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 29, 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 2.05. Costs Associated with Exit or Disposal Activities.

On November 29, 2019, the Board of Directors (the "Board") of Allena Pharmaceuticals, Inc. (the "Company") approved a reduction of its workforce that will lead to a reduction in its salary and related compensation expenses of approximately 30%. This reduction was primarily in the area of research and development and was made as part of a strategic measure to reduce expenses and preserve capital for the Company's reloxaliase programs. This action is expected to be substantially complete by the end of 2019.

As a result of this reduction of force, the Company estimates that it will incur aggregate charges of approximately $0.5 million to $0.6 million for one-time severance and employee related costs in the fourth quarter of 2019, about half of which is expected to result in cash expenditures by the end of 2019, with the remainder resulting in cash expenditures during the first quarter of 2020. The charges the Company expects to incur in connection with this reduction in force are subject to a number of assumptions, and actual results may materially differ. The Company may also incur other material charges not currently contemplated due to events that may occur as a result of, or associated with, these actions.

Item 8.01. Other Events

On December 4, 2019, the Company issued a press release in which the Company provided updates on its reloxaliase development programs and corporate activities. A copy of the press release is filed herewith as Exhibit 99.1 to this Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Allena Pharmaceuticals, Inc. dated December 4, 2019, furnished hereto.

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: December 4, 2019

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

Allena Pharmaceuticals Provides Updates on Reloxaliase Development Program and Corporate Activities

-- Prioritizing Development of Reloxaliase for Patients with Enteric Hyperoxaluria (EH) –

- Plan to Re-Engage with U.S. Food and Drug Administration (FDA) to Evaluate Opportunities to Streamline URIROX-2, Second Pivotal Phase 3 Trial of Reloxaliase in EH -

- Implementing Measures to Reduce Expenses and Preserve Capital for Reloxaliase Programs -

Newton, Mass., December 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 updates on its clinical development programs for reloxaliase, a potential first-in-class, non-absorbed, orally administered enzyme for the treatment of severe hyperoxaluria, and several initiatives to realign resources to support the continued development of reloxaliase for patients with enteric hyperoxaluria (EH).

Following positive topline results from URIROX-1 and further analysis of the data from the trial, Allena plans to re-engage with the FDA, with the request to discuss measures to potentially streamline its ongoing URIROX program through modifications to the adaptive URIROX-2 trial design. These enhancements could potentially include reducing the target enrollment in URIROX-2, conducting an earlier interim analysis of the data from URIROX-2, and modifying the requirements for filing for accelerated approval of the initial reloxaliase Biologics Licensing Application (BLA). The company expects to meet with the FDA in early 2020 and to provide an update on the final design and timing of the URIROX-2 study as it evolves.

“We continue to be encouraged by the pivotal Phase 3 URIROX-1 results and are committed to advancing reloxaliase as the first potential approved treatment for patients with EH,” said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. “Reloxaliase achieved its primary endpoint in URIROX-1, demonstrating a statistically significant and clinically meaningful reduction in urinary oxalate (UOx). Based on the positive feedback that we continue to receive from key opinion leaders and clinicians and the severity of the condition in our trial population, we are confident that reloxaliase has the potential to alter the treatment landscape for patients with EH, and offer treating physicians an important new tool for combating the toxic accumulation of excess oxalate in patients with gastrointestinal (GI) disorders. We look forward to initiating discussions with the FDA in the near-term, as we consider opportunities to streamline the URIROX-2 program and expeditiously deliver reloxaliase to patients.”

Allena is implementing several measures in order to preserve capital and focus its resources on its reloxaliase programs, while maintaining key product development and corporate capabilities:

- The company will limit the opening of new trial sites for its ongoing URIROX-2 trial and continue to enroll patients at existing sites, until further clarity from the FDA is received regarding potential changes to the URIROX program.
- The company will delay additional planned investments in manufacturing.
- The company will implement a reduction in its workforce that will lead to an approximately 30 percent reduction in salary and related compensation expenses.

Allena also remains focused on completing its ongoing Study 206 in patients with EH and advanced chronic kidney disease (CKD). Based on the results of the study and the severity of the condition, the company plans to interact with regulatory agencies in the first quarter of 2020 to discuss the registrational path, including expedited options, for reloxaliase in high-risk EH patients with CKD. Additionally, Allena remains on track to file an investigational new drug (IND) application for ALLN-346, a novel urate-degrading enzyme, this quarter, though first-in-human studies will be pursued only once additional financial resources are secured.

With these measures in place, Allena expects that its current cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2020. The company also continues to explore a range of potential financial alternatives to support the development of reloxaliase, including potential financing transactions and business development partnerships.

Dr. Brenner added: “We remain conscious of the additional resources we need to advance reloxaliase through our URIROX program. To that end, we have made the difficult decision to realign our investments and internal resources to provide us with resources to enable us to focus on, and execute against, our strategy of delivering reloxaliase for the treatment of patients across the spectrum of EH. Unfortunately, this will impact a number of our highly talented and dedicated employees. We are incredibly grateful to those who are affected by this decision, and deeply appreciative of all of their hard work to support our development of novel therapies for patients with rare and severe metabolic 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 topline data from the URIROX-1 clinical trial, Allena’s ongoing review of these data and implications for the future clinical, regulatory and commercial potential of reloxaliase, statements regarding plans to reengage with the FDA, statements regarding future plans for the URIROX-2 clinical trial, statements regarding Allena’s development of ALLN-346, including the expected timing of its IND filing, and statements concerning Allena’s cash position, potential cost savings, the sufficiency of cash to fund operations and ability to complete a financing transaction and/or business development partnership. In addition, it should be noted that additional capital will be required to fund operations, including completion of the planned URIROX-2 clinical trial, which capital may not be available to Allena on terms that are acceptable to it, if at all. If adequate funds are not available on a timely basis, Allena may be required to amend, delay, limit, reduce or terminate one or more of its ongoing or planned clinical trials of its product candidates. 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 Allena’s clinical and regulatory strategy for reloxaliase may evolve following further review of the topline data from the URIROX-1 clinical trial and Study 206, including without limitation, modifications or termination of the planned URIROX-2 clinical trial; the risk that the results of the URIROX-1 clinical trial may not be replicated in the URIROX-2 or other clinical trials of reloxaliase; the risk that the reduction in 24-hour UOx excretion observed in the placebo arm of the URIROX-1 trial may be observed in the URIROX-2 or other clinical trials of reloxaliase, which may have a negative impact on Allena’s ability to secure regulatory approval for this product candidate; the risk that results of earlier studies, or interim results, 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 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 financial condition and its need to obtain additional funding to support its business activities, including the future clinical development of reloxaliase; 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 September 30, 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.

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.

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