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 07, 2024

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		**02472**
(Address of Principal Executive Offices)		**(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 7, 2024, EyePoint Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2024 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 7, 2024
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 7, 2024

By: /s/ George O. Elston
George O. Elston
Executive Vice President and Chief Financial Officer

Exhibit 99.1

EyePoint Pharmaceuticals Reports Third Quarter 2024 Financial Results and Highlights Recent Corporate Developments

– Announced positive interim data for DURAVYU 2.7mg in DME demonstrating meaningful, early and sustained visual acuity gains, strong anatomical control and a continued favorable safety profile; BCVA and CST improvement of +8.9 letters and -68 microns, respectively, at 16-weeks –

– Dosed first patient in Phase 3 LUGANO pivotal non-inferiority clinical trial of DURAVYU™ in wet AMD; second LUCIA pivotal trial first patient dosing expected by end of 2024 –

– $161.0 million oversubscribed equity financing extends cash runway into 2027 -

WATERTOWN, Mass., November 07, 2024 (GLOBE NEWSWIRE) – EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a company committed to developing and commercializing innovative therapeutics to improve the lives of patients with serious retinal diseases, today announced financial results for the third quarter ended September 30, 2024, and highlighted recent corporate developments.

"We made tremendous progress across our pipeline in recent months, including dosing the first patient in our first global pivotal trial of DURAVYU™ in wet AMD and reading out interim 16-week data for our Phase 2 VERONA trial in DME," said Jay Duker, M.D., President and Chief Executive Officer of EyePoint. "Driven by positive clinical data in two indications, along with growing patient and investigator enthusiasm, we remain confident that DURAVYU's differentiated profile underscores its potential to be the first sustained-release maintenance therapy in two significant indications, positioning EyePoint as the leader in sustained ocular drug delivery. This is an exciting time for EyePoint, and we anticipate dosing the first patient in the second Phase 3 LUCIA trial by the end of 2024. With a strong balance sheet and compelling clinical data, we are well-positioned to continue executing across our pipeline, working to bring our potentially paradigm-shifting treatment to patients as fast as possible."

R&D Highlights and Updates

- Announced positive interim 16-week data for the ongoing open label Phase 2 VERONA clinical trial of DURAVYU for diabetic macular edema (DME) in October. DURAVYU 2.7mg demonstrated an early, sustained, and clinically meaningful improvement in best-corrected visual acuity (BCVA) with a gain of +8.9 letters compared to baseline versus +3.2 letters for aflibercept control. DURAVYU 2.7mg also demonstrated concomitant structural improvement with CST (central subfield thickness) improvement of 68.1 microns versus 30.5 microns for aflibercept control. Notably, both DURAVYU doses showed an immediate benefit over aflibercept control in both BCVA and CST demonstrating the differentiated drug release profile of DURAVYU with immediate bioavailability. Additionally, a favorable safety and tolerability profile continued for both DURAVYU arms. The Company expects to report the full topline results in the first quarter of 2025, once all patients complete the trial.

- Announced first patient dosed in the Phase 3 LUGANO clinical trial of DURAVYU™ in wet age-related macular degeneration (wet AMD). The second Phase 3 LUCIA pivotal trial initiation is expected to have first patient dosing by end of 2024. The LUGANO and LUCIA clinical trials are designed for potential global regulatory and commercial success with every six-month re-dosing in both trials. With over 160 trial sites committed and robust DAVIO 2 data the company anticipates rapid enrollment of both trials with topline data anticipated in 2026.

- Presented DAVIO 2 twelve-month data at the American Academy of Ophthalmology (AAO) 2024 Subspecialty Day in October, at the 24th EURetina Congress in September and the Retina Society 57th Annual Meeting in September.
- Presented a comparison of tyrosine kinase inhibitors being developed for intravitreal delivery at the Retina Society 57th Annual Meeting in September, demonstrating the differentiation of DURAVYU with immediate bioavailability and controlled release via zero-order kinetics for at least six months.
- Presented on sustained-release vorolanib highlighting selective pan-VEGF receptor inhibition and anti-angiogenic effects in VEGF-mediated ocular diseases at the American Retina Forum (ARF) 2024 National Meeting in August demonstrating the durable efficacy, reliable safety and reduced injection burden of treatment with DURAVYU.

Recent Corporate Highlights

- Completed an underwritten public offering with gross proceeds of $161.0 million in October. The Company sold 14,636,363 shares of its common stock, which included the exercise in full by the underwriters of their option to purchase an additional 1,909,090 shares of common stock. The shares of common stock were sold at a public offering price of $11.00 per share.
- Announced the grand opening of EyePoint's Northbridge, MA manufacturing facility in October. The 40,000 square foot Good Manufacturing Process (cGMP) compliant commercial manufacturing facility was built to meet U.S. FDA and European Medicines Agency (EMA) and will support global manufacturing across the Company's portfolio, including lead pipeline asset, DURAVYU™ upon potential regulatory approval.
- Announced the appointment of esteemed industry leader Fred Hassan to the Company's Board of Directors in September.

Review of Results for the Third Quarter Ended September 30, 2024

For the third quarter ended September 30, 2024, total net revenue was $10.5 million compared to $15.2 million for the quarter ended September 30, 2023. Net product revenue for the third quarter was $0.7 million, compared to net product revenues for the third quarter ended September 30, 2023, of $0.8 million.

Net revenue from royalties and collaborations for the third quarter ended September 30, 2024, totaled $9.9 million compared to $14.4 million in the corresponding period in 2023. This decrease was primarily driven by lower recognition of deferred revenue related to the out-license of YUTIQ® product rights.

Operating expenses for the third quarter ended September 30, 2024, totaled $43.3 million versus $29.6 million in the prior year period. This increase was primarily driven by (i) $5.4 million in costs related to the DURAVYU™ Phase 3 clinical trials for wet AMD, (ii) $3.8 million higher personnel expense for clinical and product development, including $2.1 million of non-cash stock compensation, (iii) $3 million in other R&D related expenses. Non-operating income, net, totaled $3.4 million and net loss was $29.4 million, or ($0.54) per share, compared to a net loss of $12.6 million, or ($0.33) per share, for the prior year period.

Cash and investments at September 30, 2024 totaled $253.8 million compared to $331.1 million at December 31, 2023.

Financial Outlook
We expect the cash, cash equivalents and investments on September 30, 2024, along with the net proceeds from the October $161.0 million equity financing will enable us to fund operations into 2027.

About EyePoint Pharmaceuticals

EyePoint (Nasdaq: EYPT) is a clinical-stage biopharmaceutical company committed to developing and commercializing innovative therapeutics to help improve the lives of patients with serious retinal diseases. The Company's pipeline leverages its proprietary bioerodible Durasert E™ technology for sustained intraocular drug delivery. The Company's lead product candidate, DURAVYU™ (f/k/a EYP-1901), is an investigational sustained delivery treatment for VEGF-mediated retinal diseases combining vorolanib, a selective and patent-protected tyrosine kinase inhibitor with bioerodible Durasert E™. DURAVYU is presently in Phase 3 global, pivotal clinical trials as a sustained delivery treatment for wet age-related macular degeneration (wet AMD), the leading cause of vision loss among people 50 years of age and older in the United States, and in a Phase 2 clinical trial in diabetic macular edema (DME). EyePoint expects full topline data from the Phase 2 clinical trial in DME in Q1 2025 and topline data from both Phase 3 pivotal trials in wet AMD in 2026.

Pipeline programs include EYP-2301, a TIE-2 agonist, razuprotafib, formulated in Durasert E™ to potentially improve outcomes in serious retinal diseases. The proven Durasert® drug delivery technology has been safely administered to thousands of patient eyes across four U.S. FDA approved products. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts.

Vorolanib is licensed to EyePoint exclusively by Equinox Sciences, a Betta Pharmaceuticals affiliate, for the localized treatment of all ophthalmic diseases outside of China, Macao, Hong Kong and Taiwan.

DURAVYU™ has been conditionally accepted by the FDA as the proprietary name for EYP-1901. DURAVYU is an investigational product; it has not been approved by the FDA. FDA approval and the timeline for potential approval is uncertain.

Forward Looking Statements

EYEPOINT PHARMACEUTICALS 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 our expectations regarding the timing and clinical development and potential of DURAVYU in wet AMD and DME, including our expectations regarding the announcement of full topline data from the VERONA trial in the first quarter of 2025 and initiation of the LUGANO trial and the LUCIA trial; the belief that the interim results from the VERONA trial support DURAVYU's potential to advance to non-inferiority pivotal trials; our beliefs and expectations regarding the anticipated full results from the VERONA trial; the potential for DURAVYU 2.7mg to extend treatment intervals while improving vision; the potential for DURAVYU to provide an immediate benefit over aflibercept control in both BCVA and CST; our optimism that that DURAVYU has the potential to shift the treatment paradigm in DME and improve patient outcomes; our expectations regarding clinical development of our other product candidates, including EYP-2301; our business strategies and objectives; 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, these risks and uncertainties include the timing,

progress and results of the company's clinical development activities; uncertainties and delays relating to the design, enrollment, completion, and results of clinical trials; unanticipated costs and expenses; the company's cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated; the risk that results of clinical trials may not be predictive of future results, and interim and preliminary data are subject to further analysis and may change as more data becomes available; unexpected safety or efficacy data observed during clinical trials; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways for approval of the company's product candidates; changes in the regulatory environment; changes in expected or existing competition; the success of current and future license agreements; our dependence on contract research organizations, and other outside vendors and service providers; product liability; the impact of general business and economic conditions; protection of our intellectual property and avoiding intellectual property infringement; retention of key personnel; delays, interruptions or failures in the manufacture and supply of our product candidates; the availability of and the need for additional financing; the company's ability to obtain additional funding to support its clinical development programs; uncertainties regarding the timing and results of the August 2022 subpoena from the U.S. Attorney's Office for the District of Massachusetts; uncertainties regarding the FDA warning letter pertaining to the company's Watertown, MA manufacturing facility; 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
Precision AQ (formerly 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 BALANCE SHEETS
(Unaudited)
(In thousands)

	September 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 79,830	$ 281,263
Marketable securities	173,963	49,787
Accounts and other receivables, net	378	805
Prepaid expenses and other current assets	11,571	9,039
Inventory	2,807	3,906
Total current assets	268,549	344,800
Operating lease right-of-use assets	21,405	4,983
Other assets	10,963	5,401
Total assets	$ 300,917	$ 355,184
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,509	$ 24,025
Deferred revenue	25,996	38,592
Other current liabilities	1,289	646
Total current liabilities	48,794	63,263
Deferred revenue - noncurrent	11,234	20,692
Operating lease liabilities - noncurrent	21,922	4,906
Other noncurrent liabilities	233	-
Total liabilities	82,183	88,861
Stockholders' equity:		
Capital	1,049,180	1,007,605
Accumulated deficit	(831,617)	(742,146)
Accumulated other comprehensive income	1,171	864
Total stockholders' equity	218,734	266,323
Total liabilities and stockholders' equity	$ 300,917	$ 355,184

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,	
	2024	**2023**	**2024**	**2023**
Revenues:				
Product sales, net	$ 664	$ 816	$ 2,390	$ 13,483
License and collaboration agreements	9,561	14,137	27,906	17,768
Royalty income	299	249	1,389	739
Total revenues	10,524	15,202	31,685	31,990
Operating expenses:				
Cost of sales	736	1,202	2,896	3,634
Research and development	29,542	17,363	89,554	46,711
Sales and marketing	24	479	80	11,504
General and administrative	12,970	10,556	39,770	28,854
Total operating expenses	43,272	29,600	132,300	90,703
Loss from operations	(32,748)	(14,398)	(100,615)	(58,713)
Other income (expense):				
Interest and other income, net	3,387	1,786	11,144	4,611
Interest expense	-	-	-	(1,247)
Loss on extinguishment of debt	-	-	-	(1,347)
Total other income, net	3,387	1,786	11,144	2,017
Net loss	$ (29,361)	$ (12,612)	$ (89,471)	$ (56,696)
Net loss per common share - basic and diluted	$ (0.54)	$ (0.33)	$ (1.67)	$ (1.50)
Weighted average common shares outstanding - basic and diluted	54,449	38,341	53,526	37,804