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): July 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 8.01. Other Items.

On July 18, 2022, Eliem Therapeutics, Inc. (Eliem, or the Company) provided updates on the status of the ETX-155 clinical program and certain of its other clinical and preclinical programs.

Update on ETX-155

ETX-155 is a novel, neuroactive steroid $GABA_A$ receptor positive allosteric modulator (PAM) that the Company plans to evaluate in subjects with major depressive disorder (MDD), perimenopausal depression (PMD), and epilepsy. In April 2022, the Company elected to delay advancing ETX-155 into Phase 2a depression trials to determine the root cause of a lower-than-expected exposure observed in a Phase 1b proof-of-concept trial of ETX-155 in photosensitive epilepsy (PSE). Based on an initial review of ongoing analyses, the Company believes that the reduced exposure levels were most likely related to certain aspects of the chemistry, manufacturing, and controls (CMC) for the different batches of drug product used in the Phase 1 healthy volunteer trials and the Phase 1b PSE trial. Evaluation and implementation of CMC process modifications to ensure consistency of drug product manufacturing are currently underway. In parallel, the Company plans to initiate a Phase 1 pharmacokinetic trial in healthy subjects using the drug batches that were used in the Phase 1b PSE trial. The objective of this Phase 1 trial is to identify the dose required to provide a similar exposure to that of the 60-milligram dose used in the previous 14-day repeat dose Phase 1 healthy volunteer trial. Once a dose level with appropriate exposure and safety is confirmed, the Company intends to use these same drug batches to initiate its previously planned Phase 2a trial of ETX-155 in MDD patients.

Results from the Phase 1 pharmacokinetic trial are expected in the fourth quarter of 2022, and the subsequent randomized, placebo-controlled Phase 2a trial in MDD patients is expected to initiate in the first quarter of 2023. This Phase 2a trial is anticipated to be a proof-of-concept study with 4-week treatment, with subjects randomized 1:1 to either ETX-155 or placebo, evaluating efficacy endpoints from day 3 through day 42. Assuming Phase 2a MDD trial initiation in the first quarter of 2023, topline data from this trial would be expected in mid-2024.

The Company is postponing the initiation of the planned Phase 2a trial in PMD, which will provide additional investment flexibility for the progression of Eliem's pipeline. The Company will consider resuming the PSE trial after the expected readout of the Phase 1 pharmacokinetic trial in the fourth quarter of 2022.

Update on other programs

In addition to ETX-155, the Company expects to report topline data for its clinical candidate, ETX-810, in lumbosacral radicular pain (LSRP) in the third quarter of 2022 and is progressing a novel Kv7 channel opener program that is expected to begin IND-enabling studies in the second half of 2022.

Update on cash guidance

The Company believes that its cash, cash equivalents and short- and long-term marketable securities of $149.9 million as of March 31, 2022 are sufficient to fund key pipeline catalysts and operations until mid-2024.

Forward-Looking Statements

Statements in this report that are not statements of historical fact are forward-looking statements, including, without limitation, statements relating to: the continued development and clinical and therapeutic potential of ETX-155, ETX-810 and Eliem's Kv7 channel opener program; Eliem's belief regarding the likely cause of a lower-than-expected exposure observed in the referenced Phase 1b proof-of-concept trial of ETX-155 in PSE; Eliem's plans and activities relating to ETX-155 CMC process modifications; Eliem's plans to initiate a Phase 1 pharmacokinetic trial of ETX-155 and the timing thereof, the objective of this trial and the expected availability of topline data; Eliem's plans to initiate its previously planned Phase 2a trial of ETX-155 in MDD patients and the timing thereof; the expected availability of topline data for Eliem's Phase 2a trial of ETX-810 in LSRP and the timing thereof; the progression of the Kv7 channel opener program; and the belief that Eliem has sufficient capital to fund key pipeline catalysts and operations until mid-2024. Words such as "anticipated," "believe," "expect," "initiate," "intends," "investment," "likely," "objective," "potential," "progression," "sufficient," "will," "would," 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 Current Report on Form 8-K 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2022. This filing 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 Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K. 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: July 18, 2022

By: /s/ James B. Bucher

James B. Bucher
Executive Vice President and General Counsel