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): April 25, 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 April 25, 2022, Eliem Therapeutics, Inc. (Eliem, or the Company) reported results from its Phase 2a clinical trial investigating ETX-810 for the treatment of diabetic peripheral neuropathic pain (DPNP), and provided an update on the status of the ETX-155 clinical program in epilepsy and depression.

Update on ETX-810

In the Phase 2a clinical trial in DPNP, ETX-810 did not achieve statistically significant separation from placebo on the trial's primary endpoint, which assessed 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).

The multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial evaluated the efficacy and safety of ETX-810 in 159 subjects with DPNP over four weeks of dosing. 78 patients received 1,000 mg of ETX-810 twice daily, and 81 patients received placebo. ETX-810 was well tolerated in the study, with an encouraging safety profile. However, the primary endpoint of the study was not achieved, and separation from placebo on the PI-NRS was not observed during the 4 weeks of dosing. As a result, Eliem does not currently plan to further develop ETX-810 as a potential treatment for DPNP.

The Company has also fully enrolled its Phase 2a proof-of-concept trial evaluating ETX-810 in patients with LSRP. The LSRP study has enrolled 149 patients and has a similar design to the Phase 2a DPNP study. The LSRP study is expected to report topline data in the third quarter of 2022.

Update on ETX-155

ETX-155 is in an ongoing Phase 1b proof-of-concept trial in photosensitive epilepsy (PSE). Last month, the Company received clearance from U.S. Food and Drug Administration to proceed with an Investigational New Drug (IND) application to progress ETX-155 in Phase 2a clinical trials in depression.

Eliem has reviewed interim results from the Phase 1b PSE study and has elected to delay enrollment of its Phase 2a clinical trials of ETX-155 in major depressive disorder (MDD) and perimenopausal depression (PMD). Three patients have been evaluated to date in the Phase 1b PSE study, and the results of ETX-155 on the photoparoxysmal response observed following intermittent photic stimuli were inconclusive. An analysis of the drug exposures in these patients indicated that drug levels were significantly lower than expected based on the pharmacokinetic profile observed in the two Phase 1 trials of ETX-155 in healthy subjects. The Company is currently investigating potential root causes of the observed difference in exposure from the prior studies, including evaluation of any differences between the lots of drug product used in this study and those of the prior Phase 1 trials. The Company will provide an update to timelines after the root cause is further investigated.

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements relating to: the continued development and clinical and therapeutic potential ETX-155 and ETX-810; the progression of Eliem's clinical trials of ETX-155 and the timing thereof; and the anticipated data readouts of ETX-810 in LSRP and the timing thereof. Words such as "expected," "plan," "potential," "will," 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 Annual Report on Form 10-K for the year ended December 31, 2021. 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: April 25, 2022

By: /s/ James B. Bucher

James B. Bucher
Executive Vice President and General Counsel