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): October 22, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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

On October 22, 2018, Allena Pharmaceuticals, Inc. issued a press release announcing preclinical proof-of-concept data for ALLN-346, its lead product candidate for hyperuricemia and gout in the setting of advanced chronic kidney disease. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein in its entirety by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Allena Pharmaceuticals, Inc., dated October 22, 2018.

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: October 22, 2018

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

Allena Pharmaceuticals Presents Preclinical Data Demonstrating Normalized Urine Uric Acid Excretion and Plasma Urate Reduction Following Treatment with ALLN-346

– Data Presented in Poster Session at 2018 ACR/ARHP Annual Meeting –

NEWTON, Mass., October 22, 2018 -- 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 preclinical proof-of-concept data for ALLN-346, its lead product candidate for hyperuricemia and gout in the setting of advanced chronic kidney disease (CKD). The data were presented in a poster session on Monday, October 22, 2018 at the 2018 American College of Rheumatology (ACR/ARHP) Annual Meeting in Chicago, IL.

The poster presentation includes data demonstrating urate reduction in a urate oxidase knock-out mouse model, an animal model of severe hyperuricemia with kidney damage due to urate crystal deposition. After one week of treatment, mice treated with ALLN-346 achieved a substantial reduction in urate burden on the kidney, as evidenced by normalization in urine uric acid and a significant reduction in plasma urate.

"We are excited to report preclinical proof-of-concept for ALLN-346, our enzyme designed to degrade urate in the gastrointestinal tract, and thereby limit the burden on the kidneys over time," said Alexey Margolin, Ph.D., Chief Executive Officer of Allena Pharmaceuticals. "Based on these data, we are working expeditiously to finish our preclinical program for ALLN-346 and scale our manufacturing processes for clinical studies. We expect to file an investigational new drug application with the U.S. Food and Drug Administration in 2019, as we continue to execute on our mission of advancing a product pipeline to address severe metabolic and kidney-related disorders."

Hyperuricemia results from the overproduction and/or insufficient excretion of uric acid, and is a significant predisposing condition for gout. Increased uric acid excretion in the urine and hyperuricemia are also associated with kidney stone formation and kidney damage. Patients with renal impairment who have 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 recent study, there are approximately 375,000 patients with hyperuricemia and CKD on urate lowering therapy who have uncontrolled gout.[1]

"Patients with moderate to severe CKD who experience hyperuricemia and gout are often not optimally managed with existing therapies, including xanthine oxidase inhibitors and uricosurics, due to poor tolerability, and dose restriction with reduced efficacy," said Robert Terkeltaub, M.D., Professor of Medicine at University of California San Diego and co-investigator for the study. "These preclinical results demonstrate that the underlying physiology of hyperuricemia and the extrarenal pathway for uric acid elimination correspond to the mechanism of ALLN-346, an oral enzyme designed to degrade urate in the gastrointestinal tract. As a result, they suggest that ALLN-346 may provide a new option for reducing the burden of filtered and excreted uric acid on the kidney. We look forward to evaluating the potential of this treatment in human clinical trials."

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.

About ALLN-346

ALLN-346 is an orally administered, novel, engineered urate oxidase that has been optimized for stability in the gastrointestinal (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.

References

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 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 a first in class, oral enzyme therapeutic for the treatment of 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.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding ALLN-346, including the timing of filing the IND. 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. For a discussion of these risks and uncertainties, and other important factors, see the section entitled "Risk Factors" in Item 1A of Part II of Allena's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, 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.

###

Investor Contact
Hannah Deresiewicz
Stern Investor Relations, Inc.
212-362-1200
hannahd@sternir.com

Media Contact
Adam Daley
Berry & Company Public Relations
212-253-8881
adaley@berrypr.com