Elicio Therapeutics Reports 2023 Financial Results and Provides Corporate Updates

- *ELI-002 2P clinical immunogenicity data were accepted for a poster presentation at the AACR Annual Meeting 2024*
- *ELI-007 and ELI-008 preclinical data were accepted for a poster presentation at the AACR Annual Meeting 2024*
- *Phase 2 randomized trial in PDAC is underway with enrollment expected to complete in the fourth quarter of 2024*
- *ELI-002 7P initial clinical trial data expected in the second quarter of 2024*
- *Private placement with gross proceeds of $6.0 million closed in March 2024*

BOSTON, March 29, 2024 -- Elicio Therapeutics, Inc. (Nasdaq: ELTX,"Elicio Therapeutics" or "Elicio"), a clinical-stage biotechnology company developing a pipeline of novel immunotherapies for the treatment of cancer, today reported financial results for the year ending December 31, 2023, and provided recent business highlights.

"2023 was a momentous year for Elicio with the completion of a successful reverse merger, presenting clinical data from our first-in-human trial and advancing ELI-002 into a randomized Phase 2 trial," said Robert Connelly, Elicio's Chief Executive Officer. "Already in 2024 we have built on 2023's progress with our Phase 1a clinical data being published in Nature Medicine and announcing the first patients were dosed in the randomized Phase 2 trial. We continue to focus on advancing our lead cancer vaccine candidate, ELI-002, and the progression of our randomized Phase 2 study as a monotherapy for patients with PDAC. We have an exciting year ahead as we expect to share data from the AMPLIFY-7P Phase 1 study of ELI-002 7P in the second quarter."

Corporate Updates

AMPLIFY-7P Phase 1a:

- Completed enrollment of 14 patients in the third quarter of 2023 with initial clinical data for ELI-002 7P expected in the second quarter of 2024.
- The independent data monitoring committee completed the safety review of ELI-002 7P Phase 1 trial patients and confirmed the recommended Phase 2 trial dose.

AMPLIFY-7P Phase 2:

- First patients dosed in a randomized Phase 2 study of ELI-002 7P, an investigational therapeutic cancer vaccine, administered as an adjuvant monotherapy treatment for patients with KRAS-mutated pancreatic ductal adenocarcinoma ("PDAC").

AMPLIFY-201 Phase 1a:

- Data from the first-in-human study of ELI-002 2P published in Nature Medicine shows:
  - The data were as of September 6, 2023, based on 25 patients with solid tumors (20 pancreatic, 5 colorectal) who were positive for minimal residual mKRAS disease after locoregional treatment.
  - Direct *ex vivo* mKRAS-specific T cell responses were observed in 21/25 patients (84%; 59% both CD4+ and CD8+).

- Tumor biomarker responses were observed in 21/25 patients (84%) and biomarker clearance in 6/25 patients, as determined by tumor-informed circulating tumor DNA (24%; 3 pancreatic, 3 colorectal).
- At 8.5 months median follow-up the median RFS of the 25-patient cohort was 16.33 months.
- Efficacy correlated with T cell response (≥ versus < median: 12.75-fold over baseline):
- Median tumor biomarker reduction was -76.0% compared to -10.2% in above versus below median T cell responders, respectively ($p<0.0014$).
- Median RFS was not reached compared to 4.01 months in above versus below median T cell responders, respectively (HR 0.14, 95% CI 0.03 to 0.63, $p=0.0167$).
- Patients with greater than median T cell response had an 86% reduction in the risk of progression or death.
- The association of RFS with T cell response was not correlated to baseline prognostic variables including tumor stage, recovery from prior cytotoxic therapy as assessed by absolute neutrophil count or immune system subsets such as %CD4+ or %CD8+ of CD3+ lymphocytes.
- RFS was shorter in patients who began treatment with a low absolute lymphocyte count.
- No safety concerns were identified, and no dose limiting toxicities and no ≥ grade 3 treatment related adverse events were observed.

2023 Financial Results

R&D expense for 2023 was $23.8 million, compared to $18.1 million for 2022. The increase in R&D expense was primarily due to increased manufacturing and clinical trial expenses as Elicio initiated the AMPLIFY-7P Phase 1a study and generated a clinical trial product to supply the ongoing Phase 2 trial.

G&A expense for 2023 was $11.9 million, compared to $5.6 million 2022. The increase in G&A expense was primarily attributable to professional fees, personnel expenses, and insurance associated with operating as a public company.

Net loss for 2023 was $35.2 million, compared to $28.2 million for 2022. Net loss per share for 2023 was $6.96 compared to $89.27 for 2022. The reduction in net loss per share was primarily due to an increase in weighted average common shares outstanding as a result of the reverse merger with Angion Biomedica Corp. in June 2023.

Cash and cash equivalents as of December 31, 2023, were $12.9 million, compared to $6.2 million as of December 31, 2022.

ELICIO THERAPEUTICS, INC.

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

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 23,849	$ 18,103
General and administrative	11,896	5,630
Total operating expenses	35,745	23,733
Loss from operations	**(35,745)**	**(23,733)**
Total other income (expense)	550	(4,475)
Net Loss	**(35,195)**	**(28,208)**
Other comprehensive income:		
Foreign currency translation adjustment	(197)	—
Comprehensive loss	**$ (35,392)**	**$ (28,208)**
Net loss per common share, basic and diluted	$ (6.96)	$ (89.27)
Weighted average common shares outstanding, basic and diluted	5,056,225	315,998

ELICIO THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets
(unaudited)
(in thousands)

	December 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 12,894	$ 6,156
Other current assets	3,454	4,561
Total current assets	16,348	10,717
Other assets	10,798	11,947
Total assets	**$ 27,146**	**$ 22,664**
Liabilities and stockholders' equity		
Current liabilities	$ 9,766	$ 6,868
Long-term liabilities	6,007	6,881
Total liabilities	15,773	13,749
Total stockholders' equity (deficit)	11,373	8,915
Total liabilities and stockholders' equity	**$ 27,146**	**$ 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.

About the Amphiphile Platform

Our proprietary Amphiphile ("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 the 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 AMP 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, the expected participation and presentation at upcoming conferences, 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 financial condition, including its ability to obtain the funding necessary to advance the development of ELI-002 and any other future product candidates, and Elicio's ability to continue as a going concern;

Elicio's plans to develop and commercialize its product candidates, including ELI-002; the timing of initiation of Elicio's planned clinical trials, including Elicio's expected completion of enrollment for the Phase 2 randomized trial in PDAC in the fourth quarter of 2024; the timing of the availability of data from Elicio's clinical trials, including data from the AMPLIFY-7P Phase 1 study of ELI-002 7P expected in the second quarter of 2024; 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; Elicio's ability to advance ELI-002 outside of PDAC monotherapy and Elicio's pipeline programs; 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 Annual Report on Form 10-K that is expected to be filed with the SEC on March 29, 2024, under the heading "Risk Factors", and any subsequent 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.

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