Eledon Pharmaceuticals Announces Recent Business Highlights and Third Quarter 2024 Financial Results

November 12, 2024

Completed enrollment of Phase 2 BESTOW trial of tegoprubart in kidney transplantation four months ahead of schedule; on track to report topline results in fourth quarter of 2025

Announced positive initial data from first three subjects with type 1 diabetes treated with tegoprubart as part of immunosuppression regimen following islet transplantation in investigator-initiated trial at UChicago Medicine

Announced oversubscribed $85 million underwritten offering, with proceeds expected to extend cash runway to the end of 2026

IRVINE, Calif., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc. (“Eledon”) (Nasdaq: ELDN) today reported its third quarter 2024 operating and financial results and reviewed recent business highlights.

“We believe tegoprubart has best-in-class potential as a novel immunosuppressive treatment option to prevent transplant rejection, with promising clinical results across kidney, xenograft, and now islet transplantations," said David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. “Recent encouraging data from the UChicago Medicine trial in type 1 diabetes, combined with our accelerated enrollment in the Phase 2 BESTOW trial and our strong capital position following our recent oversubscribed financing, has put us in a strong position to advance tegoprubart’s development. We look forward to sharing results from our BESTOW trial in the fourth quarter of 2025.”

Recent Business Highlights

- Completed enrollment for the Phase 2 BESTOW clinical trial, which is designed to assess the safety and efficacy of tegoprubart for the prevention of organ rejection in patients undergoing kidney transplantation. The trial reached its target enrollment of 120 participants approximately four months earlier than originally planned.
- Announced positive initial data for the first three islet transplant recipients treated with tegoprubart as part of an immunosuppressive regimen for the prevention of islet transplant rejection in subjects with type 1 diabetes in an investigator-initiated trial at the University of Chicago Medicine’s Transplantation Institute. The first two subjects achieved insulin independence and remain insulin free, with glucose control in the normal range; the third subject was recently transplanted and remains on a trajectory to also achieve insulin independence. Treatment with tegoprubart was generally well tolerated in all subjects with no unexpected adverse events. The data demonstrated potentially the first human cases of insulin independence achieved using an anti-CD40L monoclonal antibody immunosuppressive therapy without the use of tacrolimus, the current standard of care for prevention of transplant rejection.
- Completed an oversubscribed, underwritten offering of common stock and pre-funded warrants for total gross proceeds of $85.0 million, or net proceeds of approximately $79.5 million after deducting underwriting discounts, commissions, and offering expenses. The offering, which priced at a premium, included participation from both new and existing leading healthcare investors.

Anticipated Upcoming Milestones

- Mid-2025: Report updated interim clinical data from the ongoing Phase 1b and long-term safety and efficacy extension studies of tegoprubart in kidney transplantation.
- 4Q 2025: Report topline results from the Phase 2 BESTOW trial of tegoprubart in kidney transplantation.
- 2025: Report longer-term follow up from the investigator-led clinical trial with the UChicago Medicine Transplant Institute for pancreatic islet transplantation in subjects with type 1 diabetes.

Third Quarter 2024 Financial Results

Cash, cash equivalents and short-term investments totaled $78.2 million as of September 30, 2024, which does not include net proceeds of approximately $79.5 million received in the October 2024 underwritten offering. The company expects current cash, cash equivalents and short-term investments, together with the net proceeds from the October 2024 underwritten offering, to fund operations to the end of 2026.

Research and development (R&D) expenses for the third quarter of 2024 were $16.5 million, compared to $7.9 million for the comparable period in 2023, an increase of $8.6 million. The increase was primarily driven by a rise in clinical development expenses related to the Phase 1b and Phase 2 BESTOW studies, an increase in employee compensation and benefits related to increased headcount, and greater chemistry, manufacturing and controls (CMC) expenses related to the production of clinical trial materials.

General and administrative expenses for the third quarter of 2024 were $4.0 million, compared to $3.3 million for the comparable period in 2023, an increase of $0.7 million. The increase was primarily driven by a rise in professional services and an increase in general operating expenses.

Net income for the third quarter of 2024 was $77.0 million, or $1.05 per basic share, compared with a net loss of $9.9 million, or $0.33 per basic share, for the comparable period in 2023, an increase of $86.9 million. The increase in net income was primarily driven by a non-cash gain of $96.4

million related to changes in the fair value of warrant liabilities and the fair value of financial instruments issued in excess of proceeds, recorded in the third quarter ending September 30, 2024. Excluding this gain, the company would have recorded a net loss of $19.5 million for the third quarter of 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-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.

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Source: Eledon Pharmaceuticals

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

	September 30, 2024	December 31, 2023 (As Restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,751	$ 4,612
Short-term investments	71,440	46,490
Prepaid expenses and other current assets	3,318	5,027
Total current assets	81,509	56,129
Operating lease asset, net	471	365
In-process research and development	32,386	32,386
Other assets	210	186
Total assets	$ 114,576	$ 89,066
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,860	$ 967
Current operating lease liabilities	186	383
Accrued expenses and other liabilities	6,443	2,545
Total current liabilities	12,489	3,895
Deferred tax liabilities	1,752	1,752

Non-current operating lease liabilities	315	—
Warrant liabilities	23,962	76,211
Total liabilities	38,518	81,858
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 5,000,000 shares authorized at September 30, 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 September 30, 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 September 30, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2024 and December 31, 2023; 41,183,102 and 24,213,130 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	41	24
Additional paid-in capital	386,884	326,586
Accumulated other comprehensive income	102	—
Accumulated deficit	(310,969)	(319,402)
Total stockholders' equity	76,058	7,208
Total liabilities and stockholders' equity	$ 114,576	$ 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 September 30,		For the Nine Months Ended September 30,	
	2024	2023 (As Restated)	2024	2023 (As Restated)
Operating expenses				
Research and development	$ 16,520	$ 7,931	$ 34,036	$ 23,245
General and administrative	3,990	3,267	11,845	9,417
Total operating expenses	20,510	11,198	45,881	32,662
Loss from operations	(20,510)	(11,198)	(45,881)	(32,662)
Other income, net	1,042	849	2,485	1,962
Change in fair value of warrant liabilities and fair value of financial instruments issued in excess of proceeds	96,439	443	51,829	(55,738)
Net income (loss)	$ 76,971	$ (9,906)	$ 8,433	$ (86,438)
Net income (loss) attributable to common shares - basic	$ 54,429	$ (9,906)	$ 5,551	$ (86,438)
Basic net income (loss) per common share	$ 1.05	$ (0.33)	$ 0.13	$ (3.79)
Weighted-average number of shares outstanding - basic	51,945,920	29,974,400	41,443,049	22,813,085
Net income (loss) attributable to common shares - diluted	$ (17,504)	$ (9,906)	$ (61,086)	$ (86,438)
Basic net income (loss) per common share	$ (0.32)	$ (0.33)	$ (1.42)	$ (3.79)
Weighted-average number of shares outstanding - diluted	55,478,342	29,974,400	43,106,746	22,813,085

Source: Eledon Pharmaceuticals, Inc.