
**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 7, 2017

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 7, 2017, Alder BioPharmaceuticals, Inc. (“Alder”) issued a press release announcing financial results for the quarter ended September 30, 2017 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 7, 2017

INDEX TO EXHIBITS

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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 7, 2017

By: /s/ Randall C. Schatzman
Randall C. Schatzman, Ph.D.
President and Chief Executive Officer



Alder BioPharmaceuticals® Announces Third Quarter 2017 Financial and Operating Results

– PROMISE 2 pivotal trial completed enrollment and top-line data on track for 1H18 –

– Eptinezumab Biologics License Application (BLA) submission on track for 2H18 –

– Conference call scheduled for 5 p.m. ET today –

BOTHELL, Wash., Nov. 7, 2017 – Alder BioPharmaceuticals, Inc. (NASDAQ: ALDR), a clinical-stage biopharmaceutical company developing monoclonal antibody therapeutics, today announced financial results for the third quarter ended September 30, 2017, and provided a corporate update.

“In the third quarter, we continued to showcase the positive results of eptinezumab, our lead pivotal-stage product candidate for the prevention of migraine, and recently had seven presentations at the 18th Congress of the International Headache Society,” said Randall C. Schatzman, Ph.D., president and chief executive officer of Alder. “We are encouraged by the migraine community’s excitement regarding eptinezumab’s unique clinical profile, including migraine prevention as early as Day 1 and >75% responder rates achieved by month one and sustained for three months from one administration. As the first-to-market anti-CGRP infusion therapy, we are confident that eptinezumab can address a distinct market segment of five million of the most severe episodic and chronic patients who are heavily impacted by migraine. Importantly, we remain on track to announce top-line data our PROMISE 2 Phase 3 pivotal trial in the first half of 2018 and complete our planned BLA submission in the second half of 2018. We look forward to delivering on our mission to transform the treatment of migraine and creating long-term value for our shareholders.”

Recent Corporate Highlights

- Completed patient enrollment in PROMISE 2 (Prevention Of Migraine via Intravenous eptinezumab Safety and Efficacy 2), the Company’s ongoing Phase 3 pivotal trial evaluating the safety and efficacy of eptinezumab administered via infusion once every three months in approximately 1,050 patients with chronic migraine.
 - Delivered seven presentations at the 18th Congress of the International Headache Society (IHC) in Vancouver, Canada in September 2017 providing clinical data and analyses for eptinezumab, including additional Phase 3 data from the PROMISE 1 Phase 3 pivotal trial and analyses of Alder’s Phase 2b clinical trial. The data presented further supported eptinezumab’s clinical profile as a potential first-of-its-kind, highly differentiated infusion therapy to prevent migraine.
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Upcoming Milestones

- Report top-line data from the PROMISE 2 pivotal trial in the first half of 2018.
- Submit the BLA for eptinezumab with the U.S. Food and Drug Administration (FDA) in the second half of 2018.

Third Quarter 2017 Financial Results

Research and development expenses for the quarter ended September 30, 2017 totaled \$52.2 million, compared to \$29.5 million for the same period in 2016. This increase over the same period last year reflects the company's commitment to advancing the pivotal-stage eptinezumab program and commercialization preparations.

General and administrative expenses for the quarter ended September 30, 2017 totaled \$8.2 million, compared to \$6.2 million for the same period in 2016. The increases in spending were primarily due to an increase in stock-based compensation expense and salaries due to headcount growth, and an increase in professional fees and other administrative costs primarily to support commercial readiness activities.

Net loss for the quarter ended September 30, 2017 totaled \$59.6 million, or \$0.92 per share, compared to net loss of \$35.1, or \$0.70 per share, on a fully-diluted basis, for the same period in 2016.

Cash, cash equivalents, short-term investments and restricted cash totaled \$340.9 million as of September 30, 2017, compared to \$224.5 million as of June 30, 2017.

Financial Outlook

Alder estimates its available cash and cash equivalents and short-term investments, will be sufficient to meet the company's projected operating requirements through late 2018/early 2019 and enable the Company to achieve the planned BLA submission for eptinezumab and other key eptinezumab activities.

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 4399736. 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 30 days.

About Alder BioPharmaceuticals, Inc.

Alder BioPharmaceuticals, Inc. is a clinical-stage biopharmaceutical company committed to transforming the treatment paradigm for patients with migraine and other serious neurological or inflammatory conditions. Leveraging its pioneering monoclonal antibody technologies, Alder discovers and develops novel therapeutic antibodies designed to deliver highly differentiated, best-in-class clinical profiles. Alder's lead pivotal-stage product candidate, eptinezumab, is being evaluated for migraine prevention. Eptinezumab is a monoclonal antibody administered quarterly via infusion that allows for 100% of the dose available to selectively and potently inhibit the calcitonin gene-related peptide (CGRP), a protein that is active in mediating the initiation of migraine. Alder is additionally evaluating ALD1910, a preclinical product candidate also in development as a migraine prevention therapy. ALD1910 is a monoclonal antibody that inhibits pituitary adenylate cyclase-activating polypeptide-38 (PACAP-38), another protein that is active in mediating the initiation of migraine. Clazakizumab, Alder's third program, is a monoclonal antibody candidate that inhibits interleukin-6 and is licensed to Vitaeris, Inc. For more information, please visit <http://www.alderbio.com>.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements relating to: the continued development and clinical, therapeutic and commercial potential of eptinezumab; the availability of results from clinical trials; the planned BLA submission with the FDA and the potential regulatory approval of eptinezumab; eptinezumab's competitive and differentiated profile; the belief that eptinezumab can address a distinct market segment of five million of the most severe episodic and chronic patients who are heavily impacted by migraine; Alder's mission to transform the treatment of migraine and create long-term value for its shareholders; Alder's commitment to advancing the pivotal-stage eptinezumab program and commercialization preparations; Alder's efforts to manage its cash resources; and Alder's financial outlook, including the sufficiency of Alder's cash resources to meet projected operating requirements through late 2018/early 2019 and enable the achievement of the planned BLA submission for eptinezumab and other key eptinezumab activities. Words such as "on track," "continued," "encouraged," "confident," "can," "planned," "look forward," "delivering," "upcoming," "potential," "report," "submit," "commitment," "estimates," "sufficient," "will," "enable," "achieve," 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, 2017, which was filed with the Securities and Exchange Commission (SEC) on November 7, 2017, 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)

	September 30, 2017	December 31, 2016
Cash, cash equivalents, investments and restricted cash	\$ 340,885	\$ 351,867
Prepaid expenses and other assets	25,429	57,287
Total assets	\$ 366,314	\$ 409,154
Total liabilities	\$ 39,144	\$ 26,371
Total stockholders' equity	327,170	382,783
Total liabilities and stockholders' equity	\$ 366,314	\$ 409,154

**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,	
	2017	2016	2017	2016
Revenues				
Collaboration and license agreements	\$ —	\$ —	\$ 683	\$ 113
Operating expenses				
Cost of sales	—	—	683	113
Research and development	52,188	29,491	208,153	90,971
General and administrative	8,236	6,239	27,765	18,750
Total operating expenses	60,424	35,730	236,601	109,834
Gain on license of clazakizumab	—	—	—	1,050
Loss from operations	(60,424)	(35,730)	(235,918)	(108,671)
Other income, net	859	596	1,396	1,308
Net loss	\$ (59,565)	\$ (35,134)	\$ (234,522)	\$ (107,363)
Net loss per share - basic and diluted	\$ (0.92)	\$ (0.70)	\$ (4.25)	\$ (2.25)
Weighted average number of common shares used in net loss per share - basic and diluted	64,526,519	50,226,588	55,168,433	47,763,913

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