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): January 5, 2022

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, Unit 101 **Boston, MA**	**02210**
(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 8.01 Other Events.

On January 5, 2022, Aileron Therapeutics, Inc. ("Aileron") issued a press release providing a business update and outlining its strategic priorities for 2022.

New Phase 1b Clinical Trial in Patients with Neoadjuvant (Pre-Operative) Breast Cancer

Aileron plans to initiate a new clinical trial in the first half of 2022 to evaluate ALRN-6924 to protect against chemotherapy-induced bone marrow and other toxicities in ER+/HER2- breast cancer patients treated with a doxorubicin + cyclophosphamide and docetaxel chemotherapy regimen, also known as 'AC-D'. The Phase 1b trial will enroll up to 30 patients in a parallel group design trial with a dose expansion cohort. Aileron will provide more details on the planned neoadjuvant breast cancer trial design at the time of trial initiation. Aileron expects to report interim results from the trial in the fourth quarter of 2022.

Ongoing NSCLC Clinical Trial

Aileron is currently enrolling patients in the United States and Europe with advanced p53-mutated NSCLC undergoing treatment with first-line carboplatin plus pemetrexed with or without immune checkpoint inhibitors. As previously guided, Aileron anticipates reporting interim results on 20 patients in the second quarter of 2022, and topline results on 60 patients in the fourth quarter of 2022. Aileron has dosed the first 10 patients in the trial and plans to conduct a blinded safety evaluation on these patients after one cycle in the first quarter of 2022, as previously guided.

Ongoing Healthy Volunteer Study

Aileron is continuing to progress its ongoing Phase 1 pharmacology study which is evaluating ALRN-6924's induction of p21-induced cell cycle arrest in healthy, normal bone marrow cells and other cell types in healthy volunteers receiving ALRN-6924. Aileron presented initial data from the study in 2021, confirming the drug's novel p53 biomarker-driven mechanism of action, as well as its pharmacodynamic effects, including time to onset, magnitude and duration. The aim of the study is to develop a universal dosing regimen for ALRN-6924 for use as a chemoprotection agent across a range of chemotherapies and p53-mutated cancers. Aileron anticipates reporting additional findings from the study this year.

Patent Portfolio

Aileron was issued seven new international patents and four U.S. patents in 2021, including new patent protection for ALRN-6924 in China. These newly issued patents add to Aileron's intellectual property portfolio, which includes over 170 U.S. and foreign patents, with another 47 applications in prosecution worldwide. These patents and applications include ALRN-6924 methods of manufacture, methods of use, drug product formulations, and compositions of matter. The compositions of matter patent in the United States expires in 2033 with up to five additional years subject to patent term extensions. Of note, Aileron maintains worldwide rights to its proprietary peptide drug technology and ALRN-6924.

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 potential of ALRN-6924 as a chemoprotective agent and 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 anticipated or with respect to the matters anticipated; whether initial results of clinical trials will be indicative of final results of those trials or results obtained in future clinical trials, including trials in different indications; 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 or in which territories or indications ALRN-6924 may receive approval; whether, if ALRN-6924 obtains approval, it will be successfully distributed and marketed; what impact the coronavirus pandemic may have on the timing of its clinical development, clinical supply and its operations; and other factors discussed in the "Risk Factors" section of Aileron's annual report on Form 10-Q for the quarter ended September 30, 2021, filed on November 12, 2021, 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: January 5, 2022

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