

**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 28, 2023

eFFECTOR Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39866
(Commission
File Number)

85-3306396
(I.R.S. Employer
Identification No.)

142 North Cedros Avenue, Suite B
Solana Beach, California
(Address of principal executive offices)

92075
(Zip Code)

(858) 925-8215
(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:

- ☐ 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, \$0.0001 par value per share	EFTR	Nasdaq Capital Market
Warrants to purchase common stock	EFTRW	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (Sec.230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (Sec.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 8.01 Other Events.

On November 28, 2023, eFFECTOR Therapeutics, Inc. (the “Company”) announced that the U.S. Food and Drug Administration (“FDA”) has granted Fast Track designation for zotatifin in combination with fulvestrant and abemaciclib (“ZFA triplet”) as second- or third-line therapy for the treatment of adult patients with estrogen receptor-positive, human epidermal growth factor-negative advanced or metastatic breast cancer with disease progression following treatment with endocrine therapy and a CDK 4/6 inhibitor. The Fast Track designation was granted following FDA review of preclinical and clinical data for zotatifin, including recent safety and efficacy data for the ZFA triplet.

Fast Track designation is available to a product if it is intended, whether alone or in combination with one or more other drugs, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. This designation is intended to facilitate development and expedite review of drugs to treat serious and life-threatening conditions so that an approved product may reach the market expeditiously.

Forward-Looking Statements

The Company cautions you that statements contained in this report regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to: the future clinical development of our product candidates; the potential therapeutic benefits of our product candidates; and our ability to realize the benefits from zotatifin receiving Fast track designation from the FDA. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in our business, including, without limitation: Fast Track designation may not result in a more expedited development or regulatory review process, and such a designation does not increase the likelihood that zotatifin will receive marketing approval in the United States; Fast Track designation does not change the standards for regulatory approval; the FDA may later decide that zotatifin no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened; interim results of a clinical trial are not necessarily indicative of final results and one or more of the clinical outcomes may materially change as patient enrollment continues, following more comprehensive reviews of the data and more patient data become available; potential delays in the commencement, enrollment, data readouts and completion of clinical trials; the success of our clinical trials and preclinical studies for our product candidates is uncertain; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of our product candidates that may limit their development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; and other risks described in our prior filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

SIGNATURE

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.

eFFECTOR Therapeutics, Inc.

Date: November 28, 2023

By: /s/ Michael Byrnes
Name: Michael Byrnes
Title: Chief Financial Officer