
**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): January 3, 2019

EyePoint Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-51122
(Commission
File Number)

26-2774444
(IRS Employer
Identification No.)

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

02472
(Zip Code)

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

(Former name or former address, if changed since last report.)

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 8.01. Other Events.

On January 3, 2019, EyePoint Pharmaceuticals, Inc. (the “Company”) issued a press release announcing certain 2019 commercial updates, including the Company’s expectation to launch DEXYCU™ in the first quarter of calendar 2019. A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of EyePoint Pharmaceuticals, Inc., dated January 3, 2019.

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.

Date: January 14, 2019

By: /s/ Nancy Lurker

Name: Nancy Lurker

Title: President and Chief Executive Officer



EyePoint Pharmaceuticals Provides 2019 Commercial Update

- DEXYCUTM commercial launch now expected in 1Q19, earlier than prior guidance of 1H19 -

- YUTIQTM commercial launch on track for 1Q19 -

WATERTOWN, Mass., January 3, 2019 – EyePoint Pharmaceuticals (NASDAQ: EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today provided a 2019 commercial update.

“EyePoint has made significant progress in building its commercial infrastructure in preparation for two ophthalmic product launches in the near-term,” said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. “As a result of the diligence with which our team has worked to execute on commercial manufacturing scale-up, communicate with payors, build our distribution network and our hub for patient and physician support, I am pleased to be able to announce that along with the launch of YUTIQTM in the first quarter of calendar 2019, we also now anticipate launching DEXYCUTM in the first quarter of calendar 2019, earlier than initially expected. We are excited to be able to commercialize both of these innovative ocular products and we look forward to making a meaningful difference in the established treatment paradigms for cataract surgery and posterior uveitis, which are both areas of high unmet medical need.”

Key Commercial Updates

- EyePoint expects to launch DEXYCU (dexamethasone intraocular suspension) 9% in the first quarter of calendar 2019. DEXYCU, approved by the U.S. Food and Drug Administration (FDA) on February 9, 2018, is the first and only FDA-approved single dose, sustained release, intracameral steroid for the treatment of postoperative inflammation. In November 2018, the Company announced that Centers for Medicare and Medicaid Services (CMS) had assigned a specific and permanent reimbursement J-code through the Healthcare Common Procedure Coding System (HCPCS) for DEXYCU. The code, J1095, became effective on January 1, 2019, and will replace the previously issued C-code for DEXYCU (C9034) that became effective on October 1, 2018.
- The Company expects to launch YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg in the first quarter of calendar 2019. YUTIQ was approved by the FDA on October 12, 2018, and is the first long-lasting, FDA approved micro-insert for up to three years of continuous control in chronic, non-infectious posterior segment uveitis, the third leading cause of blindness in the U.S. The Company recently presented positive YUTIQ 24-month efficacy and safety data at the American Academy of Ophthalmology (AAO) 2018 Annual Meeting in October, showing a significantly increased likelihood of achieving and maintaining inflammation control for YUTIQ compared to sham, highlighting YUTIQ’s ability to decrease the rate of uveitic recurrences.

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 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 intraocular pressure increased, 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., 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, 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 and connect on Twitter, LinkedIn, Facebook and Google+.

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 plans to commercialize YUTIQ and DEXYCU, the expected timing of release of the 24-month and 36-month patient follow-up data for YUTIQ and our expectations regarding the timing of a filing of an application for approval of a next-generation, shorter-duration treatment for posterior segment uveitis, 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; fluctuations in our operating results; our ability to successfully produce commercial supply of YUTIQ and DEXYCU and commercialize YUTIQ and DEXYCU in the U.S.; our ability to successfully build a commercial infrastructure and enter into and maintain commercial agreements for the launch of DEXYCU and YUTIQ; the development of our next-generation YUTIQ short-acting treatment for uveitis; potential off-label sales of ILUVIEN for non-infectious posterior segment uveitis ("NIPU"); consequences of fluocinolone acetonide side effects; successful commercialization of, and receipt of revenues from, ILUVIEN

for diabetic macular edema (“DME”) which depends on the ability of Alimera Sciences, Inc. (“Alimera”) to continue as a going concern; Alimera’s ability to obtain additional marketing approvals and the effect of pricing and reimbursement decisions on sales of ILUVIEN for DME; Alimera’s ability to obtain marketing approval for ILUVIEN in its licensed territories for NIPU; potential declines in Retisert royalties; our ability to market and sell products; the success of current and future license agreements, including our agreement with Alimera; termination or breach of current license agreements, including our agreement with Alimera; our dependence on contract research organizations, 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; effects of the potential exit of the United Kingdom from the European Union; 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.

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