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 21, 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))

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. ☒

Item 8.01 Other Events.

On June 21, 2019, Allena Pharmaceuticals, Inc. (the "Company") issued a press release summarizing its participation and presentations at the Oxalosis and Hyperoxaluria Foundation (OHF) International Hyperoxaluria Workshop in Boston, Massachusetts, including a summary of interim data from Study 206, its Phase 2 basket clinical trial of reloxaliase, an orally-administered, recombinant oxalate-degrading enzyme therapeutic candidate. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

A summary of these same interim results were first announced by the Company on June 4, 2019, at which time the Company issued a press release and updated its investor slide deck, which press release was filed and which slide deck was furnished in a Current Report on Form 8-K. Due to a transcription error, the Company inadvertently incorrectly stated in this press release the average reduction and range of reduction in plasma oxalate in the four patients with enteric hyperoxaluria treated in Study 206. The individual patient data presented in the updated investor slide deck was correct. A corrected version of the June 4, 2019 press release is attached hereto as Exhibit 99.2 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated June 21, 2019
99.2	Press Release dated June 4, 2019 (as corrected)

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 21, 2019

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

Allena Pharmaceuticals Showcases Reloxaliase and Enteric Hyperoxaluria Program at OHF International Hyperoxaluria Workshop

NEWTON, Mass., June 21, 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 will present on its reloxaliase development program and the unmet need in patients with enteric hyperoxaluria (EH) in four sessions at the Oxalosis & Hyperoxaluria Foundation (OHF) International Hyperoxaluria Workshop, to be held June 21-22, 2019 in Boston, MA. The OHF International Hyperoxaluria Workshop is the largest gathering of hyperoxaluria patients, disease advocates and thought leaders worldwide.

"Allena's strong presence at the OHF International Hyperoxaluria Workshop highlights our progress in developing reloxaliase as a potential first-in-class therapy for patients suffering from enteric hyperoxaluria, as well as our ongoing efforts to work with advocacy groups and treating physicians to better characterize the progression of this debilitating disease," said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. "We are encouraged by the growing awareness of severe oxalate disorders and the increasingly active community focused on treating patients with enteric hyperoxaluria. Our network of investigators and patient advocates has supported us throughout the development of reloxaliase. We look forward to sharing data from our pivotal URIROX-1 Phase 3 clinical trial in the second half of the year and to laying the foundation in support of the future launch of reloxaliase."

The four presentations are summarized below:

In the session on enteric hyperoxaluria, Allena's Chief Medical Officer, Dr. Annamaria Kausz, will present data on the burden of disease and the significant unmet need in this under-recognized patient population. In addition to recurrent kidney stones, EH patients can also suffer from progressive loss of kidney function and end stage renal disease. A recent review on clinical outcomes in EH patients with oxalate nephropathy found that renal replacement therapy was required in > 50% of patients.[1] Additionally, there is increasing awareness of the association between excess urinary oxalate excretion and the risk of chronic kidney disease progression.[2]

In the session on the industry pipeline, Allena's President and Chief Executive Officer, Dr. Louis Brenner, will present an overview of the development program for reloxaliase, including the ongoing URIROX Phase 3 program and Study 206. 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 EH. These trials represent the largest studies conducted to-date in patients with EH.

In the poster session, a case series of the first four subjects with EH and advanced CKD treated with reloxaliase in Study 206 will be presented. Study 206 is a multi-center, open-label, single-arm Phase 2 basket study, designed to evaluate reloxaliase in adult and pediatric patients suffering from the progression of enteric hyperoxaluria with advanced chronic kidney disease (CKD) or primary hyperoxaluria (PH), both of which can lead to systemic oxalosis.

In the family and patient advocacy panel, Allena will join other biotechnology companies developing potential therapies that target the common enemy of excess oxalate, which can lead to severe disease in high risk patient populations.

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. 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. The European Commission has granted orphan drug designation for reloxaliase for the treatment of primary hyperoxaluria.

About 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. 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 expects to report topline data from URIROX-1 in the second half of 2019.

URIROX-2 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 urine oxalate (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.

The primary efficacy endpoint of URIROX-2 is the percent change from baseline in 24-hour UOx excretion during Weeks 1-4, comparing reduction in the average UOx excretion across Weeks 1-4 with reloxaliase to placebo, the same primary endpoint as URIROX-1. Secondary endpoints in URIROX-2 include the proportion of subjects with a 20% reduction from baseline in 24-hour UOx excretion 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.

In January 2019, Allena announced that it reached alignment with the U.S. Food and Drug Administration (FDA) on both the design of URIROX-2 and its strategy to pursue a Biologics License Application (BLA) submission for reloxaliase in patients with enteric hyperoxaluria using the accelerated approval regulatory pathway.

In March 2019, Allena announced an agreement with the Duke Clinical Research Institute (DCRI), a leading academic research institute within Duke University School of Medicine, to establish and lead an Academic Coordinating Center (ACC) in support of the URIROX-2 Phase 3 clinical trial and preparation for the potential launch of reloxaliase.

About Study 206

Study 206 is a multi-center, open-label, single-arm Phase 2 basket study, designed to evaluate reloxaliase in adult and pediatric patients suffering from the progression of EH with advanced CKD or PH, both of which can lead to systemic oxalosis. The clinical trial is designed to enroll between 15 and 20 patients aged 12 and older. Patients orally administer 7,500 units of reloxaliase with each meal or snack five times a day, for 12 consecutive weeks. The primary endpoints of the trial are change from baseline in 24-hour UOx excretion and POx levels.

This basket study is seeking to identify an efficacy signal in several high risk patient populations including enteric hyperoxaluria patients with CKD, kidney transplantation or dialysis dependence or patients with primary hyperoxaluria types 1, 2 or 3. UOx is being collected for patients who are not on dialysis. Data has been released on the first seven patients from the study. This includes the first four EH patients who demonstrated plasma oxalate (POx) reductions of 28% and 16%, compared to baseline, in the two patients not on dialysis, and 49% and 45% in the two patients on dialysis. In addition, for the two patients not on dialysis, 24 hour UOx excretion was reduced by 29% and 42%. The summary data showed a range of POx reduction from 16% to 49% with an average reduction of 35%, compared to baseline. This summary POx data corrects an inadvertent error in a press release

issued on June 4th, 2019. The individual patient data that was also publicly released on June 4th, 2019 is correct and unchanged. Three patients with PH type 2 and PH type 3 with preserved renal function were treated. These are the first patients with any form of PH treated with reloxaliase. One patient had a > 20% mean reduction in UOx excretion while the other two patients did not show a response to reloxaliase.

Based on the treatment effect observed in these four EH patients, coupled with the unmet need and high risk of morbidity and mortality in EH patients with advanced CKD, Allena intends to focus further enrollment in Study 206 on patients with EH and CKD, kidney transplantation or dialysis dependence and patients with PH and compromised renal function. Allena expects to announce topline results from the trial in the second half of 2019.

1. Lumlertgul et al, *Kidney Int Rep* 2018; 3:1363-1372.

2. Waikar SS et al, *JAMA Intern Med* 2019; 179(4):542–551.

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, without limitation, statements regarding the results of Study 206 and the clinical and commercial potential of reloxaliase for patients with primary hyperoxaluria or enteric 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 interim results or 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 in URIROX-2 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 related to Allena's use of UOx and/or POx as surrogate endpoints in its ongoing clinical trials, neither of which it believes have been previously utilized as biomarkers to support regulatory approval of other drug candidates, and the risks related to validating that reductions in UOx and/or POx correlate with meaningful clinical benefit; 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 31, 2019, 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
hannah.deresiewicz@sternir.com

Media Contact

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

Exhibit 99.2

Allena Pharmaceuticals Announces Interim Results from Study 206 of Reloxaliase in High Risk Patients with Advanced Oxalate Disorders

— Substantial Treatment Effect Observed in Patients with Enteric Hyperoxaluria, Including Robust Reductions in Both Urine and Plasma Oxalate –
— Reloxaliase Well-Tolerated Over 12 Weeks of Dosing —
— Detailed Results to be Presented at OHF International Hyperoxaluria Workshop in June 2019 —

NEWTON, Mass., June 4, 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 interim data from Study 206, its Phase 2 basket clinical trial of reloxaliase, an orally-administered, recombinant oxalate-degrading enzyme. Study 206 includes adult and pediatric patients suffering from the progression of primary hyperoxaluria (PH) or enteric hyperoxaluria (EH) with advanced chronic kidney disease (CKD), both of which can lead to systemic oxalosis, a potentially life-threating condition. Consistent with Allena's prior clinical experience, EH patients treated with reloxaliase in Study 206 demonstrated a substantial treatment effect. This includes EH patients with advanced CKD, a patient population not previously treated with reloxaliase, who showed reductions in urine oxalate (UOx) and plasma oxalate (POx). Allena plans to present detailed results at the OHF International Hyperoxaluria Workshop, June 21-22, 2019 in Boston, MA.

"We are pleased to see a robust response to reloxaliase in EH patients suffering from advanced stages of the disease. We believe this reflects reloxaliase's activity and novel mechanism of action of degrading oxalate within the GI tract, which is well-targeted to treat excess oxalate absorption driven by an underlying GI disorder. The potential to alleviate the high oxalate burden on these patients is very encouraging," said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. "To our knowledge, this is a first demonstration of a specific pharmacologic therapy leading to reduction in plasma oxalate and urinary oxalate levels in patients with EH and decreased kidney function, which represents a significant advancement for the field and especially for patients with systemic oxalosis. These results advance our efforts to develop reloxaliase as a potential first-in-class therapy for patients with enteric hyperoxaluria, and we look forward to additional data from Study 206, as well as topline data from our pivotal Phase 3 URIROX-1 trial, anticipated in the second half of the year."

Interim Data from Study 206

Study 206 is a multi-center, open-label, single-arm Phase 2 clinical trial designed to enroll between 15 and 20 patients in the United States and Europe aged 12 and older. Patients orally administer 7,500 units of reloxaliase with each meal or snack five times a day, for 12 consecutive weeks. The primary endpoints of the trial are change from baseline in 24-hour UOx excretion and POx levels. UOx was collected for patients who are not on dialysis.

The first seven patients have completed treatment, including one EH patient with advanced CKD, one EH patient with a functioning kidney transplant and two patients with EH who are on dialysis. Three patients had PH and preserved renal function.

- All four patients with EH experienced a reduction in POx, with an average reduction of 35% compared to baseline (range 16% to 49%). The two patients not on dialysis also experienced reductions in UOx of 29% and 42%, respectively. The treatment effect observed in these EH patients supports a continued focus on treating EH patients with CKD, kidney transplantation or dialysis dependence in an effort to reduce further oxalate damage.
- Three patients with PH type 2 or PH type 3 with preserved renal function were treated. These are the first patients with any form of PH treated with reloxaliase. One patient had a >20% mean reduction in UOx excretion, while the other two patients did not show a response to reloxaliase. Allena intends to narrow its further evaluation of reloxaliase in PH to patients with compromised renal function where the GI mechanism of action may play a more important role.

- This trial encompasses the longest reloxaliase treatment duration thus far. All patient populations are being treated for three months with more frequent dosing of reloxaliase than the Company's prior Phase 2 studies (7,500 units of reloxaliase, five times per day). Average patient dosing compliance was greater than 90%. Treatment with reloxaliase was well-tolerated in all patient populations, with no reported treatment-related serious adverse events.

"I am extremely encouraged by the interim data from Study 206. People living with EH and significant renal compromise suffer from underlying GI conditions, which perpetuate a vicious and potentially fatal cycle of kidney damage, transplantation and return to dialysis, and there are no approved therapies available with which to treat them," said Felix Knauf, Professor of Nephrology, Charite' University Hospital Berlin, Germany and Assistant Professor Adjunct at Yale University. "Though early, these results suggest that reloxaliase may offer a well-tolerated and easily-administered new medicine for these patients. By reducing both UOx and POx levels, reloxaliase has the potential to improve renal outcomes by lessening the likelihood that patients will develop calcium oxalate crystal deposition in their kidneys or other organs. I am eager to work with Allena to enroll additional patients in this study, as we continue to evaluate potential near- and long-term clinical benefits of reloxaliase treatment."

About Hyperoxaluria and Systemic Oxalosis

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. Systemic oxalosis occurs when excess oxalate is present throughout the body including the blood, kidney, bones, joints, eyes and heart. People living with systemic oxalosis have varying degrees of renal impairment including kidney stones, nephrocalcinosis, chronic kidney disease, and end-stage renal disease. For more information about the disorder and videos featuring patient stories, visit http://www.allenapharma.com/systemic-oxalosis.

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 and the ongoing Phase 2 basket trial for adult and pediatric patients suffering from primary hyperoxaluria or enteric hyperoxaluria with advanced chronic kidney disease. 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. The European Commission has granted orphan drug designation for reloxaliase for the treatment of primary hyperoxaluria.

About Allena Pharmaceuticals

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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 interim results or 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 in URIROX-2 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 related to Allena's use of UOx and/or POx as surrogate endpoints in its ongoing clinical trials, neither of which it believes have been previously utilized as biomarkers to support regulatory approval of other drug candidates, and the risks related to validating that reductions in UOx and/or POx correlate with meaningful clinical benefit; 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 31, 2019, 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
hannah.deresiewicz@sternir.com

Media Contact

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