

**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): September 13, 2021

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: (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))
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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 September 13, 2021, Eliem Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 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 September 13, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)



Eliem Therapeutics Reports Second Quarter Financial Results

On track to advance two clinical programs through five proof-of-concept trials and progress two preclinical programs over the next 18-24 months

Recently completed an IPO for \$92 million in gross proceeds that, along with existing cash, provides cash runway through late 2023

SEATTLE and CAMBRIDGE, UK, --(BUSINESS WIRE) – September 13, 2021 – Eliem Therapeutics, Inc., 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 ended June 30, 2021.

“It has been an exciting year thus far for Eliem, highlighted by our successful initial public offering (IPO) that we completed in August,” said Bob Azelby, Eliem’s president and chief executive officer. “In the second quarter, we continued to advance enrollment on our two Phase 2a studies for ETX-810 in patients with chronic pain conditions. We also made excellent progress toward initiating three clinical studies for ETX-155 in depressive disorders and epilepsy. The proceeds from our IPO, along with the additional capital we raised in our Series B financing in May 2021, are expected to fund our operations through late 2023. We believe this funding will take us through multiple topline clinical data readouts across five different indications and also allows us to advance our preclinical pipeline. We remain committed to developing therapies targeting debilitating disorders that impact tens of millions of people worldwide every day.”

Recent Highlights and Upcoming Milestones

Initial public offering raised \$92 million gross proceeds: In August 2021, the Company announced the public offering of 7,360,000 shares of common stock, including the exercise in full of the underwriters’ option to purchase an additional 960,000 shares of common shares, at a public offering price of \$12.50 per share. The Company received estimated net proceeds of \$83.1 million from the IPO, after deducting underwriting discounts of \$6.4 million and estimated offering costs of \$2.5 million. The IPO was preceded by a Series B financing in May 2021 that raised gross proceeds of \$60.0 million.

Program Updates and 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 patients with diabetic peripheral neuropathic pain (DPNP) and lumbosacral radicular pain (LSRP), commonly referred to as sciatica. ETX-810 was designed to optimize the oral absorption and systemic exposure of PEA, which is believed to play a critical role in the regulation of neuroinflammation and pain signaling in chronic pain.

- ETX-810 in DPNP. The Company is conducting a Phase 2a prospective, multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial to evaluate the
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efficacy and safety of ETX-810 in adults with DPNP. The Company expects to have a topline data readout during the first half of 2022.

- ETX-810 in LSRP. The Company is conducting a Phase 2a prospective, multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial to evaluate the efficacy and safety of ETX-810 in adults with LSRP. The Company expects to have a topline data readout during the first half of 2022.

ETX-155 in depression and epilepsy: ETX-155 is a novel GABA_A receptor positive allosteric modulator that Eliem plans to evaluate in patients with major depressive disorder (MDD), perimenopausal depression (PMD) and focal onset seizure (FOS). ETX-155 was designed to have broad potency across both synaptic and extrasynaptic GABA_A receptor subtypes. In Phase 1 clinical studies to date, ETX-155 was shown to be well tolerated with desirable pharmacokinetic properties, including no clinically meaningful food effect and at least a 24-hour half-life to enable once-a-day-dosing. The Company believes these attributes combine to position it well within the GABA_A PAM therapeutic class.

- ETX-155 in FOS. The Company expects to initiate a single-arm, proof-of-concept Phase 1b trial in photosensitive epilepsy patients in the second half of 2021 with topline data expected by the first half of 2022.
- ETX-155 in MDD. The Company expects to initiate a randomized, placebo-controlled, Phase 2a proof-of-concept trial of ETX-155 in the second half of 2021 with first patient dosed in early 2022 and topline data expected in the first half of 2023.
- ETX-155 in PMD. The Company expects to initiate a randomized, placebo-controlled, Phase 2a proof-of-concept trial of ETX-155 in the second half of 2021 with first patient dosed in early 2022 and topline data expected in the first half of 2023.

Preclinical Pipeline: The Company is progressing two preclinical programs currently in the discovery stage.

- Kv7.2/3 in pain and epilepsy. The lead preclinical program targets the Kv7.2/3 potassium channel that has been shown to play a role in stabilizing the membrane potential of neuronal cells and controlling neuronal excitability. The Company plans to nominate a clinical candidate in the second half of 2021.
- Anxiolytic for generalized anxiety disorder (GAD). The Company is also in early preclinical development of a novel, rapid-acting, non-sedating, non-addictive anxiolytic for the potential treatment of GAD. The Company plans to nominate a clinical candidate in 2022.

Second Quarter 2021 Financial Results

- **Cash Position:** Cash was \$99.5 million as of June 30, 2021, as compared to \$47.9 million as of March 31, 2021. This does not include an additional \$83.1 million in net proceeds from the Company's IPO in August 2021.
- **Research and Development (R&D) expenses:** R&D expenses were \$5.8 million for the three months ended June 30, 2021, compared to \$1.4 million for the same period in 2020.
- **General and Administrative (G&A) expenses:** G&A expenses were \$2.9 million for the three months ended June 30, 2021, compared to \$0.2 million for the same period in 2020.
- **Net loss:** Net loss was \$8.7 million for the three months ended June 30, 2021, compared to \$1.6 million for the same period in 2020.

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: 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; the progression of the Kv7.2/3 and next-generation anxiolytic preclinical programs; the sufficiency of Eliem's current funds and anticipated cash runway through late 2023; and Eliem's commitment to developing therapies targeting debilitating disorders. Words such as "on track," "advance," "progress," "provides," "runway," "will," "enable," "expect," "believe," "plans," "initiate," 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 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 June 30, 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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