
**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): March 3, 2022

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 March 3, 2022, EyePoint Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter and full year ended December 31, 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 March 3, 2022
104	Cover Page Interactive Data File (embedded within the inline XBRL document)



EyePoint Pharmaceuticals Reports Fourth Quarter and Full-Year 2021 Financial Results and Highlights Recent Corporate Developments

- Positive EYP-1901 DAVIO Phase 1 eight-month data was presented at Angiogenesis, Exudation, and Degeneration 2022 virtual meeting on February 12, 2022, continuing positive safety and efficacy profile seen at six-month readout
- Phase 2 trials for EYP-1901 in wet AMD and NPDR are expected to initiate in Q3 2022 and 2H 2022, respectively, with top-line data from wet AMD trial anticipated in 2H 2023
- Net product revenues for Full Year 2021 of \$35.3 million, a 70% increase vs Full Year 2020 of \$20.8 million
- Management to host a conference call and webcast today at 8:30 a.m. ET

WATERTOWN, Mass., March 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 fourth quarter and year ended December 31, 2021 and highlighted recent corporate developments.

“2021 was an exceptional year for EyePoint Pharmaceuticals as we made significant strides across clinical, financial and commercial fronts, highlighted by positive interim Phase 1 DAVIO data from our lead pipeline program, EYP-1901 for wet age-related macular degeneration (wet AMD), and the strengthening of our balance sheet with over \$230 million in proceeds from two successful follow-on offerings during the year,” said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. “In the year ahead, our priority remains on advancing EYP-1901 into a Phase 2 clinical trial for wet AMD in Q3 2022 and in non-proliferative diabetic retinopathy (NPDR) later in the second half of this year. We believe EYP-1901 has the potential to change the current treatment paradigm in wet AMD from an intensive monthly or bi-monthly regimen to a far less burdensome six-month maintenance therapy for the majority of patients.”

Ms. Lurker continued, “Our commercial team delivered a strong 2021 with \$35.3 million of net product revenue, a 70% increase over 2020, driven in part by record customer demand for both YUTIQ® and DEXYCU® in Q4 2021 despite the impact of the ongoing pandemic.”

R&D Highlights

- In February 2022, the Company presented eight-month data from the DAVIO Phase 1 clinical trial of EYP-1901 for wet AMD at the Angiogenesis, Exudation, and Degeneration 2022 virtual
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meeting. The data continued to show no dose limiting toxicities, no reports of ocular serious adverse events (SAEs) and no drug-related systemic SAEs, consistent with the six-month data presented in November 2021. The DAVIO data has also shown that following a single dose of EYP-1901, 53% and 41% of patients did not require a supplemental anti-VEGF treatment up to six and nine months, respectively. The treatment burden was reduced by 79% and 75% at six months and eight months respectively compared to prior to dosing with EYP-1901. Additionally, the eight-month data confirmed continued stable and sustained best corrected visual acuity (BCVA) (-3.0 ETDRS letters) and central subfield thickness/optical coherence tomography (CST/OCT) (+13 μm).

- In January 2022, the Company announced it completed a positive Type C meeting with the U.S. Food and Drug Administration (FDA) and expects to initiate a Phase 2 trial of EYP-1901 for wet AMD in Q3 2022 and in NPDR in 2H 2022 with initial top-line data for the wet AMD trial anticipated in 2H 2023.

Recent Business Highlights

- In January 2022, the Company appointed Michael C. Pine as its Chief Corporate Development and Strategy Officer. In this new role, Mr. Pine will be responsible for overseeing all of EyePoint's clinical and commercial business development and strategy. Mr. Pine has almost 20 years of business development and strategy experience and joins EyePoint Pharmaceuticals after serving as Senior Vice President of Business Development and Strategy at Medexus Pharmaceuticals.
 - In December 2021, the Company and Harrow Health's ImprimisRx announced an expanded U.S. commercial alliance for DEXYCU, giving ImprimisRx full responsibility for U.S. sales and marketing activities for DEXYCU, absorbing the majority of EyePoint's DEXYCU commercial organization. EyePoint Pharmaceuticals will retain the DEXYCU NDA, revenue recognition, manufacturing, and distribution responsibilities for all markets. The amended agreement expands the commercial alliance previously established in August 2020 between the companies.
 - In November 2021, the Company completed an upsized underwritten public offering with gross proceeds of \$115.4 million. The Company sold 5,122,273 shares of its common stock, which included the exercise in full by the underwriters of their option to purchase an additional 1,095,000 shares of common stock, and pre-funded warrants to purchase up to an aggregate of 3,272,727 shares of its common stock. The shares of common stock were sold at a public offering price of \$13.75 per share, and the pre-funded warrants were sold at a purchase price of \$13.74 per pre-funded warrant.
 - In November 2021, the Company appointed Jay S. Duker, M.D. as its Chief Operating Officer. In his 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.
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Commercial Performance in Fourth Quarter 2021

- Net product revenue for YUTIQ and DEXYCU was \$5.8 million and \$5.4 million, respectively.
- Customer demand for YUTIQ was approximately 650 units compared to approximately 560 units for Q3 2021, an increase of 16%.
- Customer demand for DEXYCU was approximately 13,800 units, compared to approximately 13,100 units for Q3 2021, an increase of 5%.

Review of Results for the Fourth Quarter ended December 31, 2021

For the quarter ended December 31, 2021, total net revenue was \$11.5 million compared to \$7.1 million for the quarter ended December 31, 2020. Net product revenue for the quarter ended December 31, 2021 was \$11.2 million, compared to net product revenues for the quarter ended December 31, 2020 of \$6.7 million.

Net revenue from royalties and collaborations for the quarter ended December 31, 2021 totaled \$0.4 million compared to \$0.5 million in the corresponding period in 2020.

Operating expenses for the quarter ended December 31, 2021 totaled \$29.6 million versus \$19.9 million in the prior year period. This increase was primarily due to a \$3.7 million increase in R&D expense, a \$3.4 million increase in G&A expense, a \$2.0 million increase in sales and marketing expense, and a \$0.6 million increase in cost of sales. Non-operating expense, net, totaled \$1.4 million and net loss was \$19.4 million, or (\$.59) per share, compared to a net loss of \$15.5 million, or (\$1.07) per share, for the prior year period.

Review of Results for the Full Year Ended December 31, 2021

For the full year ended December 31, 2021, total net revenue was \$36.9 million compared to \$34.4 million for the full year ended December 31, 2020. Net product revenue for the full year ended December 31, 2021 was \$35.3 million, compared to net product revenues for the full year ended December 31, 2020 of \$20.8 million.

Net revenue from royalties and collaborations for the full year ended December 31, 2021 totaled \$1.6 million compared to \$13.6 million in the corresponding period in 2020.

Operating expenses for the full year ended December 31, 2021 totaled \$92.2 million versus \$71.7 million in the prior year period. This increase was largely due to a \$11.1 million increase in R&D expense, a \$4.8 million increase in G&A expense, a \$2.4 million increase in cost of sales, and a \$2.2 million increase in sales and marketing expense. Non-operating expense, net, totaled \$3.1 million and net loss was \$58.4 million, or \$2.03 per share, compared to a net loss of \$45.4 million, or \$3.54 per share, for the prior year period.

Cash and investments on December 31, 2021 totaled \$211.6 million compared to \$44.9 million as of December 31, 2020.

Financial Outlook

We expect the cash on hand on December 31, 2021 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, 2021 and recent corporate 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 5058194. 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, 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 six-month intravitreal anti-VEGF treatment initially targeting wet age-related macular degeneration. Durasert's proven intravitreal 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 six-month 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.

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

	Three Months Ended		Twelve Months Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	\$ 11,185	\$ 6,680	\$ 35,312	\$ 20,831
License and collaboration agreements (including licensing fees from a related party of \$61 and \$0 for the three months ended December 31, 2021 and 2020, respectively and \$543 and \$11,500 for the years ended December 31, 2021 and 2020, respectively)	162	352	756	11,942
Royalty income	197	99	871	1,664
Total revenues	<u>11,544</u>	<u>7,131</u>	<u>36,939</u>	<u>34,437</u>
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	3,033	2,461	8,177	5,824
Research and development	8,918	5,205	28,500	17,424
Sales and marketing	7,811	5,810	27,503	25,293
General and administrative	9,217	5,777	25,575	20,726
Amortization of acquired intangible assets	615	615	2,460	2,460
Total operating expenses	<u>29,594</u>	<u>19,868</u>	<u>92,215</u>	<u>71,727</u>
Loss from operations	<u>(18,050)</u>	<u>(12,737)</u>	<u>(55,276)</u>	<u>(37,290)</u>
Other income (expense):				
Interest and other income, net	6	—	292	58
Interest expense	(1,388)	(1,827)	(5,498)	(7,257)
Gain (loss) on extinguishment of debt	—	(905)	2,065	(905)
Total other income (expense), net	<u>(1,382)</u>	<u>(2,732)</u>	<u>(3,141)</u>	<u>(8,104)</u>
Net loss	<u>\$ (19,432)</u>	<u>\$ (15,469)</u>	<u>\$ (58,417)</u>	<u>\$ (45,394)</u>
Net loss per common share - basic and diluted	<u>\$ (0.59)</u>	<u>\$ (1.07)</u>	<u>\$ (2.03)</u>	<u>\$ (3.54)</u>
Weighted average common shares outstanding - basic and diluted	<u>32,700</u>	<u>14,501</u>	<u>28,758</u>	<u>12,836</u>

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

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 178,593	\$ 44,909
Marketable securities	32,965	—
Accounts and other receivables, net (including due from a related party of \$414 and \$104 at December 31, 2021 and 2020, respectively)	18,354	9,453
Prepaid expenses and other current assets	4,217	3,419
Inventory	3,616	5,337
Total current assets	237,745	63,118
Operating lease right-of-use assets	2,252	2,610
Intangible assets, net	22,749	25,209
Other assets	626	780
Total assets	\$ 263,372	\$ 91,717
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 21,807	\$ 13,256
Deferred Revenue	1,069	945
Other current liabilities	782	687
Total current liabilities	23,658	14,888
Long-term debt	36,562	37,977
Deferred revenue - noncurrent	14,560	15,616
Operating lease liabilities - noncurrent	1,860	2,330
Other long-term liabilities	2,352	2,365
Total liabilities	78,992	73,176
Stockholders' equity:		
Capital	752,636	528,380
Accumulated deficit	(569,097)	(510,680)
Accumulated other comprehensive income	841	841
Total stockholders' equity	184,380	18,541
Total liabilities and stockholders' equity	\$ 263,372	\$ 91,717