UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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): May 1, 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** **(Address of Principal Executive Offices)**	**78758** **(Zip Code)**

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

Not applicable
(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:

☐ 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

The information disclosed under the heading "Cash and Cash Equivalents as of March 31, 2024" under Item 8.01 of this Current Report on Form 8-K is herein incorporated by reference.

Item 8.01. Other Events.

Data from Cohort 1 of Phase 1b Clinical Trial of LTI-03

On May 1, 2024, Aileron Therapeutics, Inc. (the "Company") announced positive data from cohort 1 of the ongoing Phase 1b clinical trial evaluating the safety and tolerability of inhaled LTI-03 in patients diagnosed with idiopathic pulmonary fibrosis, or IPF.

The Phase 1b trial of LTI-03 is a randomized, double-blind, placebo-controlled, Phase 1b clinical trial of LTI-03 in IPF patients, which is being conducted at 11 centers in the United States, the United Kingdom, Belgium, Germany and Australia. The Company plans to enroll a total of 24 patients. In the trial, these patients have a bronchoscopy at a baseline screening followed by either LTI-03 or placebo twice a day for 14 days. On day 14, shortly after the final dose, patients receive a second bronchoscopy and are monitored thereafter for seven days. In cohort 1, patients in the active arm inhaled a single 2.5 mg capsule of LTI-03 twice daily. In cohort 2, patients will receive two 2.5 mg capsules of LTI-03 for inhalation twice daily.

Of the twelve patients enrolled in cohort 1 of the trial, three were randomized to the placebo arm and nine to the active arm. In addition to the safety and tolerability of LTI-03, in the trial, various biomarkers relating to epithelial damage, fibrosis and inflammation in blood cells were assessed. The eight biomarkers that the Company evaluated in cohort 1 included: thymic stromal lymphopoietin (TSLP), galectin-7 (GAL-7), interleukin-11 (IL-11), collagen 1 alpha chain (Col-1α1), phosphorylated SMAD2/3 (pSMAD2/3/tSMAD2/3), phosphorylated AKT kinase (pAKT), soluble (sol) receptor for advanced glycation end-products (solRAGE), and CXC chemokine 7 (CXCL7).

In cohort 1, a positive trend was observed in seven out of the eight biomarkers with data from three biomarkers being statistically significant (based on a one-tailed t-test). The findings from cohort 1 include:

- LTI-03 reduced expression of multiple profibrotic proteins in both pathologic basal-like cells and fibroblasts, with statistically significant decreases observed in three biomarkers — GAL-7 (p=0.0014, SEM 0.901), TSLP (p=0.0223, SEM 5.163) and Col-1α1 (p=0.0489, SEM 0.7102) — supporting the potential of LTI-03 to reduce fibrosis, inflammation and associated changes in the lung.
- LTI-03 stimulated production of solRAGE (p=0.1407, SEM 0.3269), a factor indicative of type I epithelial cell health that is a critically important aspect of IPF and has gone largely unaddressed.
- LTI-03 did not induce inflammation in peripheral blood mononuclear cells as measured by pAKT (p=0.358, SEM 11.32).

LTI-03 was generally well-tolerated with no serious adverse events reported.

The Phase 1b trial is ongoing, with topline results from the high-dose cohort 2 expected in the third quarter of 2024.

Cash and Cash Equivalents as of March 31, 2024

The Company expects to report that it had cash and cash equivalents of approximately $12.0 million as of March 31, 2024.

The estimated cash figure is preliminary and unaudited, represents a management estimate as of the date of this report and is subject to completion of the Company's financial closing procedures. The Company's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, the estimated cash figure.

Cautionary Note Regarding Forward-Looking Statements

Any statements in this Current Report on Form 8-K about future expectations, plans, and prospects for the Company, including with respect the Company's estimated cash and cash equivalents as of March 31, 2024; the timing and expectation of the results of the Phase 1b study of LTI-03; 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, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend", "goal," "may", "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. 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 maintain the listing of the common stock of the Company 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 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. FDA and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies with respect to the Company's development candidates; the Company's ability to obtain, maintain and enforce intellectual property rights for the Company's platform and development candidates; 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 (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 the Company expressly disclaims any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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: May 1, 2024

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