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 9, 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 November 9, 2020, Allena Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 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 November 9, 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: November 9, 2020

Allena Pharmaceuticals, Inc.

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

Exhibit 99.1

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

-- Presented Data at 53rd Annual Meeting of the American Society of Nephrology (ASN) Highlighting Consistent Treatment Effects Across Phase 2 and 3 Clinical Trials of Reloxaliase in Enteric Hyperoxaluria (EH) --

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

-- Entered into $25 Million Strategic Convertible Debt Financing Agreement with Pontifax Ventures, Extending Cash Runway into the Fourth Quarter of 2021 --

NEWTON, Mass., November 9, 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 third quarter ended September 30, 2020 and provided a business update.

“In recent months, we have continued to make progress across our portfolio. We are actively enrolling URIROX-2, our pivotal trial of reloxaliase for patients with EH. We also recently completed dosing in our Phase 1 trial of ALLN-346 and we remain on track to achieve all our expected clinical milestones,” said Louis Brenner, M.D, President and Chief Executive Officer of Allena Pharmaceuticals. “In addition, at the virtual ASN meeting, we presented an aggregate review of data generated across our clinical development program for reloxaliase, which highlight reloxaliase’s consistent, clinically meaningful impact on urinary oxalate excretion (UOx) and reinforce our conviction in its potential as a novel therapeutic that could change the treatment paradigm in EH. Following our strategic debt financing agreement with Pontifax, we are well-funded, with the capital and financial flexibility to advance our mission and deliver on the promise of oral enzyme therapeutics for people with rare and severe metabolic and kidney diseases.”

Allena Pharmaceuticals also announced today the resignation of Edward Wholihan, Chief Financial Officer, who will be stepping down for personal reasons. Mr. Wholihan will continue to serve in his current role as the Company conducts a search for his successor.

Dr. Brenner continued, “On behalf of my colleagues, I want to thank Ed for his dedicated leadership and business acumen, which have been instrumental in growing Allena into a publicly-traded, late-stage company. During his tenure, Ed has built a robust financial organization, providing an important foundation that has enabled investment across our portfolio.”

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. Allena continues to expect the interim analysis from this trial in the first quarter of 2022 and to announce topline data, which are intended to support a potential Biologics License Application (BLA) submission, in the third quarter of 2022.

At the ASN meeting, held virtually in October 2020, Allena presented three posters, including an aggregate review of data from completed Phase 2 and 3 clinical trials of reloxaliase in EH and data from Study 206 in patients with EH and advanced chronic kidney disease (CKD). Data from these studies support that reloxaliase has been well-tolerated, with the potential to provide meaningful clinical benefit: across Phase 2 and 3 studies in EH, treatment with reloxaliase consistently reduced 24-hour UOx excretion in patients with EH, with reductions of 23 to 35 percent observed, and in Study 206, treatment with reloxaliase reduced both UOx and plasma oxalate (POx) excretion in patients with EH and CKD Stages 3-5. Also at ASN, Allena presented details on the study design for URIROX-2, the largest and most comprehensive randomized clinical trial to-date in EH.

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 November 2020, Allena completed dosing of all subjects in its Phase 1 clinical trial of ALLN-346. This Phase 1 clinical trial is a randomized, double blind, placebo-controlled, single ascending dose study of orally administered ALLN-346 in approximately 24 healthy volunteers. The primary objective of the study is to assess safety and tolerability over 28 days. Initial data are expected in the fourth quarter of 2020.

Corporate:

- In September 2020, Allena entered into a $25 million loan and security agreement with Pontifax Medison Finance, the healthcare-dedicated venture and debt fund of the Pontifax life sciences funds. Under the terms of the agreement, Allena will have access to up to $25 million in convertible debt financing in three tranches; the Company drew the first tranche of $10 million upon closing. Additionally, both Pontifax and Allena have the option to convert the loan drawn under the first two tranches into shares of Allena's common stock at a price of $4.10 per share, subject to certain conditions.
- In October 2020, Allena announced the appointment of Ann Miller, M.D., to its board of directors. Dr. Miller is an experienced industry executive, who has launched and grown multiple blockbuster products and built several leading franchises over the course of her career.

Third Quarter 2020 Financial Results:

- **Cash Position:** As of September 30, 2020, cash and cash equivalents were $30.1 million, as compared to $30.0 million as of December 31, 2019. The change in cash position was primarily due to gross proceeds of approximately $15.0 million received from the company's June 2020 registered direct offering and gross proceeds of approximately $7.7 million received from the company's July 2020 public underwritten offering, offset by cash used in operating activities.
- **R&D Expenses:** R&D expenses were $5.0 million for the third quarter of 2020, as compared to $10.8 million for the third 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 Study 206 trials, both of which were completed in the fourth quarter of 2019, 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 incurred in the third quarter of 2019. The Company filed an IND for ALLN-346 with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2019.
- **G&A Expenses:** G&A expenses were $3.0 million for the third quarter of 2020, as compared to $2.5 million for the third quarter of 2019. This increase was due primarily to increases in stock-based compensation and corporate directors and officers insurance costs.
- **Net Loss:** Net loss was $8.0 million for the third quarter of 2020, or a net loss per basic and diluted share of $0.22, as compared to a net loss of $13.3 million for the third quarter of 2019, or a net loss per basic and diluted share of $0.57. Contributing to the decrease in net loss per share was both a decrease in net loss for the quarter and an increase in the weighted average shares of common stock outstanding for the third quarter of 2020 compared to the weighted average shares outstanding for the third quarter of 2019, driven by the issuance of shares of common stock for the registered direct offering in June 2020 and the public underwritten offering in July 2020.

Financial Guidance:

Based on its current plans, Allena expects that its existing cash and cash equivalents, together with the funds available under its agreement with Pontifax, will be sufficient to fund its operating expenses and capital expenditure requirements into the fourth 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 development and potential commercialization of reloxaliase, changes in Allena's management, Allena's pipeline of oral enzyme therapeutic candidates and Allena's plans to build a commercial organization. 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: market and other conditions, the timing for completion of Allena's clinical trials of its product candidates, 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 September 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.

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

	As of September 30, 2020	As of December 31, 2019
Cash and cash equivalents	$ 30,136	$ 30,007
Working capital (1)	27,400	22,127
Total assets	31,968	34,108
Loan payable, net of current portion and discount	9,871	5,988
Total stockholders' equity	18,179	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 September 30,		For the Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 4,952	$ 10,806	$ 13,406	$ 28,523
General and administrative	2,966	2,532	8,595	7,709
Total operating expenses	7,918	13,338	22,001	36,232
Other income (expense), net	(108)	50	(586)	252
Net loss	$ (8,026)	$ (13,288)	$ (22,587)	$ (35,980)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.22)	$ (0.57)	$ (0.77)	$ (1.66)
Weighted-average common shares outstanding—basic and diluted	36,260,973	23,464,828	29,317,787	21,737,320