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 13, 2020

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 May 13, 2020, Allena Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended March 31, 2020 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 13, 2020, 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 13, 2020

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

Allena Pharmaceuticals Reports First Quarter 2020 Financial Results and Provides Business Update

-- Revised URIROX-2 Trial Design to Potentially Reduce Size and Cost of Trial--

-- Finalized Protocol and Selected Contract Research Organization for Phase 1 Clinical Trial of ALLN-346 –

-- Presenting Late-Breaking Abstract on Kidney Stone Risk and Association with Urinary Oxalate Levels in Conjunction with AUA Virtual Experience --

NEWTON, Mass., May 13, 2020 -- 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, 2020 and provided a business update.

“Despite the unprecedented challenges brought by the COVID-19 pandemic, we progressed our clinical development programs in the first quarter, including implementing the revised protocol for our URIROX-2 Phase 3 trial of reloxaliase in patients with enteric hyperoxaluria. In parallel, we engaged further with clinicians and key opinion leaders to educate on the results of URIROX-1. We are encouraged by the tremendous enthusiasm around our initial Phase 3 data, and look forward to continuing these interactions following the American Urological Association’s Virtual Experience this weekend, where additional data from URIROX-1 will be presented as a late breaking abstract to demonstrate the relationship between higher urinary oxalate levels and kidney stone disease,” said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. “In addition, we are exploring a range of potential funding options to support the development of our broad pipeline, including potential business development partnerships. We believe both reloxaliase and ALLN-346 have the potential to meaningfully impact the lives of people living with rare metabolic and kidney disorders, and we are seeking to secure the necessary capital to advance both programs.”

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 enteric hyperoxaluria (EH) in URIROX-2, the second pivotal Phase 3 clinical trial in its URIROX program.

In February 2020, following engagement with the U.S. Food and Drug Administration (FDA), Allena announced a streamlined design for URIROX-2, based on the higher-than-projected kidney stone (KS) event rate and the urinary oxalate (UOx) results observed in the completed URIROX-1 trial. In March 2020, Allena submitted a protocol amendment and associated study documents for the revised trial design to the FDA. The revised trial design is now effective following the FDA’s 30-day review period, and is being implemented in URIROX-2. Despite COVID-19, URIROX-2 is ongoing and study sites remain open for enrollment, although no new sites are being opened. As a result of the COVID-19 pandemic, and subject to Allena’s ability to secure additional financial resources, Allena now expects the interim analysis at the first sample size reassessment (SSR) in the first quarter of 2022 and topline data for potential BLA submission in the third quarter of 2022.

Today, Allena announced that a late-breaking abstract detailing KS risk and its association with UOx levels in patients with EH was accepted for presentation as part of the American Urilogical Association (AUA) Virtual Education Experience, which is being held in place of the cancelled AUA 2020 Annual Meeting. As detailed in the abstract, patients from the URIRIOX-1 study who experienced KS passage during the study had markedly higher baseline 24 hour UOx. Data from URIROX-1, including the data presented at AUA, underscore the potential utility of 24 hour UOx as a surrogate marker of KS risk, and increase confidence in the URIROX-2 program. Dr. Charles Scales, Associate Professor of Surgery (Urology) and Population Health Sciences at Duke University and a member of the Duke Clinical Research Institute’s Academic Coordinating Center (ACC) for URIROX-2, will deliver a virtual presentation of the data, which will be available on the AUA website on Friday, May 15, 2020.

In addition, an abstract detailing the results of Study 206, Allena's Phase 2 study of reloxaliase in patients with EH and advanced Chronic Kidney Disease (CKD), was accepted to the AUA meeting. In these patients with the most severe burden of disease, robust reductions in both UOx and plasma oxalate (POx) were observed. Allena plans to engage with the FDA in the second quarter of 2020 to explore a potential expedited registration path for reloxaliase in patients with EH and advanced CKD.

Both abstracts have been published in a special supplement to the April issue of *The Journal of Urology*, which can be found at: https://www.auajournals.org/toc/juro/203/Supplement+4.

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 for the treatment of hyperuricemia in patients with gout in the setting of advanced CKD.

In the first quarter of 2020, Allena's Investigational New Drug (IND) application for ALLN-346 received clearance from the FDA to proceed with first-in-human clinical trials. Allena has finalized the protocol for the Phase 1 clinical trial, selected a contract research organization (CRO) and, subject to its ability to secure additional financial resources, is prepared to initiate a Phase 1 clinical trial of ALLN-346 in the second quarter of 2020, with initial data expected in the fourth quarter of 2020.

First Quarter 2020 Financial Results:

- **Cash Position:** As of March 31, 2020, cash and cash equivalents were $20.5 million, as compared to $30.0 million as of December 31, 2019. This decrease was primarily due to cash used in operating activities, payment of the Company's annual bonus and restructuring charges associated with a reduction of workforce completed in December 2019, and payments of principal and interest made on the Company's credit facility.
- **R&D Expenses:** R&D expenses were $4.6 million for the first quarter of 2020 as compared to $9.1 million for the first quarter of 2019. The decrease was primarily due to a reduction of costs incurred for the reloxaliase program, including costs for the URIROX-1, URIROX-2 , and Study 206 trials. Both the URIROX-1 and Study 206 trials were completed in the fourth quarter of 2019, with associated expenses decreasing in the first quarter of 2020 accordingly.
- **G&A Expenses:** G&A expenses were $2.9 million for the first quarter of 2020 as compared to $2.4 million for the first quarter of 2019. The increase was primarily due to an increase in compensation and benefit costs, the majority of which was stock-based compensation.
- **Net Loss:** Net loss was $7.6 million for the first quarter of 2020, or a net loss per basic and diluted share of $0.31, as compared to a net loss of $11.4 million for the first quarter of 2019, or a net loss per basic and diluted share of $0.55.

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 candidate 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 statements regarding implementation of the amended trial design for URIROX-2 , the timing of sample size reassessments and interim analyses during the URIROX-2 trial, Allena's ability to utilize the accelerated approval regulatory pathway for reloxaliase, statements concerning the future clinical, regulatory and commercial potential of reloxaliase, statements regarding

the Allena's development of ALLN-346, statements regarding Allena's financial position and need for capital. In addition, it should be noted that additional capital will be required to complete the planned URIROX-2 clinical trial, including the planned interim analysis at the first sample size reassessment, 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 delay, limit, reduce or terminate its clinical development of reloxaliase. The impact of the COVID-19 coronavirus on Allena's business, the biotech sector generally and the broader macroeconomic environment is uncertain and could harm Allena's business by delaying regulatory review timelines, clinical development plans and our ability to raise necessary capital. Furthermore, Allena does not have sufficient cash to operate its business for the next 12 months, which raises substantial doubt about its ability to continue as a going concern. Allena will require additional capital to fund its planned operations, which may not be available to it on attractive terms or at all. If the company is unable to secure additional capital, it will be forced to delay, limit, reduce or terminate its development of reloxaliase and may not be able to continue as a going concern. 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 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 its ability to continue as a going concern; risks associated with Allena's dependence on third parties; and risks related to the COVID-19 coronavirus. 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 I of Allena's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, 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, 2020	As of December 31, 2019
Cash and cash equivalents	$ 20,451	$ 30,007
Working capital (1)	14,744	22,127
Total assets	23,671	34,108
Loan payable, net of current portion and discount	4,990	5,988
Total stockholders' equity	10,658	17,198

(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,	
	2020	2019
Operating expenses:		
Research and development	$ 4,646	$ 9,128
General and administrative	2,878	2,431
Total operating expenses	7,524	11,559
Other income (expense), net	(61)	140
Net loss	$ (7,585)	$ (11,419)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.31)	$ (0.55)
Weighted-average common shares outstanding—basic and diluted	24,737,127	20,814,715

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