
**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 3, 2021

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 3, 2021, EyePoint Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2021 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 3, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the inline XBRL document) |

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 3, 2021

By: /s/ George O. Elston
Name: George O. Elston
Title Chief Financial Officer and Head of Corporate Development



EyePoint Pharmaceuticals Reports Third Quarter 2021 Financial Results and Highlights Recent Corporate Developments

- Positive 3-month safety data for Phase 1 EYP-1901 DAVIO trial for the potential treatment of wet AMD featured at American Society of Retina Specialists (ASRS) –
- Topline data for DAVIO trial to be presented at American Academy of Ophthalmology (AAO) 2021 Annual Meeting on November 13, 2021 -
- Net product revenues of \$8.6 million versus \$5.8 million in Q3 2020, a 49% increase –
- Management to host a conference call and webcast today at 8:30 AM ET –

WATERTOWN, Mass., November 3, 2021 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a pharmaceutical company committed to developing and commercializing therapeutics to improve the lives of patients with serious eye disorders, today announced financial results for the third quarter ended September 30, 2021 and highlighted recent corporate developments.

“We continue to advance our pipeline, announcing positive 3-month safety data for all dose levels in our Phase 1 DAVIO trial at the American Society of Retina Specialists (ASRS) 2021 Annual Meeting held in October. We look forward to presenting topline interim safety and efficacy data for the DAVIO trial as a late breaker presentation during the Retina Subspecialty Day at the American Academy of Ophthalmology (AAO) 2021 Annual Meeting on November 13. In October, we also announced preliminary data from our YUTIQ® CALM real-world registry study at ASRS, which allows us to better understand the posterior segment uveitis patients we serve.” said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals.

Ms. Lurker continued, “Our commercial team continues to perform with solid year over year revenue growth for both DEXYCU and YUTIQ, despite a continued impact on demand caused by the COVID-19 pandemic.”

R&D Highlights

- In October 2021, the Company reported positive 3-month safety results for all dose levels from its ongoing DAVIO trial of EYP-1901 for wet-AMD at the ASRS 2021 Annual Meeting. Adverse events (AEs) reported in the 3-month safety results were all mild to moderate in severity with no ocular serious adverse events (SAEs) or drug-related systemic SAEs reported. In addition, there were no reported AEs related to significant intraocular inflammation, best corrected visual acuity (BCVA) reduction, or elevation of intra-ocular pressure (IOP). Further, no events of endophthalmitis, retinal detachment, or migration into the anterior chamber were reported.

- In September 2021, the Company announced that a late-breaking abstract highlighting topline data for the Phase 1 DAVIO trial of EYP-1901 in wet AMD was selected for presentation at the AAO 2021 Annual Meeting. The presentation is scheduled for November 13, 2021.
- In October 2021, the Company reported preliminary data from its ongoing YUTIQ® CALM real-world registry study at Retina Society and ASRS. The study is collecting data on patients who have received the fluocinolone acetonide intravitreal implant 0.18 mg and includes patients 18 years of age and older with a diagnosis of chronic noninfectious uveitis affecting the posterior segment. Interim baseline data on patients in the registry as of August 2021 show that most patients enrolled to date at entry suffer from uveitis of substantial disease duration (mean 57 months, or 4.75 years) and also have a variety of etiologies, mostly unknown, and previous treatments in their medical history. Following injection with YUTIQ® most patients have experienced relatively controlled intraocular inflammation as measured by anterior chamber cell count and vitreous haze.

Recent Business Highlights

- On November 1, 2021, the Company appointed Jay S. Duker, M.D. as its Chief Operating Officer. In his new role, Dr. Duker will be responsible for overseeing all clinical development, research, product development and manufacturing. Dr. Duker joined EyePoint as Chief Strategic Scientific Officer on a part-time basis in 2020, after serving as an independent member of the EyePoint Board of Directors since 2016. Dr. Duker has spent over 30 years in academic ophthalmology, and for the past 21 years served as Chair of the Department of Ophthalmology at Tufts Medical Center and the Tufts University School of Medicine, a position he relinquished to join EyePoint full time.

Commercial Performance in Third Quarter 2021

- Net product revenue for YUTIQ® and DEXYCU was \$3.9 million and \$4.7 million, respectively.
- Customer demand of approximately 560 units of YUTIQ and approximately 13,100 units for DEXYCU, compared to approximately 540 units and 10,900 units, respectively for Q2 2021 customer demand.

Review of Results for the Third Quarter ended September 30, 2021

For the quarter ended September 30, 2021, total net revenue was \$9.1 million compared to \$15.7 million for the quarter ended September 30, 2020. Net product revenue for the quarter was \$8.6 million, compared to net product revenues for the quarter ended September 30, 2020 of \$5.8 million.

Net revenue from royalties and collaborations for the quarter ended September 30, 2021 totaled \$0.5 million compared to \$9.9 million in the corresponding period in 2020.

Operating expenses for the quarter ended September 30, 2021 totaled \$24.4 million versus \$17.7 million in the prior year period. This increase was primarily due to a \$4.4 million increase in R&D expense, a \$2.1 million increase in sales and marketing expense, a \$0.3 million increase in G&A expense and offset by a \$0.1 million decrease in cost of sales. Non-operating expense, net, totaled \$1.4 million and net loss was \$16.7 million, or (\$0.58) per share, compared to a net loss of \$3.8 million, or (\$0.30) per share, for the prior year period.

Cash and cash equivalents at September 30, 2021 totaled \$119.7 million compared to \$44.9 million at December 31, 2020.

Financial Outlook

We expect the cash on hand at September 30, 2021 and expected net cash inflows from our product sales will enable us to fund our current and planned operations through the end of 2022.

Conference Call Information

EyePoint will host a conference call today, at 8:30 AM ET to discuss the results for the third quarter ended September 30, 2021 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 9396615. 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 EYP-1901

EYP-1901 is a potential twice-yearly sustained delivery intravitreal anti-VEGF treatment for wet age-related macular degeneration. EYP-1901 combines a bioerodible formulation of EyePoint's proprietary Durasert® sustained release technology with vorolanib, a tyrosine kinase inhibitor. Vorolanib provided clear efficacy signals in two prior human trials in wet AMD as an orally delivered therapy with no significant ocular adverse events. Preclinical studies of EYP-1901 have shown anti-VEGF activity in disease models of ocular neovascularization and no serious safety issues were observed. EYP-1901 is initially being developed as a treatment of wet AMD, with the potential for additional indications in diabetic retinopathy and retinal vein occlusion.

About YUTIQ®

YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg is indicated for the treatment of chronic, non-infectious uveitis affecting the posterior segment of the eye, and was approved by the FDA on October 12, 2018. A link to the full product label is available on the YUTIQ website at: <https://yutiq.com/downloads/US-YUT-2100035%20YUTIQ%20Prescribing%20Information-2021.pdf>.

About EyePoint Pharmaceuticals, Inc.

EyePoint Pharmaceuticals (Nasdaq:EYPT) is a pharmaceutical company committed to developing and commercializing therapeutics to help improve the lives of patients with serious eye disorders. The Company's pipeline leverages its proprietary Durasert® technology for sustained intraocular drug delivery including EYP-1901, a potential twice-yearly intravitreal anti-VEGF treatment initially targeting wet age-related macular degeneration. The Company has two commercial products: YUTIQ®, for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, and DEXYCU®, for the treatment of postoperative inflammation following ocular surgery. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. 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: To the extent any statements made in this press release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements regarding the anticipated use of proceeds for the proposed offering and other statements identified by words such as “will,” “potential,” “could,” “can,” “believe,” “intends,” “continue,” “plans,” “expects,” “anticipates,” “estimates,” “may,” other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause EyePoint’s actual results to be materially different than those expressed in or implied by EyePoint’s forward-looking statements. For EyePoint, this includes our expectations regarding the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a novel twice-yearly treatment for serious eye diseases, including wet age-related macular degeneration, diabetic retinopathy and retinal vein occlusion; the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the continued impact of the COVID-19 pandemic on EyePoint’s business, the medical community and the global economy and the impact of general business and economic conditions; 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 development of our YUTIQ line extension shorter-duration treatment for non-infectious uveitis affecting the posterior segment of the eye; the success of current and future license agreements, including our agreements with Ocumension Therapeutics and Equinox Science; termination or breach of current license agreements, including our agreements with Ocumension Therapeutics and Equinox Science; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; 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, | |
|---|-------------------------------------|-------------------|------------------------------------|--------------------|
| | 2021 | 2020 | 2021 | 2020 |
| Revenues: | | | | |
| Product sales, net | \$ 8,587 | \$ 5,758 | \$ 24,127 | \$ 14,151 |
| License and collaboration agreements | 159 | 9,535 | 594 | 11,590 |
| Royalty income | 313 | 402 | 674 | 1,565 |
| Total revenues | <u>9,059</u> | <u>15,695</u> | <u>25,395</u> | <u>27,306</u> |
| Operating expenses: | | | | |
| Cost of sales, excluding amortization of acquired intangible assets | 1,825 | 1,882 | 5,144 | 3,363 |
| Research and development | 8,498 | 4,090 | 19,582 | 12,219 |
| Sales and marketing | 7,374 | 5,269 | 19,692 | 19,483 |
| General and administrative | 6,060 | 5,796 | 16,358 | 14,949 |
| Amortization of acquired intangible assets | 615 | 615 | 1,845 | 1,845 |
| Total operating expenses | <u>24,372</u> | <u>17,652</u> | <u>62,621</u> | <u>51,859</u> |
| Loss from operations | <u>(15,313)</u> | <u>(1,957)</u> | <u>(37,226)</u> | <u>(24,553)</u> |
| Other income (expense): | | | | |
| Interest and other income, net | 6 | (4) | 286 | 58 |
| Interest expense | (1,388) | (1,840) | (4,110) | (5,430) |
| Gain on extinguishment of debt | — | — | 2,065 | — |
| Total other income (expense), net | <u>(1,382)</u> | <u>(1,844)</u> | <u>(1,759)</u> | <u>(5,372)</u> |
| Net loss | <u>\$ (16,695)</u> | <u>\$ (3,801)</u> | <u>\$ (38,985)</u> | <u>\$ (29,925)</u> |
| Net loss per common share - basic and diluted | <u>\$ (0.58)</u> | <u>\$ (0.30)</u> | <u>\$ (1.42)</u> | <u>\$ (2.44)</u> |
| Weighted average common shares outstanding - basic and diluted | <u>28,766</u> | <u>12,794</u> | <u>27,429</u> | <u>12,277</u> |

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

| | September 30, 2021 | December 31, 2020 |
|---|-----------------------|----------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 119,710 | \$ 44,909 |
| Accounts and other receivables, net | 13,602 | 9,453 |
| Prepaid expenses and other current assets | 3,892 | 3,419 |
| Inventory | 4,571 | 5,337 |
| Total current assets | 141,775 | 63,118 |
| Operating lease right-of-use assets | 2,402 | 2,610 |
| Intangible assets, net | 23,364 | 25,209 |
| Other assets | 710 | 780 |
| Total assets | \$ 168,251 | \$ 91,717 |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 18,102 | \$ 13,256 |
| Deferred Revenue | 1,035 | 945 |
| Other current liabilities | 796 | 687 |
| Total current liabilities | 19,933 | 14,888 |
| Long-term debt | 36,396 | 37,977 |
| Deferred revenue - noncurrent | 14,792 | 15,616 |
| Operating lease liabilities - noncurrent | 2,019 | 2,330 |
| Other long-term liabilities | 2,363 | 2,365 |
| Total liabilities | 75,503 | 73,176 |
| Stockholders' equity: | | |
| Capital | 641,572 | 528,380 |
| Accumulated deficit | (549,665) | (510,680) |
| Accumulated other comprehensive income | 841 | 841 |
| Total stockholders' equity | 92,748 | 18,541 |
| Total liabilities and stockholders' equity | \$ 168,251 | \$ 91,717 |