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): May 8, 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 (§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. ☒

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

Item 2.02 Results of Operations and Financial Condition.

On May 8, 2019, Allena Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended March 31, 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 May 8, 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: May 8, 2019

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

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

-- Entered into Agreement with Duke Clinical Research Institute (DCRI) to Support Phase 3 URIROX-2™ Trial and Promote Enteric Hyperoxaluria Disease Awareness –

-- All Clinical Programs Progressing on Track; Expect to Report Initial Data from Study 206 in Second Quarter and Topline Data from Phase 3 URIROX-1™ Trial in Second Half of 2019 –

-- Multiple Catalysts Expected Across Broader Pipeline in 2019 --

NEWTON, Mass., May 8, 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 first quarter ended March 31, 2019 and also provided a business update.

"Our progress in the first quarter highlights our position as pioneers in the development of oral enzyme therapeutics for the treatment of rare and severe metabolic diseases," said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. "We achieved alignment with the U.S. Food and Drug Administration (FDA) on the design of URIROX-2 and on our strategy to pursue an accelerated approval for reloxaliase in patients with enteric hyperoxaluria. We are continuing to enroll our ongoing clinical trials, with a focus on completing enrollment in URIROX-1. In addition, we are pleased to be collaborating with DCRI on URIROX-2 to better promote disease awareness, drive patient identification, and evaluate the health economic impact of reducing oxalate burden in patients with enteric hyperoxaluria, all of which should support the future potential launch of reloxaliase as the first therapeutic for these patients. Looking forward, we are excited to report data from the initial cohort of subjects from Study 206, expected in the second quarter, and topline data from URIROX-1, expected in the second half of the year."

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 in two ongoing 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. Allena plans to pursue a Biologics License Application (BLA) submission for reloxaliase using the accelerated approval regulatory pathway.

Allena is also evaluating reloxaliase in Study 206, a multi-center, open-label, single arm Phase 2 basket study of reloxaliase in adults and adolescents with primary hyperoxaluria or enteric hyperoxaluria with advanced chronic kidney disease (CKD) and elevated plasma oxalate.

- In March 2019, Allena announced an agreement with DCRI to support its URIROX-2 Phase 3 clinical trial. Under the terms of the collaboration, DCRI will establish and lead an Academic Coordinating Center (ACC), which, in addition to providing independent oversight and assisting with investigator engagement, will support Allena's ongoing efforts to prepare for the potential launch of reloxaliase. The ACC will contribute scientific expertise and thought leadership to the data analysis and publication strategy, including research on the health economic impact of reducing oxalate burden in patients with enteric hyperoxaluria.

Allena expects to achieve the following key milestones for reloxaliase:

- Report preliminary findings from Study 206 in June 2019;
- Report topline data from the URIROX-1 Phase 3 clinical trial in the second half of 2019; and
- Report topline data from Study 206 in the second half of 2019.

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 achieve the following key milestones for ALLN-346:

- File an IND application with the FDA in the second half of 2019; and
- Initiate the first clinical trial in the first half of 2020.

Corporate:

- In April 2019, Allena announced the appointment of Allene Diaz to its Board of Directors.

First Quarter 2019 Financial Results:

- **Cash Position:** As of March 31, 2019, cash and cash equivalents were $51.8 million, as compared to $61.6 million as of December 31, 2018. This decrease was primarily due to cash used in operating activities, including payment of the Company's 2018 annual bonus.
- **R&D Expenses:** R&D expenses were $9.1 million for the first quarter of 2019 as compared to $5.9 million for the first 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.
- **G&A Expenses:** G&A expenses were $2.4 million for the first quarter of 2019 as compared to $2.0 million for the first quarter of 2018. The increase was primarily due to disease awareness activities, consulting costs and accounting fees.
- **Net Loss:** Net loss was $11.4 million for the first quarter of 2019, or a net loss per basic and diluted share of $0.55, as compared to a net loss of $7.9 million for the first quarter of 2018, or a net loss per basic and diluted share of $0.38.

Financial Guidance:

Based on its current plans, Allena expects that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital requirements through at least the first half of 2020.

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 Allena's URIROX clinical program and alignment with the FDA, statements regarding the timing of announcement of release of data from its ongoing clinical trials, statements regarding Allena's ability to utilize the accelerated approval regulatory pathway for reloxaliase, statements regarding the ability of reloxaliase to provide clinical benefit to patients with hyperoxaluria, and statement regarding development plans for ALLN-346. 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 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.

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

	As of March 31, 2019	As of December 31, 2018
Cash and cash equivalents	$ 51,755	$ 61,643
Working capital (1)	46,296	58,706
Total assets	54,813	65,229
Loan payable, net of current portion and discount	8,962	9,980
Total stockholders' equity	38,679	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 March 31,	
	2019	2018
Operating expenses:		
Research and development	$ 9,128	$ 5,931
General and administrative	2,431	2,042
Total operating expenses	11,559	7,973
Other income (expense), net	140	93
Net loss	$ (11,419)	$ (7,880)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.55)	$ (0.38)
Weighted-average common shares outstanding—basic and diluted	20,814,715	20,695,386

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