

EYEPOINT PHARMACEUTICALS, INC.

FORM 8-K (Current report filing)

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Address	480 PLEASANT STREET SUITE B300 WATERTOWN, MA, 02472
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 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, 2018

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) (Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications 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 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

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

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2018, EyePoint Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its fiscal third quarter ended March 31, 2018 results and certain other information. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information contained in this report, including Items 2.02 and 9.01 and Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities under that Section, and shall not be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following Exhibit is furnished with this report on Form 8-K:

Exhibit No.	Description
99.1	Press release of EyePoint Pharmaceuticals, Inc. dated May 8, 2018.

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
Nancy Lurker
President and Chief Executive Officer

Date: May 8, 2018



EyePoint Pharmaceuticals Reports Fiscal Third Quarter 2018 Results

Completed Substantive Strategic Initiatives to Accelerate Transformation to a Commercial Company

Conference Call and Webcast Today, May 8th, at 4:30 p.m. ET

WATERTOWN, Mass., May 8, 2018 – EyePoint Pharmaceuticals (NASDAQ: EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today reported operating and financial results for its fiscal 2018 third quarter and nine months ended March 31, 2018 and provided a company update.

“The acquisition of Icon Bioscience, Inc. and its FDA approved product, DEXYCU™, significantly increases EyePoint Pharmaceuticals’ revenue potential and accelerates our planned transformation to a sustainable growth company,” said Nancy Lurker, President and Chief Executive Officer. “The combination of experienced executives leading our commercial team and the additional capital from EW Healthcare and SWK positions EyePoint to successfully execute on the launch of two new products in the first half of 2019, pending favorable regulatory review of YUTIQ™. In addition, we anticipate the annual revenue potential for DEXYCU to be \$150 - \$200 million by the end of the third year on the market.”

Key Recent Accomplishments

- Acquired privately-held Icon Bioscience, Inc. and its FDA approved product, DEXYCU™.
- DEXYCU was approved by the FDA on February 9, 2018, for the treatment of postoperative inflammation and is administered as a single intraocular injection at the end of surgery.
- EyePoint has expanded the DEXYCU global IP portfolio with Notices of Allowance for two additional patents, including potential claims relating to a method of treating inflammation of an eye following cataract surgery by delivering extremely small (4-6µL) amounts of dexamethasone in acetyl triethyl citrate. These two additional patents, once allowed, will extend to 2032 and 2034.
- A New Drug Application (NDA) for YUTIQ™ (fluocinolone acetonide intravitreal implant) 0.18 mg three-year treatment for noninfectious posterior segment uveitis was submitted to the Food and Drug Administration (FDA) in January and was accepted for filing in March with a November 5, 2018 PDUFA date.
- EyePoint has enhanced the healthcare and capital markets expertise of the Board of Directors with the appointment of Ron Eastman, a Managing Director at EW Healthcare Partners with over 40 years of experience in building healthcare companies.
- EyePoint has hired experienced executives to lead the Company’s commercial team and to ensure successful execution of the launches of DEXYCU and YUTIQ.

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- EyePoint presented data on YUTIQ at the Association for Research in Vision and Ophthalmology (ARVO) 2018 Annual Meeting.
 - EyePoint delisted from the Australian Securities Exchange effective as of May 7, 2018.

Strengthened Balance Sheet

- The Company had cash and cash equivalents totaling \$16.3 million at March 31, 2018 and, subject to stockholder approval at a special meeting of shareholders scheduled for June 22, 2018, has capital commitments of an additional \$30.5 million from EW Healthcare, a third-party investor and SWK. Therefore, the Company is currently projecting a cash balance of approximately \$38.0 million at June 30, 2018, the end of its current fiscal year.
- The Company expects these proceeds will provide the financial resources to commence the launch of DEXYCU and YUTIQ.

Near-Term Goals and Upcoming Milestones

- Gain approval of the second tranche investment by EW Healthcare at the June 22, 2018 special meeting of stockholders.
- Implement the Company's four-pillar commercialization plan:
 - Complete the build out of the sales organization;
 - Implement the marketing plan;
 - Continue to progress market access programs; and
 - Initiate medical education initiatives.
- Secure pass-through reimbursement for DEXYCU.
- Receive FDA approval for YUTIQ based on the PDUFA action date of November 5, 2018.
- Present data at leading medical congresses, including for YUTIQ at the American Society of Retina Specialists (ASRS) annual meeting being held in Vancouver from July 20-25.
- Launch DEXYCU and YUTIQ (subject to FDA approval) in the first half of calendar 2019.

Fiscal Third Quarter and Nine-Month Results

Revenue for the third fiscal quarter ended March 31, 2018, totaled \$928,000 compared to \$590,000 for the prior year quarter. Revenues in both periods were derived from feasibility study agreements and royalty income. Operating expenses for the three months ended March 31, 2018 decreased slightly to \$5.6 million from \$5.8 million a year earlier, due primarily to lower clinical trial costs and stock-based compensation expense, partially offset by higher regulatory and clinical consulting services in support of YUTIQ and higher personnel and related expenses. Net loss for the quarter ended March 31, 2018 was \$7.0 million, or \$0.15 per share, compared to a net loss of \$5.1 million, or \$0.15 per share, for the prior year quarter.

Revenue for the nine months ended March 31, 2018 was \$2.2 million compared to \$6.8 million for the nine months ended March 31, 2017. The prior year period included the recognition of deferred collaborative research and development revenue totaling \$5.6 million resulting from the termination of the Pfizer collaboration agreement. Excluding Pfizer, revenues from feasibility study agreements and royalty income increased to \$2.2 million for the nine months ended March 31, 2018

compared to \$1.2 million in the prior year period. Operating expenses for the first nine months of fiscal 2018 were \$18.7 million compared to \$19.3 million a year earlier. Net loss for the nine months ended March 31, 2018 was \$18.7 million, or \$0.43 per share, compared to a net loss of \$12.4 million, or \$0.36 per share for the corresponding fiscal 2017 year-to-date period. There are currently 54,029,917 common shares outstanding.

In connection with the first tranche EW Healthcare investment, and subject to stockholder approval, the Company agreed to issue units to EW Healthcare and a participating third-party investor, with each unit consisting of the right to purchase (a) one share of Common Stock and (b) one warrant to purchase a share of Common Stock. The purchase price of the common stock and the exercise price of the warrant are both subject to price collars that provide for either a premium or discount to the original price paid in the first tranche investment by EW Healthcare. Because of the collar, the number of units to be issued will be subject to some variability. This second tranche investment will be voted upon at a special meeting of stockholders to be held on June 22, 2018. Accounting guidance required that the future obligation to issue units in the second tranche transaction be recorded as a derivative liability and to be re-measured to fair value at each balance sheet date. As a result of the initial re-measurement, the Company recorded a non-cash charge to non-operating expense of \$2.3 million as change in fair value of derivative liability for the three and nine months ended March 31, 2018.

Conference Call Information

The conference call may be accessed by dialing (877) 312-7507 from the U.S. and Canada, or (631) 813-4828 from international locations. The conference ID is 1758647. A live webcast will be available on the Investor Relations section of the corporate website at <http://www.eyepointpharma.com>.

A replay of the call will be available beginning May 8, 2018, at approximately 7:30 p.m. ET and ending on May 15, 2018, at 11:59 p.m. ET. The replay may be accessed by dialing (855) 859-2056 within the U.S. and Canada or (404) 537-3406 from international locations, Conference ID Number: 1758647. A replay of the webcast will also be available on the corporate website during that time.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (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. The Company has developed three of only four FDA-approved sustained-release treatments for back-of-the-eye diseases. In addition, DEXYCU™ was approved by the U.S. Food and Drug Administration (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. ILUVIEN® (fluocinolone acetonide intravitreal implant), a micro-insert for diabetic macular edema, licensed to Alimera Sciences, is currently sold directly in the U.S. and several EU countries. Retisert® (fluocinolone acetonide intravitreal implant), for posterior uveitis, is licensed to and sold by Bausch & Lomb. The New Drug Application (NDA) for EyePoint's lead product candidate, YUTIQ™ for the treatment of non-infectious uveitis affecting the posterior segment of the eye, has been accepted for filing by the FDA and is currently under standard review with a Prescription Drug User Fee Act (PDUFA) date of November 5, 2018. The

Company's pre-clinical development program is focused on using its core Durasert platform technology to deliver drugs to treat wet age-related macular degeneration, glaucoma, osteoarthritis and other diseases. To learn more about the Company, please visit www.eyepointpharma.com and connect on Twitter, LinkedIn, Facebook and Google+.

About DEXYCU™

DEXYCU (dexamethasone intraocular suspension) 9% is indicated for the treatment of postoperative inflammation. **WARNINGS AND PRECAUTIONS—** Increase in Intraocular Pressure—Steroids should be used with caution in the presence of glaucoma. Delayed Healing—The use of steroids after cataract surgery may delay healing and increase the incidence of bleb formation. Exacerbation of Infection—The use of DEXYCU, as with other ophthalmic corticosteroids, is not recommended in the presence of most active viral diseases of the cornea and conjunctiva including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, and varicella, and also in mycobacterial infection of the eye and fungal disease of ocular structures. Use of a corticosteroid in the treatment of patients with a history of herpes simplex requires caution and may prolong the course and may exacerbate the severity of many viral infections. Fungal infections of the cornea are particularly prone to coincidentally develop with long-term local steroid application and must be considered in any persistent corneal ulceration where a steroid has been used or is in use. Fungal culture should be taken when appropriate. Prolonged use of corticosteroids may suppress the host response and thus increase the hazard of secondary ocular infections. In acute purulent conditions, steroids may mask infection or enhance existing infection. Cataract Progression – The use of corticosteroids in phakic individuals may promote the development of posterior subcapsular cataracts. **ADVERSE REACTIONS—**The most commonly reported adverse reactions occurred in 5-15% of subjects and included increases in intraocular pressure, corneal edema and iritis. Please see full Prescribing Information.

EyePoint expects DEXYCU to be granted pass-through status and receive separate payment from Medicare for a period of three years. If after this three-year period, payments for DEXYCU are bundled into the Medicare payment for cataract surgery, the annual revenues generated from DEXYCU would be materially reduced, but if Medicare reimbursement is extended beyond three years then the Company anticipates the revenue potential of DEXYCU could be higher.

SAFE HARBOR STATEMENTS UNDER THE PRIVATE SECURITIES LITIGATION REFORM 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 or believe may occur in the future 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 include uncertainties with respect to: our ability to achieve profitable operations and access to needed capital; our ability to achieve our projected cash balance in future periods; fluctuations in our operating results; successful commercialization of, and receipt of revenues from, ILUVIEN® for diabetic macular edema ("DME"), which depends on Alimera's ability to continue as a going concern; Alimera's ability to obtain marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN; the number of clinical trials and data required for marketing approval of YUTIQ in the U.S.; our ability to use data in promotion for YUTIQ micro insert for the treatment of non- infectious uveitis affecting the posterior segment of the eye; U.S. NDA approval which includes clinical trials outside the U.S.; our ability to

successfully commercialize and achieve the revenue potential for DEXYCU in the U.S.; our ability to obtain stockholder approval for portions of the EW Healthcare investment; our ability to successfully commercialize YUTIQ three-year uveitis, if approved, in the U.S.; potential off-label sales of ILUVIEN for uveitis; consequences of fluocinolone acetonide side effects; the development of our next-generation Durasert shorter-duration treatment for posterior segment uveitis; potential declines in Retisert[®] royalties; our ability to successfully develop product candidates, initiate and complete clinical trials and receive regulatory approvals; our ability to market and sell products; the success of current and future license agreements, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; our dependence on contract research organizations, vendors and investigators; effects of competition and other developments affecting sales of products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; effects of the potential U.K. exit from the EU; legislative or regulatory changes; volatility of stock price; possible dilution; absence of dividends; and other factors described in our filings with the Securities and Exchange Commission. You should read and interpret any forward-looking statements in light of these risks. 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.

Contact

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FINANCIAL TABLES FOLLOW

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

(Unaudited)

(In thousands, except per share amounts)

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

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

	<u>March 31,</u> <u>2018</u>	<u>June 30,</u> <u>2017</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,346	\$ 16,898
Other current assets	1,329	842
Total current assets	<u>17,675</u>	<u>17,740</u>
Intangible assets, net	31,973	364
Other assets	510	573
Total assets	<u>\$ 50,158</u>	<u>\$ 18,677</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,975	\$ 5,240
Accrued development milestone	15,000	—
Deferred revenue	240	50
Total current liabilities	<u>21,215</u>	<u>5,290</u>
Long-term debt	12,850	—
Derivative liability	6,957	—
Other long-term liabilities	938	51
Total liabilities	<u>41,960</u>	<u>5,341</u>
Stockholders' equity:		
Capital	336,924	323,323
Accumulated deficit	(329,563)	(310,820)
Accumulated other comprehensive income	837	833
Total stockholders' equity	<u>8,198</u>	<u>13,336</u>
Total liabilities and stockholders' equity	<u>\$ 50,158</u>	<u>\$ 18,677</u>