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): September 29, 2021

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 Global Select 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 Information

On September 29, 2021, Allena Pharmaceuticals, Inc. issued a press release to report that it has dosed the first patient in a second Phase 2a trial of ALLN-346, a novel, orally-administered, urate-degrading enzyme in development for the treatment of gout in patients with chronic kidney disease. A copy of the press release is filed herewith as Exhibit 99.1 to this Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Allena Pharmaceuticals, Inc., dated September 29, 2021.
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: September 29, 2021

Allena Pharmaceuticals, Inc.

By: /s/ Richard Katz
Richard Katz
Chief Financial Officer

Exhibit 99.1

Allena Pharmaceuticals Commences Dosing of Gout Patients in Second Phase 2a Trial of ALLN-346

- Fourteen-day study focused on high unmet need in patients with gout and chronic kidney disease-

- Novel therapeutic candidate targets uric acid in the GI tract –

- Initial data expected in late 2021 or early 2022 -

NEWTON, Mass., September 29, 2021 – Allena Pharmaceuticals, Inc. (NASDAQ: ALNA) ("Allena" or the "Company"), a late-stage biopharmaceutical company deploying its novel oral biologic platform to discover, develop and commercialize first-in-class, oral enzyme therapeutics for difficult-to-treat metabolic diseases, today reported that it has dosed the first patient in a second Phase 2a trial of ALLN-346 (the ALLN-346 202 Trial), a novel, orally-administered, urate-degrading enzyme in development for the treatment of gout in patients with chronic kidney disease (CKD). The Phase 2a program, comprised of this two-week outpatient trial and a one-week inpatient trial currently being conducted in a clinical pharmacology unit, is designed to assess initial bioactivity data and additional safety data for ALLN-346, the second orally delivered, non-absorbed enzyme developed using Allena's proprietary oral enzyme technology platform.

"We are pleased to initiate our second trial in the Phase 2a program for ALLN-346," noted Louis Brenner, M.D., President and Chief Executive Officer of Allena. "In gout patients with chronic kidney disease, the GI tract becomes the primary route of elimination for uric acid, and ALLN-346 is specifically designed to capitalize on this physiologic adaptation by enhancing the breakdown and excretion of uric acid in the GI tract. Currently available agents are either dose-limited or contraindicated in this challenging patient population due to safety and tolerability concerns. We have been very pleased with the results from the Phase 1 studies, in which ALLN-346 was well-tolerated with no safety signals observed."

Dr. Brenner added, "We look forward to reporting initial data from this study, as well as initial data from our ongoing seven-day inpatient study in subjects with hyperuricemia, beginning in late 2021 or early 2022. As we evaluate the initial data from the Phase 2a program, we will potentially study additional patients to assist us in determining the optimal dosing paradigm and target population for later stage clinical trials."

About the Phase 2a Program for ALLN-346

The Phase 2a trial (Study 202) announced today is an outpatient study expected to enroll 24 hyperuricemic patients with gout and mild-to-moderate chronic kidney disease. Patients are to be randomized (2:1) to receive either five capsules of ALLN-346 or matching placebo, three times daily, during a two-week treatment period. Of the two

cohorts of 12 patients each, the first cohort will consist of patients with an eGFR (estimated glomerular filtration rate) of 60-89 mls/minute, and the second will consist of patients with an eGFR of 30-59 mls/minute.

The other Phase 2a trial (Study 201), initiated in July, is a one-week study conducted in a clinical pharmacology unit (CPU) setting enrolling patients with hyperuricemia. Patients are randomized (2:1) to receive either ALLN-346 or matching placebo. Dosing of ALLN-346 for the initial cohort of approximately 12 patients is five capsules of ALLN-346 three times daily, with the dose level of ALLN-346 for any additional cohorts to be determined based upon data from the first cohort.

For both studies, key bioactivity endpoints will include measurements of serum uric acid and urine uric acid. Both studies will also assess safety and tolerability in the hyperuricemia, gout and chronic kidney disease patient populations.

Potential for ALLN-346 to Address the Underserved Gout Treatment Landscape

In June, the Company hosted a KOL webinar highlighting the treatment paradigms and also limitations of existing gout therapies with key opinion leader (KOL), Robert Terkeltaub, M.D., Professor of Medicine at the University of California San Diego School of Medicine and Section Chief of Rheumatology at the Veterans Administration Medical Center in San Diego (a replay of the webinar can be found here). Managing gout in the setting of advanced chronic kidney disease remains a significant challenge for clinicians because currently available agents are either dose-limited or contraindicated in these patients. There are approximately 500,000 patients with gout and advanced chronic kidney disease in the United States.

About ALLN-346

ALLN-346 is an investigational first-in-class, non-absorbed, orally administered enzyme for the treatment of hyperuricemia and gout, a metabolic disorder characterized by high systemic levels of uric acid that can lead to several complications, including arthritis, kidney stones, and chronic kidney disease.

Allena recently completed a Phase 1b multiple ascending dose study of ALLN-346. The study included 18 healthy volunteers, who received either ALLN-346 or placebo (2:1 randomization) for seven days. There were two cohorts consisting of nine subjects each, with the first receiving three capsules of ALLN-346 three times daily, and the second receiving five capsules of ALLN-346 three times daily. ALLN-346 was well tolerated with no evidence of systemic absorption, as confirmed by an enzyme-linked immunosorbent assay (ELISA). Evaluation of clinical and laboratory parameters revealed no significant safety signals and no serious adverse events were reported.

About Allena Pharmaceuticals

Allena Pharmaceuticals, Inc. is a late-stage biopharmaceutical company leveraging its novel oral biologic platform to discover, develop and commercialize first-in-class, oral enzyme therapeutics for difficult-to-treat metabolic diseases. Allena's lead product candidate, reloxaliase, is currently being evaluated in a pivotal Phase 3 clinical program for the treatment of enteric hyperoxaluria, a metabolic disorder characterized by markedly elevated urinary oxalate levels and commonly associated with kidney stones, chronic kidney disease and other serious kidney disorders. Allena is also developing ALLN-346 for the treatment of hyperuricemia and gout in the setting of advanced chronic kidney disease, with a Phase 1 multiple ascending dose study recently completed and a Phase 2a program recently initiated.

Forward-Looking Statements

This 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 reloxaliase, statements regarding enrollment and the timing of the planned interim analysis in the URIROX-2 trial, the impact of an earlier initial interim analysis on the size and duration of the URIROX-2 trial, statements regarding Allena's strategy of pursuing a BLA submission for reloxaliase based upon data from its URIROX program using the accelerated approval regulatory pathway, which strategy is predicated on the FDA's agreement with our predictive model supporting a relationship between UOx levels and kidney stone formation rates, 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. These 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 reloxaliase and ALLN-346 and its ability to continue as a going concern; risks associated with Allena's dependence on third parties; and risks related to the COVID-19 coronavirus. 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 June 30, 2021, 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.

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