

**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): May 10, 2022

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 May 10, 2022, eFFECTOR Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2022. 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 May 10, 2022
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: May 10, 2022

By: /s/ Michael Byrnes

Name: Michael Byrnes

Title: Chief Financial Officer



eFFECTOR Therapeutics Reports First Quarter 2022 Financial Results and Provides Corporate Update

Plan to present data at ASCO 2022 from ongoing zotatifin Phase 1/2 dose escalation and expansion trial

Intend to provide an update on expanded development of zotatifin

SAN DIEGO and REDWOOD CITY, Calif., May 10, 2022 – 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 first quarter ended March 31, 2022, and provided a corporate update.

“This year marks a period of focused execution in the clinic for both tomivosertib and zotatifin, and we are encouraged by the enthusiasm for both programs from our trial investigators and the broader oncology community,” said Steve Worland, Ph.D., president, and chief executive officer of eFFECTOR. “We are pleased with the acceptance of an abstract at ASCO related to our zotatifin program and are on track to report initial response data from the ongoing zotatifin clinical program by the end of the first half of 2022. In addition, we intend to provide an update on expanded development of zotatifin after data from the program is presented at ASCO. Beyond our progress in oncology, we will continue to develop zotatifin as a host-directed antiviral for COVID-19 in collaboration with UCSF, utilizing a newly developed subcutaneous formulation. On the corporate front, during the first quarter, we executed a committed investment agreement for up to \$50 million and amended our existing debt facility to further extend our cash runway. These transactions position us for additional expansion of our clinical development programs.”

Pipeline Highlights

Tomivosertib (eFT508): eFFECTOR’s wholly-owned, highly selective MNK inhibitor designed to enhance anti-tumor immune activity by stimulating activation, delaying exhaustion, and prolonging the memory of T cells.

- **Added new cohort to Phase 2b KICKSTART trial in NSCLC, representing additional \$5 billion U.S. market opportunity:** In the first quarter 2022, eFFECTOR announced an updated design of KICKSTART, its Phase 2b double-blind, randomized trial of tomivosertib in NSCLC to include a new cohort, which is enrolling patients with PD-L1 $\geq 1\%$ who have initiated frontline therapy with pembrolizumab combined with platinum-based chemotherapy. The company plans to enroll approximately 60 patients with PD-L1 $\geq 1\%$ NSCLC immediately after they complete the platinum chemotherapy phase (4-6 cycles) of their frontline treatment without disease progression. Patients in this cohort will be randomized 1:1 to standard-of-care maintenance therapy plus tomivosertib in the treatment group versus standard-of-care maintenance plus placebo in the control group. Enrollment continues in the PD-L1 $\geq 50\%$ cohort. The company plans to enroll approximately 60 patients in this cohort, randomized 1:1 to initiate therapy with tomivosertib plus pembrolizumab or placebo plus pembrolizumab. With the updated trial design, the addressable patient population in the KICKSTART trial now represents a combined potential U.S. market opportunity of \$9 billion. Primary data readouts from both cohorts are anticipated in the first half of 2023.

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.

- **Abstract accepted at ASCO 2022:** eFFECTOR Therapeutics will provide data from its ongoing Phase 1/2 dose escalation and expansion trial of zotatifin in multiple solid tumors at the 2022 ASCO Annual Meeting in Chicago, IL from June 3-7. The abstract will be available online at [asco.org/abstracts](https://www.asco.org/abstracts) on May 26, 2022 at 5:00 pm EDT.
 - Abstract title: First-in-human Phase 1/2 dose escalation and expansion study evaluating first-in-class eIF4A inhibitor zotatifin in patients with solid tumors
 - Presenter: Funda Meric-Bernstam, M.D., The University of Texas MD Anderson Cancer Center
 - Date: June 5, 2022
 - Time: 8:00 AM – 11:00 AM CT
 - Abstract number: 3081
 - Poster Session: Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
 - Poster number: 73
- **Phase 2 expansion cohorts:** eFFECTOR has now opened four expansion cohorts in the ongoing Phase 1/2 dose escalation and expansion trial of zotatifin. These cohorts include ER+ breast cancer evaluating zotatifin in combination with fulvestrant; ER+/Her2- breast cancer in combination with fulvestrant and abemaciclib; ER+/FGFR+ breast cancer evaluating zotatifin as monotherapy; and KRAS G12C-mutant NSCLC in combination with sotorasib. If positive activity is observed in one or more of the Phase 2a expansion cohorts, the company plans to evaluate zotatifin, potentially either as a combination in a randomized trial against a relevant comparator control group, or in a single-arm monotherapy trial. eFFECTOR anticipates reporting initial response data from one or more of the expansion cohorts, as well as additional data from the Phase 1 dose escalation portion of the trial, in the first half of 2022. The company anticipates reporting topline results from the trial in the second half of 2022.

Business Highlights:

- **UCSF Subaward Update:** The company received an extension of a subaward from University of California San Francisco (UCSF) to evaluate zotatifin as a potential host-directed anti-viral therapy in patients with mild to moderate COVID-19 disease to December 2022. The subaward also includes an amendment to the clinical protocol to allow dosing with a subcutaneous formulation of zotatifin for more convenient administration.

First Quarter 2022 Financial Results

Cash Position and Guidance: The company had cash and cash equivalents, and short-term investments totaling \$45.7 million as of March 31, 2022, compared to \$49.7 million in cash and cash equivalents as of December 31, 2021. Current cash is anticipated to be sufficient to fund readouts of topline data from its Phase 2b KICKSTART trial evaluating tomivosertib in combination with pembrolizumab in patients with NSCLC in the first half of 2023 and topline data from its Phase 2a dose expansion cohorts evaluating zotatifin in patients with certain biomarker-positive solid tumors, including ER+ breast cancer and KRAS^{mut} NSCLC, in the second half of 2022. During the first quarter of 2022, the company entered into an equity purchase agreement with Lincoln Park Capital (“LPC”), which included an initial purchase of \$3.0 million of shares of common stock and provides the availability of an additional \$47.0 million of shares of its common stock over the thirty-six month term subject to certain conditions. No additional purchases have occurred as of March 31, 2022.

Research and Development (R&D) Expenses: R&D expenses were \$3.1 million for the quarter ended March 31, 2022, compared to \$4.5 million for the same quarter of 2021. This decrease for the quarter was due to lower external development expenses primarily associated with the eFT508 and eFT226 programs, partially offset by an increase in personnel related and non-cash stock compensation expenses. R&D expenses included approximately \$0.5 million and \$0.1 million of non-cash stock compensation expense in the first quarter 2022 and 2021, respectively.

General and Administrative (G&A) Expenses: G&A expenses were \$3.4 million for the quarter ended March 31, 2022, compared to \$1.3 million for the same quarter of 2021. This increase for the quarter was primarily due to an increase in non-cash stock compensation expense, public company related expenses, including D&O insurance, and personnel related expenses. G&A expenses included approximately \$0.7 million and \$0.1 million of non-cash stock compensation expense in the quarters ended March 31, 2022 and 2021, respectively.

Other Income (Expense): Other income was \$9.6 million for the quarter ended March 31, 2022 and other expense for the quarter ended March 31, 2021 was \$0.8 million. Other income in the quarter ended March 31, 2022 consisted primarily of income related to the change in fair value of the company’s share earn-out liability. The fair value of the share earn-out liability of \$12.1 million at December 31, 2021 was remeasured at \$1.4 million as of March 31, 2022. Other expense for the quarter ended March 31, 2021 primarily consisted of a loss related to the extinguishment of its prior debt facility during the period and interest expense associated with the company’s term loans.

Net Income (Loss): Net income was \$3.1 million, or \$0.08 per basic share and \$0.07 per diluted share, for the quarter ended March 31, 2022, as compared to net loss of \$6.6 million, or a net loss of \$4.55 per basic and diluted share, for the same quarter of 2021. Net income in the quarter ended March 31, 2022 was driven primarily by the change in fair value of the company’s share earn-out liability, which was reported within other income.

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 the planned update on expanded development of zotatifin and the timing thereof; the potential therapeutic benefits of our product candidates; the potential market opportunity for our product candidates; the sufficiency of our capital resources to allow clinical trial data readouts and the expansion of our clinical development programs; and the potential to raise any capital under the LPC facility and the use of proceeds from any capital raised. 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: potential delays in the commencement, enrollment and completion of clinical trials; additional disruptions to our operations from the COVID-19 pandemic, including clinical trial and manufacturing delays; our ability to access the LPC facility is subject to certain conditions; 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 the conflict between Russia and Ukraine 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 Balance Sheets
(in thousands)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,664	\$ 49,702
Short-term investments	28,042	—
Prepaid expenses and other current assets	2,633	3,194
Total current assets	<u>48,339</u>	<u>52,896</u>
Property and equipment, net	149	91
Operating lease right-of-use assets	153	166
Other assets	854	903
Total assets	<u>\$ 49,495</u>	<u>\$ 54,056</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 294	\$ 516
Accrued expenses	2,290	3,418
Lease liabilities, current portion	46	44
Total current liabilities	<u>2,630</u>	<u>3,978</u>
Earn-out liability	1,373	12,130
Non-current term loans, net	18,816	18,760
Accrued final payment on term loans	1,100	1,100
Non-current warrant liability	233	678
Non-current lease liabilities	109	126
Total liabilities	<u>24,261</u>	<u>36,772</u>
Stockholders' equity:		
Common stock	4	4
Additional paid-in capital	143,112	138,181
Accumulated other comprehensive loss	(50)	—
Accumulated deficit	(117,832)	(120,901)
Total stockholders' equity	<u>25,234</u>	<u>17,284</u>
Total liabilities stockholders' equity	<u>\$ 49,495</u>	<u>\$ 54,056</u>

eFFECTOR Therapeutics, Inc.
Condensed Statement of Operations and Comprehensive Income (Loss)
(in thousands, except share and per share data)

	Three Months Ended	
	March 31,	
	2022	2021
Operating expenses:		
Research and development	3,112	4,468
General and administrative	3,436	1,269
Total operating expenses	6,548	5,737
Operating loss	(6,548)	(5,737)
Other income (expense)	9,617	(845)
Net income (loss)	3,069	(6,582)
Other comprehensive loss	(50)	—
Net income (loss) and comprehensive income (loss)	3,019	(6,582)
Net income (loss) per share attributable to common shareholders:		
Basic	\$ 0.08	\$ (4.55)
Diluted	\$ 0.07	\$ (4.55)
Weighted-average common shares outstanding:		
Basic	40,848,325	1,445,065
Diluted	43,382,444	1,445,065

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