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 1, 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, 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	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 June 1, 2020, Aileron Therapeutics, Inc., or the Company, posted a presentation of interim results from the Phase 1b dose-optimization part of its ongoing Phase 1b/2 clinical trial of ALRN-6924 in patients with small cell lung cancer, or SCLC, being treated with topotecan on the "Investors & Media" section of the Company's website (www.aileronrxcom). The information contained in, or that can be accessed through, the Company's website, including the presentation, is not incorporated by reference in this Item 7.01.

Item 8.01 Other Events.

On June 1, 2020, the Company announced positive interim data from the open-label Phase 1b dose optimization part of its ongoing Phase 1b/2 clinical trial. In this trial, ALRN-6924 is being evaluated as an agent to protect patients against chemotherapy-induced toxicity, a concept known as chemoprotection (or myelopreservation). Patients in the trial have advanced, p53-mutated SCLC and are being treated with second line topotecan following administration of ALRN-6924. 18 patients were enrolled across three ALRN-6924 dose levels (0.3 mg/kg, 0.6 mg/kg and 1.2 mg/kg) in the dose optimization part of the trial and 17 patients completed the first treatment cycle and therefore met protocol-defined criteria for evaluability. A protective effect against severe chemotherapy-induced anemia and thrombocytopenia was observed across all dose levels as compared to historical controls. In addition, patients treated with 0.3 mg/kg ALRN-6924 met the protocol-defined criteria for reduction of National Cancer Institute's Common Toxicology Criteria, or NCI CTC, Grade 3/4 neutropenia to £ 50% in the first treatment cycle.

Key findings from the interim analysis of the Phase 1b dose optimization part of the trial are as follows:

- Patients treated with 0.3 mg/kg ALRN-6924 showed the lowest rate of NCI CTC Grade 3/4 hematological adverse events, including 17% with anemia, 33% with thrombocytopenia and 67% with neutropenia, across all treatment cycles.
- None of the patients treated at 0.3 mg/kg dose level required transfusions of red blood cells or platelets. The expansion of the 0.3 mg/kg ALRN-6924 dose level from six to a total of 14 patients is underway.
- Across all dose levels patients showed NCI CTC Grade 3/4 hematological adverse events, including 24% with anemia, 35% with thrombocytopenia and 88% with neutropenia.
- Across all dose levels, no patients experienced febrile neutropenia or NCI CTC Grade 3/4 nausea, vomiting, diarrhea or fatigue, which are severe toxicities commonly observed with topotecan treatment in this patient population.

The key interim results from the Phase 1b dose optimization part of the trial as of the data cut-date of May 13, 2020 are shown in the table below. Three 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 doses) + Topotecan 1.5 mg/m2**
Adverse Events* NCI CTC Grade ³3	N (%) N=6	N (%) N=17
All AEs	5 (83)	16 (94)
Neutropenia	4 (67)	15 (88)
Leukopenia	2 (33)	9 (53)
Thrombocytopenia	2 (33)	6 (35)
Anemia	1 (17)	4 (24)
Fatigue	—	—
Nausea	—	—
Neutropenia NCI CTC Grade 4**	2 (33)	8 (47)

* Based on laboratory values (as applicable); all AEs presented are treatment-emergent AEs

** In the first treatment cycle

The full interim data announced by the Company are set forth on the slides filed as Exhibit 99.1 to the report, which are incorporated herein by reference.

The Phase 1b portion of the trial is designed to identify a dose and a schedule of ALRN-6924 administration to reduce chemotherapy toxicities such as severe anemia and thrombocytopenia, and other toxicities resulting from topotecan. In the ongoing dose optimization part of the study, ALRN-6924 is administered 24 hours before each dose of topotecan, which is administered daily on days 1 through 5 of every 21-day treatment cycle.

The Company is enrolling patients into the expansion cohort of its 0.3 mg/kg dose level and plans to initiate enrollment in the schedule optimization part of the Phase 1b/2 trial in June 2020.

As previously reported, the Company plans to report the top-line final data for the dose optimization and schedule optimization parts of the trial in the fourth quarter of 2020. The Company expects that these results will determine a recommended ALRN-6924 dose and schedule for subsequent trials.

The Company also plans to initiate a trial of ALRN-6924 in healthy human volunteers to develop a universal dosing regimen for ALRN-6924 for use as a cell cycle arresting agent across a range of additional chemotherapies and tumor indications. Subject to the results of this study and data from the dose- and schedule-optimization trials, and obtaining sufficient funding, the Company expects to initiate a Phase 2 randomized, placebo-controlled clinical trial in second-line SCLC in the first quarter of 2021 and a Phase 1b clinical trial in non-small cell lung cancer and in an additional cancer indication in the second quarter of 2021.

The Company is carefully monitoring the effect of the coronavirus pandemic on its clinical trial sites and the healthcare system, which may impact the future timing of the trial and the Company's planned data announcements.

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 results obtained in preclinical and nonclinical studies and clinical trials will be indicative of results obtained in future clinical trials; whether preliminary or interim results from a clinical trial such as the interim results presented will be indicative of the final results of the trial; whether 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 warrant submission for approval from the United States Food and Drug Administration or equivalent foreign regulatory agencies; whether 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; whether the coronavirus pandemic will have an impact 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, 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	Selected slides from presentation titled “Interim Results from a Phase 1b/2 Study of ALRN-6924 as a Chemoprotection Agent” dated June 1, 2020

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 1, 2020

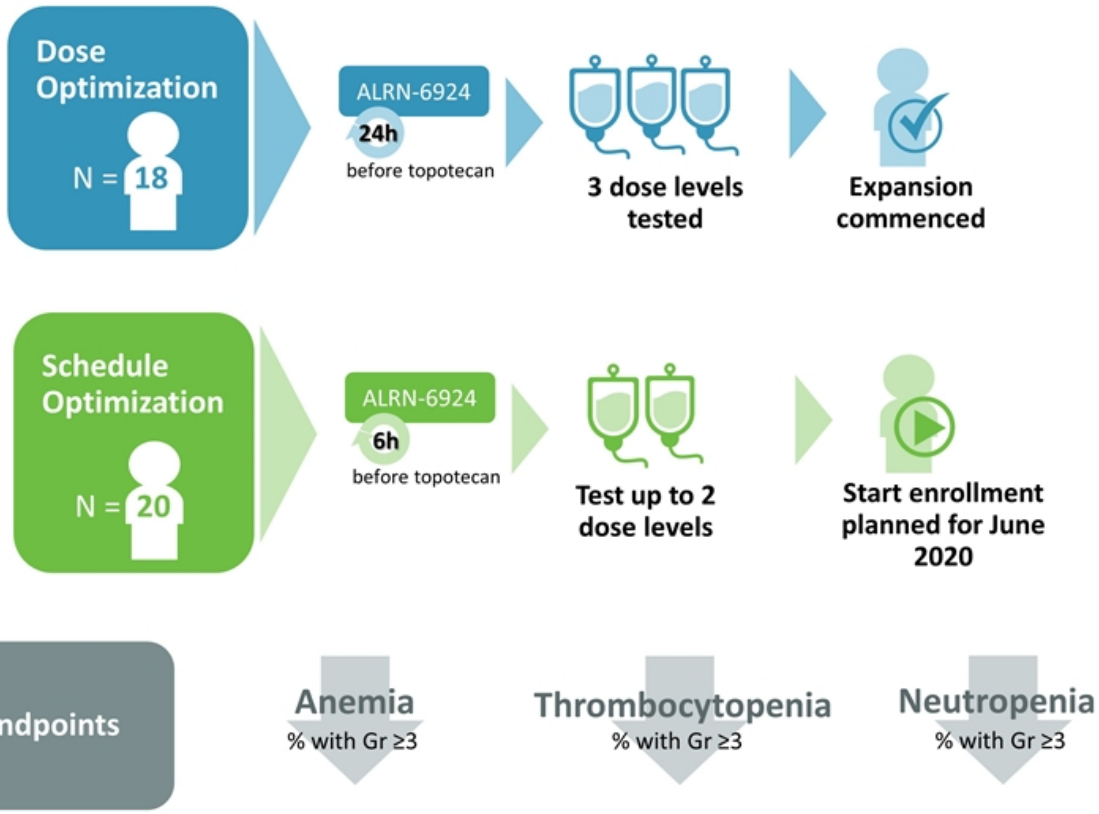
By: /s/ Richard J. Wanstall
Richard J. Wanstall
Chief Financial Officer and Treasurer

Exhibit 99.1

AILERON

Interim data from Phase 1b dose optimization trial

ALRN-6924: Ongoing Ph1b Clinical Trial in Small Cell Lung Cancer Patients Receiving Topotecan



Demographics and Key Baseline Characteristics

		0.3 mg/kg N (%) N=6	0.6 mg/kg N (%) N=5	1.2 mg/kg N (%) N=6	Total N (%) N=17
Age	Median	69.5	67	58	65
	Mean	66	64.4	59.5	63.2
Gender	Male	6 (100)	2 (40)	4 (67)	12 (71)
ECOG PS	0	6 (100)	2 (40)	3 (50)	11 (65)
	1	-	3 (60)	3 (50)	6 (35)
Baseline LDH	≥ULN	2 (33)	3 (60)	2 (33)	7 (41)
Time since previous therapy	<60 days	3 (50)	1 (20)	5 (83)	9 (53)
Stage at initial tumor diagnosis	Extensive Disease	6 (100)	5 (100)	6 (100)	17 (100)
p53 mutation status	Mutated	6 (100)	5 (100)	6 (100)	17 (100)

Data cutoff for interim analysis of the dose optimization part of the trial 5/13/2020; 3 patients on-going

Study Drug Exposure

	0.3 mg/kg N=6	0.6 mg/kg N=5	1.2 mg/kg N=6	Total N=17
Duration of exposure (days)				
Mean (SD)	49	41	61	51
Median (Min, Max)	31 (6, 103)	27 (6, 90)	42 (27, 157)	28 (6, 157)
Number of cycles completed				
Mean (SD)	2.8	2	3.3	2.8
Median (Min, Max)	2 (1, 5)	1 (1, 4)	2.5 (1, 8)	2 (1, 8)
Topotecan Dose Reductions				
Patients with any dose reductions (N, %)	-	-	1 (17)	1 (6)
ALRN-6924 Dose Reductions				
Patients with any dose reductions (N, %)	-	-	-	-

Safety: Key Adverse Events (AEs)*

	All AEs				AEs Grade ≥3			
	0.3 mg/kg N (%) N=6	0.6 mg/kg N (%) N=5	1.2 mg/kg N (%) N=6	Total N (%) N=17	0.3 mg/kg N (%) N=6	0.6 mg/kg N (%) N=5	1.2 mg/kg N (%) N=6	Total N (%) N=17
All AEs	5 (83)	5 (100)	6 (100)	16 (94)	5 (83)	5 (100)	6 (100)	16 (94)
Neutropenia	4 (67)	5 (100)	6 (100)	15 (88)	4 (67)	5 (100)	6 (100)	15 (88)
Leukopenia	4 (67)	4 (80)	3 (50)	11 (65)	2 (33)	4 (80)	3 (50)	9 (53)
Thrombocytopenia	4 (67)	4 (80)	5 (83)	13 (76)	2 (33)	2 (40)	2 (33)	6 (35)
Anemia	1 (17)	4 (80)	3 (50)	8 (47)	1 (17)	2 (40)	1 (17)	4 (24)
Fatigue	2 (33)	1 (20)	2 (33)	5 (29)	-	-	-	-
ALT increased	1 (17)	-	-	1 (6)	-	-	-	-
Creatinine increased	-	1 (20)	-	1 (6)	-	-	-	-
LDH increased	-	1 (20)	-	1 (6)	-	-	-	-
Bilirubin increased	1 (17)	-	-	1 (6)	1 (17)	-	-	1 (6)
Hyperkalemia	-	1 (20)	-	1 (6)	-	1 (20)	-	1 (6)
Lymphopenia	-	-	1 (17)	1 (6)	-	-	1 (17)	1 (6)
Nausea	1 (17)	-	-	1 (6)	-	-	-	-

*All AEs presented are treatment emergent

Other Results

SAEs

SAE	0.3 mg/kg N (%) N=6	0.6 mg/kg N (%) N=5	1.2 mg/kg N (%) N=6	Total* N (%) N=17
Neutropenia	-	1 (20)	2 (33)	3 (18)
Leukopenia	-	-	2 (33)	2 (12)
Thrombocytopenia	-	-	2 (33)	2 (12)
Anemia	-	-	2 (33)	2 (12)
Febrile neutropenia	-	-	-	-

* Total of 9 SAE's in 3 patients

Transfusions

	0.3 mg/kg N=6	0.6 mg/kg N=5	1.2 mg/kg N=6	Total N=17
RBC transfusions (% of patients, N of transfusions)	-	3 (60)	3 (50)*	6 (35)
Platelet transfusions (% of patients, N of transfusions)	-	2 (40)	1 (17)	3 (18)

*One patient received multiple RBC transfusions with Hb NCI CTC Grade 2

Performance Status

	0.3 mg/kg N=6	0.6 mg/kg N=5	1.2 mg/kg N=6	Total N=17
ECOG PS at baseline (Mean, Median)	0, 0	0.5, 0.5	0.5, 0.5	0.3, 0
ECOG final PS (Mean, Median)	0, 0	1, 1	0.5, 0.7	0.6, 0