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): August 5, 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 August 5, 2020, Allena Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended June 30, 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 August 5, 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: August 5, 2020

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

Allena Pharmaceuticals Announces Second Quarter 2020 Financial Results and Provides Business Update

-- Expanding URIROX-2 Trial Sites; Interim Analysis on Track for the First Quarter of 2022 –

-- Initiated Phase 1 Clinical Trial of ALLN-346; Initial Data Expected in the Fourth Quarter of 2020 –

-- Raised Gross Proceeds of $22.7M Through Two Public Offerings, Extending Cash Runway Beyond the Second Quarter of 2021 –

NEWTON, Mass., August 5, 2020 – Allena Pharmaceuticals (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 second quarter ended June 30, 2020 and provided a business update.

“In concert with our recent financings, our team has moved quickly to implement planned activities across our portfolio, including the expansion of URIROX-2 clinical trial sites and the initiation of our Phase 1 study of ALLN-346. We are grateful for the effort and attention of our URIROX-2 trial investigators and business partners, which has enabled us to enroll patients in this second Phase 3 trial, even in the midst of the pandemic. This is the final study necessary for filing and approval of reloxaliase as a first-in-class therapy for patients with enteric hyperoxaluria,” said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. “We are also excited to announce the initiation of our first-in-human study of ALLN-346, our second novel, oral enzyme therapeutic. We are initially developing ALLN-346 for the treatment of renally impaired patients with hyperuricemia and gout, for whom existing treatment options are inadequate due to safety and dosing limitations. As we look to the second half of 2020, we remain on track to achieve all of our clinical development milestones, with initial data for ALLN-346 expected by year end and the first interim analysis from URIROX-2 expected in the first quarter of 2022.”

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. Allena is actively expanding to new sites and new geographies in its ongoing URIROX-2 clinical trial. The Company continues to expect the interim analysis in the first quarter of 2022 and to announce topline data supporting a potential Biologics License Application (BLA) submission in the third quarter of 2022.

Allena continues to engage with the U.S. Food and Drug Administration (FDA) to explore potential expedited registration paths for reloxaliase in patients with EH and advanced chronic kidney disease (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 for the treatment of hyperuricemia in patients with gout in the setting of advanced CKD. In July 2020, Allena initiated a Phase 1 clinical trial of ALLN-346. Initial data is expected in the fourth quarter of 2020.

Corporate: In June 2020, Allena completed a registered direct offering of common stock and, in July 2020, an underwritten offering of common stock. Together, these transactions netted gross proceeds to Allena of $22.7 million.

Second Quarter 2020 Financial Results:

- **Cash Position:** As of June 30, 2020, cash and cash equivalents were $26.5 million, as compared to $30.0 million as of December 31, 2019. This decrease was primarily due to cash used in operating activities and payments of principal and interest made on the Company’s credit facility, partially offset by gross proceeds

of approximately $15.0 million received from the company's June 2020 registered direct offering. Cash and cash equivalents as of June 30, 2020 do not include gross proceeds of approximately $7.7 million received from the company's bought deal offering, which closed in July 2020.

- **R&D Expenses:** R&D expenses were $3.8 million for the second quarter of 2020 as compared to $8.6 million for the second quarter of 2019. The decrease was primarily due to a reduction of costs incurred for the reloxaliase program, including costs for the URIROX-1 and URIROX-2 trials, and a reduction of costs incurred for the ALLN-346 program, including costs for formulation and development relating to its investigational new drug (IND) application. During the fourth quarter of 2019, the Company completed its URIROX-1 trial and filed an IND for ALLN-346 with the FDA.
- **G&A Expenses:** G&A expenses were $2.8 million for the second quarter of 2020 as compared to $2.7 million for the second quarter of 2019. This increase was due to increases in compensation and benefit costs, the majority of which were related to stock-based compensation, partially offset by decreases in consulting and professional services costs.
- **Net Loss:** Net loss was $7.0 million for the second quarter of 2020, or a net loss per basic and diluted share of $0.26, as compared to a net loss of $11.3 million for the second quarter of 2019, or a net loss per basic and diluted share of $0.54.

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 expenditure requirements beyond the second quarter of 2021.

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 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 June 30, 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 June 30, 2020	As of December 31, 2019
Cash and cash equivalents	$ 26,453	$ 30,007
Working capital (1)	21,633	22,127
Total assets	29,108	34,108
Loan payable, net of current portion and discount	3,992	5,988
Total stockholders' equity	18,373	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 June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2
Operating expenses:				
Research and development	$ 3,808	$ 8,589	$ 8,454	$
General and administrative	2,751	2,746	5,629	
Total operating expenses	6,559	11,335	14,083	
Other income (expense), net	(417)	62	(478)	
Net loss	$ (6,976)	$ (11,273)	$ (14,561)	$ (
Net loss per share attributable to common stockholders—basic and diluted	$ (0.26)	$ (0.54)	$ (0.56)	$
Weighted-average common shares outstanding—basic and diluted	26,878,962	20,903,298	25,808,043	20,8

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