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 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 August 7, 2024, EyePoint Pharmaceuticals, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 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: August 7, 2024

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

Exhibit 99.1

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

– Phase 3 LUGANO pivotal non-inferiority clinical trial of DURAVYU™ in wet AMD on track for first patient dosing in 2024 –

– Positive twelve-month data from Phase 2 DAVIO 2 clinical trial evaluating DURAVYU for the treatment of wet AMD continue to demonstrate favorable safety and efficacy –

– Phase 2 VERONA trial of DURAVYU in DME fully enrolled with topline data anticipated in Q1 2025 –

- *$280.2 million of cash and investments on June 30, 2024, with cash runway through Phase 3 wet AMD topline data for DURAVYU in 2026 –*

WATERTOWN, Mass., August 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 second quarter ended June 30, 2024, and highlighted recent corporate developments.

"We continue to make excellent progress in our preparations for the upcoming Phase 3 pivotal trials evaluating DURAVYU™ in wet age-related macular degeneration (wet AMD) with over 110 trial sites now committed," said Jay Duker, M.D., President and Chief Executive Officer of EyePoint Pharmaceuticals. "Our Phase 3 non-inferiority trials are strategically designed to achieve global regulatory and commercial success, generating data that can inform clinical use in the real-world setting. DURAVYU remains on track to be the first sustained release wet AMD program to have two pivotal trials to support a New Drug Application (NDA) submission. Importantly, we also reported positive twelve-month safety and efficacy data from the DAVIO 2 clinical trial of DURAVYU in wet AMD. In addition to a continued favorable safety profile, these robust data demonstrate that the majority of patients treated with a single dose of DURAVYU did not require any supplemental treatment and had a statistically non-inferior change in visual acuity compared to the standard of care on-label aflibercept control. We believe these results underscore the potential for DURAVYU as a sustained six-month maintenance therapy, bolstering our confidence in the design of our Phase 3 program and in DURAVYU's potential to revolutionize real-world outcomes for patients. We remain on track to dose patients in the Phase 3 LUGANO trial in 2024 with the LUCIA trial patient dosing initiating shortly thereafter."

R&D Highlights and Updates

- Announced positive 12-month DAVIO 2 safety and efficacy data from the DAVIO 2 trial evaluating DURAVYU in wet AMD. Data demonstrated that eyes treated with a single dose of DURAVYU maintained stable visual acuity that was statistically non-inferior to the on-label aflibercept control group. DURAVYU treatment arms' change in best corrected visual acuity (BCVA) were nearly identical to the aflibercept control arm. Further, strong anatomical control as measured by central subfield thickness (CST) was also maintained in the DURAVYU arms. These data demonstrate that approximately half of the DURAVYU treated eyes were anti-VEGF supplement free following a single injection, while 22% of the eyes in the aflibercept control arm required additional anti-VEGF treatment despite receiving mandated bi-monthly injections through 12 months. These data also highlighted a continued positive safety profile with no

DURAVYU-related ocular or systemic SAEs reported. The full DAVIO 2 twelve-month topline data will be presented at the Retina Society Annual Meeting in September.

- Held a positive End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) and aligned on pathway to potential approval for DURAVYU in pivotal Phase 3 non-inferiority trials.
- Presented a subgroup analysis from the DAVIO 2 clinical trial of DURAVYU at the American Society of Retinal Specialists (ASRS) 2024 Annual Meeting in Stockholm, Sweden, which analyzed patterns of supplemental injections up to week 32 in the treatment arms of the Phase 2 trial. The data highlighted that approximately 8% of DURAVYU patients received supplemental injections that did not meet the pre-specified criteria. These injections represent approximately 25% of the total supplemental injections, indicating the potential for fewer supplemental injections in the Phase 3 trials.
- Completed enrollment of the VERONA Phase 2 clinical trial of DURAVYU as a potential six-month maintenance treatment for diabetic macular edema (DME), with 27 patients assigned to one of two intravitreal doses of DURAVYU or an aflibercept control. VERONA is a randomized, controlled, single-masked, clinical trial of DURAVYU in DME patients previously treated with a standard-of-care anti-VEGF therapy. Topline data is anticipated in Q1 2025.
- Announced topline safety and efficacy data of the Phase 2 PAVIA clinical trial of DURAVYU in non-proliferative diabetic retinopathy (NPDR) in May. The data demonstrated stable or improved diabetic retinopathy severity scores (DRSS) and a favorable safety profile at nine-months.
- Accepted to present 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.
- Presented an encore of the six-month DAVIO 2 data evaluating DURAVYU in wet AMD at the CTS Retina Clinical Trials at the Summit in June, highlighting the durable efficacy, reliable safety and reduced injection burden of treatment with DURAVYU.
- Accepted to present an encore presentation of the DAVIO 2 six-month subgroup analysis and the DAVIO 2 topline twelve-month data for DURAVYU at the upcoming 24th EURetina Congress in September.

Review of Results for the Second Quarter Ended June 30, 2024

For the second quarter ended June 30, 2024, total net revenue was $9.5 million compared to $9.1 million for the quarter ended June 30, 2023. Net product revenue for the second quarter was $1.1 million, compared to net product revenues for the second quarter ended June 30, 2023, of $5.3 million. This decrease in net product revenue resulted from the out-license of the YUTIQ® franchise in May 2023, completing the strategic pivot to a biopharmaceutical pipeline-focused company.

Net revenue from royalties and collaborations for the second quarter ended June 30, 2024, totaled $8.4 million compared to $3.8 million in the corresponding period in 2023. This increase was primarily due to partial recognition of deferred revenue from the license of the YUTIQ franchise, which begun in 2Q 2023 and will be recognized over a 2-year period in connection with the delivery of YUTIQ supply units.

Operating expenses for the second quarter ended June 30, 2024, totaled $44.0 million versus $31.9 million in the prior year period. This increase was primarily driven by significant growth in research and development costs, including DURAVYU clinical trial activities and personnel expenses, including stock-based compensation, and a license milestone payment for completion of our Phase 2 wet AMD (DAVIO

2) clinical trial. This was offset by reduced sales and marketing expenses from the exit of our commercial business in 1H 2023. Non-operating income, net, totaled $3.7 million and net loss was $30.8 million, or ($0.58) per share, compared to a net loss of $22.9 million, or ($0.61) per share, for the prior year period.

Cash and investments at June 30, 2024 totaled $280.2 million compared to $331.1 million at December 31, 2023.

Financial Outlook
We expect the cash, cash equivalents and investments on June 30, 2024, will enable us to fund operations through anticipated Phase 3 wet AMD topline data for DURAVYU in 2026.

About EyePoint Pharmaceuticals

EyePoint Pharmaceuticals (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™ (previously known as 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 2 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 diabetic macular edema (DME). EyePoint expects to randomize patients for inclusion in pivotal Phase 3 clinical trials in wet AMD in 2024.

Pipeline programs include EYP-2301, a promising 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 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 statements about the sufficiency of our existing cash resources through topline data for Phase 3 clinical trials for EYP-1901 (DURAVYU™) in wet AMD; our expectations regarding the timing and clinical development of our product candidates, including DURAVYU and EYP-2301; the potential for DURAVYU as a novel sustained delivery treatment for serious eye diseases, including wet age-related macular degeneration (wet AMD) and non-proliferative

diabetic retinopathy (NPDR) and diabetic macular edema (DME); the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals including potential U.S. Food and Drug Administration (FDA) regulatory approval of DURAVYU and EYP-2301; the success of current and future license agreements; our dependence on contract research organizations, co-promotion partners, and other outside vendors and service providers; the success of Durasert® as a drug delivery platform in FDA approved 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 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
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

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 90,769	$ 281,263
Marketable securities	189,479	49,787
Accounts and other receivables, net	1,375	805
Prepaid expenses and other current assets	9,636	9,039
Inventory	3,672	3,906
Total current assets	294,931	344,800
Operating lease right-of-use assets	22,269	4,983
Other assets	7,049	5,401
Total assets	$ 324,249	$ 355,184
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 27,637	$ 24,025
Deferred revenue	33,335	38,592
Other current liabilities	1,130	646
Total current liabilities	62,102	63,263
Deferred revenue - noncurrent	11,678	20,692
Operating lease liabilities - noncurrent	22,164	4,906
Total liabilities	95,944	88,861
Stockholders' equity:		
Capital	1,029,769	1,007,605
Accumulated deficit	(802,256)	(742,146)
Accumulated other comprehensive income	792	864
Total stockholders' equity	228,305	266,323
Total liabilities and stockholders' equity	$ 324,249	$ 355,184

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,	
	2024	2023	2024	2023
Revenues:				
Product sales, net	$ 1,068	$ 5,273	$ 1,726	$ 12,667
License and collaboration agreements	7,782	3,597	18,345	3,631
Royalty income	627	235	1,090	490
Total revenues	9,477	9,105	21,161	16,788
Operating expenses:				
Cost of sales	1,401	1,792	2,160	2,432
Research and development	29,822	15,730	60,011	29,348
Sales and marketing	50	5,288	56	11,025
General and administrative	12,750	9,056	26,801	18,298
Total operating expenses	44,023	31,866	89,028	61,103
Loss from operations	(34,546)	(22,761)	(67,867)	(44,315)
Other income (expense):				
Interest and other income, net	3,720	1,623	7,757	2,825
Interest expense	-	(435)	-	(1,247)
Loss on extinguishment of debt	-	(1,347)	-	(1,347)
Total other (expense) income, net	3,720	(159)	7,757	231
Net loss	$ (30,826)	$ (22,920)	$(60,110)	$(44,084)
Net loss per common share - basic and diluted	$ (0.58)	$ (0.61)	$ (1.13)	$ (1.17)
Weighted average common shares outstanding - basic and diluted	53,206	37,576	53,059	37,531