UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): April 15, 2024

Aileron Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38130**	**13-4196017**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

12407 N. Mopac Expy. Suite 250 #390	
Austin, Texas	**78758**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (737) 802-1989

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	ALRN	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition

On April 15, 2024, Aileron Therapeutics, Inc. issued a press release announcing its financial results for the full year and quarter ended December 31, 2023. A copy of the press release is furnished as Exhibit 99.1 to this report on Form 8-K and is hereby incorporated by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Document
99.1	Press Release, dated April 15, 2024
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL document.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AILERON THERAPEUTICS, INC.

Date: April 15, 2024

By: /s/ Brian Windsor, Ph.D.
Brian Windsor, Ph.D.
President and Chief Executive Officer

Aileron Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

Topline results from Phase 1b study of LTI-03, a novel Caveolin-1-related peptide in development for the treatment of idiopathic pulmonary fibrosis, expected to be reported in the third quarter of 2024

Cash runway expected to fund operations and key milestones into the fourth quarter of 2024

AUSTIN, Texas, April 15, 2024 (GLOBE NEWSWIRE) – Aileron Therapeutics, Inc. ("Aileron", the "Company", "we", "our" or "us") (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 fourth quarter and full year ended December 31, 2023 and provided a business update.

"We ended the year in a solid position after the successful completion of our merger with Lung Therapeutics, which provided a focused pipeline of promising clinical-stage candidates for life-threatening lung conditions, coupled with a strengthened balance sheet from the successful closure of a $18.4 million financing," said Brian Windsor, Ph.D., President and Chief Executive Officer of Aileron. "We anticipate 2024 as a pivotal year of execution as we continue to progress our lead product candidate, LTI-03. We expect to report topline results from the ongoing Phase 1b study of LTI-03 in the third quarter of this year. LTI-03 and its potential dual mechanism of action on both epithelial cells and fibroblasts is gaining support from the medical community, and we look forward to building upon encouraging preclinical data that LTI-03 has the potential to protect healthy lung epithelial cells and to reduce pro-fibrotic signaling."

Recent Business Highlights and Upcoming Milestones

Corporate Updates

- In October 2023, Aileron acquired Lung Therapeutics, Inc. ("Lung"), shifting the Company's disease focus to advance a pipeline of first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis diseases. The Company's lead clinical programs include LTI-03 for idiopathic pulmonary fibrosis (IPF) and LTI-01 for loculated pleural effusion (LPE).

- Immediately following the closing of Aileron's acquisition of Lung ("Lung Acquisition"), the Company entered into a definitive agreement for the sale of shares of its Series X non-voting convertible preferred stock and warrants to purchase shares of Aileron common stock in a private placement to a group of accredited investors led by Bios Partners, the majority stockholder of Lung prior to the Lung Acquisition, and including Nantahala Capital, as well as additional undisclosed investors. The private placement resulted in gross proceeds to Aileron of approximately $18 million before deducting placement agent fees and other offering expenses.
- 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 Aileron's Chief Operating Officer and President, and Chief Executive Officer and director of Lung.

Pipeline

- In February 2024, Aileron hosted a pulmonary care expert panel to discuss the potential implications of LTI-03 for IPF, featuring pulmonary care experts Fernando J. Martinez, M.D., M.S., Chief of the Pulmonary and Critical Care Medicine Division at Weill Cornell Medicine; Tejaswini Kulkarni, M.D., M.P.H., Associate Professor of Pulmonology, Allergy and Critical Care Medicine and Director of the Interstitial Lung Disease Program at University of Alabama at Birmingham Medicine; and Andreas Günther, M.D., Senior Physician of Pulmonology and Intensive Care Medicine and Chief Physician of Pulmonology and Internal Intensive Care Medicine at Agaplesion Evang. Central Hesse Hospital and Professor of Interstitial and Rare Lung Diseases at Justus Liebig University. A replay of the event can be accessed at https://investors.aileronrx.com/events-presentations/investor-events.
- **LTI-03**: a novel Caveolin-1-related (Cav1) peptide with a dual mechanism targeting both alveolar epithelial cell survival as well as inhibition of profibrotic signaling
    - LTI-03 is currently in a randomized, double-blind, placebo-controlled Phase 1b clinical trial in IPF patients. Aileron expects to report topline results from this trial in the third quarter of 2024.
- **LTI-01**: a PAI-1 resistant plasmin activated proenzyme for loculated pleural effusions
    - LTI-01 has been evaluated in Phase 1b and Phase 2a clinical trials in patients with infected, non-draining LPEs and is ready for Phase 2b. LTI-01 has received Orphan Drug Designation in the US and EU and Fast Track Designation in the US.

Fourth Quarter and Full Year 2023 Financial Results

- **Cash Position**: Cash, cash equivalents, and investments on December 31, 2023, were $17.3 million, compared to $21.2 million on December 31, 2022. Based on its current operating plan, the Company expects its existing cash, cash equivalents, and investments will fund operations into the fourth quarter of 2024.
- **Research and Development (R&D) Expenses**: R&D expenses for the quarter ended December 31, 2023, were $2.0 million, compared to $2.4 million for the quarter ended December 31, 2022. R&D expenses decreased primarily due to the termination of R&D activities related to ALRN-6924. R&D expenses for the full-year 2023 were $4.0 million, compared to $18.0 million for the prior year.
- **General and Administrative (G&A) Expenses**: G&A expenses for the quarter ended December 31, 2023, were $5.3 million compared to $2.3 million for the quarter ended December 31, 2022. G&A expenses increased due to the integration and operating activities of Lung. G&A expenses for the full-year 2023 were $11.4 million, compared to $9.7 million for the prior year.
- **Net Loss:** Net loss for the quarter ended December 31, 2023, was $7.3 million, compared to $4.5 million for the quarter ended December 31, 2022. The basic and diluted net loss per share for the quarter ended December 31, 2023 was $1.54 compared to $1.00 for the quarter ended December 31, 2022. The basic and diluted net loss per share for the full-year 2023 was $3.42 compared to $6.02 for the full-year 2022.

About Aileron Therapeutics

Aileron Therapeutics 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 of the Phase 1b study of LTI-03; future expectations, plans and prospects for the Company following the merger transaction between the Company and Lung that closed in the fourth quarter of 2023 (the "Merger"); 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 ability to recognize the anticipated benefits of the Merger; 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; 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; our ability to obtain, maintain and enforce intellectual property rights for our platform and development candidates; our potential dependence on collaboration partners; competition; uncertainties as to 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, which is on file with the United States Securities and Exchange Commission and in subsequent filings that the Company files with the Securities and Exchange Commission. 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)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and investments	$ 17,313	$ 21,242
Working capital	13,881	18,489
Total assets	106,008	22,007
Accumulated deficit	(288,517)	(272,785)
Total stockholders' equity	6,887	18,623

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	1,972	2,402	3,991	17,967
General and administrative	5,330	2,301	11,357	9,680
Restructuring and other	(12)	—	928	—
Total Operating expenses	7,290	4,703	16,276	27,647
Loss from operations	(7,290)	(4,703)	(16,276)	(27,647)
Other income (expense), net	(49)	156	544	318
Net loss	(7,339)	(4,547)	(15,732)	(27,329)
Net loss per share — basic and diluted	$ (1.54)	$ (1.00)	$ (3.42)	$ (6.02)
Weighted average common shares outstanding—basic and diluted	4,769,483	4,541,167	4,598,715	4,539,318