

**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): March 6, 2023

ELIEM THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40708
(Commission File Number)

83-2273741
(IRS Employer
Identification No.)

**23515 NE Novelty Hill Road, Suite
B221 #125
Redmond, WA**
(Address of Principal Executive Offices)

98053
(Zip Code)

Registrant's Telephone Number, Including Area Code: 1-877-ELIEMTX (354-3689)

Not Applicable
(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, par value \$0.0001 per share	ELYM	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 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 March 6, 2023, Eliem Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2022. A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Item and the exhibit attached hereto are being furnished and shall not be deemed “filed” for the 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 they be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended, whether filed before or after the date hereof and regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit Number	Description
99.1	Press release of Eliem Therapeutics, Inc., dated March 6, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)



Eliem Therapeutics Reports Fourth Quarter and Year-End Financial Results and Business Highlights

Progressing IND-enabling studies for ETX-123 and further preclinical development of Kv7.2/3 channel opener program

Implemented corporate reorganization and pipeline reprioritization extending cash runway into 2027

SEATTLE and CAMBRIDGE, UK, --(GLOBE NEWSWIRE) – March 6, 2023 – Eliem Therapeutics, Inc. (Nasdaq: ELYM), a biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems, today provided a business update and reported financial results for the quarter and year ended December 31, 2022.

“We are excited to advance our Kv7 program forward with ETX-123 as the lead candidate,” said Andrew Levin, M.D., Ph.D., Executive Chairman of Eliem Therapeutics. “Our Kv7 program utilizes a proven mechanism of action which we believe has the potential to improve the lives of patients suffering from a variety of CNS disorders. We look forward to presenting preclinical data at the 7th RSC-BMCS / SCI Symposium on Ion Channels as Therapeutic Targets being held later this month. With a strong balance sheet funding operations into 2027, we are in an optimal position to execute on ETX-123 and the Kv7 program.”

Recent Highlights

- **Announced Corporate Reorganization and Pipeline Reprioritization to Focus on Advancing High Potential Kv7 Program:** In February, the Company’s Board of Directors determined that it is in the best interests of the Company and its stockholders to reprioritize Eliem’s pipeline to focus on its high potential preclinical Kv7.2/3 program (“Kv7 Program”) and the development of its lead Kv7.2/3 candidate, ETX-123. The Company paused all further development of ETX-155, a novel GABA_A receptor positive allosteric modulator neuroactive steroid (“GABA_A PAM”) that is Phase 2-ready for major depressive disorder (MDD), with the potential to also pursue development in epilepsy. As part of this reprioritization, the Company is retaining its core R&D team under the continued leadership of Dr. Valerie Morisset, EVP R&D and Chief Scientific Officer, to carry on driving forward the Kv7 Program and exploring other pipeline opportunities, and will reduce its workforce by approximately 55% in the first half of 2023.
- **Appointed Andrew Levin as Executive Chairman:** Following the corporate reorganization and departure of Bob Azelby, Eliem's former President and Chief Executive Officer, Andrew Levin, current Chairman of the Board, was appointed as Executive Chairman overseeing the day-to-day operations of the Company.
- **Cash Runway Extended into 2027:** As a result of the corporate reorganization and pipeline reprioritization, the Company’s current cash, cash equivalents and marketable securities is expected to fund operations into 2027.

Program Updates and Anticipated Key Milestones

- The Company has initiated the scaling up synthesis of the lead Kv7 candidate, ETX-123, to enable the initiation of investigational new drug (IND)-enabling safety studies, with Phase 1 studies planned to initiate in the first half of 2024.

- The Company's novel Kv7 compounds, including additional pre-candidates, have demonstrated high potency and differentiated selectivity in electrophysiology assays, and in vivo anticonvulsant activity in the maximal electroshock seizure (MES) rat model.
- Initial ETX-123 preclinical data will be presented at the 7th RSC-BMCS / SCI Symposium on Ion Channels as Therapeutic Targets being held March 27-28, 2023 at the Wellcome Genome Campus in Cambridge, UK.

Fourth Quarter and Year-End 2022 Financial Results

- Cash Position: Cash, cash equivalents and marketable securities were \$123.6 million as of December 31, 2022, compared to \$161.4 million as of December 31, 2021.
- Research and Development (R&D) expenses: R&D expenses were \$4.9 million for the three months ended December 31, 2022, and \$26.2 million for the full year 2022, compared to \$6.9 million and \$23.3 million for comparable periods in 2021, respectively.
- General and Administrative (G&A) expenses: G&A expenses were \$4.6 million for the three months ended December 31, 2022, and \$18.9 million for the full year 2022, compared to \$3.8 million and \$12.4 million for comparable periods in 2021, respectively.
- Net loss: Net loss was \$7.8 million for the three months ended December 31, 2022, and \$45.2 million for the full year 2022, compared to \$10.5 million and \$47.5 million for comparable periods in 2021, respectively.

About Eliem Therapeutics, Inc.

Eliem Therapeutics, Inc. is a biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems. These disorders often occur when neurons are overly excited or inhibited, leading to an imbalance, and our focus is on restoring homeostasis. We are developing a pipeline of clinically differentiated product candidates focused on validated mechanisms of action with broad therapeutic potential to deliver improved therapeutics for patients with these disorders. Eliem channels its experience, energy, and passion for improving patients' quality of life to fuel our efforts to develop life-changing novel therapies. At its core, the Eliem team is motivated by the promise of helping patients live happier, more fulfilling lives. <https://eliemtx.com/>

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements relating to: the continued development and clinical and therapeutic potential of ETX-123; the progression of the Kv7.2/3 and next-generation anxiolytic preclinical programs, including the initiation of IND-enabling safety studies and planned initiation of Phase 1 studies in the first half of 2024; the exploration of future pipeline opportunities; Eliem's reorganization and pipeline reprioritization, and the anticipated results thereof; the expectation that Eliem's current cash, cash equivalents and marketable securities will fund operations through 2027; future data presentations; and Eliem's commitment to developing therapies targeting debilitating disorders. Words such as "excited," "advance," "look forward," "believe," "potential," "will," "on track," "expects," "opportunities," "planned," "runway," "initiate," "anticipated," "milestones," or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. The forward-looking statements in this press release are based upon Eliem's current plans, assumptions, beliefs, expectations, estimates and projections, and involve substantial risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements due to these risks and uncertainties as well as other factors, which include, without limitation: the clinical, therapeutic and commercial value of ETX-123 and Eliem's other preclinical programs; the availability of data at the expected times; Eliem's ability to obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of others; the uncertain timing and level of expenses associated with Eliem's preclinical and clinical development activities; the sufficiency of Eliem's capital and other resources; risks and uncertainties related to regulatory application, review and approval processes and Eliem's compliance with applicable legal and regulatory requirements; market competition; changes in economic and business conditions; impacts on Eliem's business due to external events, including health pandemics or other contagious outbreaks, such as the current COVID-19 pandemic; and other factors discussed under the caption "Risk Factors" in Eliem's Annual Report on Form 10-K for the year ended December 31, 2022. This filing, when available, is available on the SEC's website at www.sec.gov. Additional information will also be set forth in Eliem's other reports and filings it will make with the SEC from time to time. The forward-looking statements made in this press release speak only as of the date of this press release. Eliem expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Eliem's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Investors

Chris Brinzey
ICR Westwicke
chris.brinzey@westwicke.com
339-970-2843

Media

Marites Coulter
Verge Scientific
Mcoultter@vergescientific.com
415.819.2214

Eliem Therapeutics, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	As of December 31,	
	2022	2021
Assets		
Cash and cash equivalents	\$ 43,585	\$ 46,922
Short-term marketable securities	79,981	89,558
Prepaid expenses and other current assets	10,827	11,772
Total current assets	\$ 134,393	\$ 148,252
Operating lease right-of-use assets	471	—
Long-term marketable securities	—	24,919
Other long-term assets	128	70
Total assets	\$ 134,992	\$ 173,241
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 750	\$ 1,404
Accrued expenses	5,047	4,627
Operating lease liabilities	300	—
Total current liabilities	\$ 6,097	\$ 6,031
Other long-term liabilities	—	7
Operating lease liabilities, net of current portion	180	—
Total liabilities	\$ 6,277	\$ 6,038
Commitments and contingencies		
Stockholders' equity		
Common stock, \$0.0001 par value per share, 250,000,000 shares authorized; 26,567,681 shares issued and outstanding at December 31, 2022 and December 31, 2021	3	3
Additional paid-in capital	249,930	242,939
Accumulated other comprehensive loss	(358)	(123)
Accumulated deficit	(120,860)	(75,616)
Total stockholders' equity	\$ 128,715	\$ 167,203
Total liabilities and stockholders' equity	\$ 134,992	\$ 173,241

Eliem Therapeutics, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 4,927	\$ 6,879	\$ 26,214	\$ 23,322
General and administrative	4,627	3,824	18,921	12,350
Total operating expenses	9,554	10,703	45,135	35,672
Loss from operations	(9,554)	(10,703)	(45,135)	(35,672)
Other income (expense):				
Change in fair value of redeemable convertible preferred stock tranche liability	—	—	—	(11,718)
Foreign currency gain (loss)	1,032	98	(1,484)	(170)
Interest income, net	760	60	1,375	80
Total other income (expense)	1,792	158	(109)	(11,808)
Net loss	\$ (7,762)	\$ (10,545)	\$ (45,244)	\$ (47,480)
Accretion of redeemable convertible preferred stock to redemption value and cumulative preferred stock dividends	—	—	—	(4,548)
Net loss attributable to common stockholders	\$ (7,762)	\$ (10,545)	\$ (45,244)	\$ (52,028)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.29)	\$ (0.40)	\$ (1.72)	\$ (4.24)
Weighted-average number of shares outstanding used to compute net loss per share attributable to common stockholders, basic and diluted	26,372,935	26,225,842	26,311,554	12,260,551

