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 8, 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 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 Stock 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 2.02. Results of Operations and Financial Condition.

The disclosure set forth in Item 8.01 regarding the Company's approximate cash and cash equivalents as of June 30, 2022 (the "Financial Information"), is incorporated herein by reference. The Financial Information is unaudited and does not present all information necessary for an understanding of the Company's financial condition as of June 30, 2022 or its results of operations for the three or six months ended June 30, 2022.

Item 8.01. Other Events.

Allena Pharmaceuticals, Inc. Provides Clinical and Corporate Update

On July 8, 2022, Allena Pharmaceuticals, Inc. (the "Company") provided the following update on certain clinical and corporate matters.

Clinical Update on ALLN-346

Our product candidate ALLN-346 is an orally administered, novel, urate degrading enzyme for patients with hyperuricemia and gout in the setting of advanced chronic kidney disease (CKD). We have conducted a Phase 1 program, including both a single-ascending dose and multiple-ascending dose study in healthy volunteers. In both studies, ALLN-346 was well tolerated with no clinically significant safety signals and no dose-limiting toxicities observed in any cohort up to the highest administered dose. We are currently conducting two Phase 2a studies. Study 201 is a 7-day inpatient study in patients with hyperuricemia, for which we reported preliminary topline data in January 2022.

Study 202 is a 14-day outpatient study in patients with hyperuricemia, gout and varying degrees of renal insufficiency. In this study, patients are randomized (2:1) to receive either five capsules of ALLN-346 or a matching placebo three times daily, with enrollment of up to four planned cohorts, each consisting of approximately 12 patients. Cohort A is comprised of patients considered to have Stage 2, or mild CKD, and cohort B is comprised of patients considered to have Stage 3, or moderate CKD. We currently expect to announce preliminary topline from these two cohorts during the third quarter of 2022.

If we successfully complete Cohorts A and B of Study 202 and are able to secure adequate additional financing, we plan to open two additional cohorts in Study 202 later in 2022, consisting of patients with Stage 4, or advanced CKD (Cohort C), and an allopurinol combination therapy cohort in Stage 3 CKD patients (Cohort D). If we successfully complete Cohorts A and B of Study 202 and are able to secure adequate additional financing, we currently expect that we would be in a position to announce preliminary topline data from the first group of patients treated in these two cohorts by early 2023.

Update on Our Loan Agreement With Pontifax

We are party to a loan and security agreement with Pontifax Medison Finance (Israel) L.P. and Pontifax Medison Finance (Cayman) L.P. (together "Pontifax") ("Pontifax Agreement") providing up to $25.0 million of borrowings through three facilities of a term loan. An initial loan of $10.0 million was advanced on September 29, 2020. The borrowings under the Pontifax Agreement are secured by a lien on substantially all of our assets except intellectual property. The Pontifax Agreement contains customary representations, warranties and covenants.

As previously disclosed, because of our limited cash resources and the recent termination of our Phase 3 clinical trial of reloxaliase, we have had discussions with Pontifax, regarding the potential repayment of our outstanding borrowing under our loan agreement with Pontifax. In March 2022, we made voluntary repayments of $2.0 million and $3.0 million, reducing the loan balance to $5.0 million in principal.

In July 2022, we received written demand from Pontifax to move all of our cash and cash equivalents into accounts that are subject to existing account control agreements between Pontifax and us, or enter into new account control agreements which would provide Pontifax with control over all of our cash and cash equivalents. These discussions are ongoing.

The obligations under the Pontifax Agreement are subject to acceleration upon occurrence of specified events of default, including a material adverse change in our business, operations or financial or other condition. As previously disclosed, due to our current financial and operating position, we have classified the Pontifax loan balance as a current liability on our balance sheet.

Update on Our Financial Position

We have identified conditions and events that raise substantial doubt about our ability to continue operations in the near-term. We may need to seek an in-court or out-of-court restructuring of our liabilities.

We may be forced to amend, delay, limit, reduce or terminate the scope of our development program for ALLN-346 and/or limit or cease our operations if we are unable to obtain additional funding. As of June 30, 2022, we had cash and cash equivalents totaling approximately $6.6 million. We do not believe that our cash and cash equivalents as of June 30, 2022 will enable us to fund our operating expenses and capital requirements beyond the next several weeks. We will need to raise additional capital to continue as a going concern. In addition to the ongoing discussions with our senior lender, Pontifax, described above, we are in discussions with the contract research organization that conducted our reloxaliase clinical trial and is currently conducting our clinical trial for ALLN-346 about our inability to repay outstanding obligations due to them, which discussions may lead to the contract research organization ceasing further work on ALLN-346. Additionally, we have significant payment obligations to the clinical sites that participated in our URIROX-2 trial. Adequate additional financing may not be available to us on acceptable terms, or at all. The failure to obtain sufficient additional funds on commercially acceptable terms to fund our operations and satisfy our obligations to creditors may have a material adverse effect on our business, results of operations and financial condition and jeopardize our ability to continue operations in the near-term. Unless we can raise additional capital to fund operations, we will need to implement additional cost reduction strategies, which may include, among others, amending, delaying, limiting, reducing, or terminating the development program for ALLN-346, and we may need to seek an in-court or out-of-court restructuring of our liabilities. In the event of such future restructuring activities, holders of the company's preferred stock, common stock and other securities will likely suffer a total loss of their investment.

Forward-Looking Statements

This Current Report on Form 8-K release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, without limitation, statements concerning the future clinical, regulatory and commercial potential of ALLN-346; statements regarding Allena's development of ALLN-346 including the timing of planned clinical trials and the announcement of topline data for these trials; and statements regarding Allena's financial position and need for capital. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Additional risks and uncertainties include, but are not limited to: market and other conditions, the timing for completion of Allena's clinical trials of its product candidates, risks associated with obtaining, maintaining and protecting intellectual property; risks associated with Allena's ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; the risk of competition from other companies developing products for similar uses; risks associated with Allena's financial condition and its need to obtain additional funding to support its business activities, including the future clinical development of ALLN-346, and its ability to continue as a going concern; risks associated with Allena's dependence on third parties; risks related to the COVID-19 coronavirus; risks associated with Allena's ability to identify and consummate financing and strategic alternatives that yield additional value for shareholders; the timing, benefits and outcome of the Allena's strategic alternatives review process, including the determination of whether or not to pursue or consummate any strategic alternative, the structure, terms and specific risks and uncertainties associated with any potential strategic transaction, potential disruptions in Allena's business and stock price as a result of its exploration, review and pursuit of strategic alternatives or the public announcement thereof and any decision or transaction resulting from such review. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Allena's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Allena's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, as well as discussions of potential risks, uncertainties and other important factors in Allena's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Allena undertakes no duty to update this information unless required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
104	Cover Page Interactive Data File (Embedded within the Inline XBRL Document).

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: July 8, 2022

Allena Pharmaceuticals, Inc.

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