Eledon Pharmaceuticals Reports First Quarter 2025 Operating and Financial Results

May 14, 2025

On track to report topline results from Phase 2 BESTOW trial in kidney transplantation in fourth quarter of 2025

Tegoprubart used as a key component of immunosuppression regimen in its second transplant of a genetically modified pig kidney into a human conducted at Massachusetts General Hospital

Cash, cash equivalents and short-term investments of $124.9 million as of March 31, 2025

IRVINE, Calif., May 14, 2025 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (Nasdaq: ELDN) today reported its first quarter 2025 operating and financial results and reviewed recent business highlights.

"We continue to work diligently towards our goal of transforming the transplant treatment landscape and remain encouraged by the growing body of evidence supporting tegoprubart as a potential novel immunosuppression therapy to better protect transplanted organs," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "The second half of the year is positioned to be a time of significant progress for Eledon, with multiple updates planned from our tegoprubart studies in kidney transplantation, beginning with new data from our open-label Phase 1b this summer. In addition, we remain on track to report topline results from the Phase 2 BESTOW trial in the fourth quarter of 2025, which we believe has the potential to demonstrate the superiority of tegoprubart over standard of care, as measured by estimated glomerular filtration rate (eGFR)."

First Quarter 2025 and Business Highlights

- Announced the use of tegoprubart as a lead component of the immunosuppression treatment regimen following the second transplant of a genetically modified pig kidney into a human conducted at Massachusetts General Hospital on January 25, 2025. The patient was subsequently discharged from the hospital without need for continued treatment with dialysis for the first time in more than two years.

Anticipated Upcoming Milestones

- August 2025: Report updated interim clinical data from the ongoing Phase 1b open-label trial evaluating tegoprubart for the prevention of organ rejection in kidney transplant patients.
- 4Q 2025: Report topline results from the Phase 2 BESTOW trial of tegoprubart in kidney transplantation.
- Late 2025: Report updated interim clinical data from the investigator-led clinical trial with UChicago Medicine in subjects with type 1 diabetes treated with tegoprubart as part of an immunosuppression regimen for the prevention of pancreatic islet transplant rejection.

First Quarter 2025 Financial Results

Cash, cash equivalents and short-term investments totaled $124.9 million as of March 31, 2025 compared to $140.2 million as of December 31, 2024. The company expects current cash, cash equivalents and short-term investments to fund operations to the end of 2026.

Research and development (R&D) expenses for the first quarter of 2025 were $13.5 million, including $1.0 million of non-cash stock-based compensation expense, compared to $7.4 million, including $0.3 million of non-cash stock-based compensation expense, for the comparable period in 2024.

General and administrative expenses for the first quarter of 2025 were $4.4 million, including $1.8 million of non-cash stock-based compensation expense, compared to $3.5 million, including $1.3 million of non-cash stock-based compensation expense, for the comparable period in 2024.

Net loss for the first quarter of 2025 was $6.5 million, or $0.08 per basic share, compared to a net loss of $23.6 million, or $0.79 per share, for the same period in 2024. Both periods reflect the non-cash impact of changes in the fair value of warrant liabilities, resulting in a $10.1 million gain in Q1 2025 and a $13.3 million loss in Q1 2024. Excluding this impact, the company would have reported a net loss of $16.6 million for the first quarter of 2025 compared to a net loss of $10.3 million in the same period in 2024.

About Eledon Pharmaceuticals and tegoprubart

Eledon Pharmaceuticals, Inc. is a clinical stage biotechnology company that is developing immune-modulating therapies for the management and treatment of life-threatening conditions. The company's lead investigational product is tegoprubart, an anti-CD40L antibody with high affinity for the CD40 Ligand, a well-validated biological target that has broad therapeutic potential. The central role of CD40L signaling in both adaptive and innate immune cell activation and function positions it as an attractive target for non-lymphocyte depleting, immunomodulatory therapeutic intervention. The company is building upon a deep historical knowledge of anti-CD40 Ligand biology to conduct preclinical and clinical studies in kidney allograft transplantation, xenotransplantation, and amyotrophic lateral sclerosis (ALS). Eledon is headquartered in Irvine, California. For more information, please visit the company's website at www.eledon.com.

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Forward Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Any statements about the company's future

expectations, plans and prospects, including statements about planned clinical trials, the development of product candidates, expected timing for initiation of future clinical trials, expected timing for receipt of data from clinical trials, the company's capital resources and ability to finance planned clinical trials, as well as other statements containing the words "believes," "anticipates," "plans," "expects," "estimates," "intends," "predicts," "projects," "targets," "looks forward," "could," "may," and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are inherently uncertain and are subject to numerous risks and uncertainties, including: risks relating to the safety and efficacy of our drug candidates; risks relating to clinical development timelines, including interactions with regulators and clinical sites, as well as patient enrollment; risks relating to costs of clinical trials and the sufficiency of the company's capital resources to fund planned clinical trials; and risks associated with the impact of the ongoing coronavirus pandemic. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors. These risks and uncertainties, as well as other risks and uncertainties that could cause the company's actual results to differ significantly from the forward-looking statements contained herein, are discussed in our quarterly 10-Q, annual 10-K, and other filings with the U.S. Securities and Exchange Commission, which can be found at www.sec.gov. Any forward-looking statements contained in this press release speak only as of the date hereof and not of any future date, and the company expressly disclaims any intent to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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Source: Eledon Pharmaceuticals

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share data)
(Unaudited)

	March 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,496	$ 20,549
Short-term investments	116,385	119,629
Prepaid expenses and other current assets	2,837	3,552
Total current assets	127,718	143,730
Operating lease asset, net	850	926
In-process research and development	32,386	32,386
Other assets	354	363
Total assets	$ 161,308	$ 177,405
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,901	$ 5,833
Current operating lease liabilities	325	314
Accrued expenses and other liabilities	5,959	5,430
Total current liabilities	9,185	11,577
Deferred tax liabilities	2,183	2,183
Non-current operating lease liabilities	555	640
Warrant liabilities	34,805	44,865
Total liabilities	46,728	59,265
Commitments and contingencies	—	—
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized at March 31, 2025 and December 31, 2024:		
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 110,086 shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 shares issued and outstanding at March 31, 2025 and December 31, 2024	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2025 and December 31, 2024; 59,881,775 and 59,789,275 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	60	60

Additional paid-in capital	476,619	473,640
Accumulated other comprehensive income (loss)	(18)	26
Accumulated deficit	(362,081)	(355,586)
Total stockholders' equity	114,580	118,140
Total liabilities and stockholders' equity	$ 161,308	$ 177,405

ELEDON PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share data)
(Unaudited)

	For the Three Months Ended March 31,	
	2025	**2024**
Operating expenses		
Research and development	$ 13,531	$ 7,410
General and administrative	4,433	3,459
Total operating expenses	17,964	10,869
Loss from operations	(17,964)	(10,869)
Other income, net	1,409	574
Change in fair value of warrant liabilities and fair value of financial instruments issued in excess of proceeds	10,060	(13,336)
Net loss	$ (6,495)	$ (23,631)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities, net	(44)	—
Comprehensive loss	$ (6,539)	$ (23,631)
Net loss per share, basic and diluted	$ (0.08)	$ (0.79)
Weighted-average common shares outstanding, basic and diluted	77,126,763	29,989,400

Source: Eledon Pharmaceuticals, Inc.