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): June 19, 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 June 19, 2018, Allena Pharmaceuticals, Inc. issued a press release announcing the completion of an animal proof-of-concept study supporting the selection of ALLN-346 as its lead product candidate for the treatment of hyperuricemia in patients with gout and associated 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 June 19, 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: June 19, 2018

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

Allena Pharmaceuticals Completes Animal Proof-of-Concept Study for ALLN-346, Lead Product Candidate for Hyperuricemia in the Setting of Advanced Chronic Kidney Disease

— ALLN-346, a Novel, Engineered, Urate Oxidase, Demonstrates Robust Reduction of Plasma and Urine Uric Acid After Oral Administration in an Animal Model of Hyperuricemia—

— Data Supports Advancement of ALLN-346 as Allena's Next Product Candidate for the Treatment of Metabolic and Kidney-Related Disorders –

NEWTON, Mass., June 19, 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 the completion of an animal proof-of-concept study supporting the selection of ALLN-346 as its lead product candidate for the treatment of hyperuricemia in patients with gout and associated chronic kidney disease (CKD). Hyperuricemia, or elevated levels of uric acid in the blood, results from overproduction and/or insufficient excretion of uric acid. Hyperuricemia is the major predisposing condition for gout, a disease that most commonly manifests with acute flares of arthritis, and can also lead to chronic arthritis and joint damage and palpable deposits of urate crystals in the skin. Hyperuricemia and increased uric acid excretion in the urine are also associated with kidney stone formation and kidney damage.

ALLN-346 is an orally administered, novel urate oxidase that has been optimized for stability in the gastrointestinal (GI) tract. This proprietary enzyme was designed by Allena 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, who have decreased renal function and diminished capacity for urinary excretion of uric acid.

ALLN-346 has demonstrated a robust reduction in both plasma and urine uric acid levels in an established urate oxidase knock-out mouse model, a severe animal model of hyperuricemia with advanced CKD and kidney damage due to urate crystal deposition. Allena expects to present detailed preclinical data for ALLN-346 at a scientific conference in the second half of 2018. Based on the results of this study, Allena is scaling its manufacturing processes and production yield to support customary toxicology and additional preclinical studies and, consistent with prior guidance, expects to file an IND with the U.S. Food and Drug Administration in the first half of 2019.

"At Allena, we are employing a proprietary technological approach that allows for the design and formulation of oral non-absorbed, stabilized enzymes that degrade a specific metabolite within the GI tract," said Alexey Margolin, Ph.D., Chief Executive Officer of Allena Pharmaceuticals. "We believe this approach is particularly well-suited for the treatment of conditions like hyperuricemia and hyperoxaluria, which are characterized by markedly elevated levels of urate and oxalate in the blood and urine. Our product candidates are designed to reduce GI absorption of these metabolites and accumulation in the kidney, blood and other organ systems. As a result, we seek to reduce the chronic metabolic disease burden over time. We are encouraged by the preclinical data generated with ALLN-346 to-date and look forward to advancing it into the clinic next year, as we execute on our mission of addressing multiple rare and severe metabolic and kidney-related disorders."

Hyperuricemia and gout patients with renal impairment are not optimally managed with existing therapies due to safety concerns, including decreased tolerability to multiple drugs used to treat gout, dose restrictions, drug-drug interactions, contraindications and increased risk for long-term morbidity and mortality. An estimated 375,000 patients in the United States have refractory gout and CKD. Another co-morbidity of gout that is common in this patient population is cardiovascular disease.[1]

"As new data continue to emerge, the limitations associated with current agents used to treat hyperuricemia in gout patients with CKD highlight a major unmet need for new targets and therapeutic approaches," said Dr. Robert Terkeltaub, Professor of Medicine at the University of California San Diego. "The opportunity to therapeutically target GI tract elimination of uric acid with an oral medication is both novel and compelling, representing a

potentially new class of therapeutic beyond our current scope of oral uric acid-lowering drugs. Clinical investigation of ALLN-346 is strongly warranted as an effort to optimize the treatment of refractory hyperuricemia, particularly in patients with gout and CKD."

About Hyperuricemia and Gout

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. Humans lack urate oxidase, an enzyme that degrades uric acid in a wide range of other organisms, including animals, plants, bacteria and fungi. Hyperuricemia can be a predisposing condition for gouty flares, arthritis, kidney stones, and kidney damage, which is also known as urate nephropathy. Hyperuricemia is also intricately linked to various metabolic disorders, including hypertension, CKD, glucose intolerance, dyslipidemia, insulin resistance and obesity. It may also be an independent risk factor for cardiovascular disease.

Gout is a form of inflammatory arthritis caused by excess body uric acid burden. When uric acid levels are too high, hard crystals may form in the joints, causing attacks (flares) of sudden burning pain, stiffness, and swelling. These attacks can be recurrent unless gout is treated. Over time, chronic arthritis can develop, which can damage joints, tendons, and other tissues.

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.

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, ALLN-177, 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 Allena's development and regulatory plans for ALLN-346, including the timing and outcome of additional preclinical studies and any future clinical trials, the timing of filing an IND for this product candidate, as well as statements concerning the development program for Allena's lead product candidate, ALLN-177. 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: the risk that results of earlier studies of Allena's product candidates may not be predictive of future clinical trial results, and planned studies may not establish an adequate safety or efficacy profile for such product candidate that support regulatory approval; risks associated with the fact that Allena has not yet finalized the design of its pivotal Phase 3 clinical program for ALLN-177; 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 ability to manage operating expenses and/or obtain additional funding to support its business activities; and risks associated with Allena's dependence on third parties. 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 II of Allena’s Quarterly Report on Form 10-Q for the quarter ended March 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.

References:

1. Lim JJ, Fu AC, and Reasner D. Prevalence of CKD and Uncontrolled Gout Among US Adults: Results from NHANES 2007-2012. Poster presented at: The National Kidney Foundation Spring Clinical Meetings; April 18-22, 2017; Orlando Florida.

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