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): November 30, 2020 (November 30, 2020)

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 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. ☒

7.01 Regulation FD Disclosure.

On November 30, 2020, Allena Pharmaceuticals, Inc. ("Allena" or the "Company") issued a press release announcing clinical data from its Phase 1 trial of ALLN-346 in healthy volunteers. A copy of the press release is attached as Exhibit 99.1 hereto.

Additionally, the Company made available an updated copy of its Corporate Presentation on the Investor Relations section of the Company's website. The Corporate Presentation may be used at investor and other meetings. The Company does not intend to incorporate any contents from its website into this Form 8-K.

The information in this Item 7.01 of Form 8-K, including the accompanying Exhibit 99.1, 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 liability of such section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, regardless of the general incorporation language of such filing, except as shall be expressly set forth by specific reference in such filing.

Item 8.01 Other Events.

On November 30, 2020, the Company announced initial data from its Phase 1 Clinical Trial for ALLN-346. The double-blind, placebo-controlled, single-ascending dose study enrolled 24 healthy volunteers. Groups of eight study participants were randomized 3:1 to ALLN-346 or matching placebo in three sequential cohorts dosed orally with three, six, or 12 capsules in one day. Each capsule of ALLN-346 contained a target dose of 90 mg of enzyme, equivalent to 2,250 units. 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. In addition, assay of serum samples by ELISA immunoassay demonstrated that ALLN-346 was not absorbed systemically, supporting that its mechanism of action appears to be restricted to the GI tract.

Subject to feedback from the U.S. Food and Drug Administration, the Company expects to initiate a Phase 1b multiple-ascending dose trial in healthy volunteers and a Phase 2 proof-of-concept trial in patients with hyperuricemia and CKD in the first half of 2021, with initial data from both studies expected in the second half of 2021.

Forward-Looking Statements

This Current Report on Form 8-K (this "Current Report") contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 including, without limitation, statements regarding the clinical data from Allena's Phase 1 trial of ALLN-346; Allena's future development plans for ALLN-346; Allena's pipeline of oral enzyme therapeutic candidates and Allena's plans to build a commercial organization. Any forward-looking statements in this Current Report 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; risk 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 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 Item 1A of Part I of Allena's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, 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 Current Report is as of the date hereof and Allena undertakes no duty to update this information unless required by law.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Press Release issued by Allena Pharmaceuticals, Inc. dated November 30, 2020

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: November 30, 2020

Allena Pharmaceuticals, Inc.

By: /s/ Edward Wholihan
Edward Wholihan
Chief Financial Officer

Allena Pharmaceuticals Announces Initial Data from Phase 1 Trial of ALLN-346

— Single-Ascending Doses of ALLN-346 Oral Enzyme Well-Tolerated —
— Non-Absorption of ALLN-346 Demonstrated —
— Advancing to Phase 1b Multiple-Ascending Dose Study and Phase 2 Proof-of-Concept Trial; Initial Data from Both Studies Expected in Second Half of 2021 —

Newton, Mass., November 30, 2020 — Allena Pharmaceuticals, Inc. (NASDAQ: ALNA), a late-stage, biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders, today announced clinical data from its Phase 1 trial of ALLN-346 in healthy volunteers. ALLN-346 is an investigational, orally administered, novel urate-degrading enzyme that has been designed for activity and stability in the gastrointestinal (GI) tract, and is intended for the treatment of hyperuricemia in patients with gout and chronic kidney disease (CKD).

The double-blind, placebo-controlled, single-ascending dose study enrolled 24 healthy volunteers. Groups of eight study participants were randomized 3:1 to ALLN-346 or matching placebo in three sequential cohorts dosed orally with three, six, or 12 capsules in one day. Each capsule of ALLN-346 contained a target dose of 90 mg of enzyme, equivalent to 2,250 units. 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. In addition, assay of serum samples by ELISA immunoassay demonstrated that ALLN-346 was not absorbed systemically, supporting that its mechanism of action appears to be restricted to the GI tract.

“We are very encouraged by the preliminary safety and tolerability data collected for ALLN-346 in healthy volunteers,” said Louis Brenner, M.D, President and Chief Executive Officer of Allena. “While there are several classes of approved therapies to treat hyperuricemia and gout, all have significant limitations in the CKD population due to toxicity-related concerns, dose limitations, and contraindications. We specifically designed ALLN-346 to overcome these challenges, using our proprietary platform to create a stable oral enzyme that is intended to act via the gut-kidney axis, degrading urate in the GI tract and reducing the systemic and metabolic burden of urate on the kidneys. The results announced today support our belief in ALLN-346’s gut-restricted mechanism of action and support its further development as a scientifically-driven therapeutic candidate for the approximately 375,000 people living with gout and moderate-to-severe CKD. We are now preparing to advance ALLN-346 into separate Phase 1b multiple-ascending dose and Phase 2 clinical studies, and look forward to further progress, including potential proof-of-concept data, in 2021.”

Subject to feedback from the U.S. Food and Drug Administration, Allena expects to initiate a Phase 1b multiple-ascending dose trial in healthy volunteers and a Phase 2 proof-of-concept trial in patients with hyperuricemia and CKD in the first half of 2021, with initial data from both studies expected in the second half of 2021.

About Hyperuricemia

Hyperuricemia, or elevated levels of uric acid in the blood, results from overproduction or insufficient excretion of urate, or often a combination of the two. Hyperuricemia is associated with gout, a kind of arthritis caused by excess uric acid in the blood that leads to the formation of hard crystals in the joints. Hyperuricemia can also lead to increased uric acid excretion in the urine and subsequently to kidney stone formation and kidney damage also known as urate nephropathy. In addition, hyperuricemia has been linked to hypertension, CKD, glucose intolerance, dyslipidemia, insulin resistance and obesity.

CKD patients with hyperuricemia and gout are often not optimally managed due to limitations of available therapies, including decreased tolerability, dose restrictions, drug-drug interactions, and contraindications. According to a published study, there are approximately 375,000 patients in the United States with hyperuricemia and CKD on urate lowering therapy who have uncontrolled gout.[1]

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1 Lim, J., Fu, A., Reasner, D. & Taylor, D. (2017, April). *Prevalence of CKD and Uncontrolled Gout Among US Adults: Results From NHANES 2007–2012*. Poster presented at the National Kidney Foundation Spring Clinical Meetings, Orlando, FL.

About ALLN-346

ALLN-346 is an investigational, orally administered, novel, engineered urate oxidase that has been optimized for stability in the GI tract and high production yield. Allena has designed ALLN-346 to degrade urate in the GI tract and in turn, reduce the urate burden on the kidney and lower the risk of urate-related complications. ALLN-346 is targeted to lower serum uric acid in patients with CKD, whose renal function is decreased and who have diminished capacity for urinary excretion of uric acid.

About Allena Pharmaceuticals

Allena Pharmaceuticals, Inc. is a late-stage biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. 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 in the setting of gout and advanced chronic kidney disease, with a Phase 1b multiple-ascending dose study and a Phase 2 proof-of-concept study planned for 2021.

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 regarding the clinical data from Allena's Phase 1 trial of ALLN-346; Allena's future development plans for ALLN-346; Allena's pipeline of oral enzyme therapeutic candidates and Allena's plans to build a commercial organization. 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; risk 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 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 Item 1A of Part I of Allena's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, 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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