
**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): November 7, 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)

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 (see General Instruction A.2. below):

- Written communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 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

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 November 7, 2019, EyePoint Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of EyePoint Pharmaceuticals, Inc., dated November 7, 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: November 7, 2019

By: /s/ Nancy Lurker
Name: Nancy Lurker
Title: President and Chief Executive Officer

EyePoint Pharmaceuticals Reports Third Quarter 2019 Financial Results and Highlights Recent Corporate Progress

– U.S. commercial launch trajectory for DEXYCU® and YUTIQ® gains momentum with strong customer order growth over Q2 -

– DEXYCU customer orders increased 207% over Q2 with repeat customers representing 74% of order volume -

– YUTIQ customer orders up 17% over Q2 with repeat customers representing 85% of order volume and prior to effective date of permanent J-Code -

- Announced access to large integrated payor networks including U.S. Department of Veterans Affairs Federal Supply Schedule and Vizient Inc. Network -

- Management to host a conference call and webcast today at 8:30 AM ET –

WATERTOWN, Mass., November 07, 2019 -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, today reported financial results for the third quarter ended September 30, 2019 and highlighted recent corporate developments.

“We are pleased with the strong growth in customer orders during the quarter as our sales team is making significant progress in penetrating targeted accounts for both DEXYCU® and YUTIQ®,” said Nancy Lurker, President and Chief Executive Officer of EyePoint Pharmaceuticals. “At the customer level, DEXYCU is gaining momentum at high volume ambulatory surgery centers with increasing repeat orders by physicians who favor its targeted, efficient ocular administration, and its positive efficacy and safety profile. We also saw continued strong growth of 17% in physician demand for YUTIQ quarter over quarter despite a cumbersome reimbursement process under a miscellaneous J-Code. We expect that the issuance of a permanent and specific J-Code for YUTIQ, which went into effect on October 1, 2019, will enable customers to experience a faster and more straightforward reimbursement process and will support continued growth in demand for this important product. These positive customer and reimbursement trends were masked by our distributor’s strategic decision to substantially reduce carried inventory, limiting their restocking during the quarter and resulting in decreased reported revenue from the prior quarter.”

Commercial Performance in Third Quarter 2019

DEXYCU (dexamethasone intraocular suspension) 9% for the treatment of post-operative inflammation following ocular surgery

- Customer orders up 207% over Q2 with September representing the highest volume month to date, and with repeat customers representing 74% of Q3 order volume.
 - The average time for an account to re-order dropped from 4.8 weeks during Q2 to 2.5 weeks during Q3, as customers incorporate DEXYCU as part of their surgical protocol.
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- Medicare fee for service claims continue to be paid consistently, and Medicare Advantage and Commercial insurance claims increased quarter over quarter.
- The average time to payment in all payor sectors continues to improve post launch. We expect the time to payment to decrease as payor systems incorporate DEXYCU's J-Code.
- Since launch, over 5,400 patients have been injected with DEXYCU. In that time, over 500 physicians have been trained to use the product.

YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg for chronic non-infectious uveitis affecting the posterior segment of the eye

- Customer orders up 17% over Q2, prior to effective date of a permanent J-Code.
- Repeat customers represented 85% of order volume, and importantly, 40% of the target account list has ordered, representing solid adoption with continued growth opportunity.
- Medicare fee for service claims paid consistently and Medicare Advantage and Commercial payors beginning to cover YUTIQ.
- The permanent and specific J-Code, J7314, was issued by the Centers for Medicare and Medicaid Services (CMS) one quarter earlier than under prior CMS policy and is in effect as of October 1, 2019.

Corporate Developments

- In November 2019, EyePoint announced two new agreements to expand the reach of DEXYCU and YUTIQ within large integrated healthcare networks. An interim agreement with the U.S. Department of Veterans Affairs (VA) became effective on November 2, 2019, adding DEXYCU and YUTIQ to the Federal Supply Schedule. The VA serves approximately nine million beneficiaries. A final VA contract is anticipated within several months and is expected to have a five-year term. In addition, a three-year contract was signed with Vizient Inc., effective November 1, 2019, offering DEXYCU to its diverse membership network. Vizient provides solutions and services to over 50% of the nation's acute care providers, including 95% of the nation's academic medical centers, and more than 20% of ambulatory care providers.
- In August 2019, EyePoint received a \$1 million milestone payment from Ocumenion Therapeutics triggered by the approval of its Investigational New Drug (IND) in China for EyePoint's three-year intravitreal micro-insert containing 0.18mg of fluocinolone acetonide using the Duraser™ technology (known as YUTIQ in the United States). The IND allows the importation of finished product into China for use in its initiated clinical trial to support regulatory approval for the treatment of chronic uveitis affecting the posterior segment of the eye. Ocumenion 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.

R&D Highlights

- Two oral presentations highlighting 36-month data supporting YUTIQ for the treatment of non-infectious uveitis affecting the posterior segment of the eye occurred at the annual Retina Society meeting held in London, United Kingdom, on September 11-15, 2019. The first presentation "*Minimizing Uveitic Recurrences: Results from a 36M Study of Fluocinolone Acetonide Intravitreal Insert (FAi) in Subjects with Chronic Non-Infectious Uveitis Affecting the Posterior Segment*" concluded that treatment with YUTIQ not only resulted in a reduction in the 3-year rate of uveitic recurrences but that YUTIQ also reduced the cumulative number of inflammatory episodes in eyes that did relapse. The second presentation, "*The Use of Adjunctive Anti-inflammatory Medications: Results from a 36M Study of a Fluocinolone Acetonide*"
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Intravitreal Insert (FAi) in Subjects with Chronic Non-Infectious Uveitis (NIPU) Affecting the Posterior Segment” highlighted that the treatment with a single intravitreal injection of YUTIQ significantly reduced the need for adjunctive therapies in this group of patients.

- YUTIQ was highlighted in separate events at the American Academy of Ophthalmology (AAO) 2019 Annual Meeting held October 12 – 15, 2019 in San Francisco, CA. First, an oral presentation entitled, *“Effect of Fluocinolone Acetonide Insert on the Presence of Uveitic Macular Edema: Outcomes at 36 Months”* was presented at a well-attended session at the Retina Subspecialty Day and demonstrated the long-term durability of YUTIQ for this difficult to treat ocular disease. Additionally, a poster entitled, *“Fluocinolone Acetonide Intravitreal Insert for Noninfectious Posterior Uveitis: Analysis of Significant IOP Elevation”* provided further evidence of the favorable safety and tolerability profile of YUTIQ.

Review of Results for Third Quarter Ended September 30, 2019

For the three months ended September 30, 2019, total revenue was \$2.5 million. Net product revenue was \$1.0 million, primarily generated from sales of DEXYCU.

DEXYCU and YUTIQ are sold through a distributor under a title model and, accordingly, product revenue is recognized as inventory is shipped to the distributor and title transfers. Due to this title model, quarterly reported revenue and underlying customer sales will likely track separately for an extended period of time beyond initial launch, as customer demand patterns may not align with the distributor’s inventory restocking procedures.

Net revenue from licenses, royalties and collaborations for the three months ended September 30, 2019 totaled \$1.5 million compared to \$486,000 in the corresponding quarter in 2018.

Operating expenses for the three months ended September 30, 2019 increased to \$16.6 million from \$14.0 million in the prior year period, due primarily to investments in sales and marketing infrastructure and program costs, professional services, and cost of sales related to product revenue, partially offset by a decrease in research and development expense. Non-operating expense, net, for the three months ended September 30, 2019 totaled \$1.6 million of net interest expense. Net loss for the three months ended September 30, 2019 was \$15.6 million, or \$0.15 per share, compared to a net loss of \$33.1 million, or \$0.44 per share, for the prior year quarter.

Review of Nine Months Results Ended September 30, 2019

For the nine months ended September 30, 2019, total net product revenue was \$8.9 million. Neither product had net revenue in the corresponding period in 2018. Net revenue from licenses, royalties and collaborations for the nine months ended September 30, 2019 totaled \$2.8 million compared to \$2.1 million in the corresponding period in 2018.

Operating expenses for the nine months ended September 30, 2019 increased to \$50.6 million from \$30.1 million in the prior year period, due primarily to investments in sales and marketing infrastructure and program costs, professional services, stock-based compensation, cost of sales related to product revenue and amortization of the DEXYCU intangible asset, partially offset by a decrease in research and development expense. Non-operating expense, net, for the nine months ended September 30, 2019 totaled \$7.5 million and consisted of \$3.7 million of net interest expense and \$3.8 million from the loss on extinguishment of debt related to the payoff of the SWK term loan. Net loss for the nine months ended September 30, 2019 was \$46.4 million, or \$0.45 per share, compared to a net loss of \$74.5 million, or \$1.27 per share, for the prior year period.

Cash and cash equivalents at September 30, 2019 totaled \$31.8 million compared to \$44.2 million at June 30, 2019.

Financial Outlook

We expect that the Company's existing cash and cash equivalents at September 30, 2019 and cash inflows from anticipated YUTIQ and DEXYCU product sales will be sufficient to fund the Company's operating plan into 2020.

Conference Call Information

EyePoint will host a conference call today, Thursday, November 7, 2019 at 8:30 AM ET to discuss the results for the third quarter ended September 30 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 3149087. 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. (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 and connect on Twitter and LinkedIn.

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; our expectations regarding the regulatory review of our sNDA filing for our YUTIQ line extension shorter-acting treatment for non-infectious uveitis affecting the posterior segment of the eye; the expected use of proceeds from our debt refinancing and equity offering and our expectation that the Company's existing cash and cash equivalents at September 30, 2019 and cash

inflows from anticipated YUTIQ and DEXYCU product sales will be sufficient to fund our operating plan into 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 YUTIQ; 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; 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 forward-looking 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Product sales, net	\$ 1,009	\$ —	\$ 8,941	\$ —
License and collaboration agreement	1,054	56	1,125	798
Royalty income	446	430	1,666	1,331
Total revenues	2,509	486	11,732	2,129
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	327	—	1,363	—
Research and development	3,484	6,233	11,237	14,323
Sales and marketing	7,778	3,646	22,373	5,158
General and administrative	4,365	4,161	13,790	10,662
Amortization of acquired intangible assets	615	—	1,845	—
Total operating expenses	16,569	14,040	50,608	30,143
Loss from operations	(14,060)	(13,554)	(38,876)	(28,014)
Other income (expense):				
Interest and other income, net	183	129	692	181
Interest expense	(1,770)	(815)	(4,389)	(1,535)
Loss on extinguishment of debt	—	—	(3,810)	—
Change in fair value of derivative liability	—	(18,886)	—	(45,164)
Total other expense, net	(1,587)	(19,572)	(7,507)	(46,518)
Net loss	\$ (15,647)	\$ (33,126)	\$ (46,383)	\$ (74,532)
Net loss per share - basic and diluted	\$ (0.15)	\$ (0.44)	\$ (0.45)	\$ (1.27)
Weighted average shares outstanding - basic and diluted	106,938	75,170	102,900	58,840

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

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,760	\$ 45,261
Accounts and other receivables, net	8,855	627
Other current assets	6,446	1,713
Total current assets	47,061	47,601
Operating lease right-of-use assets	3,186	—
Intangible assets, net	28,284	30,129
Other assets	536	438
Total assets	\$ 79,067	\$ 78,168
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 9,907	\$ 6,429
Accrued development milestone	—	15,000
Operating lease liabilities - current portion	461	—
Deferred revenue	—	30
Total current liabilities	10,368	21,459
Long-term debt	46,733	17,621
Operating lease liabilities - noncurrent	3,028	—
Other long-term liabilities	3,000	1,455
Total liabilities	63,129	40,535
Stockholders' equity:		
Capital	469,974	445,287
Accumulated deficit	(454,876)	(408,493)
Accumulated other comprehensive income	840	839
Total stockholders' equity	15,938	37,633
Total liabilities and stockholders' equity	\$ 79,067	\$ 78,168