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): October 24, 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
(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 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 October 24, 2020, a poster titled *Prevention of Chemotherapy-induced Myelosuppression in SCLC Patients Treated with the Dual MDMX/MDM2 Inhibitor ALRN-6924*, which was submitted by Aileron Therapeutics, Inc. (the “Company”) for the 32nd EORTC-NCI-AACR Annual Symposium on Molecular Targets and Cancer Therapeutics (“ENA 2020”), was published on the ENA 2020 website (event.eortc.org/ena2020). A copy of the poster is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1 attached hereto, is furnished under Item 7.01 of Form 8-K, and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On October 24, 2020, the Company announced positive clinical data from its ongoing Phase 1b trial of ALRN-6924 demonstrating clinical proof of concept that treatment with ALRN-6924 prior to second-line topotecan administration resulted in a protective effect against severe anemia, thrombocytopenia and neutropenia in patients with p53-mutated small cell lung cancer (“SCLC”). The results were presented at ENA 2020.

As of August 31, 2020, the data cut-off date, a total of 26 adult patients were enrolled in the dose optimization part of the Phase 1b trial. Of these patients, 18 patients were enrolled across three ALRN-6924 dose levels (0.3 mg/kg, 0.6 mg/kg and 1.2 mg/kg) and eight patients were enrolled in a 0.3 mg/kg expansion cohort. 25 of the 26 total enrolled patients had completed the first treatment cycle and therefore met protocol-defined criteria for evaluability as of the August 31, 2020 data cut-off date. In this part of the trial, ALRN-6924 was administered 24 hours before each dose of topotecan. Topotecan (1.5 mg/m2) was administered on days 1 through 5 of every 21-day treatment cycle. In the trial, toxicities were evaluated using the National Cancer Institute’s (“NCI”) Common Terminology Criteria for Adverse Events (“CTCAE”). Per the Phase 1b trial protocol, patients were not permitted to receive prophylactic granulocyte-colony stimulating factor (“G-CSF”) treatment in cycle 1.

Key findings from data analysis include the following:

- A protective effect against severe chemotherapy-induced toxicities was observed across all ALRN-6924 dose levels as compared to third party historical controls.
- Across all ALRN-6924 dose levels, Grade 3/4 anemia, Grade 3/4 thrombocytopenia and Grade 4 neutropenia (defined as <500/µL) were limited to 24%, 36% and 48% of patients, respectively.
- While chemoprotection effects were observed across all ALRN-6924 dose levels, the 0.3 mg/kg dose level showed the most robust chemoprotection results, with Grade 3/4 anemia, Grade 3/4 thrombocytopenia and Grade 4 neutropenia limited to 21%, 36% and 43% of patients, respectively.
- None of the patients treated at 0.3 mg/kg dose level had hematological serious adverse events. One patient treated at 0.3 mg/kg dose level required one red blood cell transfusion and one platelet transfusion.
- At the 0.3 mg/kg ALRN-6924 dose level, no patients required erythropoiesis-stimulating agents, and seven patients (50%) required G-CSF treatment.
- Across all ALRN-6924 dose levels, no patients experienced febrile neutropenia which is a severe toxicity commonly observed with topotecan treatment in this patient population.

The key hematological toxicities from the Phase 1b dose optimization part of the trial as of the data cut-date of August 31, 2020 are shown in the table below. Four of the evaluable patients remained on treatment in the trial as of the data cut-off date.

	ALRN-6924 0.3 mg/kg + Topotecan 1.5 mg/m2	**ALRN-6924 (all dose levels) + Topotecan 1.5 mg/m2**
Adverse Events* NCI CTCAE Grade ³3	N(%) N=14	N(%) N=25
All AEs	13 (93)	24 (96)
Anemia	3 (21)	6 (24)
Thrombocytopenia	5 (36)	9 (36)
Neutropenia	11 (79)	22 (88)
Febrile Neutropenia	0 (0)	0 (0)
Neutropenia NCI CTCAE Grade 4**	6 (43)**	12 (48)**

* AEs based on laboratory values (as applicable)

** For the first treatment cycle and for all treatment cycles

Enrollment in the dose optimization part of the Phase 1b trial, in which (ALRN-6924 is administered 24 hours before each dose of topotecan), is complete, and monitoring is ongoing with four of the evaluable patients continuing treatment past the data cut-off date.

The Company continues to enroll patients in a schedule optimization part of the Phase 1b trial intended to determine whether ALRN-6924 given six hours prior to topotecan could be an alternative dosing schedule that could provide patients and healthcare providers with additional flexibility as to when to administer ALRN-6924 before topotecan. The Company plans to report the final data for the Phase 1b trial, including data from the 6 hour-schedule part, in the first quarter of 2021.

In the fourth quarter of 2020, the Company plans to initiate a study of ALRN-6924 in healthy volunteers to characterize the time to onset, and the magnitude and duration of cell cycle arrest in human bone marrow relative to ALRN-6924 administration. Subject to the results of the healthy volunteer study and the final data from the Phase 1b trial, the Company expects to initiate a clinical program in patients with non-small cell lung cancer beginning with a Phase 1b trial in the fourth quarter of 2021 and a development program in a gastrointestinal cancer indication at a later point in time. The Company does not currently plan to conduct additional development of ALRN-6924 in patients with SCLC.

Forward-Looking Statements

Statements in this report [and Exhibit 99.1] 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 June 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 and Exhibit 99.1 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

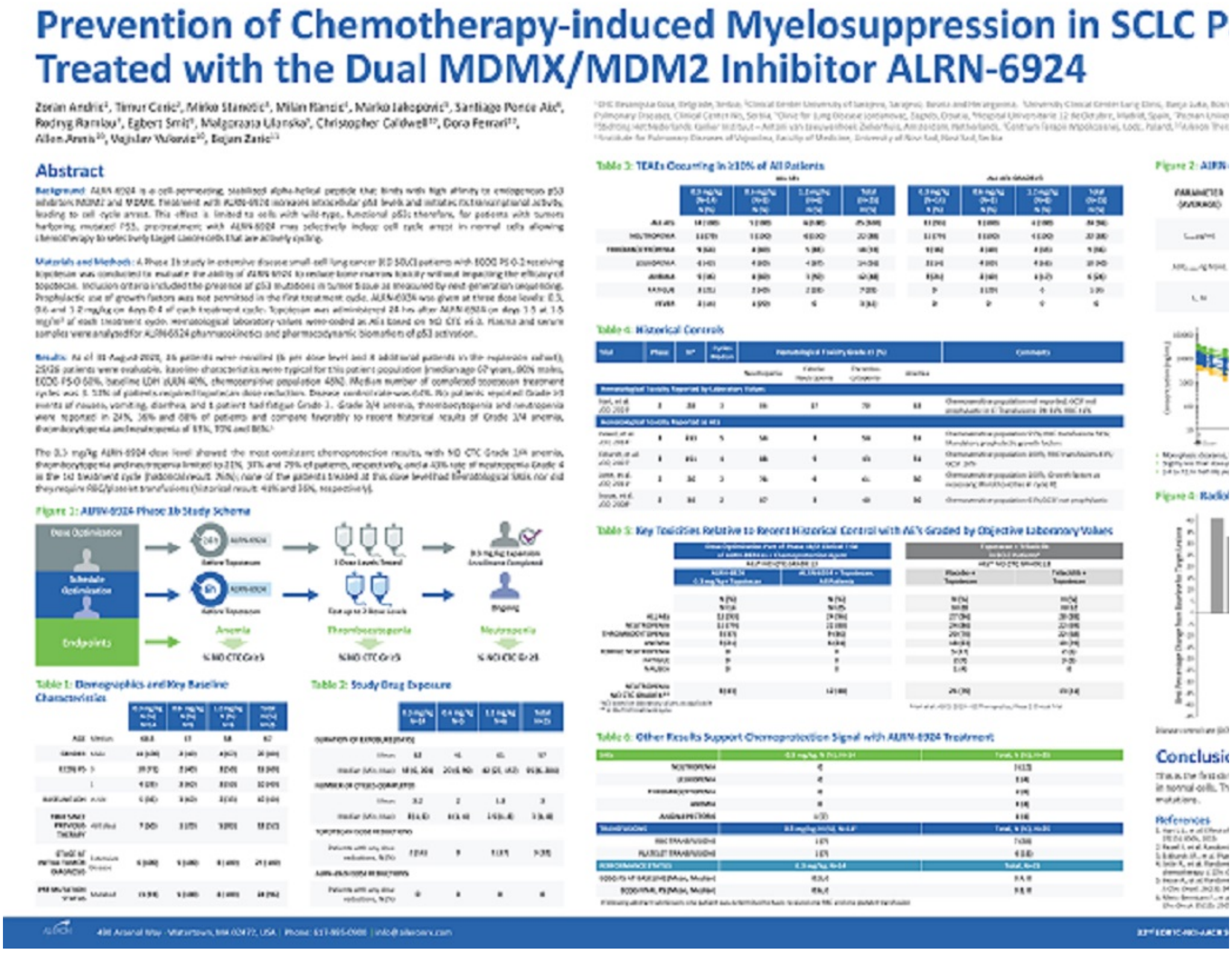
Exhibit No.	Description
99.1	Poster titled “Prevention of Chemotherapy-induced Myelosuppression in SCLC PatientsTreated with the Dual MDMX/MDM2 Inhibitor ALRN-6924”

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: October 26, 2020	By: /s/ Richard J. Wanstall Richard J. Wanstall Chief Financial Officer and Treasurer



Prevention of Chemotherapy-induced Myelosuppression in SCLC P
Treated with the Dual MDMX/MDM2 Inhibitor ALRN-6924

Zoran Andric[1], Timur Ceric[2], Mirko Stanetic[3], Milan Rancic[4], Marko Jakopovic[5], Santiago Ponce Aix[6], Rodryg Ramlau[7], Egbert Smit[8], Malgorzata Ulanska[9], Christopher Caldwell[10], Dora Ferrari[10], Allen Annis[10], Vojislav Vukovic[10], Bojan Zaric[11]

Abstract

Background:

Materials and Methods:

Results:

Figure 1: ALRN-6924 Phase 1b Study Scheme

Table 1: Demographics and Key Baseline Characteristics

Table 2: Study Drug Exposure

Table 3: TEAEs Occurring in ≥10% of All Patients

Table 4: Historical Controls

Table 5: Key Toxicities Relative to Recent Historical Control with AE's Graded by Objective Laboratory Values

Table 6: Other Results Support Chemoprotection Signal with ALRN-6924 Treatment

Figure 2: ALRN

Figure 4: Radio

Conclusio

References

480 Arsenal Way · Watertown, MA 02472, USA | Phone: 617-995-0900 | info@aileronrx.com