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 7, 2022

ELIEM THERAPEUTICS, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40708**	**83-2273741**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

23515 NE Novelty Hill Road, Suite B221 #125 Redmond, WA	**98053**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (425) 276-2300

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 7, 2022, Eliem Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and fiscal year ended December 31, 2021. 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 7, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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 thereunto duly authorized.

Eliem Therapeutics, Inc.

Date: March 7, 2022

By: /s/ Robert Azelby
Robert Azelby
President and Chief Executive Officer

Exhibit 99.1

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

Completed dosing in Phase 2a clinical trial of ETX-810 in subjects with diabetic peripheral neuropathic pain; topline data to be presented in 1H 2022

Interim data from Phase 1b clinical trial of ETX-155 in subjects with photosensitive epilepsy to be presented in 1H 2022

Submitted Investigational New Drug (IND) application for ETX-155 to the U.S. Food and Drug Administration (FDA)'s psychiatry division

SEATTLE and CAMBRIDGE, UK, --(GLOBE NEWSWIRE) – March 7, 2022 – Eliem Therapeutics, Inc. (Nasdaq: ELYM), a clinical-stage biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in chronic pain, psychiatry, epilepsy and other disorders of the peripheral and central nervous systems, today reported financial results and business highlights for the quarter and year ended December 31, 2021.

“In 2021, we made significant progress on our pipeline and raised sufficient capital to fund the company through multiple catalysts,” said Bob Azelby, president and chief executive officer of Eliem Therapeutics. “We were excited to start off the new year by completing our Phase 2a clinical trial of ETX-810 in diabetic peripheral neuropathic pain and look forward to presenting the topline data from this trial in the first half of this year. Even with a polypharmacy approach, a majority of patients with chronic pain are unable to achieve clinically significant reductions in pain and are often balancing tolerability tradeoffs to achieve additional pain reduction. With ETX-810, we believe we have the potential to introduce a differentiated chronic pain therapy that is both efficacious and well-tolerated. On our ETX-155 program, we expect to report interim data on our proof-of-concept Phase 1b study for photosensitive epilepsy, and we look forward to dosing patients in our depression studies assuming FDA clearance of our IND.”

Recent Highlights

- **Completed dosing in our Phase 2a clinical trial evaluating ETX-810 in subjects with diabetic peripheral neuropathic pain (DPNP).** The Company has completed dosing for its Phase 2a clinical trial evaluating the efficacy and safety of ETX-810 in subjects with DPNP. The Company remains on track to announce topline data from this trial in the first half of 2022.
- **Submitted IND application for ETX-155 to the psychiatry division of the FDA.** The Company submitted an IND application with the U.S. Food and Drug Administration (FDA) in the first quarter of 2022, and assuming FDA clearance to proceed, the Company expects to dose the first subjects in two randomized, placebo-controlled, Phase 2a proof-of-concept depression trials of ETX-155 in the first half of 2022.
- **Hosted a virtual investor event featuring opinion leaders in chronic pain research.** In February 2022, the Company held a virtual investor event that provided an in-depth review on the unmet needs in chronic pain treatment, the existing data supporting the mechanism of ETX-810, and ETX-810's clinical program and its potential commercial opportunity. A replay of the event can be found here.

Program Updates and Anticipated Key Milestones

ETX-810 in chronic pain: ETX-810 is a novel, new chemical entity prodrug of the bioactive lipid palmitoylethanolamide (PEA) that is currently being evaluated in two Phase 2a clinical trials in subjects with DPNP and lumbosacral radicular pain (LSRP), commonly referred to as sciatica.

- ETX-810 in DPNP. The Company expects to announce topline data in the first half of 2022 from its Phase 2a, multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial evaluating the efficacy and safety of ETX-810 in subjects with DPNP. The Company plans to present results for the primary efficacy endpoint, which is the change from baseline to week 4 in the weekly average of the daily pain score measured with the Pain Intensity Numerical Rating Scale (PI-NRS), including p-value, as well as information on safety and tolerability.
- ETX-810 in LSRP. Enrollment remains ongoing for the Phase 2a prospective, multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial evaluating the efficacy and safety of ETX-810 in subjects with LSRP. The Company continues to expect to complete enrollment in the first half of 2022 with topline data in the second half of 2022.

ETX-155 in depression and epilepsy: ETX-155 is a novel $GABA_A$ receptor positive allosteric modulator that the Company plans to evaluate in subjects with major depressive disorder (MDD), perimenopausal depression (PMD), and epilepsy.

- ETX-155 in MDD and PMD. The Company submitted an Investigational New Drug (IND) application with the U.S. Food and Drug Administration's (FDA) psychiatry division in the first quarter of 2022, including plans for characterizing and qualifying metabolites identified in its 14-day Phase 1 trial. Assuming FDA clearance to proceed, the Company expects to dose the first subjects in two randomized, placebo-controlled, Phase 2a proof-of-concept trials of ETX-155 in the first half of 2022 and expects topline data in the second half of 2023.
- ETX-155 in epilepsy. The Company plans to announce interim data in the first half of 2022 from its double-blind cross-over Phase 1b trial in subjects with photosensitive epilepsy (PSE), a single dose proof-of-concept study for epilepsy.

Kv7.2/3 channel opener program: The Company’s preclinical program targets the Kv7.2/3 potassium channel, a target that has been shown to control neuronal excitability and that has clinical validation in pain and epilepsy. The Company plans to initiate IND-enabling studies in 2022.

Anxiolytic for generalized anxiety disorder (GAD): The Company is in early preclinical development of a novel, rapid-acting, non-sedating, non-addictive anxiolytic for the potential treatment of GAD. The Company is continuing the preclinical development of this program with the intent to provide a development plan update later in 2022.

Fourth Quarter and Year-End 2021 Financial Results

- Cash Position: Cash, cash equivalents and marketable securities was $161.4 million as of December 31, 2021, as compared to $20.5 million as of December 30, 2020. This includes net proceeds from the Company’s August 2021 initial public offering. The Company’s current cash, cash equivalents and marketable securities are expected to fund operations through late 2023.
- Research and Development (R&D) expenses: R&D expenses were $6.9 million for the three months ended December 31, 2021, and $23.3 million for the full year 2021, compared to $13.6 million and $18.5 million for comparable periods in 2020, respectively. R&D expenses for the three months and year ended December 31, 2020 included $9.2 million of acquired in-process and development related to the Company's acquisition of Athenen Therapeutics, Inc.
- General and Administrative (G&A) expenses: G&A expenses were $3.8 million for the three months ended December 31, 2021, and $12.4 million for the full year 2021, compared to $1.5 million and $2.4 million for comparable periods in 2020, respectively.
- Net loss: Net loss was $10.5 million for the three months ended December 31, 2021, and $47.5 million for the full year 2021, compared to $14.9 million and $20.7 million for comparable periods in 2020, respectively.

About Eliem Therapeutics, Inc.
Eliem Therapeutics, Inc. is a clinical-stage biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in chronic pain, psychiatry, epilepsy 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 ETX-155 and ETX-810; Eliem's plans to initiate clinical trials of ETX-155 and the timing thereof; anticipated enrollment, dosing, and data readouts of ETX-810 and ETX-155 and the timing thereof; timing of regulatory filings and approvals; the progression of the Kv7.2/3 and next-generation anxiolytic preclinical programs; the expectation that Eliem's current cash, cash equivalents and marketable securities will fund operations through late 2023; and Eliem's commitment to developing therapies targeting debilitating disorders. Words such as "excited," "look forward," "believe," "potential," "on track," "expects," "opportunity," "continues," "plans," "runway," "initiate," "support," 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-810, ETX-155 and Eliem's preclinical programs; risks related to the potential failure of ETX-810 and ETX-155 to demonstrate safety and efficacy in clinical testing; Eliem's ability to initiate and conduct clinical trials and studies of ETX-810 and ETX-155 sufficient to achieve a positive completion; 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, 2021. 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.

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

Assets	**December 31, 2021**	**December 31, 2020**
Current assets:		
Cash and cash equivalents	$ 46,922	$ 20,487
Short-term marketable securities	89,558	—
Prepaid expenses and other current assets	11,772	1,511
Total current assets	$ 148,252	$ 21,998
Long-term marketable securities	24,919	—
Other long-term assets	70	2,633
Total assets	$ 173,241	$ 24,631
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities:		
Accounts payable	1,404	1,086
Accounts payable, related party	—	207
Accrued expenses	4,588	1,219
Accrued expenses, related party	39	—
Redeemable convertible preferred stock tranche liability	—	551
Total current liabilities	$ 6,031	$ 3,063
Other long-term liabilities	7	$ —
Total liabilities	$ 6,038	$ 3,063
Redeemable convertible preferred stock, $0.0001 par value per share, 10,000,000 and 12,909,389 shares authorized, 0 and 7,140,157 shares issued and outstanding with aggregate liquidation preference of $0 and $49,891 at December 31, 2021 and 2020, respectively	—	46,551
Stockholders' equity (deficit):		
Common stock, $0.0001 par value per share, 250,000,000 and 40,000,000 shares authorized and 26,235,317 and 3,418,751 shares issued and outstanding at December 31, 2021 and 2020, respectively	3	1
Additional paid-in capital	242,939	3,152
Accumulated other comprehensive income	(123)	—
Accumulated deficit	(75,616)	(28,136)
Total stockholders' equity (deficit)	$ 167,203	$ (24,983)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 173,241	$ 24,631

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,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 6,591	$ 4,125	$ 22,046	$ 8,769
Research and development, related party	288	287	1,276	573
In-process research and development	—	9,158	—	9,158
General and administrative	3,824	1,537	12,350	2,425
Total operating expenses	10,703	15,107	35,672	20,925
Loss from operations	(10,703)	(15,107)	(35,672)	(20,925)
Other income (expense):				
Change in fair value of redeemable convertible preferred stock tranche liability	—	—	(11,718)	—
Foreign currency gain (loss)	98	244	(170)	257
Other income, net	60	—	80	—
Total other income (expense)	158	244	(11,808)	257
Net loss	$ (10,545)	$ (14,863)	$ (47,480)	$ (20,668)
Accretion of redeemable convertible preferred stock to redemption value and cumulative preferred stock dividends	—	(933)	(4,548)	(2,285)
Net loss attributable to common stockholders	$ (10,545)	$ (15,796)	$ (52,028)	$ (22,953)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.40)	$ (4.99)	$ (4.24)	$ (10.49)
Weighted-average number of shares outstanding used to compute net loss per share attributable to common stockholders, basic and diluted	26,225,842	3,164,981	12,260,551	2,187,813