
**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): February 26, 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 February 26, 2018, Alder BioPharmaceuticals, Inc. (“Alder”) issued a press release announcing financial results for the fourth quarter and full year ended December 31, 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.

Exhibit No.	Description
99.1	Press Release of Alder BioPharmaceuticals, Inc. issued February 26, 2018

INDEX TO EXHIBITS

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99.1	Press Release of Alder BioPharmaceuticals, Inc. issued February 26, 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: February 26, 2018

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



Alder BioPharmaceuticals Reports Fourth Quarter and Full Year 2017 Financial and Operating Results

- *Strong cash position to support eptinezumab development through approval and commercial launch –*
- *Recently reported pivotal PROMISE 2 top-line data in chronic migraine demonstrates eptinezumab significantly reduced migraine risk in patients, met all primary and key secondary endpoints –*
- *Biologics License Application (BLA) on track for submission in 2H18 –*
- *Conference call today at 5 p.m. ET –*

BOTHELL, Wash., Feb. 26, 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 fourth quarter and full year ended December 31, 2017.

“The data from eptinezumab’s Phase 3 pivotal clinical trials in episodic and chronic migraine patients support Alder’s goal to advance the treatment paradigm for migraine prevention. In both trials, eptinezumab’s clinical profile included rapid Day 1 reduction in migraine risk, high levels of efficacy with patients achieving 75% and 100% responder rates and sustained migraine relief for 3 months following a single infusion administration,” said Randall C. Schatzman, Ph.D., President and Chief Executive Officer of Alder. “If approved, eptinezumab has the potential to provide a meaningful treatment option for millions of migraine sufferers. Looking ahead to the remainder of 2018 and into 2019, we are focused on our BLA submission, gaining FDA approval and on our commercial readiness activities ahead of eptinezumab’s launch. Our 2017 year-end cash balances, together with the net proceeds of our two successful 2018 financings, total over \$600 million, leaving us well-positioned to meet our projected operating requirements into 2020.”

Recent 2018 Company Highlights

- PROMISE 2 Phase 3 eptinezumab top-line data in chronic migraine patients:
 - Met the primary endpoint with very high statistical significance vs. placebo ($p < 0.0001$) for both dose levels tested in the trial following the first quarterly infusion.
 - Met all key secondary endpoints with very high statistical significance vs. placebo including prevention beginning Day One ($p < 0.0001$) and 50 percent ($p < 0.0001$) and 75 percent ($p < 0.0001$) responder rates month one through month three. Furthermore, an average of 15 percent of eptinezumab patients had no migraines (i.e., 100 percent response) for months one to three ($p < 0.0001$ unadjusted).
 - Safety and tolerability were similar to previously reported eptinezumab studies.
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- European patent settlement and global license agreement with Teva Pharmaceuticals International GmbH clears Alder's freedom to develop, manufacture and commercialize eptinezumab in the U.S. and globally.
- Alder received approximately \$97.7 million in net proceeds from the sale of shares of convertible preferred stock in a committed equity financing with certain institutional and other accredited investors affiliated with or managed by Redmile Group LLC.
- Alder received approximately \$277.7 million in net proceeds from an underwritten public offering of 2.5% convertible senior notes due 2025 (including approximately \$36.3 million from the exercise of an over-allotment option granted to the underwriters in the offering).

Upcoming Corporate Milestones

Planned 2018 Corporate Milestones for eptinezumab	Timing
PROMISE 1 12 month data (episodic migraine)	1H 2018
PROMISE 2 6 month data (chronic migraine)	1H 2018
12 month open label safety study	1H 2018
Pharmacokinetic comparability study	2H 2018
BLA submission	2H 2018

Key 2017 Company Highlights

- PROMISE 1 Phase 3 eptinezumab data in episodic migraine patients:
 - Met the primary endpoint with highly statistically significant reductions in monthly migraine days in the trial following the first quarterly infusion.
 - Significant clinical benefit achieved on Day One post-infusion ($p=0.0087$ unadjusted) and significant 50 percent ($p=0.0001$) and 75 percent ($p=0.0007$) responder rates month one through month three.
 - Efficacy further improved following a second quarterly infusion; an average of 17% of patients had no migraines following the first administration and that rose to 26% of patients following the second administration.
 - The safety profile was similar to placebo and consistent with previously reported eptinezumab studies.
 - Alder completed a public offering of common stock on July 18, 2017 resulting in net proceeds to Alder of approximately \$161.5 million, after underwriting discounts, commissions and offering expenses.
 - Eptinezumab data presentations at top tier medical conferences highlighted Phase 2b (chronic migraine) and PROMISE 1 Phase 3 (episodic migraine) clinical data and analyses:
 - Three scientific presentations at the 69th Annual American Academy of Neurology (AAN) April 22-28.
 - Four scientific presentations at the 59th Annual Scientific Meeting of the American Headache Society (AHS) June 8-11.
 - Seven scientific presentations at the 18th Congress of the International Headache Society (IHC) September 7-10.
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Fourth Quarter and Year-End 2017 Financial Results

- As of December 31, 2017, Alder had \$286.2 million in cash, cash equivalents, short-term investments and restricted cash, compared to \$340.9 million as of Sept. 30, 2017 and compared to \$351.9 million as of December 31, 2016.
- Research and development expenses for the fourth quarter ended December 31, 2017 totaled \$44.7 million, compared to \$41.8 million for the same period in 2016. For the full year 2017, research and development expenses totaled \$252.9 million, compared to \$132.8 million for the full year 2016. The increases in spending for both periods were primarily due to manufacturing and clinical trial costs for the company's eptinezumab program and commercialization preparations.
- General and administrative expenses for the fourth quarter ended December 31, 2017 totaled \$10.3 million, compared to \$7.4 million for the same period in 2016. For the full year 2017, general and administrative expenses totaled \$38.1 million, compared to \$26.1 million for the full year 2016. The increases in spending for both periods 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 fourth quarter ended December 31, 2017 totaled \$54.4 million, or \$0.80 per share, compared to net loss of \$48.9 million, or \$0.97 per share on a fully-diluted basis, for the same period in 2016. For the full year 2017, net loss totaled \$288.9 million, or \$4.95 per share on a fully-diluted basis, compared to net loss of \$156.3 million, or \$3.23 per share, for the full year 2016.

Financial Outlook

- Alder estimates its available cash, cash equivalents, short-term investments and restricted cash totaling \$286.2 million as of December 31, 2017, together with the net proceeds of approximately \$97.7 million received in 2018 from the sale of shares of convertible preferred stock in its committed equity financing and approximately \$277.7 million received in 2018 in its underwritten public offering of 2.5% convertible senior notes due 2025 will be sufficient to meet projected operating requirements into 2020. These projections assume the BLA filing and approval by the U.S. Food and Drug Administration and the commercial launch of the infusion formulation of eptinezumab in this time period.

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 6943609. The webcast will be broadcast live and 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, 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 as potentially the first-to-market migraine prevention infusion therapy. Eptinezumab is a monoclonal antibody (mAb) inhibiting calcitonin gene-related peptide (CGRP), which is believed to play a key role in mediating and initiating 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 planned BLA submission with the FDA and the potential regulatory approval of eptinezumab; Alder's goal to advance the treatment paradigm for migraine prevention; the belief that eptinezumab has the potential to be a meaningful treatment option; and Alder's financial outlook, including Alder's belief that it has sufficient cash resources to meet projected operating requirements into 2020 and the assumptions related thereto. Words such as "demonstrate," "support," "on track," "strong," "potential," "can," "goal," "advance," "paradigm," "option," "looking ahead," "focused," "well-positioned," "projected," "freedom," "estimates," "will," "sufficient," "upcoming," "planned," "milestones," 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the Securities and Exchange Commission (SEC) on February 26, 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>December 31,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Cash, cash equivalents, short-term investments and restricted cash	\$ 286,240	\$ 351,867
Prepaid expenses and other assets	16,896	57,287
Total assets	\$ 303,136	\$ 409,154
Total liabilities	\$ 23,861	\$ 26,371
Total stockholders' equity	279,275	382,783
Total liabilities and stockholders' equity	\$ 303,136	\$ 409,154

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

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

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
Revenues				
Collaboration and license agreements	\$ 936	\$ —	\$ 1,619	\$ 113
Operating expenses				
Cost of sales	936	—	1,619	113
Research and development	44,749	41,789	252,902	132,760
General and administrative	10,337	7,398	38,102	26,148
Total operating expenses	56,022	49,187	292,623	159,021
Gain on license of clazakizumab	—	—	—	1,050
Loss from operations	(55,086)	(49,187)	(291,004)	(157,858)
Other income, net	729	296	2,125	1,604
Net loss	\$ (54,357)	\$ (48,891)	\$ (288,879)	\$ (156,254)
Net loss per share - basic and diluted	\$ (0.80)	\$ (0.97)	\$ (4.95)	\$ (3.23)
Weighted average number of common shares used in net loss per share - basic and diluted	67,780,176	50,324,529	58,347,284	48,407,565

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