

**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): March 02, 2023

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 March 2, 2023, EyePoint Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and year ended December 31, 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 March 2, 2023
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: March 2, 2023

By: /s/ George O. Elston
George O. Elston
Chief Financial Officer

EyePoint Pharmaceuticals Reports Fourth Quarter and Full-Year 2022 Financial Results and Highlights Recent Corporate Developments

– Phase 2 DAVIO 2 clinical trial in wet AMD on track with topline data anticipated by year-end 2023 –

– Phase 2 PAVIA clinical trial in non-proliferative diabetic retinopathy (NPDR) on track with enrollment completion anticipated in 4Q 2023

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– Net product revenues for Full Year 2022 of \$39.9 million, a 13.0% increase versus Full Year 2021 of \$35.3 million –

– \$144.6M of cash and investments at December 31, 2022 with cash runway projected into 2H 2024 –

– Management to host a conference call and webcast today at 8:30 a.m. ET –

WATERTOWN, Mass., March 2, 2023 (GLOBE NEWSWIRE) – EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing therapeutics to improve the lives of patients with serious eye disorders, today announced financial results for the fourth quarter and year ended December 31, 2022 and highlighted recent corporate developments.

“2022 was an exciting year of continued execution for EyePoint Pharmaceuticals as we advanced EYP-1901 into two Phase 2 clinical trials in wet AMD and NPDR after the positive Phase 1 DAVIO results. EYP-1901 potentially brings a once every six-month maintenance treatment for wet AMD patients and once every nine-month treatment for NPDR patients, both of which need significantly longer duration treatments beyond the current standard of care. Importantly, EYP-1901 also brings a differentiated mechanism of action with vorolanib, a selective receptor binding tyrosine kinase inhibitor. We look forward to presenting preclinical data on the observed neuroprotective effect of vorolanib in a mouse model of retinal detachment at the upcoming 2023 ARVO Annual Meeting in April,” said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. “We remain keenly focused on completing enrollment for both trials and we anticipate presenting topline data for wet AMD by year-end, while we actively prepare for the initiation of pivotal Phase 3 trials in 2024.”

Ms. Lurker continued, “Our commercial YUTIQ team delivered exceptional sales results in 2022 with \$28.3 million of net product revenue for YUTIQ, a 67% increase compared with 2021, driven by strong customer demand from retinal specialists.”

R&D Highlights and Updates

- Enrollment remains on track for the Phase 2 DAVIO 2 clinical trial studying EYP-1901 as a potential six-month maintenance treatment for wet AMD, with topline data anticipated by year-end 2023.
 - The Phase 2 PAVIA clinical trial evaluating EYP-1901 as a potential nine-month treatment in NPDR continues on track with enrollment completion anticipated in 4Q 2023.
 - EyePoint and Rallybio announced a research collaboration in February to evaluate Rallybio’s complement inhibitor C5 (component 5) using EyePoint’s proprietary Durasert® technology for sustained intraocular drug delivery. The initial focus will be on developing a potential long-acting treatment for geographic atrophy, an advanced form of age-related macular degeneration that leads to irreversible vision loss.
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- The Company will present preclinical data on the neuroprotective effect of vorolanib in a mouse model of retinal detachment as well as clinical data, including an update on the YUTIQ® CALM registry study and an encore presentation of EYP-1901 final twelve-month Phase 1 DAVIO results, at the 2023 ARVO Annual Meeting in April. The CALM study is a Phase 4, multi-center registry study and a collaboration between EyePoint and the Cleveland Clinic.
- An encore presentation of the EYP-1901 final twelve-month Phase 1 DAVIO results was presented at the Macula Society 46th Annual Meeting in February 2023 and at the Retina Society 55th Annual Scientific Meeting in November 2022.
- Data from the YUTIQ® CALM registry study was presented as a poster presentation by Pouya Dayani, M.D., titled “CALM: Retrospective Registry Study to Collect Real-World Data on the Fluocinolone Acetonide Intravitreal Implant 0.18 Mg for the Treatment of Chronic Non-Infectious Uveitis Affecting the Posterior Segment - Year 1 Update” at the Retina Society 55th Annual Scientific Meeting in November 2022.

Recent Corporate Highlights

- The Company entered into a lease agreement for the construction of a 40,000-square-foot standalone commercial manufacturing facility in Northbridge, Massachusetts to support global product supply of EYP-1901 and YUTIQ. The Company was awarded \$1.9 million of state and local grants for the facility with rent payments commencing upon completion of construction in the second half of 2024.
- Jay S. Duker, M.D., who has served as the Company’s Chief Operating Officer (COO) since November 2021, was promoted to the additional role of President in January 2023. In addition to continuing to oversee his duties as COO, in his expanded role, Dr. Duker will also oversee regulatory affairs.

YUTIQ Commercial Performance in Fourth Quarter 2022

Net product revenue for YUTIQ was \$9.0 million in the fourth quarter of 2022 compared to \$5.8 million for the fourth quarter ended December 31, 2021, a 55% increase.

Customer demand for YUTIQ was approximately 980 units in the fourth quarter of 2022 compared to approximately 890 units for 3Q 2022, a 10% increase.

Review of Results for the Fourth Quarter Ended December 31, 2022

For the quarter ended December 31, 2022, total net revenue was \$10.5 million compared to \$11.5 million for the quarter ended December 31, 2021. Net product revenue for the quarter ended December 31, 2022 was \$9.9 million, compared to net product revenue for the quarter ended December 31, 2021 of \$11.2 million.

Net revenue from royalties and collaborations for the quarter ended December 31, 2022 totaled \$0.6 million compared to \$0.3 million in the corresponding period in 2021.

Operating expenses for the quarter ended December 31, 2022 totaled \$54.3 million compared to \$29.6 million in the prior year period. This increase was primarily driven by a one-time \$20.7 million non-cash impairment charge of the intangible asset associated with DEXYCU due to the loss of pass-through reimbursement by the Centers for Medicare and Medicaid (CMS) effective January 1, 2023. Further, there was a \$6.6 million increase in R&D expense and a \$0.4 million increase in the cost of sales. This was offset by a \$1.9 million decrease in sales and marketing expense and a \$0.7 million decrease in G&A expense.

Non-operating income, net, totaled \$0.3 million and net loss was \$43.5 million, or (\$1.16) per share, compared to a net loss of \$19.4 million, or (\$.59) per share, for the prior year period.

Review of Results for the Full Year Ended December 31, 2022

For the full year ended December 31, 2022, total net revenue was \$41.4 million compared to \$36.9 million for the full year ended December 31, 2021. Net product revenue for the full year ended December 31, 2022 was \$39.9 million, compared to net product revenues for the full year ended December 31, 2021 of \$35.3 million.

Net revenue from royalties and collaborations for the full year ended December 31, 2022 totaled \$1.5 million compared to \$1.6 million in the corresponding period in 2021.

Operating expenses for the full year ended December 31, 2022 totaled \$141.0 million versus \$92.2 million in the prior year period. This increase was primarily driven by a one-time \$20.7 million non-cash impairment charge of the intangible asset associated with DEXYCU, which was due to the loss of pass-through reimbursement by CMS effective January 1, 2023. Further, there was a \$21.1 million increase in R&D expense, a \$9.2 million increase in G&A expense and a \$0.1 million increase in cost of sales. This was offset by a \$2.0 million decrease in sales and marketing expense.

Non-operating expense, net, totaled \$2.6 million and net loss was \$102.3 million, or (\$2.74) per share, compared to a net loss of \$58.4 million, or (\$2.03) per share, for the prior year period.

Cash, cash equivalents and investments in marketable securities on December 31, 2022 totaled \$144.6 million compared to \$211.6 million as of December 31, 2021.

Financial Outlook

We expect the cash, cash equivalents and investments on hand on December 31, 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 fourth quarter and year ended December 31, 2022 and recent corporate developments. To access the live conference call, please register at <https://register.vevent.com/register/BI25f5945035ff443db085313b1dcde731>. A live audio webcast of the event can be accessed via the Investors section of the Company website at www.eyepointpharma.com. A webcast replay will also be available on the corporate website at the conclusion of the call.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (Nasdaq: EYPT) is a 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 treatment currently in Phase 2 clinical trials. 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 posterior segment uveitis, 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 and non-proliferative diabetic retinopathy; 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®; the loss of pass-through reimbursement status for DEXYCU as of January 1, 2023; 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 potential 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.

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Revenues:				
Product sales, net	\$ 9,857	\$ 11,185	\$ 39,905	\$ 35,312
License and collaboration agreements	202	162	362	756
Royalty income	474	197	1,137	871
Total revenues	<u>10,533</u>	<u>11,544</u>	<u>41,404</u>	<u>36,939</u>
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	3,410	3,033	8,326	8,177
Research and development	15,543	8,918	49,642	28,500
Sales and marketing	5,915	7,811	25,507	27,503
General and administrative	8,496	9,217	34,817	25,575
Amortization of acquired intangible assets	205	615	2,050	2,460
Impairment of acquired intangible assets	20,699	—	20,699	—
Total operating expenses	<u>54,268</u>	<u>29,594</u>	<u>141,041</u>	<u>92,215</u>
Loss from operations	<u>(43,735)</u>	<u>(18,050)</u>	<u>(99,637)</u>	<u>(55,276)</u>
Other income (expense):				
Interest and other income, net	1,064	6	2,131	292
Interest expense	(781)	(1,388)	(3,189)	(5,498)
(Loss) gain on extinguishment of debt	—	—	(1,559)	2,065
Total other expense, net	<u>283</u>	<u>(1,382)</u>	<u>(2,617)</u>	<u>(3,141)</u>
Net loss	<u>\$ (43,452)</u>	<u>\$ (19,432)</u>	<u>\$ (102,254)</u>	<u>\$ (58,417)</u>
Net loss per common share - basic and diluted	<u>\$ (1.16)</u>	<u>\$ (0.59)</u>	<u>\$ (2.74)</u>	<u>\$ (2.03)</u>
Weighted average common shares outstanding - basic and diluted	<u>37,352</u>	<u>32,700</u>	<u>37,317</u>	<u>28,758</u>

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

	<u>December 31,</u> 2022	<u>December 31,</u> 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 95,633	\$ 178,593
Marketable securities	48,928	32,965
Accounts and other receivables, net	15,503	18,354
Other current assets	9,858	4,217
Inventory	2,886	3,616
Total current assets	172,808	237,745
Operating lease right-of-use assets	6,038	2,252
Intangible assets, net	—	22,749
Other assets	1,510	626
Total assets	\$ 180,356	\$ 263,372
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 22,278	\$ 21,807
Deferred revenue	1,205	1,069
Short-term borrowings	10,475	—
Other current liabilities	579	782
Total current liabilities	34,537	23,658
Long-term debt	29,310	36,562
Deferred revenue - noncurrent	13,557	14,560
Operating lease liabilities - noncurrent	5,984	1,860
Other long-term liabilities	600	2,352
Total liabilities	83,988	78,992
Stockholders' equity:		
Capital	766,933	752,636
Accumulated deficit	(671,351)	(569,097)
Accumulated other comprehensive income	786	841
Total stockholders' equity	96,368	184,380
Total liabilities and stockholders' equity	\$ 180,356	\$ 263,372

