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): November 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 November 14, 2024, Aileron Therapeutics, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2024. 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 November 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: November 14, 2024

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

Aileron Therapeutics Reports Third Quarter 2024 Financial Results and Recent Business Highlights

Announced promising safety and positive biomarker data from Cohort 2 (5mg BID) of the Phase 1b clinical trial of LTI-03 in idiopathic pulmonary fibrosis (IPF) patients demonstrating dose dependent effects in five biomarkers evaluated compared to low dose LTI-03

Data from Cohort 2 of the Phase 1b clinical trial confirms results from Cohort 1, with four biomarkers achieving statistical significance in the combined Cohort 1 and Cohort 2 data set

Planning is underway for a Phase 2 clinical trial

AUSTIN, Texas, Nov. 14, 2024 (PR NEWSWIRE) – Aileron Therapeutics, Inc. ("Aileron") (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 third quarter ended September 30, 2024, and provided a business update.

"This past quarter has been one of significant progress for Aileron, as evidenced by our recent announcement of positive data from Cohort 2 of our Phase 1b clinical trial evaluating a higher dose of LTI-03 (5 mg BID) in patients with IPF, in which high dose LTI-03 demonstrated dose dependent effects in five biomarkers," said Brian Windsor, Ph.D., President and Chief Executive Officer of Aileron. "We were highly encouraged that the combined data set from Cohort 1 and 2 achieved statistical significance in four out of eight biomarkers evaluated in the trial, which along with promising safety and tolerability data, reinforce the potential of LTI-03 to improve lung function and reverse the course of the disease."

Third Quarter 2024 Highlights and Recent Updates

Corporate Updates

- In October 2024, the Company announced entry into an exclusive option agreement with Advancium Health Network for the acquisition of ALRN-6924, a clinical-stage oncology agent developed by the Company prior to its 2023 merger with Lung Therapeutics, Inc., for retinoblastoma. Under the terms of the agreement, Aileron received a non-refundable fee from Advancium for the exclusive option to acquire ALRN-6924 and related assets. If Advancium exercises its option, Aileron will receive an exercise payment with potential for additional development, regulatory and commercial milestone payments and sales royalties.

Pipeline

- In November 2024, Aileron announced positive topline data from Cohort 2 of the Phase 1b clinical trial evaluating the safety and tolerability of high dose LTI-03 (5 mg BID) and a set of exploratory biomarkers in patients diagnosed with idiopathic pulmonary fibrosis (IPF). In May, the Company reported positive biomarker data from Cohort 1 which evaluated low dose LTI-03 (2.5 mg BID).

- In August 2024, Brian Windsor, Ph.D., President and Chief Executive Officer of Aileron, presented an oral presentation at the 8th Annual IPF Summit, entitled, "Biomarker Strategies in the Clinical Development of LTI-03 in IPF".

Third Quarter 2024 Financial Results

- **Cash Position:** Cash and cash equivalents as of September 30, 2024, were $17.7 million, compared to $21.9 million as of June 30, 2024. The Company expects its existing cash and cash equivalents to be sufficient to fund operations into June 2025.
- **Research and Development ("R&D") Expenses:** R&D expenses for the quarter ended September 30, 2024, were $3.7 million, compared to less than $0.1 million for the quarter ended September 30, 2023. The increase of $3.7 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 September 30, 2024, Aileron incurred expenses of $2.1 million on clinical trials, $1.0 million on manufacturing including $0.8 million write-offs due to the temporary delay of clinical development of LTI-01, 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 September 30, 2024, were $2.3 million, compared to $2.0 million for the quarter ended September 30, 2023. The increase of $0.4 million was primarily due to increased employee and related expenses of $0.5 million as a result of increased headcount associated with the Lung Acquisition and severance expense recognized due to departure of former employees, and increased facilities and other expenses of $0.2 million, offset by decreased professional fees of $0.3 million as a result of less external consulting expenses during the quarter ended September 30, 2024 as compared to the quarter ended September 30, 2023.
- **Net Loss:** Net loss for the quarter ended September 30, 2024, was $5.8 million, compared to $1.8 million for the quarter ended September 30, 2023. The basic and diluted net loss per share for the quarter ended September 30, 2024 was $0.27 compared to $0.40 for the quarter ended September 30, 2023.

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. LTI-03 completed 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 Therapeutics, Inc. (“Aileron”, the “Company”, “we”, “our” or “us”) within the meaning of the Private Securities Litigation Reform Act of 1995, including statements with respect to: the timing and expectation of a Phase 2 trial of LTI-03; future expectations, plans and prospects for the Company; the sufficiency of the Company’s cash resources; the projected cash runway of the Company; 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, including in a Phase 2 trial of LTI-03, or that partial results of a trial will 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 our development candidates; our ability to obtain, maintain and enforce intellectual property rights for our platform and 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 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)

	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 17,652	$ 17,313
Working capital	13,025	13,881
Total assets	104,217	106,008
Accumulated deficit	(310,419)	(288,517)
Total stockholders' equity	$ 50,227	$ 6,887

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

	Three Months Ended September 30,	
	2024	2023
Revenue	$ —	$ —
Operating expenses:		
Research and development	3,722	22
General and administrative	2,349	1,955
Restructuring and other costs	—	6
Total operating expenses	6,071	1,983
Loss from operations	(6,071)	(1,983)
Other income, net	224	156
Net loss	(5,847)	(1,827)
Net loss per share—basic and diluted	$ (0.27)	$ (0.40)
Weighted average common shares outstanding—basic and diluted	21,663,089	4,541,167