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): August 11, 2023

Elicio Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-39990**	**11-3430072**
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(IRS Employer Identification No.)

451 D Street. 5th Floor
Boston, Massachusetts 02110
(Address of principal executive offices, including zip code)

(857) 209-0050
Registrant's telephone number, including area code

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 (see General Instruction A.2. below):

☐ 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)	(Name of exchange on which registered)
Common Stock, $0.01 par value per share	**ELTX**	**The Nasdaq Global Select 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. o

Item 2.02 Results of Operations and Financial Condition.

On August 11, 2023, Elicio Therapeutics, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2023. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for 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 it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Exhibit Description
99.1	Press Release dated August 11, 2023 relating to the financial results for the fiscal quarter ended June 30, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Elicio Therapeutics, Inc.

By: /s/ ROBERT CONNELLY

Robert Connelly
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 11, 2023

Elicio Therapeutics Reports Second Quarter 2023 Financial Results and Provides Corporate Updates

- *ELI-002 2P positive interim data from AMPLIFY-201 Phase 1 study presented at ASCO*
- *AMPLIFY-7P first patient dosed with ELI-002 7P*
- *Completed reverse merger becoming a publicly traded company on Nasdaq*
- *Anticipate releasing additional AMPLIFY-201 clinical data in second half 2023*

BOSTON, August 11, 2023 -- Elicio Therapeutics, Inc. (Nasdaq: ELTX), a clinical-stage biotechnology company developing a pipeline of novel immunotherapies for the treatment of cancer, today reported financial results for the second quarter ended June 30, 2023 and provided recent corporate and clinical updates.

“The second quarter represented a transformative period for Elicio as we became a public company and reported interim results for the first-in-human clinical trial of our cancer vaccine candidate ELI-002,” said Robert Connelly, Chief Executive Officer of Elicio. “We’ve seen strong interest and excitement from the oncology community following Dr. O’Reilly’s presentation at ASCO of the AMPLIFY-201 trial interim safety data and we look forward to sharing additional data from that ongoing trial later this year.”

Christopher Haqq, M.D., Ph.D., Elicio’s Chief Medical Officer, added, “The data presented at ASCO demonstrated ELI-002 was well-tolerated, and was able to generate robust KRAS-specific T-cell activity with significant reductions in tumor biomarker levels in pancreatic and colorectal cancer patients. Following up on the encouraging biomarker results from AMPLIFY-201, we look forward to reporting on key clinical outcomes including relapse-free survival and overall survival. In the near-term, we are capitalizing on the oncology community’s interest in the potential benefit of ELI-002 as we’ve seen strong enrollment in the Phase 1A of our AMPLIFY-7P trial and hope to continue that momentum when we initiate the Phase 1B monotherapy and anti-PD-1 combination therapy study.”

Corporate Updates

AMPLIFY-201 trial: Multicenter Phase 1 trial assessing the safety, immunogenicity, and antitumor activity of ELI-002 2P monotherapy in patients with mutant KRAS-driven solid tumors who are at high risk for relapse following standard surgery and chemotherapy.

- Completed enrollment of 25 patients with pancreatic ductal adenocarcinoma (PDAC) or colorectal cancer (CRC)
- Presented at the American Society of Clinical Oncology (ASCO) Annual Meeting interim Phase 1 results based on data available, as of April 2023, demonstrating that ELI-002 2P:
    - is well tolerated with no dose limiting toxicity;
    - induced mKRAS-specific T-cell response with an average 56-fold increase compared to baseline; and
    - reduced tumor biomarkers in 77% of patients with 32% of patients achieving complete biomarker clearance.

AMPLIFY-7P trial: A multicenter Phase 1/2 trial assessing ELI-002 7P in patients with high relapse risk mutant KRAS-driven solid tumors. The ELI-002 7P formulation is designed to provide immune response coverage against seven of the most common KRAS mutations expanding the number of patients eligible for treatment and potentially reducing the chance of bypass resistance mechanisms.

- Initiated enrollment of up to 18 patients in Phase 1A arm to assess safety and dose of ELI-002 7P for further enrollment in the Phase 1B and Phase 2 arms.

AMP Platform: The Amphiphile platform, or AMP, delivers immunotherapeutics directly to the lymph nodes by “hitchhiking” on albumin and trafficking through the lymphatic system. Across various preclinical models the AMP platform has demonstrated lymph node-specific engagement driving immune responses of increased magnitude, function, and durability.

- *Nature Communications* publication[1] of preclinical data supporting the utility of AMP platform in infectious disease:
    - Lymph node targeting of Amph-CpG adjuvant with Epstein Barr Virus (EBV) polypeptide immunogens induced broad humoral and cellular immunity
    - Robust and durable polyfunctional EBV-specific CD4+ and CD8+ T cells
- T-cell mediated protection against EBV-associated lymphoma in mouse model

Upcoming Anticipated Milestones

- AMPLIFY-201: Present additional analyses and data including T cell activity and relapse-free survival during the second half of 2023.
- AMPLIFY-7P: Initiate Phase 1B arm with recommended Phase 2 dose (RP2D) in the third quarter of 2023.
- ELI-008: Present initial preclinical proof of concept data for the p53 targeting cancer vaccine in the fourth quarter of 2023.
- ELI-002 7P: Begin start-up activities for combination protocol testing ELI-002 7P in combination with anti-PD-1 therapy for the treatment of KRAS-mutant PDAC in the fourth quarter of 2023.
- AMPLIFY-7P: Present initial interim data of ELI-002 7P monotherapy from Phase 1A arm in the first half of 2024.

Second Quarter 2023 Financial Results

R&D Expense: R&D expense for the second quarter of 2023 was $4.9 million, compared to $5.0 million for the second quarter of 2022. The decrease in R&D expense was primarily due to the GIRF grant offsetting increased manufacturing and clinical trial expenses as the Company focused on ELI-002 clinical development.

G&A Expense: G&A expense for the second quarter of 2023 was $2.8 million, compared to $1.2 million for the second quarter of 2022. The increase in G&A expense was primarily attributable to professional fees and personnel expense associated with the reverse merger and operating as a public company.

Net Loss and Net Loss per Share: Net loss for the second quarter of 2023 was $7.6 million, compared to $7.3 million for the second quarter of 2022. Net loss per share for the second quarter of 2023 was $2.61 compared to $23.20 for the second quarter of 2022.

Cash Position: Cash and cash equivalents as of June 30, 2023, were $21.7 million, compared to $6.2 million as of December 31, 2022.

[1] Dasari, V., McNeil, L.K., Beckett, K. *et al.* Lymph node targeted multi-epitope subunit vaccine promotes effective immunity to EBV in HLA-expressing mice. *Nat Commun* **14**, 4371 (2023). https://doi.org/10.1038/s41467-023-39770-1

ELICIO THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating expenses:				
Research and development	**$** 4,94	**$** 5,04	**$** 10,42	**$** 9,22
General and administrative	2,833	1,191	5,154	2,782
Total operating expenses	7,777	6,232	15,582	12,002
Loss from operations	**(7,777)**	**(6,232)**	**(15,582)**	**(12,002)**
Total other income (expense)	218	(1,067)	(4)	(2,357)
Net Loss	**(7,559)**	**(7,299)**	**(15,586)**	**(14,359)**
Other comprehensive income:				
Foreign currency translation adjustment	(2)	—	(2)	—
Comprehensive loss	**$(7,561)**	**$ (7,299**	**$ (15,588**	**$ (14,359**
Net loss per common share, basic and diluted	$ (2.61)	$ (23.20)	$ (9.65)	$ (45.85)
Weighted average common shares outstanding, basic and diluted	2,893,291	314,572	1,615,796	313,148

ELICIO THERAPEUTICS, INC.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	June 30, 2023	**December 31, 2022**
Assets		
Cash and cash equivalents	$ 21,682	$ 6,156
Other current asset	4,543	1,641
Total current assets	26,225	10,717
Other assets	11,394	11,947
Total assets	**$ 37,619**	**$ 22,664**
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities	7,597	6,868
Long-term liabilities	6,465	6,881
Total liabilities	14,062	13,749
Total stockholders' equity (deficit)	23,557	(102,145)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	**$ 37,619**	**$ 22,664**

About Elicio Therapeutics

Elicio Therapeutics is a clinical-stage biotechnology company developing a pipeline of novel immunotherapies for the treatment of cancer. By combining expertise in immunology and immunotherapy, Elicio is engineering investigational Amphiphile (AMP) immunotherapies intended to precisely target and fully engage the lymph nodes, the site in our bodies where the immune response is orchestrated. Elicio is engineering lymph node-targeted AMPlifiers, immunomodulators, adjuvants and vaccines for an array of aggressive cancers.

Elicio began dosing subjects in AMPLIFY-201, its Phase 1 clinical trial in solid tumor subjects for its lead AMP vaccine, ELI-002 2P, targeting mKRAS-driven cancers, in October 2021 and began dosing subjects with the new formulation, ELI-002 7P, in April 2023. The AMP platform emerged from the laboratories of Darrell Irvine, Howard Hughes Investigator and Professor of Biomedical Engineering in the Koch Institute of Integrative Cancer Research at the Massachusetts Institute of Technology.

About the Amphiphile Platform

Our proprietary Amphiphile, or AMP, platform delivers investigational immunotherapeutics directly to the “brain center” of the immune system – the lymph nodes. We believe this site-specific delivery of disease-specific antigens, adjuvants and other immunomodulators may efficiently educate, activate and amplify critical immune cells, potentially resulting in induction and persistence of potent adaptive immunity required to treat many diseases. In preclinical models, we have observed lymph node-specific engagement driving therapeutic immune responses of increased magnitude, function and durability. We believe our AMP lymph node-targeted approach will produce superior clinical benefits compared to immunotherapies that do not engage the lymph nodes based upon preclinical studies.

Our AMP platform, originally developed at the Massachusetts Institute of Technology has broad potential in the cancer space to advance a number of development initiatives through internal activities, in-licensing arrangements or development collaborations and partnerships.

The Amphiphile platform has been shown to deliver immunotherapeutics directly to the lymph nodes by latching on to the protein albumin, found in the bloodstream, as it travels to lymphatic tissue. In preclinical models, we have observed lymph node-specific engagement driving immune responses of increased magnitude, function and durability.

Cautionary Note on Forward-Looking Statements

Certain statements contained in this communication regarding matters that are not historical facts, are forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995, known as the PSLRA. These include statements regarding Elicio’s planned clinical programs, including planned clinical trials, the potential of Elicio’s product candidates, and other statements regarding management’s intentions, plans, beliefs, expectations or forecasts for the future, and, therefore, you are cautioned not to place undue reliance on them. No forward-looking statement can be guaranteed, and actual results may differ materially from those projected. Elicio undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise, except to the extent required by law. We use words such as “anticipates,” “believes,” “plans,” “expects,” “projects,” “future,” “intends,” “may,” “will,” “should,” “could,” “estimates,” “predicts,” “potential,” “continue,” “guidance,” and similar expressions to identify these forward-looking statements that are intended to be covered by the safe-harbor provisions of the PSLRA. Such forward-looking statements are based on our expectations and involve risks and uncertainties; consequently, actual results may differ materially from those expressed or implied in the statements due to a number of factors, including, but not limited to, Elicio’s plans to develop and commercialize its product candidates, including ELI-002; the timing of initiation of Elicio’s planned clinical trials; the timing of the availability of data from Elicio’s clinical trials; the timing of any planned investigational new drug application or new drug application; Elicio’s plans to research, develop and

commercialize its current and future product candidates; Elicio's ability to successfully collaborate with existing collaborators or enter into new collaborations, and to fulfill its obligations under any such collaboration agreements; the clinical utility, potential benefits and market acceptance of Elicio's product candidates; Elicio's commercialization, marketing and manufacturing capabilities and strategy; Elicio's ability to identify additional products or product candidates with significant commercial potential; developments and projections relating to Elicio's competitors and our industry; the impact of government laws and regulations; Elicio's ability to protect its intellectual property position; and Elicio's estimates regarding future revenue, expenses, capital requirements and need for additional financing.

New factors emerge from time to time, and it is not possible for us to predict all such factors, nor can we assess the impact of each such factor on the business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. These risks are more fully discussed in the current report on Form 8-K that was filed with the SEC on June 2, 2023 and Elicio's periodic reports and other documents filed from time to time with the SEC. Forward-looking statements included in this release are based on information available to Elicio as of the date of this release. Elicio does not undertake any obligation to update such forward-looking statements to reflect events or circumstances after the date of this release, except to the extent required by law.

Media Contact

Gloria Gasaatura

LifeSci Communications

ggasaatura@lifescicomms.com

646-970-4688

Investor Relations Contact

Heather DiVecchia

Elicio Therapeutics

IR@elicio.com

857-209-0153