Eledon Pharmaceuticals Reports Fourth Quarter and Full-Year 2022 Operating and Financial Results

March 30, 2023

`Four patients enrolled in open-label Phase 1b kidney transplant trial with clinical data on first three patients to be presented at the World Congress of Nephrology (WCN) on March 31, 2023

Safety data on sixteen patients enrolled in open-label Phase 2 IgA nephropathy trial also to be presented at the World Congress of Nephrology

Company to continue to prioritize and focus resources on the advancement of tegoprubart in kidney transplantation

Conference call today at 4:30 PM ET

IRVINE, Calif., March 30, 2023 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. ("Eledon") (NASDAQ: ELDN) today reported its fourth quarter and full-year 2022 operating and financial results and reviewed recent business highlights.

"Eledon began the year with a strategic decision to focus our financial and organizational resources on our kidney transplantation programs," said David-Alexandre C. Gros, M.D., Chief Executive Officer. "Our decision was based on the significant unmet need to improve long term graft function and survival in kidney transplant, and the substantial existing data from both our anti-CD40 Ligand and historical anti-CD40 Ligands demonstrating their potential in pre-clinical models of organ transplantation. We are highly encouraged by the initial results to date from our ongoing Phase 1b trial evaluating tegoprubart in kidney transplantation, as well as the supportive safety data from our ALS and IgAN trials, and we look forward to sharing our kidney transplant data at the World Congress of Nephrology."

Fourth Quarter 2022 and Recent Corporate Developments

- Dosed fourth subject in a Phase 1b, open-label study to evaluate tegoprubart for the prevention of rejection in patients receiving a kidney transplant. The study has open sites in Canada, the United Kingdom and Australia. Eledon will share safety and efficacy results from the first three participants at the WCN, taking place March 30 – April 2, 2023 in Bangkok, Thailand.
- Strategically refocused the tegoprubart pipeline on the advancement of the Company's kidney transplantation program. Eledon deprioritized the clinical development of tegoprubart in IgA Nephropathy (IgAN) and discontinued its Phase 1/2 trial for islet cell transplantation. The Company will share safety data from the Phase 2a IgAN study at the upcoming WCN meeting.
- Announced a collaboration with eGenesis for the use of tegoprubart in preclinical xenotransplantation studies. The collaboration has the potential to span multiple eGenesis programs including kidney and islet cell transplant.
- Presented data from the tegoprubart Phase 2a trial in amyotrophic lateral sclerosis (ALS) at ALS One 5th Annual ALS Research Symposium and the Northeast Amyotrophic Lateral Sclerosis Consortium (NEALS).

Upcoming Anticipated 2023 Milestones

March 2023: announce open-label safety and efficacy data on the first three enrolled participants from the ongoing Phase 1b trial of tegoprubart in kidney transplantation.

March 2023: announce open-label safety data from the first 16 enrolled participants from the Phase 2a trial of tegoprubart in IgAN.

Mid-2023: subject to financing, initiate Phase 2 BESTOW trial of tegoprubart in kidney transplantation.

Late-2023: complete enrollment in Phase 1b trial of tegoprubart in kidney transplantation.

Financial Results for the Three Months Ended December 31, 2022

The Company reported a net loss of $58.4 million, or $4.09 per share, for the three months ended December 31, 2022, compared to a net loss of $8.8 million, or $0.59 per share, for the same period in 2021. The net loss for the three months ended December 31, 2022 includes a non-cash goodwill impairment charge totaling $48.6 million. Excluding the non-cash impairment charge, net loss would be $9.7 million, or $0.68 per share.

Research and development expenses were $7.3 million for the three months ended December 31, 2022, compared to $6.2 million for the comparable period in 2021, an increase of $1.1 million. The increase was primarily due to an increase in manufacturing costs related to the increased production of clinical trial materials.

General and administrative expenses were $2.8 million for the three months ended December 31, 2022, compared to $3.2 million for the comparable period in 2021, a decrease of $0.4 million. The decrease primarily reflects a decrease in headcount costs, stock-based compensation costs and professional fees.

During the three months ended December 31, 2022, the Company recorded a non-cash goodwill impairment charge totaling $48.6 million for the full write-down of its goodwill balance.

Financial Results for the Year Ended December 31, 2022

The Company reported a net loss of $88.0 million, or $6.16 per share, for the year ended December 31, 2022, compared to a net loss of $34.5 million, or $2.33 per share, in 2021. The net loss for the year ended December 31, 2022 includes a non-cash goodwill impairment charge totaling $48.6 million. Excluding the non-cash impairment charge, net loss would be $39.3 million, or $2.75 per share.

Research and development expenses were $27.1 million for the year ended December 31, 2022, compared to $23.7 million for the year ended December 31, 2021, an increase of $3.4 million. The increase was primarily due to higher clinical development expenses, primarily with external CROs, an increase in personnel costs, including stock-based compensation costs, and an increase in manufacturing costs related to the increased production of clinical trial materials.

General and administrative expenses were $12.7 million for the year ended December 31, 2022, compared to $13.1 million for the year ended December 31, 2021, a decrease of $0.4 million. The decrease was primarily due to a decrease in personnel costs, and a decrease in professional and consulting fees, partially offset by an increase in stock-based compensation expense and general operating expenses.

The Company ended the year with approximately $56.4 million in cash and cash equivalents. Cash and cash equivalents will be sufficient to sustain operations into the first quarter of 2024.

Conference Call

Eledon will hold a conference call today, March 30, 2023 at 4:30 pm Eastern Time to discuss fourth quarter and full-year 2022 results. The dial-in numbers are 877-300-8521 for domestic callers and 412-317-6026 for international callers. The conference ID is 10175955. A live webcast of the conference call will be available on the Investor Relations section of the Company's website at www.eledon.com. The webcast will be archived on the website following the completion of the call.

About Eledon Pharmaceuticals and tegoprubart (formerly AT-1501)

Eledon Pharmaceuticals is a clinical stage biotechnology company using its expertise in targeting the CD40 Ligand (CD40L, also called CD154) pathway to develop potential treatments for persons requiring an organ or cell-based transplant, living with autoimmune disease, or living with ALS. The company's lead compound in development is tegoprubart, an anti-CD40L antibody with high affinity for CD40 Ligand, a well-validated biological target with broad therapeutic potential. Eledon is headquartered in Irvine, Calif. 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-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.
CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share data)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,409	$ 84,833
Prepaid expenses and other current assets	3,109	3,513
Total current assets	59,518	88,346
Operating lease asset, net	739	768
Goodwill	—	48,648
In-process research and development	32,386	32,386
Other assets	150	400
Total assets	$ 92,793	$ 170,548
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	$ 2,200	$ 1,813
Current operating lease liability	363	369
Accrued expenses and other liabilities	3,912	2,219
Total current liabilities	6,475	4,401
Deferred tax liability	1,752	1,752
Non-current operating lease liability	383	400
Total liabilities	8,610	6,553
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized at December 31, 2022 and 2021:		
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares designated; 117,970 and 108,070 shares issued and outstanding at December 31, 2022 and 2021, respectively	—	—
Series X non-voting convertible preferred stock, $0.001 par value, 10,000 shares designated; 6,204 shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2022 and 2021; 13,776,788 and 14,306,788 shares issued and outstanding at December 31, 2022 and 2021, respectively	14	14
Additional paid-in capital	287,034	278,880
Accumulated deficit	(202,865)	(114,899)
Total stockholders' equity	84,183	163,995
Total liabilities and stockholders' equity	$ 92,793	$ 170,548

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

	Year Ended December 31,	
	2022	**2021**
Operating expenses		
Research and development	$ 27,080	$ 23,735
General and administrative	12,700	13,132
Goodwill impairment	48,648	—
Total operating expenses	88,428	36,867
Loss from operations	(88,428)	(36,867)
Other income, net	462	7
Loss before income tax benefit	(87,966)	(36,860)
Income tax benefit	—	2,354
Net loss and comprehensive loss	$ (87,966)	$ (34,506)
Net loss per share, basic and diluted	$ (6.16)	$ (2.33)
Weighted-average common shares outstanding, basic and diluted	14,285,254	14,819,582

Source: Eledon Pharmaceuticals, Inc.