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): January 2, 2019

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. ☒

tem 8.01 Other Events.

On January 2, 2019, Allena Pharmaceuticals, Inc. issued a press release reporting that it reached alignment with U.S. Food and Drug Administration on the design of its Phase 3 clinical program and use of the accelerated approval pathway for its lead product candidate, reloxaliase, in enteric hyperoxaluria. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release by Allena Pharmaceuticals, Inc. dated January 2, 2019

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: January 2, 2019

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

Allena Pharmaceuticals Achieves Alignment with FDA on Phase 3 Program and Accelerated Approval Pathway for Reloxaliase in Enteric Hyperoxaluria

-- Primary Efficacy Endpoint of Change in Urinary Oxalate Excretion at Four Weeks --

-- URIROX-2™, Second Pivotal Phase 3 Trial, Initiated in Fourth Quarter of 2018 --

-- URIROX-1™, First Pivotal Phase 3 Trial, Enrolling; Topline Data Expected in Second Half of 2019 --

-- Reloxaliase has Potential to be First FDA-Approved Treatment for Enteric Hyperoxaluria --

NEWTON, Mass., January 2, 2019 – 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 that it has reached alignment with the U.S. Food and Drug Administration (FDA) on both the design of URIROX-2, its second pivotal Phase 3 trial of reloxaliase in patients with enteric hyperoxaluria, and its strategy to pursue a Biologics License Application (BLA) submission for reloxaliase using the accelerated approval regulatory pathway.

Allena's URIROX program consists of two pivotal Phase 3 clinical trials, URIROX-1 and URIROX-2, which are designed to evaluate the safety and efficacy of reloxaliase in patients with enteric hyperoxaluria. URIROX-1 is currently enrolling patients, and Allena initiated URIROX-2 in the fourth quarter of 2018. The primary efficacy endpoint for URIROX-2 is the percent change from baseline in 24-hour urinary oxalate (UOx) excretion measured during Weeks 1-4, the same primary efficacy endpoint as URIROX-1.

"We are very pleased with the outcome of our regulatory interactions and appreciate the FDA's guidance in finalizing the design of our URIROX Phase 3 program. As there is no precedent for the use of UOx excretion as a surrogate endpoint for kidney stone disease progression, the FDA's engagement and specific feedback was essential during this process. We believe alignment on URIROX-2's innovative trial design and disease-specific endpoints represents a watershed moment in the development of therapies for severe hyperoxaluria," said Alexey Margolin, Ph.D., Chief Executive Officer of Allena Pharmaceuticals. "We look forward to working with investigators, clinicians and patient advocates as we advance reloxaliase as potentially the first therapeutic approved for patients with enteric hyperoxaluria."

Key secondary efficacy endpoints for URIROX-2 include the proportion of subjects with a $\geq$20% reduction from baseline in 24-hour UOx excretion measured during Weeks 1-4, which is also a secondary endpoint for URIROX-1, and data on UOx change from baseline measured during Weeks 16 to 24. Twenty-four-hour UOx excretion is an established biomarker that is routinely measured in clinical practice to assess and manage patients at risk for enteric hyperoxaluria and calcium oxalate kidney stones. Data from multiple independent studies suggest that a therapeutic strategy that reduces 24-hour UOx excretion by approximately 20% could result in a 25-50% reduction in the incidence of kidney stone recurrence and may increase renal survival. The FDA agreed that, if positive, biomarker data on 24-hour UOx excretion in URIROX-1 and URIROX-2 would be used for a BLA filing for accelerated

approval of reloxaliase in enteric hyperoxaluria and that patients would continue in URIROX-2 to confirm clinical benefit during the long-term follow-up phase of the trial.

“Patients with enteric hyperoxaluria suffer from the sudden onset of debilitating kidney stone episodes in addition to the silent deposition of calcium oxalate crystals, both of which can damage the kidney, leading to progressive chronic kidney disease and ultimately end-stage renal disease. Based on the clinical data reported to-date, I believe reloxaliase has the potential to offer a critical new therapeutic option to these patients, who currently have no approved pharmacologic interventions,” said Craig Langman, M.D., Head of the Division of Kidney Diseases, Ann & Robert H. Lurie Children’s Hospital of Chicago and Isaac A. Abt, M.D. Professor of Kidney Diseases and Pediatrics at Northwestern University Feinberg School of Medicine. “Allena’s advancement of its Phase 3 clinical program highlights the potential of reloxaliase as a first-in-class oral enzyme that may effectively degrade oxalate within the gastrointestinal (GI) tract, reducing its absorption and accumulation throughout the body and its burden on the kidney.”

Pivotal Phase 3 URIROX Program
Allena’s URIROX program consists of two pivotal Phase 3 trials, URIROX-1 and URIROX-2, which are designed to evaluate the safety and efficacy of reloxaliase in patients with enteric hyperoxaluria.

URIROX-1 is a multicenter, global, randomized, double-blind, placebo-controlled study evaluating the safety and efficacy of reloxaliase in an expected 124 patients for a four-week treatment period. It has the same primary and key secondary efficacy endpoints as URIROX-2. Based on enrollment progress to date, Allena expects to report topline data from URIROX-1 in the second half of 2019.

URIROX-2 (formerly Study 302) is a multicenter, global, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of reloxaliase in patients with enteric hyperoxaluria, over a minimum treatment period of two years. The trial is designed to enroll 400 patients with 24-hour UOx excretion greater than or equal to 50 mg and a history of kidney stones, and will include patients with normal kidney function as well as chronic kidney disease (defined as an estimated glomerular filtration rate (eGFR) greater than or equal to 30). Patients will be randomized 1:1 to reloxaliase vs. placebo and will take 284 mg (equivalent to 7,500 units) of reloxaliase or placebo with each meal or snack up to five times per day, consistent with the eating patterns of patients with enteric hyperoxaluria. Allena initiated the study in the fourth quarter of 2018.

The primary efficacy endpoint of URIROX-2 is the percent change from baseline in 24-hour UOx excretion measured during Weeks 1-4, comparing mean reduction in UOx with reloxaliase to placebo. Secondary endpoints include the proportion of subjects with a ≥20% reduction from baseline in 24-hour UOx excretion measured during Weeks 1-4 and percent change from baseline in 24-hour UOx excretion during Weeks 16 to 24. The primary long-term efficacy endpoint to confirm clinical benefit is the proportion of subjects with kidney stone disease progression, defined as a composite of either symptomatic kidney stones or finding of new or enlarged kidney stones using imaging, over a minimum treatment period of two years. Secondary long-term efficacy endpoints to confirm clinical benefit include change in eGFR from baseline and emergency room visits, hospitalizations or procedures for the management of kidney stones.

URIROX-2 incorporates adaptive design elements that, through sample size re-estimations, will, if necessary, allow for increases in sample size and duration of treatment, based on accrued kidney stone disease progression rates and the conditional probability of achieving ultimate statistical success for kidney stone disease progression in the long-term follow-up phase of the trial. Consistent with FDA guidance on the accelerated approval regulatory pathway, the data package for Allena’s accelerated approval filing is expected to include a conditional power estimate based on the effect of reloxaliase on reducing kidney stone disease progression, the effects of reloxaliase on reduction of UOx in the URIROX-1 and URIROX-2 trials, and further support for the model relating UOx levels to kidney stone disease progression, including available data obtained in the URIROX-2 trial. Allena expects to submit a BLA filing to the FDA after 400 patients have been randomized and followed for six months. For the long-term follow-up phase of the trial, subjects would continue in the study for a minimum treatment period of two years to confirm clinical benefit post-approval.

About Hyperoxaluria
Hyperoxaluria is a metabolic disorder characterized by elevated urinary oxalate levels that may be due to either overproduction of oxalate by the liver from a genetic defect, known as primary hyperoxaluria, or from the excess absorption of oxalate from the diet, known as secondary hyperoxaluria. Secondary hyperoxaluria is further characterized either as enteric, resulting from a chronic and unremediable underlying GI disorder, or idiopathic, meaning the underlying cause is unknown. Kidney stones, typically the first sign of hyperoxaluria, are often painful and may require interventional procedures. Severe hyperoxaluria in settings of enteric and primary hyperoxaluria may also lead to kidney damage (nephrocalcinosis), chronic kidney disease and end-stage renal disease, which may lead to death.

Enteric hyperoxaluria is the more severe subset of secondary hyperoxaluria. Allena estimates that there are approximately 200,000 to 250,000 patients with enteric hyperoxaluria and kidney stones in the United States.

About Reloxaliase
Reloxaliase is an orally-administered, recombinant oxalate-degrading enzyme that is being developed for the treatment of severe hyperoxaluria. Reloxaliase targets oxalate in the GI tract in an effort to reduce the burden of both dietary and endogenously-produced oxalate. Reloxaliase has the potential to decrease the oxalate available systemically for deposition as calcium oxalate crystals or stones in the kidneys, as well as reduce long-term kidney complications. Reloxaliase is being evaluated in the ongoing pivotal Phase 3 URIROX-1 and URIROX-2 trials for patients with enteric hyperoxaluria. In addition, reloxaliase has been granted separate orphan drug designations by the U.S. Food and Drug Administration for the treatment of primary hyperoxaluria and for the treatment of pediatric hyperoxaluria. In addition, the European Commission has granted orphan drug designation for reloxaliase for the treatment of primary hyperoxaluria.

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 Allena's URIROX clinical program and alignment with the FDA, statements regarding the timing of announcement of topline data from the URIROX-1 trial, statements regarding the design of the URIROX-2 trial, including the number of patients to be enrolled in the URIROX-2 trial, statements regarding Allena's ability to utilize the accelerated approval regulatory pathway for reloxaliase, including the timing of any BLA submission utilizing the accelerated approval regulatory pathway, and statements regarding the ability of reloxaliase to provide clinical benefit to patients with hyperoxaluria. 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 may not be predictive of future clinical trial results, and planned and ongoing studies may not establish an adequate safety or efficacy profile for reloxaliase to support regulatory approval or the use of the accelerated approval regulatory pathway; risks related to Allena's ability to utilize the accelerated approval pathway for reloxaliase, including the risk that available data at the time of any sample size re-estimation or interim analysis conducted during the URIROX-2 trial may not be sufficient to demonstrate an increased probability of kidney stone events in patients with enteric hyperoxaluria and increasing UOx levels; the risk that the FDA may require that Allena increase the sample size or duration of treatment following the sample size reassessments to be conducted in accordance with the adaptive design element of the trial or otherwise collect additional clinical data from the URIROX-2 or other clinical trials prior to submitting a BLA for reloxaliase; risks associated with Allena's ability to enroll a sufficient number of patients to adequately power URIROX-2 in order to

achieve ultimate statistical success for kidney stone disease progression in the long-term follow-up phase of the trial; 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 year ended September 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