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): March 18, 2022

Allena Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE	001-38268	45-2729920
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

One Newton Executive Park, Suite 202 Newton, Massachusetts	02462
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code (617) 467-4577

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:

☐ 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 or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	**ALNA**	**The 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.

As previously planned, the first of two planned Sample Size Reestimations (SSR1) of the Phase 3 URIROX-2 Trial for the development of reloxaliase for patients with enteric hyperoxaluria has been conducted by an independent data safety monitoring board (DSMB) statistician. SSR1 is designed to assess the effect of reloxaliase vs. placebo on the reduction of urinary oxalate (UOx) levels over the first 28 days of the trial, the primary endpoint to support a potential accelerated approval filing. The trial has been initially sized at 200 subjects, which would provide more than 90% power for the primary UOx endpoint based on an assumption of a 15% greater effect size of reloxaliase over placebo. The DSMB was provided with data for the first 78 subjects enrolled in the trial. Based on the results of its unblinded analysis, the DSMB has recommended that the trial size be increased from the initial 200 subjects to the maximum allowed number of 400 subjects under the pre-specified rules. However, even with this maximum recommended sample size increase, the power to detect an effect of reloxaliase vs. placebo would still be less than 80% based on the available data. Based upon this recommendation, the company believes that the separation between the reloxaliase and placebo groups for the UOx primary endpoint is lower than expected, and therefore that the likelihood of success for the long term endpoint of reduction in kidney stone disease progression is also lower than expected. As such, the company has decided to terminate the URIROX-2 study and plans to promptly initiate the process of closing the study with the CRO, investigative sites, patients, and business partners. The company thanks the patients, investigative sites, clinical investigators and their staffs for their participation in this study. No further clinical studies of reloxaliase are planned at this time.

Subject to reaching agreement on satisfactory payment terms with the contract research organization assisting in the conduct of the trial, the company intends to continue its second clinical program ALLN-346, in Phase 2a development with FDA Fast-Track designation for the treatment of hyperuricemia in patients with gout and chronic kidney disease. We are currently enrolling patients in two Phase 2a studies for the program: Study 201, a 7-day inpatient study in patients with hyperuricemia, and Study 202, a 14-day outpatient study in patients with hyperurcemia, gout, and chronic kidney disease. However, the company has limited financial resources, and there can be no assurance that these trials will be completed, or if completed, that they will be successful.

As previously disclosed, the company is pursuing a process to explore a range of strategic and financing alternatives to maximize shareholder value and has engaged the investment bank Stifel, Nicolaus & Company, Incorporated (“Stifel”) to act as a strategic advisor for this process. As a result of the company’s decision to terminate the development of reloxaliase, the company and Stifel now plan to focus their efforts on ALLN-346. However, there can be no assurance that this strategic review process will result in the Company pursuing any transaction or that any transaction, if pursued, will be completed. The Company has not set a timetable for completion of this strategic review process, and the Company does not intend to comment further unless or until its Board of Directors has approved a definitive course of action, the review process is concluded, or it is determined other disclosure is appropriate.

Of note, the failure to obtain sufficient additional funds on commercially acceptable terms to fund the company’s operations may have a material adverse effect on the company’s business, results of operations and financial condition and jeopardize the company’s ability to continue operations in the near-term. The company will likely need to consider additional cost reduction strategies, which may include, among others, amending, delaying, limiting, reducing, or terminating the development program for ALLN-346, and the company may need to seek an in-court or out-of-court restructuring of its liabilities. In the event of such future bankruptcy proceeding, holders of the company’s common stock and other securities will likely suffer a total loss of their investment.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 18, 2022

Allena Pharmaceuticals, Inc.

By: /s/ Richard Katz
Richard D. Katz, M.D.
Chief Financial Officer