Eledon Pharmaceuticals Reports First Quarter 2024 Operating and Financial Results

May 9, 2024

Completed oversubscribed $50 million private placement

First participant dosed in clinical trial at University of Chicago Medicine assessing the use of tegoprubart to prevent islet cell transplant rejection in patients with type 1 diabetes

Reported updated data from ongoing Phase 1b trial evaluating tegoprubart for prevention of rejection in kidney transplantation

Tegoprubart used as part of immunosuppressive treatment following the first-ever kidney xenotransplant

IRVINE, Calif., May 09, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (Nasdaq: ELDN) today reported its first quarter 2024 operating and financial results and reviewed recent business highlights.

"We are pleased with the significant progress made so far this year in the development of tegoprubart for use both in kidney transplantation and in the emerging fields of xenotransplantation and islet cell transplantation. This progress reinforces tegoprubart's potential to become the first-line immunosuppressive treatment option of choice for a broad range of transplant procedures," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon.

First Quarter 2024 and Recent Corporate Developments

- First participant in an investigator-led clinical trial has received an islet cell transplant and is being treated with a novel immunosuppression regimen including tegoprubart, the company's novel anti-CD40L antibody, which is in development for the prevention of pancreatic islet cell transplant rejection in patients with type 1 diabetes. The study is being conducted by the research team at the University of Chicago's Pancreatic and Islet Transplant Program in collaboration with Eledon, the Juvenile Diabetes Research Foundation, and The Cure Alliance.
- Announced the use of tegoprubart as part of the immunosuppressive treatment regimen used following the first-ever kidney xenotransplant procedure of a genetically modified kidney from a pig to a human.
- Enrolled the 12th participant in March 2024 in the ongoing Phase 2 BESTOW trial assessing tegoprubart head-to-head with tacrolimus for the prevention of rejection in kidney transplantation.
- Completed a private placement financing for total gross proceeds of $50.0 million, before deducting any offering related expenses, to a select group of institutional and accredited investors at a price per share of $2.37.

Anticipated 2024 Milestones

- June 2024: Report updated interim clinical data from the ongoing Phase 1b trial and open-label extension study of tegoprubart in kidney transplantation at the American Transplant Congress in Philadelphia, PA.
- End of 2024: Complete enrollment in the Phase 2 BESTOW trial of tegoprubart in kidney transplantation.

First Quarter 2024 Financial Results

The Company reported a net loss of $10.3 million, or $0.34 per share, for the three months ended March 31, 2024, compared to a net loss of $10.8 million, or $0.75 per share, for the same period in 2023.

Research and development expenses were $7.4 million for the three months ended March 31, 2024, compared to $8.1 million for the comparable period in 2023, a decrease of $0.7 million.

General and administrative expenses were $3.5 million for the three months ended March 31, 2024, compared to $3.0 million for the comparable period in 2023, an increase of $0.5 million.

Eledon ended the first quarter with approximately $42.9 million in cash, cash equivalents and short-term investments, which excludes the $50.0 million in gross proceeds received in the recently completed private placement.

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 CD40 Ligand, a well-validated biological target within the costimulatory CD40/CD40L cellular pathway. 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 sides, 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-Qs, 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.

Investor Contact:

Stephen Jasper
Gilmartin Group
(858) 525 2047
stephen@gilmartinir.com

Media Contact:

Jenna Urban
Berry & Company Public Relations
(212) 253 8881
jurban@berrypr.com

Source: Eledon Pharmaceuticals

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

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,655	$ 4,612
Short-term investments	37,207	46,490
Prepaid expenses and other current assets	5,115	5,027
Total current assets	47,977	56,129
Operating lease asset, net	270	365
In-process research and development	32,386	32,386
Other assets	185	186
Total assets	$ 80,818	$ 89,066
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,864	$ 967
Current operating lease liabilities	284	383
Accrued expenses and other liabilities	2,099	2,545
Total current liabilities	4,247	3,895
Deferred tax liabilities	1,752	1,752
Total liabilities	5,999	5,647
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized at March 31, 2024 and December 31, 2023:		
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, 2024 and December 31, 2023	—	—
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 4,422 shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2024 and December 31, 2023; 24,813,130 and 24,213,130 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	25	24
Additional paid-in capital	328,280	326,586
Accumulated deficit	(253,486)	(243,191)

Total stockholders' equity	74,819	83,419
Total liabilities and stockholders' equity	$ 80,818	$ 89,066

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,	
	2024	**2023**
Operating expenses		
Research and development	$ 7,410	$ 8,113
General and administrative	3,459	2,997
Total operating expenses	10,869	11,110
Loss from operations	(10,869)	(11,110)
Other income, net	574	338
Net loss and comprehensive loss	$ (10,295)	$ (10,772)
Net loss per share, basic and diluted	$ (0.34)	$ (0.75)
Weighted-average common shares outstanding, basic and diluted	29,989,400	14,285,905

Source: Eledon Pharmaceuticals, Inc.