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): December 14, 2017

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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 December 14, 2017, Allena Pharmaceuticals, Inc. issued a press release announcing its financial results for the quarter ended September 30, 2017 and providing 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. dated December 14, 2017

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.

Allena Pharmaceuticals, Inc.

Date: December 14, 2017

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

Exhibit 99.1

Allena Pharmaceuticals Reports Third Quarter 2017 Financial Results and Provides Business Update

— Successfully Completed Initial Public Offering, Raising $74.9 Million in Gross Proceeds
— Presented Final Results from Phase 2 Trials of ALLN-177 in Secondary Hyperoxaluria at ASN Kidney Week 2017
— Received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) and European Commission for ALLN-177 in Primary Hyperoxaluria

NEWTON, Mass., December 14, 2017 – Allena Pharmaceuticals, Inc., a late-stage clinical 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 and provided a business update for the third quarter ended September 30, 2017.

"Our third quarter and recent accomplishments represent significant progress across our business," said Alexey Margolin, Ph.D., Chief Executive Officer of Allena Pharmaceuticals. "In November, we presented the final results from our Phase 2 trials of ALLN-177 in secondary hyperoxaluria at the Kidney Week Conference of the American Society of Nephrology (ASN), which suggest that ALLN-177 may offer patients with enteric hyperoxaluria the first potential therapy for reducing urinary oxalate levels and, we believe, support its advancement into pivotal Phase 3 studies. We also received orphan drug designation for ALLN-177 for primary hyperoxaluria in both the United States and Europe. We are committed to addressing the significant unmet need for patients with severe oxalate disorders, for which there are no FDA or European Commission approved therapies. Following the completion of our initial public offering, we are well-funded, with resources expected to be sufficient to advance our clinical, preclinical, and manufacturing development into 2020."

Third Quarter and Recent Business Highlights:

Pipeline:

ALLN-177: ALLN-177, Allena's lead product candidate, is a first-in-class, non-absorbed, orally-administered enzyme for the treatment of severe hyperoxaluria. Allena expects to initiate the first of two planned pivotal Phase 3 clinical trials for ALLN-177 in enteric hyperoxaluria in the first quarter of 2018 and to announce topline data in the second half of 2019. The Company also plans to initiate a Phase 2 clinical trial of ALLN-177 in adolescents and adults with primary hyperoxaluria or severe forms of secondary hyperoxaluria in the first quarter of 2018, with interim data expected in the second half of 2018.

- In November 2017, Allena presented final results from its Phase 2 clinical trials of ALLN-177 in patients with secondary hyperoxaluria at the American Society of Nephrology (ASN) Kidney Week 2017 in New Orleans, LA. In patients with enteric hyperoxaluria, ALLN-177 substantially reduced urinary oxalate (UOx) excretion and was well-tolerated, with no drug-related serious or severe adverse events (SAEs) and no discontinuations of study drug due to SAE. Also at the ASN meeting, Allena presented preclinical data from a porcine dietary model of severe hyperoxaluria, which showed a significant reduction in both plasma oxalate and UOx excretion. This preclinical study supported the Company's orphan drug designation in primary hyperoxaluria and demonstrated animal proof-of-concept for the upcoming Phase 2 clinical trial in patients with severe hyperoxaluria and hyperoxalemia (elevated plasma oxalate). Hyperoxalemia increases the risk of systemic oxalosis, which refers to the presence of excess oxalate throughout the body, including the blood, bones, joints, eyes and heart.
- In July 2017, Allena received orphan drug designation from both the FDA and the European Commission for ALLN-177 for the treatment of primary hyperoxaluria (PH). PH is a severe rare genetic disorder caused by endogenous overproduction of oxalate by the liver that can result in kidney stone disease, kidney damage, kidney failure, and systemic oxalosis, which may lead to death.

ALLN-346: ALLN-346, Allena's second product candidate, is a first-in-class, orally-administered, non-absorbed, urate-degrading enzyme in preclinical development for patients with hyperuricemia and moderate to severe chronic kidney disease (CKD). These patients are challenging to manage due to limitations of existing therapies, such as poor tolerability, reduced efficacy, dose restriction or contraindications.

- Allena initiated a preclinical study for ALLN-346 in December 2017 and expects to file an investigational new drug (IND) application for ALLN-346 in the first half of 2019.

Corporate:

- In November 2017, Allena completed its initial public offering of common stock at $14.00 per share, raising gross proceeds of $74.9 million.

Third Quarter 2017 Financial Results:

- Cash Position: As of September 30, 2017, cash and cash equivalents were $33.9 million, as compared to cash, cash equivalents and short-term investments of $48.8 million as of December 31, 2016. Cash and cash equivalents as of September 30, 2017 do not include the proceeds from the Company's initial public offering of common stock, which was completed in November 2017. The Company expects that its cash, cash equivalents, and short-term investments will enable it to fund its operating plan into 2020.
- R&D Expenses: R&D expenses were $2.9 million for the third quarter of 2017, as compared to $5.3 million for the third quarter of 2016. This decrease was primarily due to the decrease in clinical costs. During the third quarter of 2016, the Company incurred clinical trial costs for its 649 and 713 studies for ALLN-177, which were active during the third quarter of 2016 and concluded prior to the third quarter of 2017.
- G&A Expenses: G&A expenses were $1.4 million for the third quarter of 2017, as compared to $0.8 million for the third quarter of 2016. This increase was primarily due to an increase in legal and consulting costs incurred during the third quarter of 2017.
- Net Loss: Net loss was $4.7 million for the third quarter of 2017, or $3.49 per basic and diluted share, as compared to a net loss of $6.1 million for the third quarter of 2016, or $4.59 per basic and diluted share.

About Allena Pharmaceuticals

Allena Pharmaceuticals, Inc. is a late-stage clinical 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, ALLN-177, 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 statements regarding the safety, efficacy and potential clinical benefits of Allena's product candidates, the timing of initiation of Allena's planned Phase 3 clinical trials for ALLN-177 and the announcement of data from these trials, the timing of the filing of an IND for ALLN-346, and Allena's financial condition and cash runway into 2020. 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 studies may not establish an adequate safety or efficacy profile for ALLN-177 and other product candidates that support regulatory approval; risks associated with the fact that Allena has not yet finalized the design of its pivotal Phase 3 clinical program for ALLN-177, including the primary and secondary endpoints and the statistical analyses for these planned Phase 3 clinical trials, and that the FDA and

comparable foreign regulators may not agree with the proposed Phase 3 clinical program, in which case Allena may be required to modify its planned clinical trials, or run additional clinical trials, before it can submit a BLA or comparable foreign applications for this product candidate; risks associated with a potential accelerated approval pathway, which would require that Allena conduct one or more confirmatory clinical trials to verify the clinical benefit of Allena's 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 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 the final prospectus related to Allena's initial public offering filed with the Securities and Exchange Commission pursuant to Rule 424(b) of the Securities Act of 1933, as amended, 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 Sheet

(in thousands)

(unaudited)

	September 30, 2017	December 31, 2016
Cash, cash equivalents and short term-investments	$ 33,874	$ 48,755
Working capital (1)	27,313	46,025
Total assets	36,263	49,479
Loan payable, net of current portion and discount	6,620	9,409
Convertible preferred stock	95,779	95,727
Total stockholders' deficit	(74,000)	(59,277)

(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.

Selected Condensed Consolidated Statement of Operations

(in thousands, except share and per share data)

(unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 2,949	$ 5,263	$ 10,758	$ 15,288
General and administrative	1,413	839	3,621	2,896
Total operating expenses	4,362	6,102	14,379	18,184
Other income (expense), net	(308)	(34)	(594)	(104)
Net loss	$ (4,670)	$ (6,136)	$ (14,973)	$ (18,288)
Net loss per share attributable to common stockholders—basic and diluted	$ (3.49)	$ (4.59)	$ (11.19)	$ (13.70)
Weighted-average common shares outstanding—basic and diluted	1,343,429	1,341,385	1,342,898	1,338,539

Investor Contact

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