Eliem Therapeutics Reports Third Quarter Financial and Business Highlights

November 8, 2021

Advanced ETX-155 clinical development program, with the first subject successfully screened in epilepsy proof-of-concept trial and significant progress made toward the initiation of major depressive disorder (MDD) and perimenopausal depression (PMD) clinical trials

Continued to enroll ETX-810's two Phase 2a chronic pain clinical trials, with topline data anticipated in the first half of 2022

On track to progress Kv7.2/3 channel opener program into Investigational New Drug (IND)-enabling studies in the first half of 2022

SEATTLE and CAMBRIDGE, United Kingdom, Nov. 08, 2021 (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 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 September 30, 2021.

"Our clinical execution is progressing well," said Bob Azelby, Eliem's president and chief executive officer. "For ETX-155, we are excited to report that we have completed our Phase 1 studies, we have successfully screened our first patient in our photosensitive epilepsy (PSE) proof-of-concept clinical trial and we continue to progress clinical development activities for the launch of our phase 2a trials evaluating ETX-155 in patients with MDD and PMD. As we look to expand our clinical pipeline, we are increasingly excited about the potential of our Kv7.2/3 channel opener program as a clinically validated mechanistic approach to treat diseases such as epilepsy, pain and MDD, and we remain on track to progress the program into IND-enabling studies in the first half of 2022."

Third Quarter 2021 Highlights and Recent Developments

Completed 14-day repeat dose Phase 1 study demonstrating ETX-155 was well tolerated with an approximate 40-hour half-life supporting once-daily dosing. The 14-day, repeat dose, Phase 1 study evaluated the pharmacokinetic profile and safety of ETX-155 in 20 healthy human subjects, evaluating 60 mg ETX-155 (n=15) or placebo (n=5) dosed daily in the evening for 14 days. Results demonstrated ETX-155 reached steady state concentration at Day 8 and had an approximate 40-hour half-life, confirming ETX-155's desirable profile for a once-daily dosing regimen. The study also confirmed that ETX-155 was generally well tolerated with no severe or serious adverse events, or discontinuations. All treatment-emergent adverse events (TEAEs), including central nervous system (CNS) adverse events, were mild/moderate and transient. In particular, all somnolence adverse events were mild and the incidence was comparable in the ETX-155 and placebo groups. Notably, somnolence events were sporadic, and no subject who reported somnolence in either the ETX-155 or placebo arms reported it more than once during the dosing or follow-up period. In addition, there was no clinically meaningful difference compared to placebo in sleep quality or next morning state of arousal, as measured by the Leeds Sleep Evaluation Questionnaire. The tolerability and safety findings of this study were consistent with those of the previous 7-day repeat dose and single ascending dose Phase 1 study. Collectively, the Company's Phase 1 studies have demonstrated that ETX-155 has differentiated pharmacokinetic properties, including no clinically meaningful food effect and an approximate 40-hour half-life to enable a once-daily dosing regimen.

Screened the first subject in ETX-155 photosensitive epilepsy clinical trial: The Company anticipates dosing the first subject in the single-arm proof-of-concept Phase 1b PSE trial by the end of 2021. Precedent literature demonstrates that activity in single-dose PSE trials can be a reliable predictor of anticonvulsant activity in various forms of epilepsy, such as focal onset seizure.

Advanced study start-up activities for ETX-155 Phase 2a clinical trials in MDD and PMD: The Company anticipates dosing the first subject in each of these studies in early 2022, assuming regulatory approval of its IND application.

Program Updates and Anticipated Milestones

ETX-810 in chronic pain: ETX-810 is a novel new chemical entity prodrug of the bioactive lipid palmitoylethanolamide that is currently being evaluated in two Phase 2a clinical trials in subjects with diabetic peripheral neuropathic pain (DPNP) and lumbosacral radicular pain (LSRP), commonly referred to as sciatica.

- ETX-810 in DPNP. The ongoing Phase 2a prospective, multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial evaluating the efficacy and safety of ETX-810 in subjects with DPNP remains on track to have topline data readout during the first half of 2022.

- ETX-810 in LSRP. The ongoing Phase 2a prospective, multi-center, randomized, double-blind, placebo-controlled, parallel-group clinical trial evaluating the efficacy and safety of ETX-810 in subjects with LSRP remains on track to have 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 (PAM) that Eliem plans to evaluate in subjects with MDD, PMD and focal onset seizure (FOS).

- ETX-155 in FOS. The Company expects to report topline data from its ongoing single-arm, proof-of-concept Phase 1b trial

in subjects with PSE in the first half of 2022. This study is intended to support progression into a Phase 2 study in FOS, given precedent literature demonstrating that activity in single dose PSE trials can be a reliable predictor of anticonvulsant activity in focal onset seizure.

- ETX-155 in MDD and PMD. Assuming regulatory approval of the Company's IND application, the Company expects to dose its first subjects in two randomized, placebo-controlled, Phase 2a proof-of-concept trials of ETX-155 in early 2022. Topline data from each trial is expected in the first half of 2023.

Kv7.2/3 channel opener program: The Company's preclinical program targets the Kv7.2/3 potassium channel that has been shown to control neuronal excitability, with clinical validation in pain and epilepsy. The program remains on track to progress to IND-enabling studies in the first half of 2022.

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, based on a clinically validated mechanism. The Company plans to continue the preclinical development of this program in 2022.

Third Quarter 2021 Financial Results

- Cash Position: Cash, cash equivalents and marketable securities was $169.6 million as of September 30, 2021, as compared to $99.5 million as of June 30, 2021. This includes net proceeds from the Company's August 2021 initial public offering. The Company's current cash, cash equivalents and marketable securities are expected to fund operations through late 2023.
- Research and Development (R&D) expenses: R&D expenses were $6.0 million for the three months ended September 30, 2021, compared to $1.9 million for the same period in 2020.
- General and Administrative (G&A) expenses: G&A expenses were $3.4 million for the three months ended September 30, 2021, compared to $0.3 million for the same period in 2020.
- Net loss: Net loss was $9.6 million for the three months ended September 30, 2021, compared to $2.3 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: 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; the progression of the Kv7.2/3 and next-generation anxiolytic preclinical programs; the expectation that Eliem's current cash, cash equivalents and marketable securities will fund operations through late 2023; and Eliem's commitment to developing therapies targeting debilitating disorders. Words such as "on track," "advance," "progress," "toward," "continue," "excited," "potential," "expand," "anticipate," "milestones," "expect," "demonstrates," "intended," "plans," "runway," "initiate," "support," "enable," 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 September 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.

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	September 30, 2021	December 31, 2020
Current assets:		
Cash and cash equivalents	$ 62,819	$ 20,487
Short-term marketable securities	83,199	—
Prepaid expenses and other current assets	12,614	1,511
Total current assets	$ 158,632	$ 21,998
Long-term marketable securities	23,619	—
Other long-term assets	—	2,633
Total assets	$ 182,251	$ 24,631
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	2,579	1,086
Accounts payable, related party	—	207
Accrued expenses	2,979	1,219
Accrued expenses, related party	32	—
Redeemable convertible preferred stock tranche liability	—	551
Total current liabilities	$ 5,590	$ 3,063
Total liabilities	$ 5,590	$ 3,063
Commitments and contingencies		
Redeemable convertible preferred stock, $0.0001 par value, 10,000,000 and 12,909,389 shares authorized, 0 and 7,140,157 shares issued and outstanding with aggregate liquidation preference of $0 and $49,891 at September 30, 2021 and December 31, 2020, respectively	—	46,551
Stockholders' equity (deficit):		
Common stock, $0.0001 par value per share, 250,000,000 and 40,000,000 shares authorized; 26,199,262 and 3,418,751 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	3	1
Additional paid-in capital	241,747	3,152
Accumulated other comprehensive income	(18)	—
Accumulated deficit	(65,071)	(28,136)
Total stockholders' equity (deficit)	$ 176,661	$ (24,983)
Total liabilities, redeemable convertible preferred stock, and stockholders' equity (deficit)	$ 182,251	$ 24,631

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 5,704	$ 1,930	$ 15,455	$ 4,644
Research and development, related party	285	17	988	286
General and administrative	3,394	312	8,526	888
Total operating expenses	9,383	2,259	24,969	5,818
Loss from operations	(9,383)	(2,259)	(24,969)	(5,818)
Other income (expense):				

Change in fair value of redeemable convertible preferred stock tranche liability	—	—	(11,718)	—
Foreign currency gain (loss)	(252)	1	(268)	13
Other income, net	20	—	20	—
Total other income (expense)	(232)	1	(11,966)	13
Net loss	$ (9,615)	$ (2,258)	$ (36,935)	$ (5,805)
Accretion of redeemable convertible preferred stock to redemption value and cumulative preferred stock dividends	(1,322)	(461)	(4,548)	(1,352)
Net loss attributable to common stockholders	$ (10,937)	$ (2,719)	$ (41,483)	$ (7,157)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.70)	$ (1.46)	$ (5.49)	$ (3.85)
Weighted-average number of shares outstanding used to compute net loss per share attributable to common stockholders, basic and diluted	15,585,611	1,863,860	7,554,300	1,859,713