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): September 28, 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** **(Address of Principal Executive Offices)**	**02472** **(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 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 September 28, 2019, Aileron Therapeutics, Inc. ("Aileron" or the "Company") announced the presentation of interim results from its ongoing Phase 2a clinical trial evaluating the combination of ALRN-6924 and Pfizer's IBRANCE® (palbociclib) for the treatment of patients with tumors harboring wild-type p53 and MDM2 amplification or MDM2/CDK4 co-amplification at the 2019 Congress of the European Society for Medical Oncology (ESMO).

As of the data cutoff date of September 2, 2019, the trial had enrolled 26 patients. The reported safety results showed that the combination has been very well-tolerated in the trial, with the most common non-hematological related adverse events grade £2 being nausea (46%) and fatigue (23%). Neutropenia was the only grade ³3 hematological related AE occurring in >5% of patients (27%), while grade ³3 thrombocytopenia and leukopenia each were observed in only one patient (3.8%).

The preliminary analysis of activity in the 17 evaluable patients with liposarcoma showed a disease control rate of 88% and a median progression-free survival of 4.4 months with 53% censoring. No partial or complete responses have been observed. Patients who have had at least one post-baseline assessment and have MDM2-amplified, TP53-WT tumors were deemed evaluable.

The Company expects that the first indication for the combination of ALRN-6924 and palbociclib may be MDM2-amplified sarcoma patients, for whom there exists a substantial unmet need across all lines of treatment for the estimated 15,000 patients worldwide diagnosed each year. In addition, these results have further encouraged the Company to expand enrollment to a total of 35 patients in order to evaluate the combination on the treatment of other MDM2-amplified cancers. The Company expects to announce a final data readout in the second quarter of 2020.

Forward-Looking Statements

Statements in this report about Aileron'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 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 preliminary or interim results from a clinical trial will be indicative of the final results of the trial; 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 June 30, 2019, filed on August 6, 2019, and risks described in other filings that Aileron may make with the Securities and Exchange Commission. Any forward-looking statements contained in this report 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: September 30, 2019

By: /s/ Richard J. Wanstall
Richard J. Wanstall
Vice President of Finance and Operations