Eledon Pharmaceuticals Reports Fourth Quarter and Full-Year 2020 Operating and Financial Results

March 30, 2021

Continued enrollment in Phase 2 clinical trial of AT-1501 in amyotrophic lateral sclerosis (ALS)

First patient to be enrolled in Phase 2 clinical trial of AT-1501 in islet cell transplantation for type 1 diabetes expected in Q2'21

Cash Balance of $114.2 million at December 31, 2020

IRVINE, Calif., March 30, 2021 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc., ("Eledon") (NASDAQ: ELDN), a clinical stage biopharmaceutical company focused on developing targeted medicines for persons living with an autoimmune disease, requiring an organ or cell-based transplant, or living with amyotrophic lateral sclerosis (ALS), today reported its fourth quarter and full-year 2020 operating and financial results.

"2020 was a transformational year highlighted by our acquisition of Anelixis Therapeutics and recent name change to Eledon Pharmaceuticals, reflecting our evolution in therapeutic focus to transplantation, autoimmune diseases and ALS, areas of significant unmet medical need," stated David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon Pharmaceuticals, Inc. "Our lead asset, AT-1501, has unique attributes that we believe make it a potential best in class molecule as a humanized IgG1 anti-CD40 ligand antibody targeting a well-validated pathway that has shown promise in multiple indications. We are financed to advance up to four Phase 2 clinical trials of AT-1501, covering multiple indications, with data readouts expected to begin in the first half of 2022."

Fourth Quarter 2020 and Recent Corporate Developments

- Commenced enrollment in an open-label Phase 2a clinical trial of AT-1501 in ALS.
- Received clearance from Health Canada to proceed with the initiation of a Phase 2 clinical trial of AT-1501 in islet cell transplantation for type 1 diabetes.
- Appointed June Lee, MD to Board of Directors. Dr. Lee brings extensive clinical and development expertise as the former Chief Development and Chief Operating Officer of MyoKardia, Inc.
- Announced name change to Eledon Pharmaceuticals, Inc. (Nasdaq: ELDN), from Novus Therapeutics, to reflect the company's new focus on autoimmune diseases, transplantation, and ALS.
- Expanded management team to include Paul Little as Chief Financial Officer, and Jeffrey Bornstein, M.D., as Chief Medical Officer.

Upcoming Anticipated Milestones

- Continue patient enrollment in ongoing Phase 2 trial in ALS with top line data readout expected in first half 2022.
- Enroll first patient in Phase 2 trial of AT-1501 in islet cell transplantation for type 1 diabetics in Q2'21, with interim data readout expected in first half 2022.
- Initiate Phase 2 trial of AT-1501 in renal transplantation in late 2Q/mid-2021.
- Initiate Phase 2 trial of AT-1501 in an autoimmune nephritis indication in late 2021.

Financial Results for the Three Months Ended December 31, 2020

The company reported a net loss of $5.9 million, or $2.13 per share, for the three months ended December 31, 2020, compared to a net loss of $4.1 million, or $5.75 per share, for the same period in 2019.

- Research and development expenses were $3.0 million for the three months ended December 31, 2020, compared to $1.3 million for the comparable period in 2019, an increase of $1.7 million. The increase in research and development spend primarily reflects clinical and formulation costs associated with increased activity for lead asset AT-1501.
- General and administrative expenses were $3.3 million for the three months ended December 31, 2020, compared to $1.0 million for the comparable period in 2019, an increase of $2.3 million. The increase in general and administrative spend primarily reflects merger and integration related expenses associated with the Anelixis acquisition and stock-based compensation expense of $0.8 million.

Financial Results for the Year Ended December 31, 2020

The company reported a net loss of $22.8 million, or $15.72 per share, for the year ended December 31, 2020, compared to a net loss of $16.0 million, or $24.42 per share, for the year ended December 31, 2019.

- Research and development expenses were $6.1 million for the year ended December 31, 2020, compared to $8.1 million for the year ended December 31, 2019, a decrease of $2.0 million. The decrease in research and development spend primarily reflects a decrease in clinical and development costs related to completion of our legacy lead Phase 2a study for acute otitis media, partially offset by an increase in stock-based compensation expense.
- General and administrative expenses were $10.1 million for the year ended December 31, 2020, compared to $6.1 million for the year ended December 31, 2019, an increase of $4.0 million. The increase in general and administrative spend primarily reflects merger and integration related expenses associated with the Anelixis acquisition and stock-based compensation expense of $1.0 million.

Financial Liquidity at December 31, 2020

Concurrent with the acquisition of Anelixis Therapeutics in September 2020, the company raised gross proceeds of $108 million through a private placement of shares to a group of premier life science investors, led by BVF Partners L.P., with participation from Cormorant Asset Management, Ecor1 Capital, Logos Capital, Fidelity Management and Research Company, Adage Capital Partners L.P., Woodline Partners LP, Ridgeback Capital, Janus Henderson Investors, and Samsara BioCapital, among others.

The company had approximately $114.2 million in cash and cash equivalents as of December 31, 2020, compared to $8.8 million in cash and cash equivalents as of December 31, 2019. The Company believes that it has sufficient financial resources to fund up to four Phase 2 clinical trials with AT-1501 and fund operating activities well into 2023.

Conference Call

Eledon will hold a conference call today, March 30, 2021 at 4:30 pm Eastern Time to discuss fourth quarter results. The dial-in numbers are 877-407-9039 for domestic callers and 201-689-8470 for international callers. The conference ID is 13717918. 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 AT-1501

Eledon Pharmaceuticals is a clinical stage biotechnology company using its expertise in targeting the CD40L pathway to develop potential treatments for patients living with an autoimmune disease, patients requiring an organ or cell-based transplant, and for patients living with ALS. The company's lead compound in development is AT-1501, an anti-CD40L antibody with high affinity for CD40 ligand (CD40L, also called CD154), a well-validated biological target with broad therapeutic potential. AT-1501 is a humanized IgG1 antibody engineered to potentially both improve safety and provide pharmacokinetic, pharmacodynamic, and dosing advantages compared to other anti-CD40 approaches. The CD40L/CD40 pathway is widely recognized for its prominent role in immune regulation. CD40L is primarily expressed on activated $CD4^+$ T cells, platelets and endothelial cells while the CD40 receptor is constitutively expressed on antigen presenting cells such as B cells, macrophages, and dendritic cells. By blocking CD40L and not the CD40 receptor, AT-1501 inhibits both the CD40 and CD11 costimulatory signaling pathways, providing the potential for improved efficacy compared to anti-CD40 receptor approaches. Blocking CD40L also increases polarization of $CD4^+$ lymphocytes to Tregs, a specialized subpopulation of T cells that act to suppress an immune response, thus creating a more tolerogenic environment, which may also play a therapeutic role for autoimmune diseases and in the transplant setting. 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 involves substantial risks and uncertainties. Any statements about the company's future expectations, plans and prospects, including statements about 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 SEC, 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 data)

	December 31,	
	2020	**2019**

ASSETS		
Current assets:		
Cash and cash equivalents	$ 114,195	$ 8,791
Prepaid expenses and other current assets	1,435	1,180
Total current assets	115,630	9,971
Property and equipment, net	—	5
Operating lease asset, net	138	316
Goodwill	48,648	—
In-process research and development	32,386	—
Other assets	383	639
Total assets	$ 197,185	$ 10,931
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,366	$ 329
Current operating lease liability	144	180
Accrued severance	12	—
Accrued expenses and other liabilities	961	813
Total current liabilities	2,483	1,322
Deferred tax liability	4,106	—
Non-current operating lease liability	—	144
Total liabilities	6,589	1,466
Commitments and contingencies		
Stockholders' equity:		
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares authorized; 108,070 and no shares issued and outstanding at December 31, 2020 and 2019, respectively	—	—
Series X preferred stock, $0.001 par value, 10,000 shares authorized; no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2020 and 2019; 15,160,397 and 720,408 shares issued and outstanding at December 31, 2020 and 2019, respectively	15	1
Additional paid-in capital	270,974	67,046
Accumulated deficit	(80,393)	(57,582)
Total stockholders' equity	190,596	9,465
Total liabilities and stockholders' equity	$ 197,185	$ 10,931

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

	Year Ended December 31,	
	2020	**2019**
Operating expenses		
Research and development	$ 6,131	$ 8,128
General and administrative	10,052	6,056
Restructuring expense	2,282	—
Goodwill impairment	—	1,867
Total operating expenses	18,465	16,051
Loss from operations	(18,465)	(16,051)
Other income, net	79	40
Warrant inducement expense	(4,829)	—
Loss before income tax benefit	(23,215)	(16,011)
Income tax benefit	404	—
Net loss and other comprehensive loss	$ (22,811)	$ (16,011)
Net loss per share, basic and diluted	$ (15.72)	$ (24.42)
Weighted-average common shares outstanding, basic and diluted	1,451,432	655,526

Source: Eledon Pharmaceuticals, Inc.