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): December 21, 2020

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

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

490 Arsenal Way **Watertown, MA**	**02472**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 995-0900

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 (*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	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ALRN**	**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 7.01 Regulation FD Disclosure.

On December 21, 2020, Aileron Therapeutics, Inc. (the "Company") posted a Corporate Overview presentation on the "Investors & Media" section of the Company's website (www.aileronrx.com).

The information in this Item 7.01 is furnished under Item 7.01 of Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the 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 8.01 Other Events.

On December 21, 2020, the Company provided a business update and outlined its strategic priorities for 2021, including announcing more details about the design and conduct of a Phase 1b randomized, double-blind, placebo-controlled clinical trial of ALRN-6924 in patients with advanced non-small cell lung cancer ("NSCLC") undergoing treatment with first-line carboplatin doublet chemotherapy (with or without immune checkpoint inhibitors), planned to begin enrolling in the second quarter of 2021.

The Company plans to begin enrolling patients its planned Phase 1b clinical trial of ALRN-6924 in patients with NSCLC in the second quarter of 2021, subject to obtaining funding for the trial. The Company expects that the randomized, double-blind, placebo-controlled trial will be part of a registration program designed to ultimately support approval for ALRN-6924 in NSCLC. The Company anticipates enrolling approximately 40 patients with stage IV NSCLC undergoing treatment with first-line carboplatin doublet chemotherapy with or without an immune checkpoint inhibitor. Patients will be randomized 1:1 to receive either 0.3 mg/kg of ALRN-6924 or placebo. Endpoints will include the effect of ALRN-6924 to limit chemotherapy-induced bone marrow toxicities. The Company anticipates reporting initial results from the trial late in the fourth quarter of 2021 and full results in mid-2022.

In 2021, the Company plans to report additional results from its ongoing Phase 1b clinical trial in patients with small cell lung cancer ("SCLC"). In October 2020, the Company presented positive clinical data from the trial demonstrating clinical proof-of-concept that treatment with ALRN-6924 resulted in a protective effect against severe anemia, thrombocytopenia and neutropenia in patients with p53-mutated SCLC treated with topotecan. The data set from this trial, which the Company plans to announce in the first quarter of 2021, will include results across all dose levels evaluating ALRN-6924 administered 24 hours prior to topotecan administration, including an exploratory 0.2 mg/kg dose level, as well as results from a cohort evaluating 0.3 mg/kg ALRN-6924 administered six hours prior to topotecan administration, which has now completed enrollment, with a total of six patients.

In addition, the Company initiated a healthy volunteer study in November 2020 to characterize the time to onset, magnitude and duration of cell cycle arrest in human bone marrow relative to ALRN-6924 administration. Due to COVID-19-related delays, the Company is updating its guidance on the readout of the healthy volunteer study from the second quarter of 2021 to mid-2021.

Forward-Looking Statements

Statements in this report about Company's future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements about the Company's strategy and clinical development plans. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to 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 whether the Company's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; whether the Company will obtain sufficient cash resources to conduct its planned clinical trials; whether results obtained in clinical trials will be indicative of results obtained in future clinical trials; whether third party data would be indicative of the data that would be obtained in a randomized, head-to-head clinical trial; whether the Company's product candidates will advance through the clinical trial process on a timely basis, or at all; whether the results of such trials will be accepted by and warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether the Company's product candidates will receive approval from regulatory agencies on a timely basis or at all; whether, if product candidates obtain approval, they will be successfully distributed and marketed; what impact the coronavirus pandemic may have on the timing of our clinical development, clinical supply and our operations; and other factors discussed in the "Risk Factors" section of the Company's quarterly report on Form 10-Q for the period ended September 30, 2020, and risks described in other filings that the Company may make with the Securities and Exchange Commission. Any forward-looking statements contained in this report speak only as of the date hereof, and the Company specifically disclaims any obligation to update any forward-looking statement, whether because of new information, future events or otherwise.

SIGNATURES

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

Aileron Therapeutics, Inc.

Date: December 21, 2020

By: /s/ Richard J. Wanstall
Richard J. Wanstall
Chief Financial Officer and Treasurer