# 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): July 1, 2021**

# 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.)** |

| | |
|---|---|
| **285 Summer Street, Suite 101**<br>**Boston, MA**<br>**(Address of Principal Executive Offices)** | **02210**<br>**(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 8.01 Other Events.**

On March 2, 2021, Aileron Therapeutics, Inc. (the "Company") announced that it has initiated its first randomized, double-blind, placebo-controlled clinical trial of ALRN-6924 in the United States and in Europe as a chemoprotective agent to treat patients with non-small cell lung cancer ("NSCLC") undergoing chemotherapy. The Company plans to enroll 60 patients with advanced p53-mutated NSCLC undergoing treatment with first-line carboplatin plus pemetrexed with or without immune checkpoint inhibitors in the Phase 1b trial.

Patients enrolled in the Company's NSCLC trial will be randomized 1:1 to receive carboplatin/pemetrexed plus 0.3 mg/kg ALRN-6924 or placebo for at least four 21-day treatment cycles. Primary endpoints are the proportion of treatment cycles free of severe hematological and other toxicities, including Grade ³ 3 neutropenia, Grade ³ 3 thrombocytopenia, Grade ³ 3 anemia, Grade 4 neutropenia and febrile neutropenia, as well as duration of Grade 4 neutropenia. An additional primary endpoint is the proportion of completed treatment cycles without chemotherapy dose reduction or without the use of growth factors or transfusions. Other endpoints include the proportion of patients with National Cancer Institute (NCI) Common Terminology Criteria Adverse Events (CTCAE) Grade 3/4 treatment-emergent adverse events (TEAEs), quality of life, overall response rate, and progression-free survival.

The Company anticipates reporting first interim safety data from the trial late in the fourth quarter of 2021 and full results in mid-2022.

**Forward-Looking Statements conform**

Statements in this report about the 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 anticipated; whether results of clinical trials will be indicative of results obtained in later clinical trials; whether ALRN-6924 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 ALRN-6924 will receive approval from regulatory agencies on a timely basis or at all; whether, if ALRN-6924 obtains approval, it will be successfully distributed and marketed; uncertainties as to the 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 March 31, 2021, filed on May 5, 2021, 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: July 1, 2021

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