

**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 13, 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 2.02 Results of Operations and Financial Condition.

On November 13, 2023, eFFECTOR Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended September 30, 2023. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on November 13, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 13, 2023

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



**eFFECTOR Therapeutics Reports Third Quarter
2023 Financial Results and Provides Corporate Update**

Management intends to provide an update on its zotatifin clinical development program in estrogen receptor-positive (ER+) metastatic breast cancer (mBC) at the 2023 San Antonio Breast Cancer Symposium (SABCS)

Topline results from Phase 2b KICKSTART trial in non-small cell lung cancer (NSCLC) now anticipated in first quarter of 2024

Collaboration initiated with Northwestern University on investigator-initiated Phase 1 dose escalation trial with tomivosertib in patients with Acute Myeloid Leukemia (AML)

SOLANA BEACH and REDWOOD CITY, Calif., November 13, 2023 – eFFECTOR Therapeutics, Inc. (NASDAQ: EFTR), a leader in the development of selective translation regulator inhibitors (STRIs) for the treatment of cancer, today reported financial results for the third quarter ended September 30, 2023 and provided a corporate update.

“I am very pleased with the current position of the company, with two clinical programs approaching important data readouts,” said Steve Worland, Ph.D., president and chief executive officer of eFFECTOR. “We now anticipate reporting topline results in our Phase 2b KICKSTART clinical trial of tomivosertib combined with pembrolizumab for the treatment of NSCLC in the first quarter of 2024. These results, if positive, would enable activities, including interactions with regulatory agencies, intended to support initiation of a Phase 3 registrational trial. Regarding our zotatifin program in ER+ mBC, we’re encouraged by the PFS data for the ZFA triplet, which is now mature, and anticipate providing a program update at the 2023 SABCS in December. We are now focusing on defining our registrational path for zotatifin in ER+ mBC and believe that the drug can be positioned as a second line therapy in multiple patient segments, with and without defined resistance mutations.”

“We are also excited with the growing interest by clinicians and investigators to study both of our wholly-owned drug candidates in a variety of different indications,” continued Dr. Worland. “Earlier this year we announced the initiation of an investigator-initiated trial at Stanford Medicine to evaluate zotatifin in patients with genomically-defined types of ER+ breast cancer and more recently we announced the initiation of an investigator-initiated trial at Northwestern University to evaluate tomivosertib in patients with relapsed/refractory AML.”

Pipeline Highlights

Tomivosertib (eFT508): eFFECTOR’s wholly owned, highly selective MNK inhibitor designed to enhance anti-tumor immune activity by activating T cells, delaying their exhaustion, and expanding the pool of central memory T cells:

- **Topline results from Phase 2b KICKSTART trial in NSCLC now anticipated in the first quarter of 2024.** As a result of enrollment progress and accrual of Progression Free Survival (PFS) events, the Company expects to report topline data in the first quarter of 2024. Top line results will reflect the trial’s primary analysis of approximately 38 PFS events, defined as radiographic progression per RECIST 1.1 or death, and additional endpoints. The company recently expanded enrollment to ex-US countries with the goal of achieving the targeted full enrollment of 60 patients to support additional analyses of Overall Survival (OS) and safety. The KICKSTART trial includes patients with PD-L1 expression $\geq 50\%$ who receive tomivosertib or placebo in combination with pembrolizumab as their initial therapy for metastatic disease.

- **Collaboration with Northwestern University on investigator-initiated Phase 1 dose escalation trial in patients with relapsed/refractory Acute Myeloid Leukemia (AML).** This trial, which is now enrolling, is being led by Shira Dinner, M.D., Associate Professor of Medicine (Hematology and Oncology) at the Robert H. Lurie Comprehensive Cancer Center of Northwestern University. The trial is designed to capitalize on previously published results that showed preclinical activity of tomivosertib in AML models. Once the appropriate dose for tomivosertib in AML is identified, the company hopes to expand the trial to test tomivosertib in combination with venetoclax and azacytidine.

Zotatifin (eFT226): eFFECTOR's wholly-owned potent and selective inhibitor of mRNA helicase eIF4A designed to downregulate expression of key oncoproteins and cell cycle proteins that drive tumor growth and resistance:

- **Additional data from ZFA triplet, including median PFS, is anticipated to be reported in Q4 2023.** This data builds on positive clinical results for zotatifin in combination with fulvestrant and abemaciclib (ZFA triplet) in ER+ breast cancer previously presented at the 2023 American Society of Clinical Oncology Annual Meeting 2023 in June. At that time, it was reported that five out of 19 (26%) RECIST-evaluable patients achieved a partial response (PR), including four confirmed and one unconfirmed. Efficacy results had exceeded the company's expectations for fulvestrant and abemaciclib (FA doublet) in such heavily pre-treated patients after CDK4/6, endocrine and/or chemotherapies. The ZFA triplet was generally well tolerated with the large majority of adverse events being Grade 1 or 2. PFS data from the ZFA cohort are now mature and are expected to be reported in Q4 2023.
- **On track to report additional data from dose escalation in Q4 2023.** Favorable safety results from initial expansion cohorts have allowed resumption of dose escalation to determine the safety of higher doses of zotatifin combined with fulvestrant (ZF doublet). If positive, these data would support exploration of higher doses of zotatifin in the ZFA triplet, for which promising activity was already reported. Initial data from three dose escalation cohorts are anticipated in Q4 2023.
- **Stanford Medicine investigator-initiated randomized Phase 2 study enrolling patients with ER+ breast cancer.** This trial, which is now enrolling, is being led by Jennifer Caswell-Jin, M.D., Assistant Professor of Medicine at Stanford Medicine, and brings to the clinic the science of integrative subgroups of breast cancer, building on work done by Christian Curtis, Ph.D., Professor of Medicine, Genetics, and Biomedical Data Science, and Director of Artificial Intelligence and Cancer Genomics at Stanford Medicine. The trial is being conducted as part of a collaboration with Stanford Medicine in which zotatifin is being tested in specific genomically-defined subgroups, including standard risk patients as well as high-risk patients carrying specific markers predictive of relapse.

Third Quarter 2023 Financial Results

Cash Position and Guidance: The company had cash, cash equivalents, and short-term investments totaling \$17.8 million as of September 30, 2023, compared to \$25.0 million as of June 30, 2023. The company anticipates that its current cash, cash equivalents and short-term investments will be sufficient to fund operations into the second quarter of 2024.

Research and Development (R&D) Expenses: R&D expenses were \$5.4 million for the quarter ended September 30, 2023, compared to \$6.6 million for the same quarter of 2022. This decrease for the quarter was due to lower external development expenses primarily associated with the timing of clinical trial and manufacturing related activities for both the tomivosertib and zotatifin programs, which also included a decrease in costs associated with the COVID-19 program. R&D expenses included approximately \$0.5 million and \$0.8 million of non-cash stock compensation expense in the quarters ended September 30, 2023 and 2022, respectively.

General and Administrative (G&A) Expenses: G&A expenses were \$2.5 million for the quarter ended September 30, 2023, compared to \$3.5 million for the same quarter of 2022. This decrease was primarily associated with lower employee related costs, consulting and D&O insurance for the three months ended September 30, 2023 compared to the same period in 2022. G&A expenses included approximately \$0.6 million and \$0.8 million of non-cash stock compensation expense in the quarters ended September 30, 2023 and 2022, respectively.

Other Income (Expense): Other expense was \$0.4 million for the quarter ended September 30, 2023, compared to \$0.3 million for the same quarter of 2022. The increase in other expense was primarily attributable to increased interest expense associated with the company's term loans, which was partially offset by an increase in interest income.

Net Loss: Net loss was \$8.3 million, or \$0.13 per basic and diluted share, for the quarter ended September 30, 2023, as compared to \$9.6 million, or \$0.23 per basic and diluted share, for the same quarter of 2022.

About eFFECTOR Therapeutics

eFFECTOR is a clinical-stage biopharmaceutical company pioneering the development of a new class of oncology drugs referred to as STRIs. eFFECTOR's STRI product candidates target the eIF4F complex and its activating kinase, mitogen-activated protein kinase interacting kinase (MNK). The eIF4F complex is a central node where two of the most frequently mutated signaling pathways in cancer, the PI3K-AKT and RAS-MEK pathways, converge to activate the translation of select mRNA into proteins that are frequent culprits in key disease-driving processes. Each of eFFECTOR's product candidates is designed to act on a single protein that drives the expression of a network of functionally related proteins, including oncoproteins and immunosuppressive proteins in T cells, that together control tumor growth, survival and immune evasion. eFFECTOR's lead product candidate, tomivosertib, is a MNK inhibitor currently being evaluated in KICKSTART, a randomized, double-blind, placebo-controlled Phase 2b trial of tomivosertib in combination with pembrolizumab in patients with metastatic non-small cell lung cancer (NSCLC). Zotatifin, eFFECTOR's inhibitor of eIF4A, is currently being evaluated in Phase 2a expansion cohorts in certain biomarker-positive solid tumors, including ER+ breast cancer and KRAS-mutant NSCLC. eFFECTOR has a global collaboration with Pfizer to develop inhibitors of a third target, eIF4E.

Forward-Looking Statements

eFFECTOR cautions you that statements contained in this press release 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, including expectations on enrollment and the timing of reporting data from ongoing clinical trials and Phase 3 registrational programs; the potential therapeutic benefits of our product candidates, including potential lines of therapy and in multiple patient segments; and the sufficiency of our capital resources to fund operations into the second quarter of 2024. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: 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; our dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; the success of our clinical trials and preclinical studies for our product candidates is uncertain; we may use our capital resources sooner than expected and they may be insufficient to allow clinical trial readouts; 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; our ability to obtain and maintain intellectual property protection for our product candidates; any future impacts to our business resulting from inflation or the conflict between Russia and Ukraine or other geopolitical developments outside our control; 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.

eFFECTOR Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,386	\$ 8,708
Short-term investments	12,393	17,602
Prepaid expenses and other current assets	1,503	1,704
Total current assets	19,282	28,014
Property and equipment, net	244	241
Operating lease right-of-use assets	68	111
Other assets	567	711
Total assets	\$ 20,161	\$ 29,077
Liabilities and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,136	\$ 1,486
Accrued expenses	1,982	3,368
Current term loans, net	19,299	19,061
Accrued final payment on term loans, current	1,100	1,100
Lease liabilities, current portion	71	60
Total current liabilities	23,588	25,075
Other accrued liabilities, non-current	493	—
Earn-out liability	—	6
Non-current warrant liability	40	40
Non-current lease liabilities	6	60
Total liabilities	24,127	25,181
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	6	4
Additional paid-in capital	166,276	147,476
Accumulated other comprehensive loss	(1)	(18)
Accumulated deficit	(170,247)	(143,566)
Total stockholders' equity (deficit)	(3,966)	3,896
Total liabilities and stockholders' equity (deficit)	\$ 20,161	\$ 29,077

eFFECTOR Therapeutics, Inc.
Condensed Consolidated Statement of Operations and Comprehensive loss
(Unaudited)
(in thousands, except share and per share data)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Grant revenue	\$ —	\$ 867	\$ —	\$ 2,878
Operating expenses:				
Research and development	5,355	6,632	16,845	16,663
General and administrative	2,500	3,486	8,401	9,895
Total operating expenses	7,855	10,118	25,246	26,558
Operating loss	(7,855)	(9,251)	(25,246)	(23,680)
Other income (expense)				
Interest income	296	142	749	230
Interest expense	(750)	(570)	(2,161)	(1,554)
Other income (expense), net	—	38	(29)	(525)
Change in fair value of earn-out liability	6	82	6	12,124
Other income (expense)	(448)	(308)	(1,435)	10,275
Net loss	(8,303)	(9,559)	(26,681)	(13,405)
Other comprehensive income (loss)	(2)	13	17	(69)
Comprehensive loss	\$ (8,305)	\$ (9,546)	\$ (26,664)	\$ (13,474)
Net loss per share, basic and diluted	\$ (0.13)	\$ (0.23)	\$ (0.53)	\$ (0.33)
Weighted-average common shares outstanding, basic and diluted	61,767,952	41,171,990	50,604,982	41,047,533

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