Eledon Pharmaceuticals Reports Second Quarter 2021 Operating and Financial Results

August 12, 2021

Received approval from Health Canada to initiate a clinical trial of AT-1501 in kidney transplantation; company expects to initiate trial in Q4 with initial data in late 2022

Reached agreement with the FDA to conduct a preclinical renal transplant study evaluating AT-1501 monotherapy in four non-human primates; launched academic collaboration to conduct the study with data expected mid-2022

Announces plans to develop AT-1501 as a therapy for IgA nephropathy (IgAN), the fourth potential indication for clinical development of AT-1501; company expects to initiate Phase 2 by year-end 2021

Conference call today at 4:30 PM ET

IRVINE, Calif., Aug. 12, 2021 (GLOBE NEWSWIRE) -- Eledon Pharmaceuticals, Inc., ("Eledon") (NASDAQ: ELDN), a clinical stage biopharmaceutical company focused on developing targeted medicines for persons living with autoimmune disease, requiring an organ or cell-based transplant, or living with amyotrophic lateral sclerosis (ALS), today reported its second quarter 2021 operating and financial results.

"We have made significant progress since the announcement in April of our updated development strategy for AT-1501 in renal transplantation," stated David-Alexandre C. Gros, M.D., Chief Executive Officer of Eledon. "Enrollment in our ALS study is progressing well and we anticipate completing enrollment in the 4th quarter. Separately, we received a No Objection Letter from Health Canada in response to our Clinical Trial Application proposing to initiate a clinical trial evaluating AT-1501, in 6 to 12 subjects, replacing tacrolimus as an immunosuppressive regimen component in patients undergoing kidney transplantation. We believe that replacing tacrolimus as an agent in renal transplantation can reduce immunosuppressive side effects and improve long-term graft survival. We look forward to reporting initial clinical data from the study late next year. In addition, we plan to initiate a preclinical renal transplant study evaluating AT-1501 monotherapy in four non-human primates, as requested by the U.S. Food and Drug Administration, with data expected in mid-2022."

"In addition to our progress in ALS and renal transplant, we have selected IgA nephropathy as the fourth indication for the clinical development of AT-1501," said Steven Perrin, Ph.D., President and Chief Scientific Officer of Eledon. "There is strong scientific rationale for this indication, as blocking CD40 ligand has been shown in preclinical studies to slow disease progression and improve renal function in animal models of autoimmune nephritis. We look forward to initiating a Phase 2 trial for this fourth indication in the coming months."

Second Quarter 2021 and Recent Corporate Developments

- Completion of enrollment in third of four cohorts in the Phase 2 study of AT-1501 in ALS expected shortly with full enrollment of the trial expected to be completed by year end 2021.
- Received clearance from Health Canada in response to Clinical Trial Application to initiate a clinical trial of AT-1501 for the prevention of kidney transplant rejection.
- Reached agreement on the design of an FDA-requested preclinical renal transplant study in non-human primates (n = 4) evaluating AT-1501 monotherapy and launched academic collaboration to conduct the study.
- Announced selection of IgA nephropathy (IgAN) as fourth indication for clinical development of AT-1501.
- Presented two posters and two oral presentations at the American Society of Transplantation annual meeting held in June.
- Appointed leading immunology and rheumatology expert Dr. Jan Hillson to its Board of Directors.

Upcoming Anticipated Milestones

- Presentation at the International Pancreas and Islet Transplantation World Congress annual meeting, which is being held virtually October 20-23, 2021.
- Q4 2021: initiation of non-human primate renal transplant study of AT-1501 monotherapy.
- Q4 2021: initiation of clinical trial of AT-1501 for the prevention of kidney transplant rejection.
- Q4 2021: initiation of clinical trial of AT-1501 in IgAN.
- H1 2022: topline data from Phase 2 trial of AT-1501 in ALS.
- H1 2022: initial data from Phase 2 trial of AT-1501 in islet cell transplantation.
- Mid-2022: completion of non-human primate renal transplant study of AT-1501 monotherapy.

- Late 2022: initial data from clinical trial of AT-1501 in kidney transplantation.

Financial Results for the Three Months Ended June 30, 2021

- The company reported a net loss of $7.4 million, or $0.50 per share, for the three months ended June 30, 2021, compared to a net loss of $2.6 million, or $2.74 per share, for the same period in 2020.

- Research and development expenses were $4.2 million for the three months ended June 30, 2021, compared to $0.8 million for the comparable period in 2020, an increase of $3.4 million. The increase in research and development spend primarily reflects clinical and formulation costs associated with increased activity for our lead asset AT-1501.

- General and administrative expenses were $3.7 million for the three months ended June 30, 2021, compared to $1.3 million for the comparable period in 2020, an increase of $2.4 million. The increase in general and administrative spend primarily reflects increased personnel and stock-based costs, legal and other professional fees.

- The company had approximately $101.1 million in cash and cash equivalents as of June 30, 2021, compared to $114.2 million in cash and cash equivalents as of December 31, 2020. The Company believes that it has sufficient financial resources to fund operations as currently planned well into 2023.

Conference Call

Eledon will hold a conference call today, August 12, 2021, at 4:30 pm Eastern Time to discuss second quarter results. The dial-in numbers are 877-407-9039 for domestic callers and 201-689-8470 for international callers. The conference ID is 13720793. 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.

Follow Eledon Pharmaceuticals on social media: @Eledon_Pharma and LinkedIn.

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 a planned clinical trial in kidney transplant patients, 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

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 101,133	$ 114,195
Prepaid expenses and other current assets	1,449	1,435
Total current assets	102,582	115,630
Operating lease asset, net	267	138
Goodwill	48,648	48,648
In-process research and development	32,386	32,386
Other assets	422	383
Total assets	$ 184,305	$ 197,185
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 857	$ 1,366
Current operating lease liability	179	144
Accrued expenses and other liabilities	1,641	973
Total current liabilities	2,677	2,483
Deferred tax liabilities	3,017	4,106
Non-current operating lease liability	90	—
Total liabilities	5,784	6,589
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Series X[1] non-voting convertible preferred stock, $0.001 par value, 515,000 shares authorized; 108,070 shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Series X preferred stock, $0.001 par value, 10,000 shares authorized; 6,204 and no shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	—	—
Common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2021 and December 31, 2020; 14,306,614 and 15,160,397 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	14	15
Additional paid-in capital	274,783	270,974
Accumulated deficit	(96,276)	(80,393)
Total stockholders' equity	178,521	190,596
Total liabilities and stockholders' equity	$ 184,305	$ 197,185

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 June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses				
Research and development	$ 4,242	$ 832	$ 9,895	$ 2,480
General and administrative	3,729	1,269	7,081	2,999
Restructuring expense	—	490	—	490
Total operating expenses	7,971	2,591	16,976	5,969
Loss from operations	(7,971)	(2,591)	(16,976)	(5,969)
Other income (expense), net	(1)	5	4	35
Warrant inducement expense	—	—	—	(4,829)
Loss before income tax benefit	(7,972)	(2,586)	(16,972)	(10,763)
Income tax benefit	588	—	1,089	—
Net loss and comprehensive loss	$ (7,384)	$ (2,586)	$ (15,883)	$ (10,763)
Net loss per share, basic and diluted	$ (0.50)	$ (2.74)	$ (1.07)	$ (11.31)
Weighted-average common shares outstanding, basic and diluted	14,815,731	943,419	14,823,348	951,352



Source: Eledon Pharmaceuticals, Inc.