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): January 18, 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 January 18, 2022, Eliem Therapeutics, Inc. (Eliem, or the Company) issued a press release providing program updates, announcing expected upcoming milestones and providing an update on the Company's unaudited cash, cash equivalents and marketable securities as of December 31, 2021. In such press release, the Company estimated that its unaudited cash, cash equivalents and marketable securities were approximately $160 million as of December 31, 2021 and expects that this amount will be sufficient to fund operations through late 2023.

Item 8.01. Other Events.

Program Updates and Anticipated Key Milestones

Eliem also provided the following program updates and announced expected upcoming milestones.

ETX-810, one of the Company's two lead product candidates, is a novel, new chemical entity prodrug of the bioactive lipid palmitoylethanolamide that is currently being evaluated in two Phase 2a prospective, multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trials in subjects with diabetic peripheral neuropathic pain (DPNP) and lumbosacral radicular pain (LSRP), commonly referred to as sciatica. The Company announced that it has reached full enrollment in its Phase 2a DPNP trial. Enrollment is still ongoing in the Company's Phase 2a LSRP trial, but the Company expects enrollment for that trial to be completed in the first half of 2022. The Company expects topline data from its DPNP and LSRP trials in the first and second halves of 2022, respectively. The Company's current plan is to initiate Phase 2b dose-range finding trials in both DPNP and LSRP indications in the second half of 2022 and first half of 2023, respectively.

ETX-155, the Company's other lead product candidate, is a novel $GABA_A$ receptor positive allosteric modulator that it plans to evaluate in subjects with major depressive disorder (MDD), perimenopausal depression (PMD), and epilepsy. The Company previously planned to submit an investigational new drug (IND) application with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2021 for MDD and PMD, but announced that it delayed that submission due to the identification of an uncharacterized metabolite in December 2021. The Company instead expects to submit an IND application for MDD and PMD, updated with a plan to characterize the metabolite, in the first quarter of 2022. 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 MDD and PMD in the first half of 2022 and expects topline data for both trials in the second half of 2023. The Company also announced that enrollment is ongoing for the single-arm Phase 1b trial in subjects with photosensitive epilepsy (PSE), a single dose proof-of-concept study for epilepsy, and that the Company expects interim data from that study in the first half of 2022.

The Company also currently has two preclinical programs, its Kv7.2/3 channel opener program, which 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, and its program to develop a novel, rapid-acting, non-sedating, non-addictive anxiolytic for the potential treatment of generalized anxiety disorder (GAD). The Company plans to pursue IND-enabling studies for its Kv7.2/3 channel opener program in 2022 and intends to provide a development plan update for its GAD anxiolytic program later in 2022.

Forward-Looking Statements

Statements in this report that are not statements of historical fact are forward-looking statements, including, without limitation, statements relating to: expected milestones; 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 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; and Eliem's commitment to developing therapies targeting debilitating disorders. Words such as "expected," "estimated," "will," "sufficient," "anticipated," "plans," "assuming," 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 report are based upon the 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 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 Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2021. The forward-looking statements made in this report speak only as of the date of report. 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.

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: January 18, 2022

By: /s/ Robert W. Azelby

Robert W. Azelby
Chief Executive Officer