ALDER BIOPHARMACEUTICALS INC

FORM 8-K
(Current report filing)

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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): June 27, 2017

Alder BioPharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36431**	**90-0134860**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

11804 North Creek Parkway South **Bothell, WA**	**98011**
(Address of principal executive offices)	**(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 8.01 Other Events.

On June 27, 2017, Alder BioPharmaceuticals, Inc. (the "Company") announced that eptinezumab met the primary and key secondary endpoints in the Company's PR evention O f M igraine via I ntravenous ALD403 S afety and E fficacy (PROMISE 1) clinical trial. This Phase 3 pivotal clinical trial is evaluating the safety and efficacy of eptinezumab administered at three dose levels (300mg, 100mg and 30mg) and placebo via infusion once every 12 weeks for one year in approximately 900 patients with frequent episodic migraine.

The primary endpoint, demonstrating statistically significant reductions in monthly migraine days from baseline (average of 8.6 days) over weeks 1 through 12 was 4.3 monthly migraine days for 300mg (p=0.0001) and 3.9 days for 100mg (p=0.0179) compared to an average 3.2 days for placebo. The 30mg dose level was not formally tested as per the prespecified statistical analysis plan.

Secondary endpoints evaluating time points through the first quarterly dose include:

- ≥ 75% reduction in monthly migraine days achieved over weeks 1 through 4 of 31.5% for 300mg (p=0.0066), and 30.8% for 100mg (p=0.0112) compared to 20.3% for placebo.
- ≥ 75% reduction in monthly migraine days achieved over weeks 1 through 12 of 29.7% for 300mg (p=0.0007), and 22.2% for 100mg (not statistically significant) compared to 16.2% for placebo.
- ≥ 50% reduction in monthly migraine days achieved by 56.3% of patients over weeks 1 through 12 for 300mg (p=0.0001), and 49.8% for 100mg (p=0.0085, unadjusted) compared to 37.4% for placebo.
- 53.6% reduction in the proportion of patients experiencing migraine on the day following administration at 300mg (p=0.0087, unadjusted), and 51.3% at 100mg (p=0.0167, unadjusted), compared to 20.7% for placebo.

Secondary endpoints demonstrated responses that were improved through the second quarterly dose period, and include:

- ≥ 75% reduction in monthly migraine days achieved over weeks 13 through 24 of 40.1% for 300mg (p=0.0006, unadjusted), and 33.5% for 100mg (p=0.0434, unadjusted) compared to 24.8% for placebo.
- Average of one in five patients receiving 300mg (20.6%) had 100% responses with no migraines in any given month (months 1 through 6).

The observed safety profile in this study to date was similar to placebo. Both the safety profile and the placebo rates were consistent with previously reported eptinezumab studies. Full safety data will be available at the end of the study.

The statistical significance of the PROMISE 1 results for each dose level across endpoints was assessed in a hierarchy set forth in a prespecified statistical analysis plan (generally assessing the 300mg dose level for a group of endpoints, 100mg dose level for a group of endpoints and 30mg dose level for a group of endpoints in sequence). Since the result for the 100mg dose level for the ≥ 75% reduction in monthly migraine days over weeks 1 through 12 endpoint was not statistically significant, the 30mg dose level was not formally tested per the statistical analysis plan.

Additional results, including future analysis of additional secondary endpoints, from the trial are expected to be presented at future medical meetings and published in peer-reviewed medical journals.

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements relating to: the continued development and clinical, therapeutic and commercial potential of eptinezumab; the availability of clinical trial data; and future data presentations and publications. Words such as "will," "believes," "future," "expected," or other similar words or expressions, identify forward-looking statements, but the absence of these words or expressions 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 Current Report on Form 8-K are based upon the Company'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; the availability of data at the expected times; the clinical, therapeutic and commercial value of eptinezumab; risks and uncertainties related to regulatory review and approval processes and the Company's compliance with applicable legal and regulatory requirements; the uncertain timing and level of expenses associated with the development of eptinezumab; the sufficiency of the Company's capital and other resources; market competition; changes in economic and business conditions; and other factors discussed under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, which was filed with the Securities and Exchange Commission (SEC) on April 27, 2017, and is available on the SEC's website at www.sec.gov, and in the Company's other filings with the SEC. The forward-looking statements made in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K. The Company 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 the Company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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.

Dated: June 30, 2017

Alder BioPharmaceuticals, Inc.

By: /s/ James B. Bucher
James B. Bucher
Senior Vice President and General Counsel