

**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): August 03, 2022

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, Massachusetts
(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))

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 Global Market |

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 August 3, 2022, EyePoint Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2022 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 August 3, 2022 |
| 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: August 3, 2022

By: /s/ George O. Elston

George O. Elston

Chief Financial Officer

EyePoint Pharmaceuticals Reports Second Quarter 2022 Financial Results and Highlights Recent Corporate Developments

- *First patient dosed in the Phase 2 DAVIO 2 clinical trial for wet age-related macular degeneration (wet AMD) –*
- *Presented positive twelve-month safety and efficacy data from Phase 1 DAVIO clinical trial for EYP-1901 in wet AMD at American Society of Retina Specialists (ASRS) 2022 Annual Meeting –*
- *Announced in conjunction with OcuMension Therapeutics, approval of New Drug Application by China’s National Medical Products Administration (NMPA) for YUTIQ® for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye –*
 - *Net product revenue of \$11.3 million in Q2 2022; a 30% increase from Q2 2021 –*
 - *Management to host a conference call and webcast today at 8:30 a.m. ET –*

WATERTOWN, Mass., August 3, 2022 (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 second quarter ended June 30, 2022 and highlighted recent corporate developments.

“We continue to make significant progress at EyePoint, with the recent Phase 2 clinical trial initiation for EYP-1901 for the treatment of wet AMD, demonstrating the team’s continued strong execution in advancing our innovative pipeline,” said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. “In addition to this key milestone, we presented 12-month Phase 1 DAVIO safety and efficacy results at the ASRS 2022 Annual Meeting, further bolstering our belief that EYP-1901 has the potential to significantly reduce the treatment burden of this serious eye disease by providing the majority of patients with a safe and reliable maintenance therapy option for up to six months without supplemental anti-VEGF therapy. With these positive results in-hand, supported by our strong balance sheet, we are well-positioned to advance EYP-1901 through these important Phase 2 trials.”

Ms. Lurker continued, “On the commercial front, we had our strongest quarter to-date with \$11.3 million in net product revenue, an increase of 30% from the first quarter of this year along with continued strong customer demand for both YUTIQ® and DEXYCU®.”

R&D Highlights and Updates

- The first patient was dosed in the Phase 2 DAVIO 2 clinical trial of EYP-1901 for the treatment of wet AMD in July 2022. The twelve-month, randomized, controlled DAVIO 2 trial is expected to enroll approximately 150 patients previously treated with a standard-of-care anti-VEGF therapy, and topline data is expected in the second half of 2023. More information about the study is available at clinicaltrials.gov (identifier: NCT05381948).
- Final twelve-month data from the Phase 1 DAVIO clinical trial of EYP-1901 for wet AMD was presented at the ASRS 2022 Annual Meeting in July 2022. Data presented reinforced a positive safety and efficacy profile for EYP-1901 and showed no dose limiting toxicities, no reports of ocular serious adverse events (SAEs) and no drug-related systemic SAEs. There were no reported events of vitreous floaters, endophthalmitis, retinal detachment, implant migration in the anterior chamber, retinal vasculitis, or posterior segment inflammation. The data also confirmed stable best corrected visual acuity (BCVA) (-4.12 ETDRS letters), stable central subfield thickness (CST) on optical coherence tomography (OCT) (-2.76 μm), and a clinically significant 74% reduction in treatment burden (79% at six-months). These data also showed that 53% of eyes did not require any supplemental anti-VEGF injections up to six-months and 35% up to twelve months following a single dose of EYP-1901.
- In a poster presentation at the Association for Research in Vision and Ophthalmology (ARVO) 2022 Annual Meeting in May 2022, the Company provided an update on the YUTIQ[®] CALM registry study. Data from this Phase IV, multi-center registry study indicated effective control of non-infectious uveitis, with no significant changes in visual acuity and without major safety signals. The CALM study is a joint collaboration between EyePoint and the Cleveland Clinic and could become a valuable resource in furthering the understanding of posterior segment uveitis.

Recent Corporate Highlights

- Karen Zaderej, M.B.A. was appointed to the Company's Board of Directors in July 2022. Ms. Zaderej brings more than 35 years of biopharmaceutical and medical device experience to the role, and currently serves as the President and CEO of AxoGen, a leading company focused specifically on the science, development and commercialization of technologies for peripheral nerve regeneration and repair.
 - In July 2022, the Company announced that the CMS indicated its intention not to provide further pass-through extension to expiring products, including DEXYCU[®] in its draft 2023 CMS HOPPS (Hospital Outpatient Prospective Payment System) rule. If the draft rule becomes final, DEXYCU will lose pass-through separate reimbursement status on December 31, 2022 and will instead be bundled into the general Cataract procedure reimbursement code starting on January 1, 2023. The Company intends to request longer pass-through status given the ongoing pandemic.
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- Anthony (Tony) Adamis, M.D. was elected to the Company's Board of Directors in June 2022. Dr. Adamis is a highly accomplished ophthalmology executive with more than 30 years of research and development experience in the biopharmaceutical industry. He is best-known for his co-discovery of the role of vascular endothelial growth factor (VEGF) in ocular disease, including wet AMD and NPDR.
- In June 2022, the Company and OcuMension Therapeutics announced that China's National Medical Products Administration (NMPA) has approved YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18mg for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.
- The Company entered into an exclusive license agreement with Betta Pharmaceuticals Co. Ltd. (Betta) to develop and commercialize EYP-1901 in China, Hong Kong, Macau and Taiwan (the Territory) in May 2022. Under the terms of this agreement, EyePoint retains all ophthalmic rights for EYP-1901 in the entire world outside of the Territory. Concurrently, EyePoint and Betta affiliate, Equinox Sciences LLC executed an amendment to their 2020 exclusive license agreement, expanding EyePoint's exclusive rights to develop and commercialize vorolanib, the tyrosine kinase inhibitor used in EYP-1901, through localized delivery for the treatment of all ophthalmic diseases in the entire world outside of the Territory.

Commercial Performance in Second Quarter 2022

- Net product revenue for YUTIQ and DEXYCU was \$7.4 million and \$3.9 million, respectively.
- Customer demand for YUTIQ was approximately 900 units, representing approximately 40% growth from Q1 2022.
- Customer demand for DEXYCU was approximately 14,700 units, consistent with Q1 2022.

Review of Results for the Second Quarter ended June 30, 2022

For the second quarter ended June 30, 2022, total net revenue was \$11.6 million compared to \$9.0 million for the quarter ended June 30, 2021. Net product revenue for the second quarter was \$11.3 million, compared to net product revenues for the second quarter ended June 30, 2021 of \$8.7 million.

Net revenue from royalties and collaborations for the second quarter ended June 30, 2022 totaled \$0.3 million compared to \$0.3 million in the corresponding period in 2021.

Operating expenses for the second quarter ended June 30, 2022 totaled \$30.8 million versus \$20.0 million in the prior year period, primarily driven by an increase in clinical trial costs for EYP-1901 and an increase in investment across the organization in personnel and stock-based compensation. Non-operating expense, net, totaled \$0.2 million and net loss was \$19.4 million, or (\$0.52) per share, compared to a net loss of \$10.0 million, or (\$0.35) per share, for the prior year period.

Cash and investments at June 30, 2022 totaled \$171.2 million compared to \$190.8 million at March 31, 2022.

Financial Outlook

We expect the cash, cash equivalents and investments on hand on June 30, 2022 and expected net cash inflows from our product sales will enable us to fund our current and planned operations into the second half of 2024.

Conference Call Information

EyePoint will host a conference call today, at 8:30 a.m. ET to discuss the results for the second quarter ended June 30, 2022 and recent corporate developments. To access the conference call, please register at <https://register.vevent.com/register/B12bbb04b8ff6f4995988cc55bd04b8f78>. A live webcast and replay will be available on the Investor Relations section of the corporate website at <http://www.eyepointpharma.com>.

About EyePoint Pharmaceuticals

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, an investigational sustained delivery intravitreal anti-VEGF treatment initially targeting wet age-related macular degeneration. The proven Durasert drug delivery platform has been safely administered to thousands of patients' eyes across four U.S. FDA approved products, including YUTIQ® for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, which is currently marketed by the Company. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts.

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 use of proceeds for the 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 uncertainties regarding the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration; the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; the success of current and future license agreements; 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 our commercialized products, YUTIQ® and DEXYCU®; market acceptance of our products; product liability; industry consolidation; compliance with environmental laws; risks and costs of international business operations; volatility of stock price; possible dilution; absence of dividends; 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; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; manufacturing risks; 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. EyePoint undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

Investors:

Christina Tartaglia
Stern IR
Direct: 212-698-8700
christina.tartaglia@sternir.com

Media Contact:

Amy Phillips
Green Room Communications
Direct: 412-327-9499
aphillips@greenroompr.com

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|--------------------------------|--------------------|------------------------------|--------------------|
| | 2022 | 2021 | 2022 | 2021 |
| Revenues: | | | | |
| Product sales, net | \$ 11,318 | \$ 8,738 | \$ 20,328 | \$ 15,540 |
| License and collaboration agreements | 49 | 94 | 108 | 435 |
| Royalty income | 198 | 181 | 423 | 361 |
| Total revenues | <u>11,565</u> | <u>9,013</u> | <u>20,859</u> | <u>16,336</u> |
| Operating expenses: | | | | |
| Cost of sales, excluding amortization of acquired intangible assets | 1,734 | 1,929 | 3,511 | 3,319 |
| Research and development | 12,992 | 5,605 | 22,937 | 11,084 |
| Sales and marketing | 6,883 | 6,659 | 13,576 | 12,318 |
| General and administrative | 8,557 | 5,184 | 17,106 | 10,299 |
| Amortization of acquired intangible assets | 615 | 615 | 1,230 | 1,230 |
| Total operating expenses | <u>30,781</u> | <u>19,992</u> | <u>58,360</u> | <u>38,250</u> |
| Loss from operations | <u>(19,216)</u> | <u>(10,979)</u> | <u>(37,501)</u> | <u>(21,914)</u> |
| Other income (expense): | | | | |
| Interest and other income, net | 362 | 280 | 423 | 281 |
| Interest expense | (552) | (1,376) | (1,745) | (2,722) |
| Gain (loss) on extinguishment of debt | - | 2,065 | (1,559) | 2,065 |
| Total other income (expense), net | <u>(190)</u> | <u>969</u> | <u>(2,881)</u> | <u>(376)</u> |
| Net loss | <u>\$ (19,406)</u> | <u>\$ (10,010)</u> | <u>\$ (40,382)</u> | <u>\$ (22,290)</u> |
| Net loss per common share - basic and diluted | <u>\$ (0.52)</u> | <u>\$ (0.35)</u> | <u>\$ (1.08)</u> | <u>\$ (0.83)</u> |
| Weighted average common shares outstanding - basic and diluted | <u>37,322</u> | <u>28,744</u> | <u>37,288</u> | <u>26,750</u> |

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

| | <u>June 30,</u> <u>2022</u> | <u>December 31,</u> <u>2021</u> |
|---|--------------------------------|------------------------------------|
| Assets | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 82,134 | \$ 178,593 |
| Marketable securities | 89,033 | 32,965 |
| Accounts and other receivables, net | 22,594 | 18,354 |
| Prepaid expenses and other current assets | 8,851 | 4,217 |
| Inventory | 3,254 | 3,616 |
| Total current assets | <u>205,866</u> | <u>237,745</u> |
| Operating lease right-of-use assets | 4,787 | 2,252 |
| Intangible assets, net | 21,519 | 22,749 |
| Other assets | 1,261 | 626 |
| Total assets | <u>\$ 233,433</u> | <u>\$ 263,372</u> |
| Liabilities and stockholders' equity | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | \$ 21,370 | \$ 21,807 |
| Deferred revenue | 1,137 | 1,069 |
| Short-term borrowings | 10,475 | - |
| Other current liabilities | 408 | 782 |
| Total current liabilities | <u>33,390</u> | <u>23,658</u> |
| Long-term debt | 29,181 | 36,562 |
| Deferred revenue - noncurrent | 14,070 | 14,560 |
| Operating lease liabilities - noncurrent | 4,826 | 1,860 |
| Other long-term liabilities | 600 | 2,352 |
| Total liabilities | <u>82,067</u> | <u>78,992</u> |
| Stockholders' equity: | | |
| Capital | 760,243 | 752,636 |
| Accumulated deficit | (609,479) | (569,097) |
| Accumulated other comprehensive income | 602 | 841 |
| Total stockholders' equity | <u>151,366</u> | <u>184,380</u> |
| Total liabilities and stockholders' equity | <u>\$ 233,433</u> | <u>\$ 263,372</u> |

