Aileron Therapeutics Reports First Quarter 2024 Financial Results and Business Highlights

May 15, 2024

Announced positive data from Cohort 1 of the Phase 1b clinical trial of LTI-03 in idiopathic pulmonary fibrosis (IPF) patients with positive trends observed in seven of the eight biomarkers evaluated

Topline results from Cohort 2 evaluating high-dose LTI-03 (5 mg BID) expected in the third quarter of 2024

AUSTIN, Texas, May 15, 2024 (GLOBE NEWSWIRE) -- Aileron Therapeutics, Inc. (“Aileron” or the “Company”) (NASDAQ: ALRN), a biopharmaceutical company advancing a novel pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications, today reported financial results for the first quarter ended March 31, 2024, and provided a business update.

“In the first quarter, we made steady progress against our key priorities of advancing LTI-03 and generating data from Cohort 1 in IPF,” said Brian Windsor, Ph.D., President and Chief Executive Officer of Aileron. “We are encouraged that low dose LTI-03 achieved statistical significance in three out of eight biomarkers evaluated in the trial, along with promising safety and tolerability that reinforce the potential of LTI-03 to improve lung function and reverse the course of the disease. We expect to report topline results from Cohort 2 in the ongoing Phase 1b study in the third quarter of this year.”

First Quarter 2024 Highlights and Recent Updates

Financing and Management Updates

- In May 2024, the Company closed on an underwritten registered direct offering of 4,273,505 shares of its common stock and accompanying warrants to purchase an aggregate of 4,273,505 shares of common stock resulting in aggregate gross proceeds to the Company of approximately $20 million, before deducting underwriting discounts and commissions and other offering expenses payable by the Company, and excluding any proceeds that may be received from exercise of the warrants. Each share of common stock and accompanying warrant were sold together at a combined public offering price of $4.68 The exercise of the warrants issued in the offering has the potential to result in additional proceeds to the Company of up to approximately $20 million.

- In March 2024, the Company announced the appointment of Brian Windsor, Ph.D., as President and Chief Executive Officer and to the Board of Directors. Dr. Windsor previously served as the Company’s Chief Operating Officer and President, and Chief Executive Officer and director of Lung Therapeutics, Inc. (“Lung”).

Pipeline

- Announced positive Cohort 1 data from the Phase 1b clinical trial evaluating the safety and tolerability of inhaled LTI-03 in patients diagnosed with IPF.
    - Following inhaled administration of low dose LTI-03 (2.5 mg BID, or twice daily) in twelve patients, a positive trend was observed in seven out of eight biomarkers with evidence of reduced expression among profibrotic proteins produced by basal-like cells and fibroblasts that contribute to the progression of IPF, including data from three out of eight biomarkers that were statistically significant, reinforcing the potential of LTI-03 to improve lung function and reverse the course of IPF.
    - LTI-03 was also found to stimulate production of solRAGE, a factor indicative of type I epithelial cell health that is a critically important aspect of IPF and has gone largely unaddressed. Results show LTI-03 to be generally well-tolerated with no serious adverse events (SAEs) reported.
    - The Phase 1b study is ongoing, with topline results from the high-dose cohort expected in the third quarter of 2024.

- On May 1, 2024, the Company hosted a pulmonary care expert call to discuss the Cohort 1 Phase 1b results of LTI-03, featuring pulmonary care expert Andreas Günther, M.D., Head of the Center for Interstitial and Rare Lung Diseases at the Justus Liebig University in Giessen, Germany. A replay of the event can be accessed at https://investors.aileronrx.com/events-presentations/investor-events.

First Quarter 2024 Financial Results

- **Cash Position:** Cash and cash equivalents on March 31, 2024, were $12.0 million, compared to $17.3 million on December 31, 2023. After including the net proceeds raised from the May 2024 offering and based on its current operating plan, the Company expects its existing cash and cash equivalents to fund operations into the second half of 2025.

- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended March 31, 2024, were $3.5 million, compared to $1.8 million for the quarter ended March 31, 2023. The increase of $1.7 million was primarily a result of the Company's acquisition of Lung in October 2023. During the quarter ended March 31, 2024, Aileron spent $1.1 million on clinical trials, $1.6 million on manufacturing, and $0.2 million on regulatory and development consulting as well as $0.6 million on employee and related expenses related to Lung's programs acquired as a result of the Company's acquisition of Lung in October 2023. These activities did not exist during the quarter ended March 31, 2023 and were offset by the termination of ALRN-6924 activities during the quarter ended March 31, 2023.

- **General and Administrative (G&A) Expenses:** G&A expenses for the quarter ended March 31, 2024, were $3.7 million compared to $2.2 million for the quarter ended March 31, 2023. The increase of $1.5 million was primarily due to increased professional fees of $1.0 million and increased employee and related expenses of $0.3 million in the quarter ended March 31, 2024 as compared to the quarter ended March 31, 2023. The majority of the increase related to the acquisition of Lung, which closed in October 2023.

- **Net Loss:** Net loss for the quarter ended March 31, 2024, was $7.1 million, compared to $4.8 million for the corresponding quarter in 2023. The basic and diluted net loss per share for the quarter ended March 31, 2024 was $0.86 compared to $1.05 for the quarter ended March 31, 2023.

About Aileron Therapeutics

Aileron Therapeutics, Inc. is a biopharmaceutical company advancing a novel pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications. Aileron's lead product candidate, LTI-03, is a novel, synthetic peptide with a dual mechanism targeting alveolar epithelial cell survival as well as inhibition of profibrotic signaling. Currently, LTI-03 is being evaluated in a Phase 1b clinical trial for the treatment of idiopathic pulmonary fibrosis. Aileron's second product candidate, LTI-01, is a proenzyme that has completed Phase 1b and Phase 2a clinical trials for the treatment of loculated pleural effusions. LTI-01 has received Orphan Drug Designation in the US and EU and Fast Track Designation in the US.

Forward-Looking Statements

This press release may contain forward-looking statements of Aileron within the meaning of the Private Securities Litigation Reform Act of 1995, including statements with respect to: the timing and expectation of the topline results from Cohort 2 of the Phase 1b study of LTI-03; the sufficiency of the Company's cash resources; the projected cash runway of the Company; the status and plans for clinical trials, including the timing of data; future product development; and the potential commercial opportunity of LTI-03 and LTI-01. We use words such as "anticipate," "believe," "estimate," "expect," "hope," "intend," "may," "plan," "predict," "project," "target," "potential," "would," "can," "could," "should," "continue," and other words and terms of similar meaning to help identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks and uncertainties related to: the Company's ability to maintain the listing of its common stock on The Nasdaq Capital Stock Market; changes in applicable laws or regulations; the possibility that the Company may be adversely affected by other economic, business, and/or competitive factors, including risks inherent in pharmaceutical research and development, such as: adverse results in the Company's drug discovery; preclinical and clinical development activities; the risk that the results of preclinical studies and early clinical trials may not be replicated in later clinical trials or that partial results of a trial such as the Cohort 1 results from the Company's ongoing Phase 1b trial may not be indicative of the full results of the trial; the Company's ability to enroll patients in its clinical trials; and the risk that any of its clinical trials may not commence, continue or be completed on time, or at all; decisions made by the U.S. Food and Drug Administration and other regulatory authorities; investigational review boards at clinical trial sites and publication review bodies with respect to the Company's development candidates; competition; the sufficiency of the Company's cash resources to fund its planned activities for the periods anticipated and the Company's ability to manage unplanned cash requirements; and general economic and market conditions; as well as the risks and uncertainties discussed in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2024, which are on file with the United States Securities and Exchange Commission (the "SEC") and in subsequent filings that the Company files with the SEC. These forward-looking statements should not be relied upon as representing the Company's view as of any date subsequent to the date of this press release, and we expressly disclaim any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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Aileron Therapeutics, Inc.
Balance Sheet Data
(Unaudited)
(In thousands)

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 12,042	$ 17,313
Working capital	8,232	13,881
Total assets	99,192	106,008
Accumulated deficit	(295,630)	(288,517)
Total stockholders' equity	$ 44,750	$ 6,887

Aileron Therapeutics, Inc.
Condensed Consolidated Statement of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	2023
Revenue	$ -	$ -
Operating expenses:		
Research and development	3,463	1,810
General and administrative	3,742	2,179
Restructuring and other costs	-	1,022
Total operating expenses	7,205	5,011
Loss from operations	(7,205)	(5,011)
Other income (expense), net	92	232
Net loss	(7,113)	(4,779)
Net loss per share — basic and diluted	$ (0.86)	$ (1.05)
Weighted average common shares outstanding—basic and diluted	8,301,798	4,541,167