
**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 5, 2018

Alder BioPharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36431
(Commission
File Number)

90-0134860
(IRS Employer
Identification No.)

11804 North Creek Parkway South
Bothell, WA
(Address of principal executive offices)

98011
(Zip Code)

(425) 205-2900
Registrant's telephone number, including area code:

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 (§ 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 5, 2018, Alder BioPharmaceuticals, Inc. (“Alder”) issued a press release announcing financial results for the quarter ended September 30, 2018 and providing a corporate update. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

The information in this report, including the exhibit hereto, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained herein and in the accompanying exhibit shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Alder, whether made before, on or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Alder BioPharmaceuticals, Inc. issued November 5, 2018

INDEX TO EXHIBITS

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99.1	Press Release of Alder BioPharmaceuticals, Inc. issued November 5, 2018

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.

Alder BioPharmaceuticals, Inc.

Dated: November 5, 2018

By: /s/ Robert W. Azelby
Robert W. Azelby
President and Chief Executive Officer



Alder BioPharmaceuticals® Reports Third Quarter 2018 Financial and Operating Results

- Biologics License Application (BLA) submission on track for Q1 2019 -

- Robust manufacturing package for BLA submission to include positive results from pharmacokinetic comparability study -

- Conference call today at 5:00 p.m. ET -

BOTHELL, Wash., Nov. 5, 2018 – Alder BioPharmaceuticals, Inc. (NASDAQ:ALDR), a biopharmaceutical company focused on developing novel therapeutic antibodies for the treatment of migraine, today provided a corporate update and reported its financial results for the third quarter ended September 30, 2018.

“We are pleased to have recently announced the positive results from our pharmacokinetic (PK) comparability study for eptinezumab as we are now in the final stages of compiling the integrated data package for our BLA submission, which continues to be on track for the first quarter of 2019,” said Bob Azelby, president and chief executive officer of Alder. “Market research and positive physician feedback have reinforced our confidence in eptinezumab’s encouraging clinical profile, and we believe we are well-positioned to maximize eptinezumab’s potential to treat highly impacted migraine patients.”

Recent Company Highlights

- Announced positive results from a PK study intended to support the comparability evaluation of the clinical supply for eptinezumab and its planned commercial supply. Both the primary and key secondary PK results met the standard pre-specified acceptance criteria for drug product comparability. Further, the test and reference products were well-tolerated with a similar adverse event profile, and this safety profile was consistent with what has previously been reported for eptinezumab.
 - Remains on track to complete a robust and integrated BLA submission in the first quarter of 2019, including chemistry, manufacturing, and controls (CMC) processes, positive results from the comparative PK study and data from eptinezumab’s PROMISE 1 and PROMISE 2 pivotal Phase 3 clinical trials, as well as the long-term safety study.
 - Continued to conduct commercial readiness activities, including expanding the Company’s Medical Science Liaison team; recruiting commercial personnel; and building its reimbursement and distribution services in anticipation of eptinezumab’s potential launch in the first quarter of 2020.
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Third Quarter 2018 Financial Results

- As of September 30, 2018, Alder had \$484.7 million in cash, cash equivalents, investments and restricted cash compared to \$536.1 million as of June 30, 2018.
- Research and development expenses for the third quarter ended September 30, 2018 totaled \$47.8 million, compared to \$52.2 million for the same period in 2017. The decrease in expenses was primarily due to lower eptinezumab clinical trial expense as the Company nears completion of patient treatments for several clinical trials, offset by an increase in manufacturing activities and consulting fees to support the planned BLA submission and the production of commercial supply.
- General and administrative expenses for the third quarter ended September 30, 2018 totaled \$10.7 million, compared to \$8.2 million for the same period in 2017. The increase in spending was primarily due to headcount growth and expenses to support commercial readiness activities.
- Net loss applicable to common stockholders for the third quarter ended September 30, 2018 totaled \$62.2 million, or \$0.91 per share, compared to net loss of \$59.6 million, or \$0.92 per share on a fully-diluted basis, for the same period in 2017.

Financial Outlook

- Alder believes its available cash, cash equivalents, investments and restricted cash will be sufficient to meet the company's projected operating requirements into 2020.

Conference Call and Webcast

Alder will host a conference call today at 5:00 p.m. ET to discuss these financial results and recent corporate highlights. The live call may be accessed by dialing (877) 430-4657 for domestic callers or (484) 756-4339 for international callers and providing conference ID number 9574606. The webcast will be broadcast live and can be accessed from the Events & Presentations page in the Investors section of Alder's website at www.alderbio.com. The webcast will be available for replay following the call for at least 30 days.

About Alder BioPharmaceuticals, Inc.

Alder BioPharmaceuticals is a clinical-stage biopharmaceutical company focused on transforming the migraine treatment paradigm through the discovery, development and commercialization of novel therapeutic antibodies. Alder's lead product candidate, eptinezumab, is a monoclonal antibody (mAb) that inhibits calcitonin gene-related peptide (CGRP) and is currently in late-stage clinical development for the prevention of migraine. Unlike other CGRP inhibitors, eptinezumab was specifically designed as an infusion therapy to address significant patient need. Alder is also developing ALD1910, a preclinical mAb that inhibits pituitary adenylate cyclase-activating polypeptide-38 (PACAP-38) for migraine prevention. For more information, please visit www.alderbio.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements relating to: the planned BLA submission with the FDA, including the preparation, contents and timing thereof; Alder's confidence in eptinezumab's clinical profile; eptinezumab's potential as a treatment for highly impacted migraine patients; and Alder's belief that its available cash, cash equivalents, investments and restricted cash will be sufficient to meet the company's projected operating requirements into 2020. Words such as "on track," "pleased," "continues," "reinforced," "encouraging," "believe," "well-positioned," "potential," "anticipation," "will," "sufficient," or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. The forward-looking statements in this press release are based upon Alder's current plans, assumptions, beliefs, expectations, estimates and projections, and involve substantial risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements due to these risks and uncertainties as well as other factors, which include, without limitation: risks related to the potential failure of eptinezumab to demonstrate safety and efficacy in clinical testing; Alder's ability to conduct clinical trials and studies of eptinezumab sufficient to achieve a positive completion; the availability of data at the expected times; the clinical, therapeutic and commercial value of eptinezumab; risks and uncertainties related to regulatory application, review and approval processes and Alder's compliance with applicable legal and regulatory requirements; risks and uncertainties relating to the manufacture of eptinezumab; Alder's ability to obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of others; the uncertain timing and level of expenses associated with Alder's development and commercialization activities; the sufficiency of Alder's capital and other resources; market competition; changes in economic and business conditions; and other factors discussed under the caption "Risk Factors" in Alder's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2018, which was filed with the Securities and Exchange Commission (SEC) on November 5, 2018, and is available on the SEC's website at www.sec.gov. Additional information will also be set forth in Alder's other reports and filings it will make with the SEC from time to time. The forward-looking statements made in this press release speak only as of the date of this press release. Alder expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Alder's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Condensed Consolidated Balance Sheets
(Unaudited)
(Amounts in thousands)

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Cash, cash equivalents, investments and restricted cash	\$ 484,684	\$ 286,240
Prepaid expenses and other assets	12,069	16,896
Total assets	\$ 496,753	\$ 303,136
Convertible notes, net of discount	\$ 179,038	\$ —
Other liabilities	32,588	23,861
Convertible preferred stock	101,095	—
Total stockholders' equity	184,032	279,275
Total liabilities, convertible preferred stock and stockholders' equity	\$ 496,753	\$ 303,136

**Condensed Consolidated Statements of Operations
(Unaudited)**

(Amounts in thousands, except share and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Revenues				
Collaboration and license agreements	\$ —	\$ —	\$ —	\$ 683
Operating expenses				
Cost of sales	—	—	—	683
Research and development	47,793	52,188	174,659	208,153
General and administrative	10,685	8,236	34,501	27,765
Total operating expenses	58,478	60,424	209,160	236,601
Loss from operations	(58,478)	(60,424)	(209,160)	(235,918)
Other income (expense), net	(2,442)	859	(7,180)	1,396
Net loss	\$ (60,920)	\$ (59,565)	\$ (216,340)	\$ (234,522)
Dividends on convertible preferred stock	(1,279)	—	(4,664)	—
Deemed dividend on convertible preferred stock related to accretion of beneficial conversion feature	—	—	(29,460)	—
Net loss applicable to common stockholders	\$ (62,199)	\$ (59,565)	\$ (250,464)	\$ (234,522)
Net loss per share applicable to common stockholders - basic and diluted	\$ (0.91)	\$ (0.92)	\$ (3.68)	\$ (4.25)
Weighted average number of common shares used in net loss per share - basic and diluted	68,232,765	64,526,519	68,015,989	55,168,433

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