
**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): August 4, 2021

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 August 4, 2021, EyePoint Pharmaceuticals, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 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 June 30, 2021
104	Cover Page Interactive Data File (embedded within the inline XBRL document)



EyePoint Pharmaceuticals Reports Second Quarter 2021 Financial Results and Highlights Recent Corporate Developments

Positive 30-Day Safety Data Reported for EYP-1901 DAVIO study for the potential treatment of wet AMD; study remains on track for initial readout in Q4 2021

-Net product revenues of \$8.7 million versus \$3.7 million in Q2 2020, a 136% increase;

- Management to host a conference call and webcast today at 8:30 AM ET –

WATERTOWN, Mass., August 4, 2021 (GLOBE NEWSWIRE) -- EyePoint Pharmaceuticals, Inc. (NASDAQ: EYPT), a pharmaceutical company committed to developing and commercializing therapeutics to help improve the lives of patients with serious eye disorders, today announced financial results for the second quarter ended June 30, 2021 and highlighted recent corporate developments.

“We made significant progress in Q2 with our Phase 1 DAVIO trial for EYP-1901 and we substantially grew our net product revenue to \$8.7M, a 136% increase vs Q2 2020. Most importantly, we continue to seamlessly execute our Phase 1 DAVIO trial and have achieved several important milestones, starting with the dosing of the first patient in January, the completion of enrollment in May, and our announcement of positive 30-day safety data in July. We remain on track and look forward to providing top line six-month interim safety and efficacy data in the fourth quarter of this year,” said Nancy Lurker, Chief Executive Officer of EyePoint Pharmaceuticals.

Ms. Lurker continued, “Additionally, we are pleased that customer demand for our commercial products, DEXYCU and YUTIQ has continued to grow this quarter with DEXYCU setting an all-time high of approximately 10,900 units, a 404% increase from Q2 2020. This momentum has driven year-to-date net product revenues for both products significantly ahead of 2020 and we continue to see solid customer demand for both products into the third quarter.”

R&D Highlights

- In July 2021, the Company reported positive 30-day safety results for all cohorts from the DAVIO trial of EYP-1901 for wet-AMD. The DAVIO clinical trial of EYP-1901 enrolled 17 wet AMD patients across three dose cohorts. Key safety observations through at least 30-Day post-dosing follow-up for all patients include no serious adverse events (SAEs), ocular or systemic, no reported adverse events (AEs) related to significant intraocular inflammation, best-corrected visual acuity (BCVA) reduction, or elevation of intraocular pressure, and no events of endophthalmitis, retinal detachment, or migration into the anterior chamber.
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- In May 2021, the Company completed patient enrollment of its Phase 1 clinical trial of EYP-1901 as a potential twice-yearly sustained delivery anti-VEGF treatment targeting wet age-related macular degeneration (wet AMD). The ongoing Phase 1 DAVIO trial for EYP-1901 is an open-label twelve-month dose escalation trial examining wet AMD patients who were responsive to previous anti-VEGF therapies. The primary endpoint of the trial is safety and key secondary endpoints are changes in best-corrected visual acuity (BCVA) and central subfield thickness.
- DEXYCU was presented in three separate oral presentations, one poster session and a video symposium at the American Society of Cataract and Refractive Surgery (ASCRS) Annual Meeting.

Corporate Update

- In August 2021, the Company announced the establishment of its Executive Scientific Advisory Board with prestigious members made up of some of the leading retinal surgeons in the world and chaired by Dr. Carl Regillo MD, FACS, Chief of the Retina Service at Wills Eye Hospital. Other members of the Board include Drs. Sophie J. Bakri, MD, Mayo Clinic, Caroline R. Baumal, MD, Tufts Medical Center, David S. Boyer, MD, University of Southern California Keck School of Medicine, Glenn J. Jaffe, MD, Duke University, Rishi Singh, MD, Cleveland Clinic, and Charles C. Wykoff, MD, PhD, Weill Cornell Medical College.
- In July 2021, the Company announced a new Category III CPT Code for the injection of medicines, like DEXYCU®, approved by the American Medical Association. The code, OX78T, becomes effective January 1, 2022, providing an opportunity for an additional reimbursement pathway for the administration of DEXYCU in addition to the pass-through payment.
- In July 2021, DEXYCU received a preliminary nine-month extension to its pass-through payment status, as referenced in the draft 2022 Centers for Medicare and Medicaid Services (CMS) Hospital Outpatient Prospective Payment System (HOPPS) rules. The draft rules are subject to a public comment period prior to the issuance of the final HOPPS rules, anticipated in November 2021. If granted, the pass-through reimbursement period for DEXYCU will extend to December 31, 2022.
- In June 2021, the Company was added to the small-cap Russell 2000® Index and the broad-market Russell 3000® Index.

Commercial Performance in Second Quarter 2021

- Net product revenue for YUTIQ and DEXYCU was \$4.1 million and \$4.6 million, respectively.
 - Customer demand of approximately 540 units of YUTIQ and approximately 10,900 units for DEXYCU, an increase of 26% and 404%, respectively from Q2 2020.
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Review of Results for the Second Quarter ended June 30, 2021

For the quarter ended June 30, 2021, total net revenue was \$9.0 million compared to \$4.1 million for the quarter ended June 30, 2020. Net product revenue for the quarter was \$8.7 million, compared to net product revenues for the quarter ended June 30, 2020 of \$3.7 million.

Net revenue from royalties and collaborations for the quarter ended June 30, 2021 totaled \$0.3 million compared to \$0.4 million in the corresponding period in 2020.

Operating expenses for the quarter ended June 30, 2021 totaled \$20.0 million versus \$15.3 million in the prior year period. This increase was primarily due to a \$2.3 million increase in R&D expense, a \$1.4 million increase in cost of sales, a \$0.4 million increase in G&A expense, and a \$0.6 million increase in sales and marketing expense. Non-operating income, net, totaled \$1.0 million and net loss was \$10.0 million, or (\$0.35) per share, compared to a net loss of \$13.0 million, or (\$1.04) per share, for the prior year period.

Cash and cash equivalents at June 30, 2021 totaled \$127.6 million compared to \$44.9 million at December 31, 2020.

Financial Outlook

We expect the cash on hand at June 30, 2021 and expected net cash inflows from our product sales will enable us to fund our current and planned operations through the end of 2022.

Conference Call Information

EyePoint will host a conference call today, at 8:30 AM ET to discuss the results for the second quarter ended June 30, 2021 and recent operational 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 1261618. 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 EYP-1901

EYP-1901 is a potential twice-yearly sustained delivery intravitreal anti-VEGF treatment for wet age-related macular degeneration. EYP-1901 leverages a bioerodible formulation of EyePoint's proprietary Durasert® sustained release technology with vorolanib, a tyrosine kinase inhibitor. Vorolanib provided clear efficacy signals in two prior human trials in wet AMD as an orally delivered therapy with no significant ocular adverse events. EYP-1901 is currently in a Phase 1 clinical trial initially targeting treatment of wet AMD, with the potential for additional indications in diabetic retinopathy and retinal vein occlusion.

About EyePoint Pharmaceuticals, Inc. (Nasdaq: EYPT) is a pharmaceutical company committed to developing and commercializing innovative 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 twice-yearly sustained delivery intravitreal anti-VEGF treatment initially targeting wet age-related macular degeneration. The Company has two commercial products: YUTIQ®, for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye, and DEXYCU®, for the

treatment of postoperative inflammation following ocular surgery. EyePoint Pharmaceuticals is headquartered in Watertown, Massachusetts. To learn more about the Company, please visit www.eyepointpharma.com and connect on Twitter and LinkedIn.

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 anticipated use of proceeds for the proposed 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 our expectations regarding the timing and clinical development of our product candidates, including EYP-1901; the potential for EYP-1901 as a novel twice-yearly treatment for serious eye diseases, including wet age-related macular degeneration, diabetic retinopathy and retinal vein occlusion; the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; 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; our ability to achieve profitable operations and access to needed capital; fluctuations in our operating results; our ability to successfully produce sufficient commercial quantities of YUTIQ and DEXYCU and to successfully commercialize YUTIQ and DEXYCU in the U.S.; our ability to sustain and enhance an effective commercial infrastructure and enter into and maintain commercial agreements for YUTIQ and DEXYCU; the development of our YUTIQ line extension shorter-duration treatment for non-infectious uveitis affecting the posterior segment of the eye; the success of current and future license agreements, including our agreements with Ocumension Therapeutics and Equinox Science; termination or breach of current license agreements, including our agreements with Ocumension Therapeutics and Equinox Science; 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 products; market acceptance of products; effects of guidelines, recommendations and studies; protection of intellectual property and avoiding intellectual property infringement; retention of key personnel; product liability; industry consolidation; compliance with environmental laws; manufacturing risks; risks and costs of international business operations; volatility of stock price; possible dilution; absence of dividends; 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. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized.

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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,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	\$ 8,738	\$ 3,706	\$ 15,540	\$ 8,393
License and collaboration agreements	94	35	435	2,055
Royalty income	181	381	361	1,163
Total revenues	9,013	4,122	16,336	11,611
Operating expenses:				
Cost of sales, excluding amortization of acquired intangible assets	1,929	502	3,319	1,482
Research and development	5,605	3,276	11,084	8,129
Sales and marketing	6,659	6,089	12,318	14,214
General and administrative	5,184	4,792	10,299	9,152
Amortization of acquired intangible assets	615	615	1,230	1,230
Total operating expenses	19,992	15,274	38,250	34,207
Loss from operations	(10,979)	(11,152)	(21,914)	(22,596)
Other income (expense):				
Interest and other income, net	280	8	281	62
Interest expense	(1,376)	(1,806)	(2,722)	(3,590)
Gain on extinguishment of debt	2,065	—	2,065	—
Total other income (expense), net	969	(1,798)	(376)	(3,528)
Net loss	\$ (10,010)	\$ (12,950)	\$ (22,290)	\$ (26,124)
Net loss per common share - basic and diluted	\$ (0.35)	\$ (1.04)	\$ (0.83)	\$ (2.17)
Weighted average common shares outstanding - basic and diluted	28,744	12,477	26,750	12,015

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

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 127,630	\$ 44,909
Accounts and other receivables, net	15,111	9,453
Prepaid expenses and other current assets	3,704	3,419
Inventory	5,381	5,337
Total current assets	151,826	63,118
Operating lease right-of-use assets	2,353	2,610
Intangible assets, net	23,979	25,209
Other assets	665	780
Total assets	\$ 178,823	\$ 91,717
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 14,535	\$ 13,256
Deferred Revenue	1,008	945
Other current liabilities	707	687
Total current liabilities	16,250	14,888
Long-term debt	36,235	37,977
Deferred revenue - noncurrent	15,132	15,616
Operating lease liabilities - noncurrent	2,013	2,330
Other long-term liabilities	2,328	2,365
Total liabilities	71,958	73,176
Stockholders' equity:		
Capital	638,994	528,380
Accumulated deficit	(532,970)	(510,680)
Accumulated other comprehensive income	841	841
Total stockholders' equity	106,865	18,541
Total liabilities and stockholders' equity	\$ 178,823	\$ 91,717