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 13, 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 2.02 Results of Operations and Financial Condition.

On November 13, 2019, Allena Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2019 and provided a business update. The full text of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information under this Item 2.02 is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release of Allena Pharmaceuticals, Inc. (concerning financial results) dated November13, 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: November 13, 2019

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

Allena Pharmaceuticals Reports Third Quarter 2019 Financial Results and Provides Business Update

— Reported Positive Topline Results from Pivotal Phase 3 URIROX-1 Trial of Reloxaliase in Enteric Hyperoxaluria (EH), with Statistically Significant Reduction in Urinary Oxalate (UOx) Compared to Placebo —

— Reported Positive Data from Study 206 of Reloxaliase, Demonstrating Substantial Plasma Oxalate (POx) and UOx Reductions in Patients with EH and Advanced Chronic Kidney Disease (CKD) —

— Plan to Pursue Accelerated Approval Based on URIROX-1 Data and Results of 24-Week Data from URIROX- 2 —

— Exploring Registrational Path for Reloxaliase in High-Risk EH Patients with CKD —

NEWTON, Mass., November 13, 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 reported financial results for the third quarter ended September 30, 2019 and also provided a business update.

"We are excited about the presentation of positive topline results from URIROX-1 and Study 206 in EH patients that we presented at the American Society of Nephrology (ASN) Annual Meeting," said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. "As we engaged with key opinion leaders at the meeting, we were encouraged by the positive reception to reloxaliase's consistent treatment effect across URIROX-1 and our Phase 2 studies, and reminded of the tremendous unmet need facing patients living with EH, for whom there are no approved therapies today. These interactions reinforced our confidence in reloxaliase's emerging therapeutic profile and potential as a first-in-class treatment for EH. We look forward to further analyzing the datasets from URIROX-1 and Study 206 and applying these insights to increase the likelihood of success in URIROX-2, and to inform our engagement with the U.S. Food and Drug Administration (FDA) as we explore the registrational path for reloxaliase in EH patients with advanced CKD."

Recent Business Highlights and Upcoming Milestones:

Reloxaliase: Reloxaliase is a first-in-class, non-absorbed, orally administered enzyme for the treatment of severe hyperoxaluria. Allena is currently evaluating reloxaliase for patients with EH in the pivotal Phase 3 URIROX program, and for patients with EH and advanced CKD and elevated POx in the Phase 2 Study 206.

At the American Society of Nephrology (ASN) Annual Meeting in November 2019, Allena presented positive topline results from its first pivotal Phase 3 trial, URIROX-1.

- URIROX-1 achieved its primary endpoint, with a mean reduction of 22.6% in average 24-hour UOx excretion measured during Weeks 1-4 in patients on reloxaliase, compared to 9.7% in patients on placebo (least square (LS) mean treatment difference of -14.3%,. p=0.004).
- The study approached statistical significance on the lead secondary endpoint, with 48.3% of patients on reloxaliase achieving a ≥20% reduction from baseline in 24-hour UOx excretion, compared to 31.6% of patients on placebo (p=0.06).
- In a pre-specified analysis of bariatric surgery patients (68% of the total study population), patients treated with reloxaliase achieved a mean reduction of 21.2% in average 24-hour UOx excretion, compared to 6.0% for patients treated with placebo (LS mean difference of -16.2%, p=0.01). In the stratified analysis of the key secondary endpoint, 50.0% of patients on reloxaliase achieved a ≥20% reduction from baseline in 24-hour UOx excretion, compared to 28.9% of patients on placebo (p=0.036).
- Consistent with prior clinical experience, reloxaliase was well-tolerated.

Allena continues to evaluate the full data from URIROX-1 and will assess the implications for URIROX-2, its second, larger pivotal Phase 3 trial, including the adaptive design elements of URIROX-2. URIROX-2 is ongoing, with topline data expected in the second half of 2021. Allena plans to file a Biologics License Application (BLA) with the FDA for reloxaliase using the accelerated approval regulatory pathway based on the URIROX-1 results and 24-week biomarker data from the ongoing URIROX-2 trial, pending positive results. Patients will continue on therapy in URIROX-2 to confirm clinical benefit during the long-term follow-up phase of the trial.

Also at ASN, Allena presented additional, positive data from Study 206. Study 206 has enrolled patients with EH and advanced CKD, which can lead to systemic oxalosis, a potentially life-threatening condition. This includes end-stage renal disease patients who are on dialysis and patients who have undergone kidney transplantation.

- Two patients with CKD Stage 3 demonstrated a substantial reduction in 24-hour UOx excretion (mean reductions of 29% and 42%, respectively) and in POx levels (mean reductions of 42% and 16%, respectively) over Weeks 4-12.
- Six patients with CKD Stage 5, including five patients on dialysis, demonstrated substantial reductions in POx levels over Weeks 4-12 (reductions ranged from 19% to 68%).
- Consistent with prior clinical experience, reloxaliase was generally well-tolerated out to 12 weeks of treatment.

Based on these results, Allena plans to meet with regulatory agencies in the first quarter of 2020 to discuss the registrational path for reloxaliase in high-risk EH patients with CKD.

ALLN-346: ALLN-346 is a first-in-class, orally administered, novel urate degrading enzyme that has been designed for activity and stability in the gastrointestinal tract. Allena is completing its preclinical development of ALLN-346 for the treatment of hyperuricemia in patients with gout in the setting of advanced CKD and also scaling its manufacturing processes to support clinical studies. Allena expects to file an Investigational New Drug (IND) application with the U.S. FDA this quarter and to initiate the first clinical trial of ALLN-346 in the first half of 2020.

At the American College of Rheumatology 2019 ACR/ARP Annual Meeting in November 2019, Allena presented new preclinical data, demonstrating that enteral administration of ALLN-346 decreases serum urate in a pig model of hyperuricemia.

Third Quarter 2019 Financial Results:

- **Cash Position**: As of September 30, 2019, cash and cash equivalents were $39.4 million, as compared to $61.6 million as of December 31, 2018. This decrease was primarily due to cash used in operating activities, partially offset by aggregate gross proceeds of approximately $10 million from the Company's registered direct offering of common stock, which closed in June 2019.
- **R&D Expenses**: R&D expenses were $10.8 million for the third quarter of 2019, as compared to $7.3 million for the third quarter of 2018. The increase was primarily due to costs incurred for the URIROX-2 trial, which was initiated during the fourth quarter of 2018, and an increase of formulation and development costs incurred advancing ALLN-346.
- **G&A Expenses**: G&A expenses were $2.5 million for the third quarter of 2019, as compared to $2.4 million for the third quarter of 2018. The increase was primarily due to an increase in employee compensation and benefit costs.
- **Net Loss**: Net loss was $13.3 million for the third quarter of 2019, or a net loss per basic and diluted share of $0.57, as compared to a net loss of $9.5 million for the third quarter of 2018, or a net loss per basic and diluted share of $0.46.

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 topline data from the URIROX-1 clinical trial and Study 206, Allena's ongoing review of these data and implications for the future clinical, regulatory and commercial potential of reloxaliase, statements regarding the ability of reloxaliase to provide clinical benefit to patients, statements regarding future plans for the URIROX-2 clinical trial, including the adaptive design elements of this trial, statements regarding the future development of reloxaliase for patients with EH and advanced CKD, statements regarding the URIROX clinical program generally, statements regarding Allena's ability to utilize the accelerated approval regulatory pathway for reloxaliase, and statements regarding Allena's development of ALLN-346, including the expected timing of its IND filing. In addition, it should be noted that additional capital will be required to complete 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 theURIROX-1 clinical trial may not be replicated in theURIROX-2 or other clinical trials of reloxaliase; the risk that the reduction in 24-hour UOx excretion observed in the placebo arm of theURIROX-1 trial may be observed in theURIROX-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-termfollow-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.

Allena Pharmaceuticals, Inc
Selected Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	As of September 30, 2019	As of December 31, 2018
Cash and cash equivalents	$ 39,419	$ 61,643
Working capital (1)	31,091	58,706
Total assets	42,767	65,229
Loan payable, net of current portion and discount	6,986	9,980
Total stockholders' equity	25,191	49,456

(1) The Company defines working capital as current assets less current liabilities. See the Company's condensed consolidated financial statements for further detail regarding its current assets and current liabilities.

Allena Pharmaceuticals, Inc
Condensed Consolidated Statements of Operations
(in thousands, except share and per share data)
(unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 10,806	$ 7,316	$ 28,523	$ 19,107
General and administrative	2,532	2,389	7,709	6,706
Total operating expenses	13,338	9,705	36,232	25,813
Other income (expense), net	50	195	252	(224)
Net loss	$ (13,288)	$ (9,510)	$ (35,980)	$ (26,037)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.57)	$ (0.46)	$ (1.66)	$ (1.26)
Weighted-average common shares outstanding - basic and diluted	23,464,828	20,753,215	21,737,320	20,727,426

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