
**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): May 8, 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 May 8, 2018, Alder BioPharmaceuticals, Inc. (“Alder”) issued a press release announcing financial results for the quarter ended March 31, 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 May 8, 2018

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: May 8, 2018

By: /s/ Paul B. Cleveland
Paul B. Cleveland
Interim President and Chief Executive Officer



Alder BioPharmaceuticals® Reports First Quarter 2018 Financial and Operating Results

- 12-Month Data Presented at American Academy of Neurology (AAN) Annual Meeting Demonstrated Eptinezumab Further Reduced Migraine Risk Following Third and Fourth Quarterly Infusions -

- Biologics License Application (BLA) Submission Expected in Q1 2019 -

- Key Clinical Data Milestones, CMC Studies and Commercial Preparedness Activities Remain on Track -

- Strengthened the Board of Directors and Management Team –

- Conference Call Today at 5 p.m. ET -

BOTHELL, Wash., May 8, 2018 – Alder BioPharmaceuticals, Inc. (NASDAQ:ALDR) (“Alder” or the “Company”), a biopharmaceutical company focused on developing novel therapeutic antibodies for the treatment of migraine, today provided a business update and reported its financial results for the first quarter ended March 31, 2018.

“During the first quarter of 2018, we continued to achieve key data milestones for eptinezumab that further reinforced the encouraging clinical profile demonstrated by our earlier data. At the AAN Annual Meeting in April, we presented new 12-month data from our PROMISE 1 Phase 3 clinical trial evaluating eptinezumab in prevention of episodic migraine. The data demonstrated that patients experienced even further long-term reductions in migraine following the third and fourth quarterly infusions. In addition, eptinezumab PROMISE 2 Phase 3 data in chronic migraine was selected by the AAN Science Committee as one of the most noteworthy clinical trial presentations, and was the only migraine presentation featured in the exclusive plenary session of the meeting. Further, we are encouraged by the positive feedback from the physician community regarding eptinezumab’s clinical profile and the consistency of data across clinical trials,” said Paul B. Cleveland, Alder’s Interim President and Chief Executive Officer.

Mr. Cleveland continued, “Our primary goal is the submission of a high-quality BLA that will meet the U.S. Food and Drug Administration’s (FDA) requirements for approval and ensure eptinezumab’s successful commercial launch. As we committed, we have completed an internal review of all activities related to our BLA and have concluded that we can achieve a high-quality BLA submission in the first quarter of 2019. To support these efforts, we have appointed Dr. Eric Carter as Interim Chief Medical Officer and have added additional outside resources to complement our team. Importantly, all key clinical and chemistry, manufacturing and controls (CMC) study milestones remain on track, and there are no new clinical or CMC data that change our confidence in our ability to pursue FDA approval of eptinezumab. We are continuing to position the Company for our next phase of growth by enhancing our management team and Board with Eric’s appointment and with the recent additions of Erin Lavelle as Chief Operating Officer and Jeremy Green as a Director.”

2018 Key Milestones and Company Highlights

- On April 26, Jeremy Green, Founder and Portfolio Manager of Redmile Group, LLC, was appointed to the Company's Board of Directors.
 - In April 2018, Alder delivered eight eptinezumab presentations at the 70th Annual AAN Annual Meeting in Los Angeles, California, which included new data from the PROMISE 1 Phase 3 clinical trial in episodic migraine patients that demonstrated the following:
 - Following one quarterly infusion, patients with a 75% or greater response experienced increased migraine-free intervals (median 32.5 days) and improved quality of life outcomes
 - Long-term and further reduction in migraine risk following the third and fourth quarterly infusions, with more than 50% of patients on average achieving a 75% reduction or greater of monthly migraine days from baseline
 - On April 23, 2018, Eric Carter was appointed as Interim Chief Medical Officer.
 - On April 16, 2018, Erin Lavelle was appointed to the newly created role of Chief Operating Officer.
 - On March 15, 2018, Alder Board member Paul B. Cleveland was appointed as Interim President and Chief Executive Officer.
 - In February 2018, the Company 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).
 - On January 12, 2018, the Company 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.
 - On January 8, 2018, the Company announced eptinezumab significantly reduced migraine risk and met primary and all key secondary endpoints in its pivotal PROMISE 2 Phase 3 clinical trial for chronic migraine prevention.
 - On January 5, 2018, the Company entered into a European patent settlement and global license agreement with Teva Pharmaceuticals International GmbH, which clarified Alder's freedom to develop, manufacture and commercialize eptinezumab in the United States and globally.
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Upcoming Corporate Milestones

Planned 2018 Corporate Milestones for eptinezumab	Timing
PROMISE 2 six-month data (chronic migraine)	June 2018
12-month open label safety study	June 2018
Pharmacokinetic comparability study	2H 2018
BLA submission	Q1 2019

First Quarter 2018 Financial Results

- As of March 31, 2018, Alder had \$587.0 million in cash, cash equivalents, short-term investments and restricted cash compared to \$286.2 million as of December 31, 2017.
- Research and development expenses for the first quarter ended March 31, 2018 totaled \$74.0 million, compared to \$90.7 million for the same period in 2017. The decrease in expenses was primarily due to lower manufacturing costs driven by timing of expenses, which can fluctuate from quarter to quarter. Research and development expenses for 2018 included a one-time payment of \$25 million under the settlement and global license agreement with Teva Pharmaceuticals International GmbH.
- General and administrative expenses for the first quarter ended March 31, 2018 totaled \$11.7 million, compared to \$10.0 million for the same period in 2017. The increase in spending was primarily due to headcount growth.
- Net loss applicable to common stockholders for the first quarter ended March 31, 2018 totaled \$117.6 million, or \$1.73 per share, compared to net loss of \$100.3 million, or \$1.99 per share on a fully-diluted basis, for the same period in 2017.

Financial Outlook

- The Company believes its available cash, cash equivalents, short-term 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 1767109. 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 accompanying slides are available now at 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 continued development and clinical, therapeutic and commercial potential of eptinezumab; the planned BLA submission with the FDA and the potential regulatory approval of eptinezumab; steps to position Alder for its next phase of growth; Alder's belief that it has sufficient cash resources to meet projected operating requirements into 2020; and Alder's focus on transforming the treatment paradigm for migraine prevention. Words such as "expected," "on track," "demonstrate," "encouraging," "goal," "will," "can," "position," "upcoming," "planned," "milestones," "believe," "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 March 31, 2018, which was filed with the Securities and Exchange Commission (SEC) on May 8, 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>March 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
Cash, cash equivalents, investments and restricted cash	\$ 587,047	\$ 286,240
Prepaid expenses and other assets	12,366	16,896
Total assets	\$ 599,413	\$ 303,136
Convertible notes, net of discount	\$ 173,197	\$ —
Other liabilities	26,108	23,861
Convertible preferred stock	97,710	—
Total stockholders' equity	302,398	279,275
Total liabilities, convertible preferred stock and stockholders' equity	\$ 599,413	\$ 303,136

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

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

	Three Months Ended	
	March 31,	
	2018	2017
Revenues		
Collaboration and license agreements	\$ —	\$ —
Operating expenses		
Research and development	74,048	90,689
General and administrative	11,662	9,981
Total operating expenses	85,710	100,670
Loss from operations	(85,710)	(100,670)
Other income (expense), net	(1,321)	342
Net loss	\$ (87,031)	\$ (100,328)
Accrued dividends on convertible preferred stock	(1,083)	—
Deemed dividend on convertible preferred stock related to accretion of beneficial conversion feature	(29,460)	—
Net loss applicable to common stockholders	\$ (117,574)	\$ (100,328)
Net loss per share applicable to common stockholders - basic and diluted	\$ (1.73)	\$ (1.99)
Weighted average number of common shares used in net loss per share - basic and diluted	67,844,872	50,395,632

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