UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): May 8, 2019

EyePoint Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware (State or Other Jurisdiction of Incorporation) 000-51122 (Commission File Number) 26-2774444 (I.R.S. Employer Identification No.)

480 Pleasant Street
Watertown, MA 02472
(Address of Principal Executive Offices, and Zip Code)

(617) 926-5000 Registrant's Telephone Number, Including Area Code

(Former Name or Former Address, if Changed Since Last Report)

	opriate box below if the Form 8-K filing is intended sions (<i>see</i> General Instruction A.2. below):	to simultaneously satisfy the filing	g obligation of the registrant under any of the		
□ Wri	tten communication pursuant to Rule 425 under the	Securities Act (17 CFR 230.425)			
□ Soli	citing material pursuant to Rule 14a-12 under the E	xchange Act (17 CFR 240.14a-12)			
□ Pre-	Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))				
□ Pre-	Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))				
Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).					
			Emerging growth company $\ \Box$		
0 0	growth company, indicate by check mark if the regis Financial accounting standards provided pursuant to		1 1 5 5		
Securities regist	ered pursuant to Section 12(b) of the Act:				
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered		
Comm	on Stock, par value \$0.001	EYPT	The Nasdaq Stock Market LLC		

Item 2.02. Results of Operations and Financial Condition.

On May 8, 2019, EyePoint Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2019 and certain other information. A copy of the press release is furnished as Exhibit 99.1 hereto.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 <u>Press release of EyePoint Pharmaceuticals, Inc., dated May 8, 2019.</u>

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 hereunto duly authorized.

EYEPOINT PHARMACEUTICALS, INC.

By: /s/ Nancy Lurker

Date: May 8, 2019

Name: Nancy Lurker

Title President and Chief Executive Officer



EyePoint Pharmaceuticals Reports First Quarter 2019 Financial Results and Highlights Recent Company Progress

- YUTIQ $^{\text{\tiny{TM}}}$ and DEXYCU $^{\text{\tiny{TM}}}$ commercially launched in 1Q2019 -
- YUTIQ recommended for specific J-code by Centers for Medicare & Medicaid Services -
- Debt refinancing and equity public offering generated net proceeds of approximately \$30.0 million -
- Company optimistic that current cash balance and cash inflows from product sales to provide sufficient capital to fund operations through to positive cash flow in 2020 -
 - Management to host a conference call and webcast today at 8:30 AM ET -

WATERTOWN, Mass., May 8, 2019 - EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today reported financial results for the first quarter ended March 31, 2019, and highlighted recent corporate developments.

"The initial launches of our two commercial ocular products, DEXYCUTM and YUTIQTM, have generated a strong initial reception by treating physicians and patients, which we will look to leverage to drive sales growth in the coming quarters," said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. "We are now a fully-integrated, commercial-stage specialty ophthalmology company and are very pleased with the early momentum we are seeing for our two new innovative ocular products, each of which have significant market potential. We are also optimistic that we are well-positioned financially to execute on our goals following the addition of a new credit facility in February with CRG and the recent equity offering that we completed in April to support our operations through to positive cash flow in 2020."

Recent Highlights

 YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye was made commercially available on February 4, 2019. YUTIQ received a preliminary recommendation from the Centers for Medicare & Medicaid Services (CMS) for a specific J-code through the Healthcare Common Procedure Coding System (HCPCS).

- Ten Key Account Managers (KAMs) are dedicated to calling predominantly uveitis specialists across the U.S.
- Since the February launch, approximately 95% of the top decile uveitis specialists have been visited by 10 KAMs.
- Since launch, over 100 YUTIQ orders have been shipped for use in patients.
- Over 300 benefit investigations have been received.
- YUTIQ has been included in 9 academic formularies and is pending inclusion for an additional 11.
- As of April 30, our market access initiatives have resulted in over 93% of commercial lives covered, over 75% of Medicare Advantage lives covered and 95% of Medicare Fee-For-Service lives covered.
- DEXYCU (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following cataract surgery was made commercially available on March 12, 2019.
 - 34 KAMs dedicated to the promotion of DEXYCU have focused on a phased launch program to ensure proper physician training for the preparation, application and administration of DEXYCU.
 - Since launch, nearly 200 surgeons in more than 150 ambulatory surgical centers (ASCs) have completed the training/certification program and are now able to purchase DEXYCU.
 - Since launch, over 1,200 patients have been injected with DEXYCU via the Company's sampling program.
 - Since launch, over 2,000 medical professionals and office staff have been called on to discuss DEXYCU.
 - As of April 30, our market access initiatives have resulted in over 90% of commercial lives covered, over 75% of Medicare Advantage lives covered and 100% of Medicare Fee-For-Service lives covered.
- At the 2019 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting in Vancouver, British Columbia, 36-month efficacy and safety data supporting YUTIQ was presented in an oral session entitled, "Treatment of Non-infectious Uveitis that Affects the Posterior Segment with a Single Intravitreal Fluocinolone Acetonide Insert (FAi) 3-year Results." The 36-month follow up data of the Phase 3 clinical trial of YUTIQ showed a 56.3% recurrence rate of uveitis eye flares, significantly lower than eyes treated with sham (92.9%). The p-value was <0.001. 19.5% of YUTIQ treated eyes needed the assistance of adjunctive intraocular/periocular injection medication for uveitic inflammation compared to 69.0% for sham treated eyes. 34.5% of YUTIQ treated eyes needed the assistance of an adjunctive systemic steroid or immunosuppressant compared to 50.0% for sham treated eyes. Intraocular pressure (IOP) lowering drops were used in 42% of YUTIQ treated eyes and 33% of sham treated eyes with IOP lowering surgeries performed in 6% of YUTIQ treated eyes and 12% of sham treated eyes. Safety and side effects were consistent with those reported for previous analyses of earlier timepoints. These durable 36-month results continue to reinforce the potential of YUTIQ as a long-acting treatment option for patients suffering from this chronic disease.

- At the 2019 American Society of Cataract and Refractive Surgery (ASCRS) and American Society of Ophthalmic Administrators (ASOA) Annual Meeting in San Diego, California, data supporting DEXYCU was presented in a paper session entitled, "Effect of Dexamethasone Intraocular Suspension 9% on IOP after Cataract Surgery: Results of Two Phase 3 Studies." An analysis of the IOP data from two Phase 3 studies of DEXYCU showed that the IOP effect of DEXYCU was comparable to short-term topically administered prednisolone acetate or placebo in cataract surgery patients. Mean IOP was only slightly elevated, to approximately 19 and 18 mmHg at postoperative Day 1 in the DEXYCU and prednisolone acetate arms, respectively, and it returned to baseline in both arms by Day 3. The proportion of patients at each measured IOP category in both studies were similar between the DEXYCU and control group cohorts. These data further support DEXYCU's safety profile for the treatment of post-operative inflammation.
- On April 1, 2019, the Company completed a public offering of 10,526,500 shares of its common stock at a public offering price of \$1.90 per share. The net proceeds of the offering to the Company were approximately \$18.6 million.
- During April 2019, the Company exercised its option to draw an additional \$15.0 million under the CRG Loan Agreement and paid a \$15.0 million development milestone that was due to the former Icon security holders following the first commercial sale of DEXYCU. At April 30, 2019, the Company had \$56.9 million of cash and cash equivalents.

Review of First Quarter Results Ended March 31, 2019

For the three months ended March 31, 2019, total net revenue was \$2.0 million compared to \$928,000 for the three months ended March 31, 2018. Net revenue from DEXYCU was \$684,000, and for YUTIQ net revenue was \$543,000. Neither of these products had net revenue in the corresponding quarter in 2018. Net revenue from royalties and collaborations for the three months ended March 31, 2019 totaled \$785,000 compared to \$928,000 in the corresponding quarter in 2018.

Operating expenses for the three months ended March 31, 2019 increased to \$16.7 million from \$5.6 million in the prior year period, due primarily to investments in sales and marketing infrastructure and program costs, professional services, stock-based compensation and amortization of the DEXYCU intangible asset. Non-operating expense, net, for the three months ended March 31, 2019 totaled \$4.6 million and consisted of \$777,000 of net interest expense and \$3.8M from the loss on extinguishment of debt related to the pay off of the SWK term loan. Net loss for the three months ended March 31, 2019 was \$19.2 million, or \$0.20 per share, compared to a net loss of \$7.0 million, or \$0.15 per share, for the prior year quarter.

Cash and cash equivalents at March 31, 2019 totaled \$43.4 million compared to \$45.3 million at December 31, 2018. At April 30, 2019, the total amount outstanding under the CRG debt facility was \$50 million and cash and cash equivalents as of that date were \$56.9 million.

Financial Outlook

Early sales of YUTIQ and DEXYCU have been encouraging, and the Company is optimistic that existing cash and cash equivalents at April 30, 2019, and cash inflows from anticipated YUTIQ and DEXYCU product sales, will be sufficient to fund the Company's current and planned operations through to the generation of positive cash flow in 2020.

Conference Call Information

EyePoint will host a conference call today, Wednesday, May 8, 2019, at 8:30 AM ET to discuss the results for the first quarter ended March 31 and recent operational developments. To access the conference call, please dial (877) 312-7507 from the U.S. and Canada or (631) 813-4828 (international) at least 10 minutes prior to the start time and refer to conference ID 1192368. A live webcast will be available on the Investor Relations section of the corporate website at http://www.eyepointpharma.com. A replay of the webcast will also be available on the corporate website.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals, Inc. (formerly pSivida Corp.) (www.eyepointpharma.com), headquartered in Watertown, MA, is a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products in indications with high unmet medical need to help improve the lives of patients with serious eye disorders. With the approval by the FDA on October 12, 2018 of the YUTIQ™ three-year treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, the Company has developed five of the six FDA-approved sustained-release treatments for eye diseases. The most common adverse reactions reported for YUTIQ were cataract development and increases in intraocular pressure. DEXYCU™ was approved by the FDA on February 9, 2018. DEXYCU, administered as a single intraocular dose at the end of ocular surgery for the treatment of postoperative inflammation, is the first and only FDA-approved intraocular product with this indication. The most common adverse reactions reported by 5-15% of patients were increased intraocular pressure, corneal edema and iritis. DEXYCU employs the Verisome® extended-release drug delivery technology, which encompasses a broad number of related, but distinct drug delivery systems with the potential of incorporating an extensive range of active agents, including small molecules, proteins and monoclonal antibodies. ILUVIEN® (fluocinolone acetonide intravitreal implant), a micro-insert for diabetic macular edema, licensed to Alimera Sciences, Inc. ("Alimera"), is currently sold directly in the U.S. and several EU countries. Retisert® (fluocinolone acetonide intravitreal implant), for non-infectious posterior segment uveitis, is licensed to and sold by Bausch & Lomb, Inc. The Company's pre-clinical development program is focused on using its core Durasert™ and the Verisome platform technologies to deliver drugs to treat wet age-related macular degeneration, glaucoma, and other diseases. To learn more about the Company, please visit www.eyepointpharma.com

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION ACT OF 1995: Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect, plan or believe may occur in the future, including but not limited to statements about our commercialization of YUTIQ and DEXYCU, the potential for our products to alter the treatment landscape for ocular diseases; the expected use of proceeds from our debt refinancing and equity offering and our optimism that our existing cash and cash equivalents at April 30, 2019 and cash inflows from anticipated YUTIQ and DEXYCU product sales will be sufficient to fund our operations through to the generation of positive cash flow in 2020, are forward-looking statements. 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 are risks and uncertainties inherent in our business

including, without limitation: 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 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 YUTIO: consequences of dexamethasone side effects for DEXYCU: successful commercialization of, and receipt of revenues from, ILUVIEN for diabetic macular edema, or 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 the territories in which Alimera is licensed to do so; potential declines in Retisert royalties; our ability to market and sell products; the success of current and future license agreements; termination or breach of current license agreements; our dependence on contract research organizations, contract sales organizations, vendors and investigators; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forwardlooking statement will be realized. 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.

Contacts

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EYEPOINT PHARMACEUTICALS, INC. AND SUBSIDIARIES CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

(In thousands, except per share amounts)

	Three Mont	n 31,
D	2019	2018
Revenues:	Ф. 4.00	ф
Product sales, net	\$ 1,227	\$ —
Collaborative research and development	65	524
Royalty income	720	404
Total revenues	2,012	928
Operating expenses:		
Cost of sales, excluding amortization of acquired intangible assets	330	
Research and development	3,797	3,325
Sales and marketing	7,311	
General and administrative	4,610	2,281
Amortization of acquired intangible assets	615	_
Total operating expenses	16,663	5,606
Loss from operations	(14,651)	(4,678)
Other income (expense), net		
Interest and other income	243	25
Interest expense	(1,020)	_
Loss on extinguishment of debt	(3,810)	_
Change in fair value of derivative liability	_	(2,325)
Total other expense, net	(4,587)	(2,300)
Net loss	\$(19,238)	\$ (6,978)
Net loss per common share:		
Basic and diluted	\$ (0.20)	\$ (0.15)
Weighted average common shares outstanding:		
Basic and diluted	95,452	45,644

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

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 43,379	\$ 45,261
Accounts receivable	2,258	627
Other current assets	2,735	1,713
Total current assets	48,372	47,601
Operating lease right-of-use assets	3,393	_
Intangible assets, net	29,514	30,129
Other assets	575	438
Total assets	\$ 81,854	\$ 78,168
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,242	\$ 6,429
Accrued development milestone	15,000	15,000
Operating lease liabilities - current	417	_
Deferred revenue		30
Total current liabilities	24,659	21,459
Long-term debt	31,952	17,621
Operating lease liabilities - noncurrent	3,266	_
Other long-term liabilities	2,100	1,455
Total liabilities	61,977	40,535
Stockholders' equity:		
Capital	446,769	445,287
Accumulated deficit	(427,731)	(408,493)
Accumulated other comprehensive income	839	839
Total stockholders' equity	19,877	37,633
Total liabilities and stockholders' equity	\$ 81,854	\$ 78,168