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): March 16, 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 March 16, 2020, Allena Pharmaceuticals, Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 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 March 16, 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: March 16, 2020

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

Allena Pharmaceuticals Reports Fourth Quarter 2019 and Full Year 2019 Financial Results and Provides Business Update

-- Streamlined URIROX-2 Design Potentially Reduces Target Length and Cost of Trial --

-- Regulatory Engagement on Registrational Path for Reloxaliase in High-Risk Enteric Hyperoxaluria (EH) Patients with Chronic Kidney Disease (CKD) Expected in 2Q 2020 --

-- Investigational New Drug (IND) Application for ALLN-346 Receives Clearance to Proceed with First-in-Human Clinical Trial --

NEWTON, Mass., March 16, 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 fourth quarter and full year ended December 31, 2019 and provided a business update.

“The evolving COVID-19 pandemic has reminded us of the critical importance of medical innovation, and the value of both acute responsiveness to healthcare crises and the longer-term development of novel therapies to sustain and improve human health,” said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. “This dovetails with our mission at Allena, where we are committed to advancing safe and effective treatments for people living with rare and severe metabolic and kidney disorders. In 2019, we made important strides toward achieving this goal, announcing positive results from our Phase 3 URIROX-1 trial, in which reloxaliase demonstrated a statistically significant reduction in urinary oxalate (UOx) in EH patients. Based on these data, together with observations regarding the high burden of kidney disease amongst patients enrolled in our study, we worked closely with the U.S. Food and Drug Administration (FDA) to streamline the design of our ongoing URIROX-2 trial by reducing the target enrollment from 400 to 200 subjects and introducing an earlier interim analysis. We look forward to continuing to enroll patients in URIROX-2, as we work to potentially deliver reloxaliase as the first therapeutic to patients with EH, who experience daily challenges due to their disease and have no available treatment options.”

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 URIROX-2, the second pivotal Phase 3 clinical trial in its URIROX program, and also plans to engage with the FDA in the second quarter of 2020 to explore a possible registration path for reloxaliase in patients with EH and advanced CKD.

In February 2020, following engagement with the FDA, Allena announced a streamlined design for URIROX-2, based on the higher-than-projected kidney stone (KS) event rate and the UOx results observed in the completed URIROX-1 trial. The streamlined design includes:

- Reduction in the target enrollment to 200 subjects to support a potential Biologics License Application (BLA) filing for accelerated approval.
- The first sample size reassessment (SSR) based on total accrued KS events once 130 subjects have reached six months of treatment.
- Inclusion of a new sponsor-blinded estimation of the conditional probability of achieving the study’s primary and key secondary UOx endpoints at the time of the first SSR.

Allena expects to submit a protocol amendment and associated study documents for the revised trial design in the first quarter of 2020. Subject to Allena's ability to secure additional financial resources and the impact of COVID-19 on its business, the first SSR is expected in the third quarter of 2021.

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. Subject to Allena's ability to secure additional financial resources and the impact of COVID-19 on its business, Allena expects to initiate a Phase 1 clinical trial of ALLN-346 in the first half of 2020 and to report initial data from the trial in the fourth quarter of 2020.

Corporate: In December 2019, Allena announced several initiatives to preserve capital and focus its resources on its reloxaliase programs, while maintaining key product development and corporate capabilities. These measures included delaying additional planned investments in manufacturing and implementing a reduction in workforce. The company is exploring a range of potential financial alternatives to support the development of reloxaliase, including potential financing transactions and business development partnerships.

Fourth Quarter and Full Year 2019 Financial Results:

- **Cash Position**: As of December 31, 2019, cash and cash equivalents were $30.0 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 $12.0 million of net proceeds from the issuance of common stock during 2019.
- **R&D Expenses**: R&D expenses were $8.7 million for the fourth quarter of 2019 and $37.2 million for the year ended December 31, 2019, as compared to $7.3 million for the fourth quarter of 2018 and $26.4 million for the year ended December 31, 2018. This increase was primarily due to costs incurred for the URIROX-2 trial, which was initiated in the fourth quarter of 2018, an increase in formulation and development costs incurred advancing ALLN-346 to IND and an increase in employee-related costs. These costs were partially offset by a decrease of costs for the URIROX-1 trial, for which the company reported topline data in the fourth quarter of 2019.
- **G&A Expenses**: G&A expenses were $2.0 million for the fourth quarter of 2019 and $9.7 million for the year ended December 31, 2019, as compared to $2.5 million for the fourth quarter of 2018 and $9.2 million for the year ended December 31, 2018. This increase was primarily due to an increase in employee compensation and benefit costs.
- **Restructuring Charges**: Allena incurred restructuring charges of $0.6 million for the fourth quarter 2019 and for the year ended December 31, 2019 due to a reduction of workforce completed in December 2019.
- **Net Loss**: Net loss was $11.4 million for the fourth quarter of 2019 and $47.3 million for the year ended December 31, 2019, or a net loss per basic and diluted share of $0.47 and $2.13, respectively, as compared to a net loss of $9.6 million for the fourth quarter of 2018 and $35.6 million for the year ended December 31, 2018, or a net loss per basic and diluted share of $0.46 and $1.72, respectively.

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 the planned amended trial design for URIROX-2 and agreement in principle with the FDA about the amended design, 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. The planned amended trial design for URIROX-2 will be subject to a protocol amendment and associated study documents, which Allena plans to submit to the FDA shortly, and additional modifications to URIROX-2 may be required, which modifications could be material. The FDA has advised Allena that, while it agrees in principle with the planned revisions to URIROX-2, certain details, to be specified in the protocol amendment and associated study documents for the revised trial design, remain subject to further clarification and confirmation with the FDA. 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 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

Annual Report on Form 10-K for the year ended December 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 December 31,	
	2019	2018
Cash and cash equivalents	$ 30,007	$ 61,643
Working capital (1)	22,127	58,706
Total assets	34,108	65,229
Loan payable, net of current portion and discount	5,988	9,980
Total stockholders' equity	17,198	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 December 31,		For the Year Ended December 31,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 8,721	$ 7,269	$ 37,244	$ 26
General and administrative	1,967	2,511	9,676	9
Restructuring charges	605	—	605	
Total operating expenses	11,293	9,780	47,525	35
Other income (expense), net	(66)	169	186	
Net loss	$ (11,359)	$ (9,611)	$ (47,339)	$ (35,
Net loss per share attributable to common stockholders—basic and diluted	$ (0.47)	$ (0.46)	$ (2.13)	$ (1
Weighted-average common shares outstanding—basic and diluted	23,497,048	20,782,177	22,180,868	20,741

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