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): June 5, 2019

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, Suite 210
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(s)	Name of each exchange on which registered
Common Stock, $0.001 per share	**ALRN**	**Nasdaq Global 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 8.01 Other Events.

On June 5, 2019, Aileron Therapeutics, Inc. (the "Company") announced updated information regarding the design and anticipated timing of data from its ongoing and planned clinical trials of ALRN-6924.

Combination with Palbociclib (Ibrance) in MDM2-Amplified Advanced Solid Tumors

The Company is conducting a Phase 2a clinical trial of the combination of ALRN-6924 and palbociclib (Ibrance), marketed by Pfizer, Inc., for the treatment of MDM2-amplified advanced solid tumors. The Company plans to enroll up to 25 patients in this trial. The objectives of this trial include evaluation of the safety, tolerability and activity of the combination, including determination of the overall response rate and other measures of activity including progression-free survival and overall survival. The Company plans to use the data from the trial to identify an indication to investigate in further trials of the combination.

The Company plans to disclose interim data from 15 patients enrolled in this trial at the European Society for Medical Oncology Congress 2019, which is scheduled from September 27 through October 1, 2019, and to have final data from all 25 patients in this trial in the second quarter of 2020.

Myelopreservation Trial in Combination with Topotecan

In September 2019, the Company plans to begin enrolling patients with advanced small cell lung cancer who are treated with topotecan in a Phase 1b/2 trial of ALRN-6924 to assess ALRN-6924 as a myelopreservative agent protecting against chemotherapy-induced bone marrow toxicity. The Company plans to enroll up to 40 patients in the Phase 1b portion of the trial and, subject to funding, up to 60 patients in the Phase 2 portion of the trial.

In the trial, patients will receive administration of ALRN-6924 on days 0-4 and administration of topotecan on days 1-5 of every 21-day treatment cycle. The objectives of the trial include evaluation of the safety and efficacy of ALRN-6924 as a myelopreservative agent, including determining whether patients experience a reduction of grade 3 or greater neutropenia, anemia and thrombocytopenia and reduction of febrile neutropenia.

The Company plans to disclose data from the Phase 1b portion of the trial in the second quarter of 2020.

Forward-Looking Statements

Any statements in this Form 8-K about Aileron's future expectations, plans and prospects, including statements about the Company's future operations, and clinical trials and other statements containing the words "believes," "anticipates," "estimates," "expects," "intends," "plans," "predicts," "projects," "targets," "may," "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 whether Aileron's cash resources will be sufficient to fund its continuing operations for the periods and/or trials anticipated; whether results obtained in preclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether Aileron's product candidates will advance through the clinical trial process on a timely basis, or at all; whether the results of such trials will warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether Aileron'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; and other factors discussed in the "Risk Factors" section of Aileron's quarterly report on Form 10-Q for the period ended March 31, 2019, filed on May 8, 2019, and risks described in other filings that Aileron may make with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and Aileron 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: June 5, 2019

By: /s/ Manuel Aivado
Manuel Aivado
President and Chief Executive Officer