Eliem Therapeutics Reports Second Quarter Financial and Business Highlights

August 15, 2022

Initiated Phase 1 pharmacokinetic trial for ETX-155 with expected results in Q4 2022

Capital now expected to fund operations into 2025

SEATTLE and CAMBRIDGE, United Kingdom, Aug. 15, 2022 (GLOBE NEWSWIRE) -- Eliem Therapeutics, Inc. (Nasdaq: ELYM), a clinical-stage biotechnology company focused on developing novel therapies for neuronal excitability disorders to address unmet needs in psychiatry, epilepsy, chronic pain, and other disorders of the peripheral and central nervous systems, today provided a business update and reported financial results for the quarter ended June 30, 2022.

"We continue to advance our pipeline targeting neuronal excitability disorders," said Bob Azelby, president and chief executive officer of Eliem Therapeutics. "While we are disappointed with our recent announcement regarding the discontinuation of ETX-810, we continue to actively progress ETX-155. We have initiated our previously announced Phase 1 pharmacokinetic study of ETX-155 that is intended to confirm the dose that we will advance into a Phase 2a clinical trial in patients with major depressive disorder (MDD). We are encouraged by the precedent validation of the $GABA_A$ PAM class in multiple large depression trials and believe ETX-155 has the potential to be a clinically differentiated $GABA_A$ PAM product candidate."

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). On August 2, 2022, the Company reported that ETX-810 did not achieve statistically significant separation from placebo on the primary endpoint in the Phase 2a clinical trial investigating ETX-810 for the treatment of lumbosacral radicular pain. This result is consistent with the lack of separation from placebo observed in the Phase 2a clinical trial in diabetic peripheral neuropathic pain, as reported in April 2022. Therefore, the Company has discontinued further development of ETX-810.

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) and epilepsy. In July 2022, the Company initiated a Phase 1 pharmacokinetic trial in healthy subjects using the drug batches that were used in the Phase 1b photosensitive epilepsy (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. Results from the Phase 1 pharmacokinetic trial are expected in the fourth quarter of 2022. Once a dose level with appropriate exposure and safety is confirmed, the Company intends to initiate its previously planned randomized, placebo-controlled Phase 2a clinical trial in MDD patients. Assuming success in the Phase 1 pharmacokinetic trial in healthy subjects, the Company anticipates initiating this Phase 2a trial in MDD in the first quarter of 2023, and topline data would be expected in mid-2024. The Company will consider resuming the PSE trial after the expected readout of the Phase 1 pharmacokinetic trial in the fourth quarter of 2022.

Kv7.2/3 channel opener program: The Company's preclinical program targets the Kv7.2/3 potassium channel, a target that has clinical validation in pain and epilepsy. The Company has filed foundational intellectual property claims on its novel Kv7 development candidate and remains on track 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.

Second Quarter 2022 Financial Results

- Cash Position: Cash, cash equivalents and short- and long-term marketable securities was $134.7 million as of June 30, 2022, as compared to $161.4 million as of December 31, 2021. With the discontinuation of ETX-810, the Company's current cash, cash equivalents and short- and long-term marketable securities are now expected to fund operations into 2025.
- Research and Development (R&D) expenses: R&D expenses were $8.8 million for the three months ended June 30, 2022, compared to $5.8 million for the same period in 2021.
- General and Administrative (G&A) expenses: G&A expenses were $4.9 million for the three months ended June 30, 2022, compared to $2.9 million for the same period in 2021.
- Net loss: Net loss was $14.6 million for the three months ended June 30, 2022, compared to $8.7 million for the same period in 2021. The three months ended June 30, 2022 includes an unrealized foreign currency loss of $1.0 million primarily resulting from the effect of unfavorable exchange rates on the remeasurement of our British Pound denominated assets.

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 psychiatry, epilepsy, chronic pain, 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 advancement of Eliem's pipeline; the continued development and clinical and therapeutic potential of ETX-155 and Eliem's Kv7.2/3 channel opener program; Eliem's plans for clinical trials of ETX-155 and the timing thereof; the progression of the Kv7.2/3 channel opener and next-generation anxiolytic preclinical programs, and Eliem's plans with respect thereto; the expectation that Eliem's current cash, cash equivalents and short- and long-term marketable securities will fund operations into 2025; and Eliem's commitment to developing therapies targeting neuronal excitability disorders. Words such as "advance," "anticipates," "assuming," "believe," "continue," "encouraged," "expects," "focus," "intended," "objective," "on track," "potential," "progress," "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 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-155 and Eliem's preclinical programs; risks related to the potential failure of ETX-155 to demonstrate safety and efficacy in clinical testing; Eliem's ability to initiate and conduct clinical trials and studies of 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 June 30, 2022. 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.

Investors
Chris Brinzey
ICR Westwicke
chris.brinzey@westwicke.com
339-970-2843

Media
Marites Coulter
Verge Scientific
Mcoulter@vergescientific.com
415.819.2214

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

Assets	June 30, 2022	December 31, 2021
Current assets:		
Cash and cash equivalents	$ 32,602	$ 46,922
Short-term marketable securities	90,349	89,558
Prepaid expenses and other current assets	10,125	11,772
Total current assets	$ 133,076	$ 148,252

Operating lease right-of-use assets	697	—
Long-term marketable securities	11,701	24,919
Other long-term assets	4,631	70
Total assets	$ 150,105	$ 173,241
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	1,061	1,404
Accounts payable, related party	21	—
Accrued expenses	6,072	4,588
Accrued expenses, related party	21	39
Operating lease liabilities, current	439	—
Total current liabilities	$ 7,614	$ 6,031
Other long-term liabilities	—	7
Operating lease liabilities, net of current portion	256	—
Total liabilities	$ 7,870	$ 6,038
Stockholders' equity		
Common stock, $0.0001 par value per share, 250,000,000 shares authorized; 26,567,681 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	3	3
Additional paid-in capital	246,252	242,939
Accumulated other comprehensive loss	(604)	(123)
Accumulated deficit	(103,416)	(75,616)
Total stockholders' equity	$ 142,235	$ 167,203
Total liabilities and stockholders' equity	$ 150,105	$ 173,241

Eliem Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 8,740	$ 5,478	$ 16,851	$ 9,751
Research and development, related party	29	315	178	703
General and administrative	4,932	2,914	9,804	5,132
Total operating expenses	13,701	8,707	26,833	15,586
Loss from operations	(13,701)	(8,707)	(26,833)	(15,586)
Other income (expense):				
Change in fair value of redeemable convertible preferred stock tranche liability	—	—	—	(11,718)
Foreign currency loss	(1,042)	(12)	(1,199)	(16)
Other income, net	147	—	232	—
Total other income (expense)	(895)	(12)	(967)	(11,734)
Net loss	$ (14,596)	$ (8,719)	$ (27,800)	$ (27,320)
Accretion of redeemable convertible preferred stock to redemption value and cumulative preferred stock dividends	—	(2,141)	—	(3,226)
Net loss attributable to common stockholders	$ (14,596)	$ (10,860)	$ (27,800)	$ (30,546)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.56)	$ (3.11)	$ (1.06)	$ (8.80)
Weighted-average number of shares outstanding used to compute net loss per share attributable to common stockholders, basic and diluted	26,296,560	3,488,017	26,267,914	3,472,086