares. At June 30, 2020, a total of approximately 5.8 million 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 six months ended June 30, 2020:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at January 1, 2020	10,909,800	\$ 2.52		
Granted	3,613,897	1.30		
Exercised	—	—		
Forfeited	(437,482)	1.84		
Expired	(413,865)	3.70		
Outstanding at June 30, 2020	<u>13,672,350</u>	<u>\$ 2.18</u>	<u>7.93</u>	<u>\$ —</u>
Exercisable at June 30, 2020	<u>5,689,656</u>	<u>\$ 2.74</u>	<u>6.47</u>	<u>\$ —</u>

In January 2019, the Company expanded the terms of its annual stock option grants to include vesting ratable monthly over four years, or with 25% vesting after one year followed by ratable monthly vesting over three years. Previously, the Company’s option grants generally had ratable annual vesting over three years, or 1-year cliff vesting. Nonemployee awards are granted similar to the Company’s employee awards. All option grants have a 10-year term. Options to purchase a total of 1,385,308 shares of the Company’s Common Stock vested during the six months ended June 30, 2020.

In determining the grant date fair value of option awards during the six months ended June 30, 2020, the Company applied the Black-Scholes option pricing model based on the following key assumptions:

Option life (in years)	5.5-6.02
Stock volatility	63.85%-66.9%
Risk-free interest rate	0.51%-2.51%
Expected dividends	0.0%

The following table summarizes information about employee, non-executive director and external consultant stock options for the six months ended June 30, 2020 (in thousands, except per share amount):

	Six Months Ended June 30, 2020
Weighted-average grant date fair value per share	\$ 0.76
Total cash received from exercise of stock options	—
Total intrinsic value of stock options exercised	—

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 six months ended June 30, 2020:

	Number of Restricted Stock Units	Weighted Average Grant Date Fair Value
Nonvested at January 1, 2020	786,899	\$ 1.83
Granted	1,437,750	1.29
Vested	(697,505)	1.53
Forfeited	(63,623)	1.85
Nonvested at June 30, 2020	<u>1,463,521</u>	<u>\$ 1.44</u>

At June 30, 2020, the weighted average remaining vesting term of the RSUs was 1.21 years.

Deferred Stock Units

There were no non-vested deferred stock units (“DSUs”) issued and outstanding to the Company’s non-executive directors at each of June 30, 2020 and December 31, 2019, respectively. 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 June 30, 2020, there were 45,001 vested DSUs that have not been settled in shares of the Company’s Common Stock.

Employee Stock Purchase Plan

On June 25, 2019, the Company’s stockholders approved the adoption of the EyePoint Pharmaceuticals, Inc. 2019 Employee Stock Purchase Plan (the “ESPP”) and authorized up to 1,100,000 shares of Common Stock reserved for issuance to participating employees. The ESPP allows qualified participants to purchase the Company’s Common Stock twice a year at 85% of the lesser of the average of the high and low sales price of the Company’s Common Stock on (i) the first trading day of the relevant offering period and (ii) the last trading day of the relevant offering period. The number of shares of the Company’s Common Stock each employee may purchase under this plan, when combined with all other employee stock purchase plans, is limited to the lower of an aggregate fair market value of \$25,000 during each calendar year, or 50,000 shares of the Company’s Common Stock in any one offering period. The first six month offering period under the ESPP began on August 1, 2019 and ended on January 31, 2020. As of June 30, 2020, 161,660 shares of the Company’s Common Stock were issued pursuant to the ESPP.

The Company estimated the fair value of the option component of the ESPP shares at the date of grant using a Black-Scholes valuation model. During the three and six months ended June 30, 2020, the compensation expense from ESPP shares was immaterial, respectively.

Stock-Based Compensation Expense

The Company's consolidated statements of comprehensive loss included total compensation expense from stock-based payment awards for each of the three and six months ended June 30, 2020 and 2019, respectively, as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Compensation expense included in:				
Research and development	\$ (49)	\$ 268	\$ 214	\$ 664
Sales and marketing	141	179	393	323
General and administrative	643	1,049	1,288	1,747
	<u>\$ 735</u>	<u>\$ 1,496</u>	<u>\$ 1,895</u>	<u>\$ 2,734</u>

At June 30, 2020, there was approximately 4.2 million of unrecognized compensation expense related to outstanding equity awards under the 2016 Plan, the 2008 Plan, the inducement awards and the ESPP that is expected to be recognized as expense over a weighted-average period of approximately 1.52 years.

11. In-License Agreement

Equinox Science, LLC

In February 2020, the Company entered into an Exclusive License Agreement with Equinox Science, LLC ("Equinox"), pursuant to which Equinox granted us an exclusive, sublicensable, royalty-bearing right and license to certain patents and other Equinox intellectual property to research, develop, make, have made, use, sell, offer for sale and import the compound vorolanib and any pharmaceutical products comprising the compound for the prevention or treatment of age-related macular degeneration, diabetic retinopathy and retinal vein occlusion using our proprietary localized delivery technologies, in each case, throughout the world except China, Hong Kong, Taiwan and Macau.

In consideration for the rights granted by Equinox, the Company (i) made a one time, non-refundable, non-creditable upfront cash payment of \$1.0 million to Equinox in February 2020, and (ii) agreed to pay milestone payments totaling up to \$50 million upon the achievement of certain development and regulatory milestones, consisting of (a) completion of a Phase II clinical trial for the Compound or a Licensed Product, (b) the filing of a new drug application or foreign equivalent for the Compound or a Licensed Product in the United States, European Union or United Kingdom and (c) regulatory approval of the Compound or a Licensed Product in the United States, European Union or United Kingdom.

The Company also agreed to pay Equinox tiered royalties based upon annual net sales of Licensed Products in the Territory. The royalties are payable with respect to a Licensed Product in a particular country in the Territory on a country-by-country and Licensed Product-by-Licensed Product basis until the later of (i) twelve years after the first commercial sale of such Licensed Product in such country and (ii) the first day of the month following the month in which a generic product corresponding to such Licensed Product is launched in such country (collectively, the "Royalty Term"). The royalty rates range from the high-single digits to low-double digits depending on the level of annual net sales. The royalty rates are subject to reduction during certain periods when there is no valid patent claim that covers a Licensed Product in a particular country.

The Company recorded \$0 million and \$1.0 million of R&D expense for the three and six months ended June 30, 2020 due to the early stage of its preclinical drug development studies.

12. Restructuring Charges

Fiscal Year 2020 Restructuring Plan

On April 1, 2020, the Company committed to and announced a restructuring plan (the "Plan") with regard to its commercial operations. The Plan is a result of decline in product demand associated with shut-downs of customer facilities and postponements of elective surgical procedures in response to the Pandemic. In connection with the Plan, the Company, among other things, downsized its current workforce, with reductions coming primarily from its external DEXYCU sales force and supporting commercial operations, as cataract surgery is considered a non-essential procedure due to the Pandemic. The Company recorded approximately \$590,000 of external DEXYCU

sales force personnel and employee severance for discretionary termination benefits during the second quarter ended June 30, 2020, upon notification of the affected external DEXYCU sales force personnel and employees in accordance with ASC 420, *Exit or Disposal Cost Obligations*. The charges of \$590,000 were recognized in the Company's operating results, of which \$542,000 and \$48,000 were included in sales and marketing expense and general and administrative expense, respectively. The Company expects the implementation of the Plan will be substantially completed by the end of fiscal 2020.

	Employee Severance and Benefits	Total
Beginning balance at March 31, 2020	\$ —	\$ —
Restructuring charge	590	590
Cash payments	(264)	(264)
Ending balance at June 30, 2020	<u>\$ 326</u>	<u>\$ 326</u>

13. Fair Value Measurements

The following tables summarize the Company's assets carried at fair value measured on a recurring basis at June 30, 2020 and December 31, 2019 by valuation hierarchy (in thousands):

Description	June 30, 2020			
	Total Carrying Value	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Assets:				
Cash equivalents	\$ 19,036	\$ 19,036	\$ —	\$ —
	<u>\$ 19,036</u>	<u>\$ 19,036</u>	<u>\$ —</u>	<u>\$ —</u>
Description	December 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	\$ 19,976	\$ 19,976	\$ —	\$ —
	<u>\$ 19,976</u>	<u>\$ 19,976</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 June 30, 2020 and December 31, 2019, 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.

The carrying amounts of accounts receivable, accounts payable and accrued expenses approximate fair value because of their short-term maturity.

The fair value of the Company's CRG Loan is determined using a discounted cash flow analysis based on market rates for observable similar instruments as of the condensed consolidated balance sheet dates. Accordingly, the fair value of the CRG Loan is categorized as Level 2 within the fair value hierarchy. The carrying value of the CRG Loan at June 30, 2020 was approximately \$51.2 million, and consisted of \$48.2 million of its carrying amount as reported in long-term debt, and \$3.0 million of debt exit fee as reported in other long-term liabilities of the

condensed consolidated balance sheet, respectively. The fair value of the CRG Loan was approximately \$51.0 million at June 30, 2020. The fair value of the CRG Loan approximated its carrying value at December 31, 2019.

14. 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.

U.S. Securities and Exchange Commission Subpoena

On May 14, 2020, the Company received a subpoena from the Division of Enforcement of the SEC seeking production of certain documents and information on topics including product sales and demand, revenue recognition and accounting in relation to product sales, product sales and cash projections, and related financial reporting, disclosure and compliance matters. The Company is cooperating fully in connection with this investigation. Based on procedures performed to date in relation to the Company's revenue recognition practices, the Company has not identified any accounting items that are not in accordance with GAAP. At this time, the Company is unable to predict the duration, scope or outcome of this matter or whether it could have a material impact on the Company's financial condition, results of operations or cash flow.

15. Net Loss per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period. For periods in which the Company reports net income, diluted net income per share is determined by adding to the basic weighted average number of common shares outstanding the total number of dilutive common equivalent shares using the treasury stock method, unless the effect is anti-dilutive. Potentially dilutive shares were not included in the calculation of diluted net loss per share for each of the three and six months ended June 30, 2020 and 2019, respectively, as their inclusion would be anti-dilutive.

Potential common stock equivalents excluded from the calculation of diluted earnings per share for each of the three and six months ended June 30, 2020 and 2019, respectively, because the effect would have been anti-dilutive were as follows:

	Three and Six Months Ended	
	June 30,	
	2020	2019
Stock options	13,672,350	11,552,639
ESPP	97,415	—
Warrants	486,812	486,812
Restricted stock units	1,463,521	1,376,364
Performance stock units	—	301,666
Deferred stock units	—	417
	<u>15,720,098</u>	<u>13,717,898</u>

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 extent to which our business, the medical community and the global economy will continue to be materially and adversely impacted by the effects of the COVID-19 coronavirus Pandemic or by other pandemics, epidemics or outbreaks;
- 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 continued commercialization of DEXYCU and YUTIQ;
- our ability to further develop sales and marketing capabilities, whether alone or with potential future collaborators;
- our expectations regarding the timing and clinical development of our product candidates, including EYP-1901 and YUTIQ50 ;
- our expectations to avoid the toxicity seen in the prior clinical studies of orally delivered vorolanib, a tyrosine kinase inhibitor (“TKI”) by delivering vorolanib locally using our bioerodible Durasert technology as EYP-1901 at a significantly lower total dose;
- the potential for EYP-1901, as a single dose six-month treatment for serious eye diseases including wet age-related macular degeneration (“wAMD”), with potential in diabetic retinopathy (“DR”) and retinal vein occlusion (“RVO”);
- our expectations regarding the timing and outcome of Good Laboratory Practices (“GLP”) toxicology studies for EYP-1901 to support the filing of an Investigational New Drug (“IND”) application with the FDA;
- our expectations regarding the timing and results of the Securities and Exchange Commission, or SEC, investigation;
- the potential for our PPP Loan to be forgiven in full;
- our ability to regain compliance with the listing requirements of the Nasdaq Global Market;
- our ability to further develop sales and marketing capabilities, whether alone or with potential future collaborators;
- our belief that our cash and cash equivalents of \$22.8 million at June 30 2020 and expected cash inflows under our product sales and royalty agreements, coupled with cash conservation activities will enable us to fund our current and planned operations into 2021;
- our ability to obtain additional capital in sufficient amounts and on terms acceptable to us, and the consequences of failing to do so;
- future expenses and capital expenditures;
- our expectations regarding the timing and design of our clinical development plans;
- our ability to establish or maintain collaborations and obtain milestone, royalty and/or other payments from any such collaborators;
- the ability of Alimera Sciences, Inc., (“Alimera”), to commercialize ILUVIEN® for the treatment of non-infectious uveitis affecting the posterior segment of the eye in Europe, the Middle East and Africa (the “EMEA”);
- 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® technologies;
- our expectations regarding our ability to obtain and adequately maintain sufficient intellectual property protection for DEXYCU, YUTIQ, EYP-1901 and YUTIQ50 and future product candidates, and to avoid claims of infringement of third-party intellectual property rights;
- the scope and duration of intellectual property protection;

- our expectation that we will continue to incur significant expenses and that our operating losses and our net cash outflows to fund operations will continue for the foreseeable future;
- the expected costs associated with termination benefits and the financial impact of the Plan and reduction in force;
- our plans to allocate our remaining DEXYCU commercial resources to high-volume ASCs in key regions, subject to the availability of such ASCs to perform elective cataract surgery upon the lifting of restrictions associated with the COVID-19 Pandemic; 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: the continued impact of the COVID-19 Pandemic on our business, the medical community and the global economy; the impact of the workforce reduction on our operations; the sufficiency of the PPP Loan to support our operations for a limited period of time; the duration, scope and outcome of the SEC investigation and its impact on our financial condition, results of operations and cash flows; our ability to regain compliance with the listing requirements of the Nasdaq Global market; the effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data; the timeliness of regulatory approval; 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, 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; 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 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and the supplementary risks set forth under Item 1A of this Quarterly Report on Form 10-Q 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 pharmaceutical company committed to developing and commercializing innovative ophthalmic products for the treatment of serious eye diseases. We have two products that were approved by the United States (“U.S.”) Food and Drug Administration (“FDA”) in 2018 and commercially launched in the U.S. during the first quarter of 2019. We also are developing a pipeline of product candidates utilizing our proprietary Durasert technology.

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg for intravitreal injection, was approved by the FDA in October 2018 and we commercially launched YUTIQ 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 60,000 to 100,000 people each year in the U.S., causes approximately 30,000 new cases of blindness every year and is the third leading cause of blindness. YUTIQ is a non-erodible intravitreal implant containing 0.18 mg fluocinolone acetonide (“FA”), designed to release FA at an initial rate of 0.25 mcg/day, and lasting for up to 36 months. Injected into the eye during a physician office visit, YUTIQ delivers a micro-dose of a corticosteroid to the back of the eye on a sustained nearly constant (zero order release) basis. YUTIQ utilizes our proprietary Durasert® sustained-release drug delivery technology that can deliver drugs for predetermined periods of time ranging from months to years.

DEXYCU® (dexamethasone intraocular suspension) 9%, for intraocular administration, was approved by the FDA in February 2018 for the treatment of post-operative ocular inflammation and commercially launched in the U.S. in March 2019 with a primary focus on its use immediately following cataract surgery. DEXYCU is administered as a single dose directly into the surgical site at the end of ocular surgery and is the first long-acting intraocular product approved by the FDA for the treatment of post-operative inflammation. DEXYCU utilizes our proprietary Verisome® drug-delivery technology, which allows for a single intraocular injection that releases dexamethasone, a corticosteroid, for up to 22 days. In 2018, there were approximately 3.8 million cataract surgeries performed in the U.S.

EYP-1901 is being developed as a potential single dose, 6-month therapy for the treatment of wet age-related macular degeneration (“wAMD”) with future potential indications in diabetic retinopathy (“DR”) and retinal vein occlusion (“RVO”). EYP-1901 utilizes our bioerodible Durasert technology and vorolanib, an anti-VEGF tyrosine kinase inhibitor (“TKI”). Vorolanib has previously been studied in human clinical trials as an oral therapy and is anticipated to be delivered as an intra-vitreous treatment in EYP-1901. We have completed initial animal pharmacokinetic and toxicology studies and initiated GLP toxicology studies in March 2020 to support the anticipated filing of an Investigational New Drug (“IND”) application with the FDA by the end of 2020. A Phase 1 clinical trial is expected to follow shortly afterwards upon acceptance of the IND by the FDA.

YUTIQ50 is being developed by us as a potential 6-month dosing option for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye. We have consulted with the FDA and identified a clinical pathway for an sNDA filing that involves a clinical trial of a small study of patients, randomized 2:1. We are currently evaluating the timeline and investment requirements for the initiation of this trial.

We are entitled to royalties pursuant to license and collaboration agreements utilizing our Durasert technology platform. These include ILUVIEN® for the treatment of diabetic macular edema (“DME”), and pursuant to EMEA regulatory approval received in March 2019, ILUVIEN for uveitis indication, licensed to Alimera Sciences, Inc. (“Alimera”).

We also earn revenues from research collaborations, license agreements and other arrangements, that include upfront fees, research funding and development funding, milestone payments and royalties. These include license agreements and, from time to time, funded feasibility study agreements. These agreements include (i) an exclusive license with OncoSil Medical Ltd for the development and commercialization of a product candidate for the treatment of pancreatic cancer and (ii) exclusive license agreements with Ocumension Therapeutics (“Ocumension”) for the development and commercialization in Mainland China, Hong Kong, Macau and Taiwan of (a) our Durasert three-year treatment of non-infectious uveitis affecting the posterior segment of the eye and (b) DEXYCU, for the treatment of post-operative ocular inflammation. We also undertake research agreements with collaborators which include formulation, clinical and non-clinical manufacturing and other pre-clinical studies designed to evaluate the

use of our Durasert technology platform, or potentially in the future our Verisome technology platform, for the delivery of third-party proprietary compounds for various eye diseases or other indications.

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

- Underlying customer demand and Distributor purchases by specialty distributors and specialty pharmacies (collectively, the “Distributors”) of both products was negatively impacted during the second quarter of 2020 due to shut downs associated with the COVID-19 Coronavirus Pandemic (the “Pandemic”) in the U.S. Although we did see a modest return of customer demand in June 2020, we expect this demand level to continue at current decreased levels through the duration of the COVID-19 Pandemic until restrictions on elective surgeries and office visits are removed and customer demand returns to pre-Pandemic levels. During the first quarter of 2020, public health authorities and government agencies including the Centers for Medicare & Medicaid Services (CMS), recommended the postponement of all non-essential elective surgeries, including cataract surgery, for an extended period of time during the Pandemic. As a result, ambulatory surgery centers (ASCs) closed or limited operations, decreasing DEXYCU product demand and orders. This status continued into the second quarter of 2020 with some areas of the U.S. beginning to reopen. With limited on-site access during the Pandemic, our sales organization has maintained contact with customers during the Pandemic by providing virtual support and education with regard to DEXYCU.
- Although many uveitis and retinal specialist offices remained open during the Pandemic, YUTIQ demand was reduced to mostly emergency cases because chronic non-infectious uveitis affecting the posterior segment of the eye can lead to blindness if left untreated. During the Pandemic, our sales organization continued to call on such offices, though at a reduced frequency.
- There have been no disruptions to the supply chains for YUTIQ and DEXYCU during the Pandemic and we continue to produce finished product for commercial sale.
- In April, we announced a reorganization of our commercial operations and the cancellation or deferral of planned spending to conserve cash due to the impact of the COVID-19 Pandemic, particularly the postponement of nearly all elective surgeries including cataract surgery. This reorganization was primarily focused on a reduction in the external contract sales organization for DEXYCU. We plan to allocate our remaining DEXYCU commercial resources to high-volume ASCs in key U.S. regions. The reorganization is expected to result in annual savings of approximately \$7 million and one-time savings of approximately \$10 million from other planned expenditure cancellations and deferrals.
- In April 2020, we received a \$2.0M Paycheck Protection Program (PPP) loan through the Small Business Administration's Paycheck Protection Program (PPP) under the Coronavirus Aid, Relief and Economic Security Act of 2020 (the CARES Act). We expect the PPP loan will enable us to retain key commercial infrastructure and employees and avoid furloughs as product demand and revenues remain significantly reduced due to ASC and physician office closures necessitated by the COVID-19 Pandemic. We plan to use the proceeds of the PPP loan to cover payroll costs, rent and utilities in accordance with the CARES Act and anticipate the loan will be fully forgiven.
- In July 2020, we announced the appointment of Dr. Jay Duker as our Chief Strategic Scientific Officer. Dr. Duker brings more than thirty years of ophthalmology experience to EyePoint with roles held in the clinical, research, business, and academic settings. Dr. Duker is also the Director of the New England Eye Center. He is also Professor and Chair of Ophthalmology at Tufts Medical Center and Tufts University School of Medicine, as well as the Chairman of the Board of Sesen Bio, Inc., a publicly traded clinical stage biopharmaceutical company.

R&D Highlights

- In March 2020, we initiated GLP toxicology studies for EYP-1901, an anti-VEGF, tyrosine kinase inhibitor (TKI) six-month sustained release potential therapy using our bioerodible Durasert technology. EYP-1901 is being developed as a treatment for wet age-related macular degeneration (wet AMD), with the potential for future development of treatments for diabetic retinopathy and retinal vein occlusion, all of which are disease indications representing attractive market opportunities in need of long-lasting treatments to potentially save patient's eyesight as current treatments require intensive eye injection regimens resulting in patients skipping these vital treatments. We expect to file an IND with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2020 with a Phase 1 clinical trial expected to commence shortly thereafter.
- In May 2020, four abstracts highlighting data from our ongoing retrospective study of real-world use of DEXYCU were presented at the American Society of Cataract and Refractive Surgery 2020 Virtual Annual Meeting. The data demonstrated DEXYCU's early-acting anti-inflammatory activity as measured by high levels of complete anterior chamber cell clearing and no anterior chamber flares at postoperative day 1, 8, 14 and 30. DEXYCU also received high marks on the physician survey of product satisfaction, ease of use, efficacy compared to topic steroids and patient satisfaction.
- In June 2020, supportive data from the Phase 2 trial of orally delivered vorolanib, the TKI molecule in EYP-1901, conducted by Tyrogenex, Inc. for the treatment of wAMD were published in the British Journal of Ophthalmology. Oral vorolanib demonstrated non-inferiority in visual acuity compared to placebo with best corrected visual acuity (BCVA) stable through 12-months. The three oral vorolanib dose levels studied also demonstrated a decreased intravitreal anti-VEGF injection burden and a longer time to first treatment as compared to placebo. There were several instances in which patients on vorolanib did not require another anti-VEGF injection after screening. The trial was prematurely stopped due to gastrointestinal and hepatobiliary toxicity concerns. These side effects are known to be associated with this class of compounds when given orally but in the oral vorolanib studies they all resolved after discontinuation of use. The efficacy results provide additional validation of vorolanib for use in EYP-1901 as a potential single dose sustained release treatment for wAMD.
- In June 2020, a post-hoc analysis of cases of bilateral uveitis in the first Phase 3 trial of YUTIQ was presented virtually at the Association for Research in Vision and Ophthalmology Annual Meeting. Outcomes for the untreated fellow eye were examined as a means of understanding the natural history of the disease and showed a recurrence rate of 86.4% compared to 56.3% for YUTIQ treated eyes at 36-months. At 36-months, fellow eyes also showed a higher rate of the need for the assistance of adjunctive intraocular/periorcular injection medication for uveitic inflammation, more macular edema, and a one-line average decrease in Best Corrected Visual Acuity (BCVA). We believe these supportive results reinforce the long-term, anti-inflammatory and eyesight protecting activity of YUTIQ for this difficult to treat disease.
- In July 2020, data from the first Phase 3 trial of YUTIQ were presented at the American Society of Retina Specialists Virtual Annual Meeting. A post-hoc analysis of imputed recurrences revealed over half were from confounding systemic medication use, which suggest the recurrence rate for YUTIQ is actually lower than the reported 56% at 36-months. The results also demonstrated YUTIQ increased the resolution of macular edema and improved visual acuity at 36-months.

Critical Accounting Policies and Estimates

The preparation of consolidated financial statements in conformity with GAAP requires that we make certain estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. We base our estimates, judgments and assumptions on historical experience, anticipated results and trends, and on various other factors that we believe are reasonable under the circumstances at the time. By their nature, these estimates, judgments and assumptions are subject to an inherent degree of uncertainty. Actual results may differ from our estimates under different assumptions or conditions. In our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, we set forth our critical accounting policies and estimates, which included revenue recognition and recognition of expense in outsourced clinical trial agreements. In the first quarter of 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 June 30, 2020 Compared to Three Months Ended June 30, 2019:

	Three Months Ended		Change	
	2020	2019	Amounts	%
(In thousands except percentages)				
Revenues:				
Product sales, net	\$ 3,706	\$ 6,705	\$ (2,999)	(45)%
License and collaboration agreement	35	5	30	600%
Royalty income	381	500	(119)	(24)%
Total revenues	<u>4,122</u>	<u>7,210</u>	<u>(3,088)</u>	<u>(43)%</u>
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	502	706	(204)	(29)%
Research and development	3,276	3,955	(679)	(17)%
Sales and marketing	6,089	7,284	(1,195)	(16)%
General and administrative	4,792	4,815	(23)	(0)%
Amortization of acquired intangible assets	615	615	—	na
Total operating expenses	<u>15,274</u>	<u>17,375</u>	<u>(2,101)</u>	<u>(12)%</u>
Loss from operations	<u>(11,152)</u>	<u>(10,165)</u>	<u>(987)</u>	<u>(10)%</u>
Other income (expense):				
Interest and other income	8	266	(258)	(97)%
Interest expense	(1,806)	(1,599)	(207)	(13)%
Loss on extinguishment of debt	—	—	—	na
Other expense, net	<u>(1,798)</u>	<u>(1,333)</u>	<u>(465)</u>	<u>(35)%</u>
Net loss	<u>\$ (12,950)</u>	<u>\$ (11,498)</u>	<u>\$ (1,452)</u>	<u>(13)%</u>

Product Sales, net

Product sales, net represents the gross sales of DEXYCU and YUTIQ less provisions for product sales allowances. Product sales, net decreased by \$3.0 million to \$3.7 million for the three months ended June 30, 2020 compared to \$6.7 million for the three months ended June 30, 2019. This reduction in revenue was primarily attributable to underlying customer demand and Distributor purchases of both products being negatively impacted by shutdowns associated with the COVID-19 Pandemic in the U.S. Although we did see a modest return of customer demand for both products in June 2020, we expect this demand level to continue at decreased levels through the duration of the COVID-19 Pandemic until restrictions on elective surgeries and office visits are removed. Please see the Recent Development section for more information on the impact of the Pandemic on, among other things, our product sales.

License and collaboration agreement

License and collaboration agreement revenues increased by \$30,000 for the three months ended June 30, 2020 compared to \$5,000 for the three months ended June 30, 2019. This increase was attributable primarily to the recognition of \$30,000 in deferred revenue from a research collaboration agreement.

Royalty Income

Royalty income decreased by \$119,000, or 24%, to \$381,000 for the three months ended June 30, 2020 compared to \$500,000 for the three months ended June 30, 2019. The decrease was attributable primarily to lower ILUVIEN net sales under the Amended Alimera Agreement. Alimera indicated in their second quarter earning's press release that their sales were impacted by the Pandemic.

Cost of Sales, Excluding Amortization of Acquired Intangible Assets

Cost of sales, excluding amortization of acquired intangible assets, decreased by \$204,000, or 29%, to \$502,000 for the three months ended June 30, 2020 from \$706,000 for the three months ended June 30, 2019. This decrease was primarily attributable to reduced costs associated with lower product sales, primarily costs of goods and distribution fees.

Research and Development

Research and development expenses decreased by \$679,000, or 17%, to \$3.3 million for the three months ended June 30, 2020 from \$4.0 million for the same period in the prior year. This decrease was attributable primarily to (i) a \$511,000 in personnel and related expenses, primarily lower stock based compensation and lower recruiting fees and (ii) approximately \$332,000 in consulting expense, partially offset by an increase in pre-clinical expenses.

Sales and Marketing

Sales and marketing expenses decreased by \$1.2 million, or 16%, to \$6.1 million for the three months ended June 30, 2020 from \$7.3 million for the same period in the prior year. This decrease was attributable primarily to (i) \$1.1 million of net contract sales organization expenses due to the reduction in DEXYCU KAMs as per our previously announced restructuring plan, including severance and (ii) approximately \$204,000 in decreased marketing expenses, partially offset by an approximate \$103,000 increase in personnel and related expenses primarily from the full quarter impact of prior year additions.

General and Administrative

General and administrative expenses decreased by \$23,000 in the three months ended June 30, 2020 from the same period in the prior year. This decrease was attributable primarily to an \$832,000 decrease in personnel and related expenses, primarily stock-based compensation and recruiting fees, partially offset by increases of (i) \$471,000 in legal, audit and other professional fees, (ii) \$197,000 increase in insurance expense and (iii) \$178,000 in consulting expenses.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets totaled \$615,000 for both the three months ended June 30, 2020 as well as the same period in the prior year. This amount was attributable to the DEXYCU product intangible asset that resulted from the Icon Acquisition (see Note 4).

Interest (Expense) Income

Interest expense totaled \$1.8 million for the three months ended June 30, 2020, which included \$177,000 of amortization of debt discount and \$324,000 of non-cash payment-in-kind interest expense all related to the CRG Debt. Interest expense in the three months ended June 30, 2019 was \$1.6 million which included \$130,000 of amortization of debt discount and \$294,000 of non-cash payment-in-kind interest expense.

Interest income from amounts invested in an institutional money market fund decreased to \$8,000 for the three months ended June 30, 2020 compared to \$266,000 in the prior year quarter, due primarily to higher interest-bearing assets and higher money market interest rates in the prior year quarter.

Six Months Ended June 30, 2020 Compared to Six Months Ended June 30, 2019:

	Six Months Ended June 30,		Change	
	2020	2019	Amounts	%
(In thousands except percentages)				
Revenues:				
Product sales, net	\$ 8,393	\$ 7,932	\$ 461	6%
License and collaboration agreement	2,055	70	1,985	2836%
Royalty income	1,163	1,220	(57)	(5)%
Total revenues	11,611	9,222	2,389	26%
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	1,482	1,035	447	43%
Research and development	8,129	7,753	376	5%
Sales and marketing	14,214	14,595	(381)	(3)%
General and administrative	9,152	9,425	(273)	(3)%
Amortization of acquired intangible assets	1,230	1,230	—	na
Total operating expenses	34,207	34,038	169	0%
Loss from operations	(22,596)	(24,816)	2,220	9%
Other income (expense):				
Interest and other income	62	509	(447)	(88)%
Interest expense	(3,590)	(2,619)	(971)	(37)%
Loss on extinguishment of debt	—	(3,810)	3,810	na
Other expense, net	(3,528)	(5,920)	2,392	40%
Net loss	\$ (26,124)	\$ (30,736)	\$ 4,612	15%

Product Sales, net

Product sales, net represents the gross sales of DEXYCU and YUTIQ less provisions for product sales allowances. Product sales, net increased by \$461,000 to \$8.4 million for the six months ended June 30, 2020 compared to \$7.9 million for the six months ended June 30, 2019. We commenced U.S. commercial sales of YUTIQ in February 2019 and DEXYCU in March 2019. Product sales for the six-months ended June 30, 2020 were negatively impacted due to shutdowns associated with the COVID-19 Pandemic in the U.S. Although we did see a modest return of customer demand for both products in June 2020, we expect this demand level to continue at current decreased levels through the duration of the COVID-19 Pandemic until restrictions on elective surgeries and office visits are removed. Please see the Recent Development section for more information on the impact of the Pandemic on, among other things, our product sales.

License and collaboration agreement

License and collaboration agreement revenues increased by \$2.0 million for the six months ended June 30, 2020 compared to \$70,000 for the six months ended June 30, 2019. This increase was attributable primarily to the recognition of approximately \$2.0 million from Ocumension upon signing a license agreement for DEXYCU in China.

Royalty Income

Royalty income decreased by \$57,000, or 5%, to \$1.2 million for the six months ended June 30, 2020. The decrease was attributable primarily to lower ILUVIEN net sales under the Amended Alimera Agreement in the second quarter of 2020. Alimera indicated in their second quarter earning's press release that their sales were impacted by the Pandemic. Royalty income was also impacted by recognizing no revenue after the quarter ended March 31, 2019 for Retisert royalty as the licensee, Bausch and Lomb informed us in early 2019 that they consider this agreement to have ended due to the expiration of certain patents.

Cost of Sales, Excluding Amortization of Acquired Intangible Assets

Cost of sales, excluding amortization of acquired intangible assets, increased by \$447,000, or 43%, to \$1.5 million for the six months ended June 30, 2020 from \$1.0 million for the six months ended June 30, 2019. This increase was primarily attributable to (i) a \$400,000 royalty expense associated with the Ocumension Dexycu signing payment received and (ii) higher costs associated with higher product sales, primarily costs of goods and distribution fees.

Research and Development

Research and development expenses increased by \$376,000, or 5%, to \$8.1 million for the six months ended June 30, 2020 from \$7.8 million for the same period in the prior year. This increase was attributable primarily to (i) a \$1.0 million payment to Equinox for the licensing of Vorolanib, (ii) approximately \$423,000 of increased expense for pre-clinical studies and (iii) approximately \$272,000 of increased expense related to pharmacovigilance, investigator-initiated studies and other medical affairs related costs, partially offset by approximate decreases of (i) \$552,000 in stability and other testing, (ii) \$507,000 in personnel and relates expenses and (iii) \$358,000 in consulting expenses.

Sales and Marketing

Sales and marketing expenses decreased by \$381,000, or 3%, to \$14.2 million for the six months ended June 30, 2020 from \$14.6 million for the same period in the prior year. This decrease was primarily attributable to (i) approximately \$915,000 of net contract sales organization (CSO) expenses due to the reduction in DEXYCU KAMs as per our previously announced restructuring plan, including severance and (ii) \$397,000 in marketing and related expenses, partially offset by (i) an approximate \$800,000 increase in personnel and related expenses, primarily from the full year to date impact of prior year additions and (ii) approximately \$225,000 in increased expenses related to our HUB, which performs benefit investigations on behalf of patients for providers, and other market access initiatives.

General and Administrative

General and administrative expenses decreased by \$273,000, or 3%, to \$9.2 million for the six months ended June 30, 2020 from \$9.4 million for the same period in the prior year. This decrease was attributable primarily to (i) a \$1.2 million decrease in personnel and related expenses, primarily stock-based compensation and recruiting fees, partially offset by increases of, (i) \$373,000 in legal, audit and other professional fees, (ii) \$357,000 in insurance expense and (iii) \$225,000 in consulting expenses.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets totaled \$1.2 million for both the six months ended June 30, 2020 as well as the same period in the prior year. This amount was attributable to the DEXYCU product intangible asset that resulted from the Icon Acquisition (see Note 4).

Interest (Expense) Income

Interest expense totaled \$3.6 million for the six months ended June 30, 2020, which included \$348,000 of amortization of debt discount and \$647,000 of non-cash payment-in-kind interest expense all related to the CRG Debt. Interest expense in the six months ended June 30, 2019 was \$2.6 million which included \$185,000 of amortization of debt discount and \$406,000 of non-cash payment-in-kind interest expense. During the prior year period, we extinguished the SWK Loan and established a new term loan facility with CRG (see Note 7).

Interest income from amounts invested in an institutional money market fund decreased to \$62,000 for the six months ended June 30, 2020 compared to \$509,000 in the prior year, due primarily to higher interest-bearing assets and higher money market interest rates in the prior year.

Liquidity and Capital Resources

We have had a history of operating losses and an absence of significant recurring cash inflows from revenue, and at June 30, 2020 we had a total accumulated deficit of \$491.2 million. Our operations have been financed primarily from sales of our equity securities, issuance of debt and a combination of license fees, milestone payments, royalty income and other fees received from collaboration partners. In the first quarter of 2019, we commenced the U.S. launch of our first two commercial products, YUTIQ and DEXYCU. However, we have not received sufficient revenues from our product sales to fund operations and we do not expect revenues from our product sales to generate sufficient funding to sustain our operations in the near-term. 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 the financial statements included in this report. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Financing Activities

Our total cash and cash equivalents were \$22.8 million at June 30, 2020. During the six months ended June 30, 2020, we received net cash proceeds of \$20.0 million on February 25, 2020 from the issuance of shares of our common stock (“Common Stock”) in an underwritten public offering (see Note 9). In addition, on April 8, 2020, we submitted an application through Silicon Valley Bank for the Paycheck Protection Program Loan (the “PPP Loan”) pursuant to the *Coronavirus Aid, Relief and Economic Security Act* administered by the U.S. Small Business Administration (the “SBA”). On April 22, 2020, we received PPP Loan proceeds of \$2.0 million. Under the terms of the PPP Loan, the Company is prohibited from changing ownership without the consent of the SBA and Silicon Valley Bank (“SVB”), which may include the sale or issuance of our equity securities. Neither the SBA nor SVB has provided any guidance on this prohibition. We did not sell any shares of our common stock under our at-the-market facility during the six months ended June 30, 2020.

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. In 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 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 (ii) 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, 2020 and ending on December 31, 2020, of at least \$45 million, (ii) for the twelve-month period beginning on January 1, 2021 and ending on December 31, 2021, of at least \$80 million and (iii) for the twelve-month period beginning on January 1, 2022 and ending on December 31, 2022, of at least \$90 million.

On November 19, 2019, we entered into a Waiver to the CRG Loan Agreement (the “Waiver”) pursuant to

which CRG waived the financial covenant associated with our revenue derived from sales of DEXYCU and YUTIQ for the twelve-month period ended December 31, 2019. Due to the Pandemic, we do not expect to meet the financial covenants associated with our revenue derived from sales of DEXYCU and YUTIQ for the twelve-month period ending December 31, 2020. We are in discussions with CRG about this covenant. If we do not maintain compliance with all of the continuing covenants and other terms and conditions of the CRG Loan or secure a waiver for any non-compliance, then the Lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, plus penalties and interest, including an exit fee and any prepayment fees, and foreclose on the collateral granted to them to secure such indebtedness. Such repayment would have a material adverse effect on our business and financial condition.

Future Funding Requirements

In the first quarter of 2019, we commenced the U.S. launch of our first two commercial products, YUTIQ and DEXYCU. To date, management does not yet have sufficient historical evidence to assert that it is probable that we will receive sufficient revenues from our sales of YUTIQ and DEXYCU to generate cash to fund operations. In addition, the COVID-19 Coronavirus Pandemic (the “Pandemic”) has had, and will likely continue to have, a material and adverse impact on our business, including as a result of preventive and precautionary measures that we, other businesses, and governments are taking. Due to these impacts and measures, we have experienced and will likely continue to experience significant and unpredictable reductions in the demand for our commercial products as customers have shut down their facilities and non-essential surgical procedures have been postponed in an effort to promote social distancing and to redirect medical resources and priorities towards the treatment of COVID-19. As of June 30, 2020, we had recurring operating losses since our inception and have an accumulated deficit of approximately \$491.2 million and working capital of \$30.4 million. We have not received sufficient revenues from our product sales to fund operations and we do not expect revenues from our product sales to generate sufficient funding to sustain our operations in the near-term.

Our plans that are intended to mitigate those conditions include continuing to fulfill our funding needs through cash inflows from revenue of YUTIQ and DEXYCU product sales, licensing and research collaboration transactions, additional capital raises and other arrangements. Our plans also include the continuation of expense reductions to conserve cash in response to a material adverse impact on our revenues due to a significant decline in product demand associated with shut downs of customer facilities and postponements of elective surgical procedures and physician office visits in response to the Pandemic. We believe that our cash and cash equivalents of \$22.8 million at June 30, 2020 and expected cash inflows from our product sales and royalty agreements, coupled with cash conservation activities will enable us to fund our current and planned operations into 2021. There can be no assurance, that we will receive the additional funding from any of these potential resources and even if cash proceeds are received, that such proceeds would be sufficient to support our current operating plan for the next twelve months from the date of issuance of these financial statements. 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.

Actual cash requirements may differ from projections and will depend on many factors, including, but not limited to:

- the effect of the Pandemic on our business, the medical community and the global economy;
- the duration, scope and outcome of the SEC investigation and its impact on our financial condition, results of operations or cash flows;
- the success of our direct U.S. 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. 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;
- 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;
- continued real world efficacy and safety results in line with or better than our products labels;
- changes in our operating plan, resulting in increases or decreases in our need for capital;
- the forgiveness of the \$2.0M PPP Loan by the U.S. Small Business Administration

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 in an offering, we do not know whether and to what extent we will be able to do so, or on what terms. Further, the continued spread of COVID-19 has also led to severe disruption and volatility in the global capital markets, which could increase our cost of capital and adversely affect our ability to access the capital markets in the future. 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):

	Six Months Ended		
	June 30,		
	2020	2019	Change
Net loss:	\$ (26,124)	\$ (30,736)	\$ 4,612
Changes in operating assets and liabilities	450	(8,233)	8,683
Other adjustments to reconcile net loss to cash flows from operating activities	4,208	8,528	(4,320)
Net cash used in operating activities	<u>\$ (21,466)</u>	<u>\$ (30,441)</u>	<u>\$ 8,975</u>
Net cash used in investing activities	<u>\$ (42)</u>	<u>\$ (207)</u>	<u>\$ 165</u>
Net cash provided by financing activities	<u>\$ 22,108</u>	<u>\$ 29,548</u>	<u>\$ (7,440)</u>

Operating cash outflows for the six months ended June 30, 2020 totaled \$21.5 million, primarily due to our net loss of \$26.1 million, reduced by \$4.2 million of non-cash expenses, which included \$1.9 million of stock-based compensation, \$1.2 million of amortization of the DEXYCU finite-lived intangible asset, and \$995,000 of non-cash interest and amortization of debt discount.

Operating cash outflows for the six months ended June 30, 2019 totaled \$30.4 million, primarily due to our net loss of \$30.7 million, reduced by \$8.4 million of non-cash expenses, which included a \$3.8 million loss on extinguishment of our SWK Loan, \$2.7 million of stock-based compensation and \$1.2 million of amortization of the DEXYCU finite-lived intangible asset, and \$676,000 of non-cash interest and amortization of debt discount.

Net cash used in investing activities for the six months ended June 30, 2020 consisted of \$42,000 of purchases of property and equipment. Net cash used in investing activities for the six months ended June 30, 2019 consisted of \$207,000 of purchases of property and equipment.

Net cash provided by financing activities for the six months ended June 30, 2020 totaled \$22.1 million and consisted of the following:

- (i) \$20.0 million of net proceeds from the issuance of 15,000,000 shares of our Common Stock; and
- (ii) \$2.0 million of net proceeds from the PPP Loan; and
- (iii) \$187,000 of proceeds from stock issued our employee stock purchase plan.

Net cash provided by financing activities for the six months ended June 30, 2019 totaled \$29.5 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) \$18.3 million of net proceeds from the issuance of 10,526,500 shares of our common stock (“Common Stock”); and
- (iii) \$15.0 million of net proceeds from our second drawdown under the CRG Loan Agreement offset by payment of a \$15.0 million development milestone that was due to the former Icon security holders following the first commercial sale of DEXYCU; and
- (iv) \$308,000 of proceeds from the exercise of stock options; partially offset by
- (v) \$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.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of June 30, 2020 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 a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information under this item.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of June 30, 2020. 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 our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure, particularly during the period in which this Quarterly Report on Form 10-Q was being prepared. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of June 30, 2020, our principal executive officer and our 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 June 30, 2020, 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.

Due to the continued COVID-19 pandemic, certain employees of the Company continued working remotely during the quarter. As a result of the continued remote working environment the Company has not identified any material changes in the Company’s internal control over financial reporting. The Company is continually monitoring and assessing the COVID-19 situation to determine any potential impacts on the design and operating effectiveness of our internal controls over financial reporting.

Item 1. Legal Proceedings

On May 14, 2020, we received a subpoena from the Division of Enforcement of the SEC seeking production of certain documents and information on topics including product sales and demand, revenue recognition and accounting in relation to product sales, product sales and cash projections, and related financial reporting, disclosure and compliance matters. We are cooperating fully in connection with this investigation. Based on procedures performed to date in relation to our revenue recognition practices, we have not identified any accounting items that are not in accordance with GAAP. In addition, we believe our public statements regarding our business, including with respect to product sales and demand, have been and are in compliance with federal securities laws. At this time, we are unable to predict the duration, scope or outcome of this matter or whether it could have a material impact on our financial condition, results of operations or cash flow.

Item 1A. Risk Factors

This section augments and updates certain risk factors disclosed in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2019 (the "Annual Report"). The following risk factor supersedes the corresponding risks described in the Annual Report and should be read together with the other risk factors disclosed in the Annual Report. In addition to the other information in this Quarterly Report on Form 10-Q, all of the risk factors should be carefully considered in evaluating us and our common stock. Any of these risks, many of which are beyond our control, could materially and adversely affect our financial condition, results of operations or cash flows, or cause our actual results to differ materially from those projected in any forward-looking statements. We may also face other risks and uncertainties that are not presently known, are not currently believed to be material, or are not identified below because they are common to all businesses. Past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. For more information, see "Note Regarding Forward-Looking Statements" in this Quarterly Report on Form 10-Q.

We received a subpoena from the SEC Enforcement Division requesting documents and information in an investigation relating to product sales and demand, revenue recognition and accounting. If the SEC commences an enforcement action against us, the resolution of such an enforcement action could have a material adverse effect on our business, financial condition, results of operations and cash flows. In addition, we have expended and expect to continue to expend significant financial and managerial resources responding to the SEC subpoena, which could also have a material adverse effect on our business, financial condition, results of operations and cash flows.

In May 2020, we received a subpoena from the SEC Enforcement Division requesting documents and information on topics including product sales and demand, revenue recognition and accounting in relation to product sales, sales and cash guidance, and related financial reporting, disclosure and compliance matters. We have cooperated and continue to cooperate with the SEC's investigation. We cannot predict the outcome of the investigation, but there can be no assurance that the SEC will not commence an enforcement action against us, or as to what the ultimate outcome of any such investigation might be. Under applicable law, the SEC has the ability to impose sanctions on companies which are found to have violated the provisions of applicable federal securities laws, including civil monetary penalties, cease and desist orders, and other remedies. The resolution of any such enforcement action, should there be one, could have a material adverse effect on our business, financial condition, results of operations and cash flows. We have expended and expect to continue to expend significant financial and managerial resources in connection with the investigation, which also could have a material adverse effect on our business, financial condition, results of operations and cash flow.

The ongoing novel coronavirus (COVID-19) pandemic has had and will likely continue to have a material and adverse impact on our business.

The novel coronavirus (COVID-19) pandemic has had, and will likely continue to have, a material and adverse impact on our business, including as a result of preventive and precautionary measures that we, other businesses, and governments are taking. Due to these impacts and measures, we have experienced and will likely continue to experience significant and unpredictable reductions in the demand for our products as customers have shut down their facilities and non-essential surgical procedures have been postponed in an effort to promote social distancing and to redirect medical resources and priorities towards the treatment of COVID-19.

As a result, on April 1, 2020, we committed to and announced a restructuring plan (the “Plan”) with respect to our commercial operations. The Plan includes the cancellation or deferral of planned spending to conserve cash. We have also commenced downsizing our workforce, with reductions coming primarily from our external DEXYCU sales force and supporting commercial operations, as cataract surgery is considered a non-essential procedure due to the Pandemic. The workforce reduction may have an adverse impact on our operations.

In addition, the Pandemic has and will likely continue to result in social, economic and labor instability in the countries in which we or the third parties with whom we engage operate. For example, we have licensed DEXYCU and Duraser FA to Ocumension for Mainland China, Hong Kong, Macau and Taiwan. Ocumension’s ability to conduct clinical trials may be materially and adversely affected due to COVID-19, which could have the result of, among other things, delaying the enrollment of patients in clinical trials, causing delays in the delivery of product supply for clinical trials and affecting the ability of clinical investigators, contract research organizations and other third-party service providers to devote sufficient time and resources to the clinical development programs.

While we cannot presently predict the future scope and severity of current or any potential business shutdowns or disruptions related to COVID-19, if we or any of the third parties with whom we engage, including the suppliers, manufacturers and other third parties in our global supply chain, clinical trial sites, regulators, surgeons, ASCs, potential business development partners and other third parties with whom we conduct business, were to experience prolonged shutdowns or other business disruptions, including the imposition of restrictions on the export or import of our key supplies from countries outside of the United States, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted. In addition, the pandemic’s ongoing impact on the medical community and the global economy could have a prolonged adverse impact on our product sales and royalty income on products we license to third parties such as Alimera if, for example, fewer uveitis or DME procedures are performed than we or Alimera previously anticipated or if the performance of elective surgeries such as cataract surgery do not resume to pre-pandemic levels in the near term. Further, any sustained disruption in the capital markets from the Pandemic could negatively impact our ability to raise capital.

To the extent the Pandemic continues to adversely affect our business, results of operations, financial condition and cash flows, it may also heighten many of the other risks described in the “Risk Factors” section of our Annual Report. The ultimate impact of the Pandemic on our business, results of operations, financial condition and cash flows is dependent on future developments, which are still highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, as well as the timing and phasing of business reopening, including the resumption of the performance of elective surgical procedures such as cataract surgeries.

We must maintain compliance with the terms of our loan or receive a waiver for any non-compliance. Our failure to comply with the covenants or other terms of the loan, including as a result of events beyond our control, could result in a default under the loan agreement that would materially and adversely affect the ongoing viability of our business.

On February 13, 2019 (the “CRG Closing Date”), we entered into the CRG Loan Agreement with 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”). We utilized the proceeds from the CRG Initial Advance for the repayment in full of all outstanding obligations under our prior credit agreement (the “SWK Credit Agreement”) with SWK Funding LLC (“SWK”). In April 2019, we exercised our option to borrow an additional \$15 million of the CRG Loan (the “CRG Second Advance”). We had the option to 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. We did not make any additional draws under the CRG Loan on or prior to June 30, 2020.

The CRG Loan Agreement contains affirmative and negative covenants, 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 our subsidiary 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 us 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.

On November 19, 2019, we entered into a Waiver to the CRG Loan Agreement (the “Waiver”) pursuant to which CRG waived the financial covenant associated with our revenue derived from sales of DEXYCU and YUTIQ for the twelve-month period ended December 31, 2019. Due to the Pandemic, we do not expect to meet the financial covenants associated with our revenue derived from sales of DEXYCU and YUTIQ for the twelve-month period ending December 31, 2020. We are in discussions with CRG about this covenant. If we do not maintain compliance with all of the continuing covenants and other terms and conditions of the CRG Loan or secure a waiver for any non-compliance, then the Lenders may choose to declare an event of default and require that we immediately repay all amounts outstanding, plus penalties and interest, including an exit fee and any prepayment fees, and foreclose on the collateral granted to them to secure such indebtedness. Such repayment would have a material adverse effect on our business, operating results and financial condition.

Our loan under the Paycheck Protection Program may not be forgiven or may subject us to challenges and investigations regarding qualification for the loan.

On April 22, 2020, we received a PPP Loan, which was established under the CARES Act in the principal amount of \$2.0 million. Pursuant to Section 1106 of the CARES Act we may apply for and be granted forgiveness for all or a portion of the PPP Loan. Such forgiveness will be determined, subject to limitations, based on the use of the loan proceeds for qualifying expenses, which include payroll costs, rent, and utility costs over the allowable measurement period following receipt of the loan proceeds.

The SBA continues to develop and issue new and updated guidance regarding the PPP Loan application and forgiveness process, including guidance regarding required borrower certifications and requirements for forgiveness of loans made under the program. Given the evolving nature of the guidance and depending upon our ability to use the loan proceeds for qualifying expenses, we cannot give any assurance that our PPP Loan will be forgiven in whole or in part.

Additionally, the PPP Loan application required us to certify that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation. In addition, the SBA has stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good faith belief that we satisfied all eligibility requirements for the PPP Loan, we are found to have been ineligible to receive the PPP Loan or in violation of any of the laws or regulations that apply to us in connection with the PPP Loan, including the False Claims Act, we may be subject to penalties, including significant civil, criminal and administrative penalties and would be required to repay the PPP Loan. In the event that we seek forgiveness of all or a portion of the PPP Loan, we will also be required to make certain certifications which will be subject to audit and review by governmental entities and could subject us to significant penalties and liabilities if found to be inaccurate, including being required to repay the PPP loan. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could materially harm our business, results of operations and financial condition.

If we issue or sell additional equity securities, we may not qualify for forgiveness under the Paycheck Protection

Program, and we may be required to repay the entire principal amount of our PPP loan plus any interest accrued thereon.

On April 8, 2020, we received a \$2.0M loan through the SBA's Paycheck Protection Program (PPP) under the CARES Act. Under the terms of our note (the Note) with SVB and according to applicable SBA rules, the Company is prohibited from changing ownership without the consent of the SBA and SVB, which may include the sale or issuance of our equity securities. Neither SBA nor SVB has provided any guidance on this prohibition. If we sell or otherwise issue additional equity securities prior to the PPP Loan being forgiven, we may be in breach of the terms of the Note and applicable PPP rules and be required to repay the entire principal amount of our PPP Loan plus any interest accrued thereon, which could have material adverse impact on our financial condition and cash flows.

If we are unable to regain compliance with the listing requirements of the Nasdaq Global Market, our common stock may be delisted from the Nasdaq Global Market which could have a material adverse effect on our financial condition and could make it more difficult for you to sell your shares.

Our common stock is listed on the Nasdaq Global Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly-held shares, market value of listed shares, minimum bid price per share, and minimum stockholders' equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from the Nasdaq Global Market.

On June 12, 2020, we received a letter (the "Letter") from the Listing Qualifications Department (the "Staff") of The Nasdaq Stock Market LLC ("Nasdaq") indicating that our common stock did not meet the minimum bid price of \$1.00 per share required for continued listing on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1) based on the closing bid price of our common stock for the 30 consecutive business days prior to the date of the Letter. The Letter has no effect at this time on the listing of our common stock, which will continue to trade on the Nasdaq Global Market under the symbol "EYPT".

Under Nasdaq Listing Rule 5810(c)(3)(A), if during the 180 calendar day period following the date of the Letter the closing bid price of our common stock is at or above \$1.00 for a minimum of 10 consecutive business days, we will regain compliance with the minimum bid price requirement and our common stock will continue to be eligible for listing on the Nasdaq Global Market, absent noncompliance with any other requirement for continued listing. On April 16, 2020, Nasdaq announced it was providing temporary relief from continued listing bid price requirements through June 30, 2020. Under the relief we will have additional time to regain compliance with the listing bid price requirements, with the compliance period beginning July 1, 2020. As such, our compliance period will expire on December 28, 2020.

If we do not regain compliance by December 28, 2020, we may be eligible for an additional 180 calendar day grace period if we meet the continued listing requirement for market value of publicly held shares (\$1.0 million) and all other Nasdaq initial listing standards which require, among other things, that we have at least \$5.0 million of stockholders' equity or at least \$4.0 million of stockholders' equity and \$50.0 million market value of listed shares. If we fail to regain compliance during the applicable period, we will receive notification from Nasdaq that our common stock is subject to delisting. At that time, we may then appeal the delisting determination to a Hearings Panel. Such notification will have no immediate effect on our listing on the Nasdaq Global Market, nor will it have an immediate effect on the trading of our common stock pending such hearing. There can be no assurance, however, that we will be able to regain compliance with Nasdaq's minimum bid price requirement. If we regain compliance with Nasdaq's minimum bid price requirement, there can be no assurance that we will be able to maintain compliance with the continued listing requirements for the Nasdaq Global Market or that our common stock will not be delisted from the Nasdaq Global Market in the future. In addition, we may be unable to meet other applicable listing requirements of the Nasdaq Global Market, including maintaining minimum levels of stockholders' equity or market values of our common stock in which case, our common stock could be delisted notwithstanding our ability to demonstrate compliance with the minimum bid price requirement.

Delisting from the Nasdaq Global Market may adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

If we are delisted from Nasdaq and we are not able to list our common stock on another exchange, our common stock could be quoted on the OTC Bulletin Board or in the “pink sheets.” As a result, we could face significant adverse consequences including, among others:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a “penny stock” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and little or no analyst coverage for us;
- we would no longer qualify for exemptions from state securities registration requirements, which may require us to comply with applicable state securities laws; and
- a decreased ability to issue additional securities (including pursuant to short-form Registration Statements on Form S-3) or obtain additional financing in the future.

If our common stock becomes subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain our listing on the Nasdaq Global Market and if the price of our common stock is less than \$5.00, our common stock may be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser’s written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

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

On July 30, 2020, we terminated the At Market Issuance Sales Agreement, dated January 18, 2019, between us and B. Riley FBR, Inc., effective as of August 4, 2020.

Item 6. Exhibits

Exhibit No.	Exhibit Description	Incorporated by Reference to SEC Filing		
		Form	SEC Filing Date	Exhibit No.
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	Certificate of Amendment of the Certificate of Incorporation, as amended, of EyePoint Pharmaceuticals, Inc.	8-K	6/23/20	3.1
3.6	Bylaws of EyePoint Pharmaceuticals, Inc.	10-K	09/18/18	3.5
3.7	Amendment No. 1 to the By-Laws of EyePoint Pharmaceuticals, Inc.	8-K	11/06/18	3.1
4.1	Form of Specimen Stock Certificate for Common Stock	8-K12G3	06/19/08	4.1
4.2	Warrant to Purchase Common Stock of pSivida Corp., issued March 28, 2018, to SWK Funding, LLC	8-K	3/29/18	4.1
4.3	Registration Rights Agreement, dated as of March 28, 2018, by and among pSivida Corp. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P.	8-K	3/29/18	10.3
4.4	Second Registration Rights Agreement, dated as of June 25, 2018, by and among EyePoint Pharmaceuticals, Inc. and EW Healthcare Partners, L.P. and EW Healthcare Partners-A, L.P. and each other person identified on the signature pages thereto	8-K	06/27/18	10.1
10.1	Note dated April 21, 2020 between EyePoint Pharmaceuticals, Inc. and Silicon Valley Bank	8-K	04/28/20	99.1
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			

<u>101.INS</u>	<u>XBRL Instance Document</u> (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).
<u>101.SCH</u>	<u>Inline XBRL Taxonomy Extension Schema Document.</u>
<u>101.CAL</u>	<u>Inline XBRL Taxonomy Extension Calculation Linkbase Document.</u>
<u>101.DEF</u>	<u>Inline XBRL Taxonomy Extension Definition Linkbase Document</u>
<u>101.LAB</u>	<u>Inline XBRL Taxonomy Extension Label Linkbase Database.</u>
<u>101.PRE</u>	<u>Inline XBRL Taxonomy Extension Presentation Linkbase Document.</u>
104	Cover Page Interactive Data File (Embedded within the Inline XBRL document and included in Exhibit 101).

* 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: August 5, 2020

EyePoint Pharmaceuticals, Inc.

By: /s/ Nancy Lurker

Name: Nancy Lurker

Title: President and Chief Executive Officer
(Principal 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: August 5, 2020

/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, George Elston, 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: August 5, 2020

/s/ George Elston

Name: George Elston

Title: Chief Financial Officer and Head of Corporate Development
(Principal Financial Officer and Principal Accounting 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 June 30, 2020, 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: August 5, 2020

/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 June 30, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, George Elston, Chief Financial Officer and Head of Corporate Development 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: August 5, 2020

/s/ George Elston

Name: George Elston
Title: Chief Financial Officer and Head of Corporate Development
(Principal Financial Officer and Principal Accounting Officer)