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): August 14, 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 August 14, 2024, Aileron Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended June 30, 2024. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Document
99.1	Press Release, dated August 14, 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: August 14, 2024

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

Aileron Therapeutics Reports Second Quarter 2024 Financial Results and Business Highlights

Announced positive data from Cohort 1 of the ongoing Phase 1b clinical trial of LTI-03 evaluating low dose LTI-03 (2.5 mg BID) 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, Aug 14, 2024 (PR NEWSWIRE) – Aileron Therapeutics, Inc. ("Aileron" or the "Company") (NASDAQ: ALRN), a biopharmaceutical company advancing a pipeline of potential first-in-class medicines to address significant unmet medical needs in orphan pulmonary and fibrosis indications, today reported financial results for the second quarter ended June 30, 2024, and provided a business update.

"Throughout the first half of the year, we focused on strengthening our balance sheet and advancing the development of inhaled LTI-03 in IPF," said Brian Windsor, Ph.D., President and Chief Executive Officer of Aileron. "We are extremely pleased with the positive data from Cohort 1 of the ongoing Phase 1b clinical trial announced in May, particularly the achievement of statistical significance in three out of eight biomarkers which is a testament to the potential of LTI-03 to inhibit fibrosis and improve lung function. Additionally, in May, we raised approximately $18.2 million in net proceeds in an underwritten registered direct offering, which provides us with the resources to further validate LTI-03 in the ongoing Phase 1b trial. We look forward to reporting topline results from the high-dose cohort in the third quarter of this year."

Second Quarter 2024 Highlights and Recent Updates

Corporate Updates

- In May 2024, the Company completed 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 its common stock. Net proceeds from the offering were approximately $18.2 million, after deducting underwriting discounts and commissions and other offering expenses. The Company has the potential to receive approximately $20.0 million in additional proceeds from the exercise of the warrants issued in the offering.

Pipeline

- Announced positive Cohort 1 data from the ongoing 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. The findings included:
    - Evidence of LTI-03 reducing expression of multiple profibrotic proteins produced in both basal-like cells and fibroblasts that contribute to the progression of IPF, with statistically significant decreases in three biomarkers, reinforcing the potential of LTI-03 to inhibit fibrosis, inflammation and associated changes in the lungs.
    - LTI-03 stimulated production of solRAGE, a factor indicative of type I epithelial cell health, a critically important aspect of IPF that has gone largely unaddressed.
    - LTI-03 was generally well-tolerated with no serious adverse events ("SAEs") reported.
  - The Phase 1b trial is ongoing, with topline results from the high-dose Cohort 2 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.
- LTI-01 is in development for loculated pleural effusion ("LPE"), a serious consequence of pneumonia with significant unmet medical need.

Second Quarter 2024 Financial Results

- **Cash Position:** Cash and cash equivalents as of June 30, 2024, were $21.9 million, compared to $12.0 million as of March 31, 2024. 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 be sufficient to fund the completion of the Phase 1b clinical trial and its operations into the second half of 2025.
- **Research and Development ("R&D") Expenses:** R&D expenses for the quarter ended June 30, 2024, were $3.7 million, compared to $0.2 million for the quarter ended June 30, 2023. The increase of $3.5 million was primarily a result of the clinical programs acquired as part of the Company's acquisition of Lung Therapeutics, Inc. in October 2023 (the "Lung Acquisition"). During the quarter ended June 30, 2024, Aileron incurred expenses of $1.1 million on clinical trials, $2.0 million on manufacturing, and $0.1 million on regulatory and development consulting as well as $0.5 million on employee and related expenses associated with clinical programs acquired in the Lung Acquisition.
- **General and Administrative ("G&A") Expenses:** G&A expenses for the quarter ended June 30, 2024, were $5.3 million, compared to $1.9 million for the quarter ended June 30, 2023. The increase of $3.4 million was primarily due to increased professional fees of $1.0 million and increased employee and related expenses of $1.8 million as a result of increased business activity and headcount associated with the Lung Acquisition, and increased facilities and other expenses of $0.5 million during the quarter ended June 30, 2024 as compared to the quarter ended June 30, 2023.

- **Net Loss:** Net loss for the quarter ended June 30, 2024, was $8.9 million, compared to $1.8 million for the quarter ended June 30, 2023. The basic and diluted net loss per share for the quarter ended June 30, 2024 was $0.45 compared to $0.39 for the quarter ended June 30, 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: 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 results from Cohort 1 of the Company's ongoing Phase 1b clinical trial of LTI -03 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 quarter 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)

	June 30, 2024	December 31, 2023
Cash and cash equivalents	$ 21,917	$ 17,313
Working capital	18,222	13,881
Total assets	109,400	106,008
Accumulated deficit	(304,572)	(288,517)
Total stockholders' equity	$ 56,016	$ 6,887

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

	Three Months Ended June 30,	
	2024	2023
Revenue	$ —	$ —
Operating expenses:		
Research and development	3,741	187
General and administrative	5,298	1,893
Restructuring and other costs	—	(88)
Total operating expenses	9,039	1,992
Loss from operations	(9,039)	(1,992)
Other income (expense), net	97	205
Net loss	(8,942)	(1,787)
Net loss per share — basic and diluted	$ (0.45)	$ (0.39)
Weighted average common shares outstanding—basic and diluted	19,911,462	4,541,167