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): November 02, 2022

EyePoint Pharmaceuticals, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**000-51122**	**26-2774444**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 November 2, 2022, EyePoint Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 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.

Exhibit No.	Description
99.1	Press Release of EyePoint Pharmaceuticals, Inc., dated November 2, 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: November 2, 2022

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

Exhibit 99.1

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

– Initiated Phase 2 DAVIO 2 clinical trial for wet age-related macular degeneration (wet AMD) and Phase 2 PAVIA clinical trial for non-proliferative diabetic retinopathy (NPDR) –

– 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 and American Academy of Ophthalmology (AAO) 2022 Annual Meeting –

– Net product revenue of $9.7 million in Q3 2022; a 13% increase from Q3 2021 –

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

WATERTOWN, Mass., November 2, 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 third quarter ended September 30, 2022 and highlighted recent corporate developments.

"In the third quarter, we continued to execute on key catalysts across our clinical-stage pipeline with the initiation of two Phase 2 clinical trials studying EYP-1901 in wet AMD and NPDR, following our encouraging positive safety and efficacy Phase 1 data," said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals. "There is a great unmet need in wet AMD and NPDR for convenient, safe and efficacious long-acting treatment options that maintain the patient's existing vision proactively. Bolstered by our strong balance sheet, we are well-positioned to advance EYP-1901 through these trials and explore its potential to significantly improve the lives of patients living with these serious eye disorders."

Ms. Lurker continued, "Our commercial team delivered a strong quarter with $9.7 million in net product revenue, driven by strong customer demand for YUTIQ® by retinal specialists."

R&D Highlights and Updates

- The first patient was dosed in the Phase 2 PAVIA clinical trial of EYP-1901 for the treatment of NPDR in September 2022. This twelve-month, randomized, controlled trial is expected to enroll approximately 105 patients randomly assigned to one of two doses of EYP-1901 (approximately 2 mg or 3 mg), or to the control group receiving a sham injection. More information about the study is available at clinicaltrials.gov (identifier: NCT05383209).
- 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. This twelve-month, randomized, controlled trial is expected to enroll approximately 150 patients previously treated with a standard-of-care anti-VEGF therapy, randomly assigned to one of two doses of EYP-1901 (approximately 2 mg or 3 mg) or an aflibercept control. Topline data is expected in the fourth quarter of 2023. More information about the study is available at clinicaltrials.gov (identifier: NCT05381948).
- The Company will be presenting data at the Retina Society 55th Annual Scientific Meeting in November 2022. Sunil Patel, M.D., Ph.D. will present an encore oral presentation of the EYP-1901 final twelve-month Phase 1 DAVIO results with an additional subset analysis of patients with no excess fluid at screening. Also, data from the YUTIQ® CALM registry study will be 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". The CALM study is a Phase 4, multi-center registry study and a collaboration between EyePoint and the Cleveland Clinic.

- Final twelve-month data from the Phase 1 DAVIO clinical trial of EYP-1901 for wet AMD was presented at the AAO 2022 Annual Meeting in September 2022 and topline data was presented at the ASRS 2022 Annual Meeting in July 2022. The data 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 73% reduction in treatment burden (75% at six-months).

Recent Corporate Highlights

- In October 2022, the Company and ImprimisRx mutually terminated an agreement for the commercialization of DEXYCU effective December 31, 2022. This is a result of the proposed "Medicare Hospital Outpatient Prospective Payment System and ASC Payment System Proposed Rule" published in the Federal Register by the Center for Medicare & Medicaid Services (CMS) on July 26, 2022, not containing an extension of the pass-through payment period for DEXYCU® beyond December 31, 2022. The final rule was published on November 1, 2022, confirming that CMS will not extend pass-through reimbursement status for DEXYCU beyond December 31, 2022.
- Karen Zaderej 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 board, and currently serves as the President and CEO of AxoGen.

Commercial Performance in Third Quarter 2022

Net product revenue for YUTIQ and DEXYCU was $7.3 million and $2.4 million, respectively.

Customer demand for YUTIQ and DEXYCU was approximately 890 units and 14,100 units, respectively.

Review of Results for the Third Quarter ended September 30, 2022

For the third quarter ended September 30, 2022, total net revenue was $10.0 million compared to $9.1 million for the quarter ended September 30, 2021. Net product revenue for the third quarter was $9.7 million, compared to net product revenues for the third quarter ended September 30, 2021 of $8.6 million.

Net revenue from royalties and collaborations for the third quarter ended September 30, 2022 totaled $0.3 million compared to $0.5 million in the corresponding period in 2021.

Operating expenses for the third quarter ended September 30, 2022 totaled $28.4 million versus $24.4 million in the prior year period, primarily driven by investment in personnel across the organization, including non-cash stock compensation, and ongoing clinical trial and development costs for EYP-1901. Non-operating expense, net, totaled $0.02 million and net loss was $18.4 million, or ($.49) per share, compared to a net loss of $16.7 million, or ($0.58) per share, for the prior year period.

Cash and investments at September 30, 2022 totaled $157.3 million compared to $171.2 million at June 30, 2022.

Financial Outlook

We expect the cash, cash equivalents and investments on hand on September 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 third quarter ended September 30, 2022 and recent corporate developments. To access the live conference call, please register at https://register.vevent.com/register/BIc813a58533cb4c0191e12c73ab3f1232. 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 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 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 at the end of 2022; 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenues:				
Product sales, net	$ 9,720	$ 8,587	$ 30,048	$ 24,127
License and collaboration agreements	52	159	160	594
Royalty income	240	313	663	674
Total revenues	10,012	9,059	30,871	25,395
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	1,405	1,825	4,916	5,144
Research and development	11,162	8,498	34,099	19,582
Sales and marketing	6,016	7,374	19,592	19,692
General and administrative	9,212	6,060	26,321	16,358
Amortization of acquired intangible assets	615	615	1,845	1,845
Total operating expenses	28,410	24,372	86,773	62,621
Loss from operations	(18,398)	(15,313)	(55,902)	(37,226)
Other income (expense):				
Interest and other income, net	640	6	1,067	286
Interest expense	(662)	(1,388)	(2,408)	(4,110)
Gain (loss) on extinguishment of debt	—	—	(1,559)	2,065
Total other expense, net	(22)	(1,382)	(2,900)	(1,759)
Net loss	$ (18,420)	$ (16,695)	$ (58,802)	$ (38,985)
Net loss per common share - basic and diluted	$ (0.49)	$ (0.58)	$ (1.58)	$ (1.42)
Weighted average common shares outstanding - basic and diluted	37,338	28,766	37,305	27,429

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

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 75,362	$ 178,593
Marketable securities	81,897	32,965
Accounts and other receivables, net	20,876	18,354
Prepaid expenses and other current assets	10,436	4,217
Inventory	3,531	3,616
Total current assets	192,102	237,745
Operating lease right-of-use assets	6,319	2,252
Intangible assets, net	20,904	22,749
Other assets	1,165	626
Total assets	$ 220,490	$ 263,372
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 22,116	$ 21,807
Deferred revenue	1,169	1,069
Short-term borrowings	10,475	—
Other current liabilities	496	782
Total current liabilities	34,256	23,658
Long-term debt	29,251	36,562
Deferred revenue - noncurrent	13,798	14,560
Operating lease liabilities - noncurrent	6,235	1,860
Other long-term liabilities	600	2,352
Total liabilities	84,140	78,992
Stockholders' equity:		
Capital	763,596	752,636
Accumulated deficit	(627,899)	(569,097)
Accumulated other comprehensive income	653	841
Total stockholders' equity	136,350	184,380
Total liabilities and stockholders' equity	$ 220,490	$ 263,372