
**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): January 28, 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 8.01. Other Events.

On January 28, 2021, EyePoint Pharmaceuticals, Inc. issued a press release announcing the first patient dosed in phase 1 clinical trial of EYP-1901 for the treatment of wet age-related macular degeneration (“wet AMD”). A copy of the press release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

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 January 28, 2021
104	Cover Page Interactive Data File (embedded within the inline XBRL document)



EyePoint Pharmaceuticals Announces First Patient Dosed in Phase 1 Clinical Trial of EYP-1901 for the Treatment of Wet AMD

WATERTOWN, Mass., January 28, 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 that the first patient has been dosed in the 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).

EYP-1901 leverages the Company's proprietary Durasert® drug delivery technology that has been used in four FDA-approved products, including EyePoint's YUTIQ® for chronic non-infectious uveitis affecting the posterior segment of the eye. EYP-1901 uses a bioerodible Durasert formulation combined with a clinically validated anti-VEGF molecule, vorolanib. In oral formulation, vorolanib demonstrated efficacy and ocular safety through Phase 2 trials in wet AMD. In addition to wet AMD, EYP-1901 is anticipated to be studied for the potential treatment of diabetic retinopathy and retinal vein occlusion in future clinical trials.

The Phase 1 DAVIO open-label, dose escalation trial, will examine thirteen wet AMD patients who were responsive to previous anti-VEGF treatments. EYP-1901 will be delivered via a single intravitreal injection in the physician's office. The primary endpoint of the trial is safety, and key secondary endpoints are best-corrected visual acuity (BCVA) and central subfield thickness. Based on clinical outcomes during the initial dose escalation phase, there is a potential to expand the trial.

"We believe EYP-1901 represents a promising new approach for treating wet AMD, a disease that despite the availability of current anti-VEGF therapies continues to progressively impair vision in millions of patients," said Nancy Lurker, President and Chief Executive Officer, EyePoint Pharmaceuticals. "Current approved treatments are effective, but they require monthly or bi-monthly eye injections in a physician's office, which can cause inconvenience and discomfort and often lead to reduced compliance and poor outcomes. The sustained release, intravitreal anti-VEGF formulation of EYP-1901 has the potential to become the first treatment for wet AMD with twice yearly dosing, representing a significant market opportunity for EyePoint."

"The potential efficacy of vorolanib coupled with the well-characterized safety and predictable drug release kinetics of the Durasert delivery technology offer the potential to provide millions of wet AMD sufferers a convenient and effective treatment option, if approved," stated Jay S. Duker, M.D., Chief Strategic Scientific Officer, EyePoint Pharmaceuticals and Chair of Ophthalmology at Tufts Medical Center and Tufts University School of Medicine. "We are excited to have this trial underway and are looking forward to seeing initial data as early as the second half of this year."

About EYP-1901

EYP-1901 is a potential twice-yearly sustained delivery intravitreal anti-VEGF treatment for wet age-related macular degeneration. EYP-1901 combines 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. Preclinical studies of EYP-1901 have

shown anti-VEGF activity in disease models of ocular neovascularization and no serious safety issues were observed. EYP-1901 is initially being developed as a treatment of wet AMD, with the potential for additional indications in diabetic retinopathy and retinal vein occlusion.

About EyePoint Pharmaceuticals

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 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. The Company's pipeline leverages its proprietary bioerodible Durasert® technology for extended intraocular drug delivery including EYP-1901, a potential twice-yearly sustained delivery intravitreal anti-VEGF treatment initially targeting wet age-related macular degeneration. 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: Various statements made in this release are forward-looking, and are inherently subject to risks, uncertainties and potentially inaccurate assumptions. All statements that address activities, events or developments that we intend, expect, plan or believe may occur in the future, including but not limited to statements about our expectations regarding the timing and clinical development of our product candidates, including EYP-1901; and 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, are forward-looking statements. Some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the extent to which COVID-19 impacts our business; the effectiveness and timeliness of clinical trials, and the usefulness of the data; the timeliness of regulatory approvals; 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; potential off-label usage in the U.S. of ILUVIEN® for non-infectious uveitis affecting the posterior segment of the eye; consequences of fluocinolone acetonide side effects for YUTIQ; consequences of dexamethasone side effects for DEXYCU; our ability to market and sell products; 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, contract sales organizations, vendors and investigators; 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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