ALDER BIOPHARMACEUTICALS INC
Form 8-K
October 24, 2018

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): October 23, 2018

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.

Results from Pharmacokinetic Comparability Study

On October 23, 2018, Alder BioPharmaceuticals, Inc. (Alder) announced positive results from a comparative pharmacokinetic (PK) study intended to support the comparability evaluation of the clinical supply for eptinezumab and its planned commercial supply. Eptinezumab is Alder s lead investigational product candidate for migraine prevention targeting calcitonin gene-related peptide (CGRP).

The PK study was designed to confirm that the planned commercial supply of eptinezumab had a comparable pharmacokinetic profile to the eptinezumab that was utilized in Alder s clinical trials. Comparative PK profiles were demonstrated between the test and reference products; 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.

Alder remains on track to submit the Biologics License Application (BLA) for eptinezumab with the U.S. Food and Drug Administration in the first quarter of 2019.

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements relating to: the planned commercial supply of eptinezumab; and the timing of the referenced BLA submission. Words such as planned, on track, or other similar words or expressions, identify forward-looking statements. 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 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 June 30, 2018, which was filed with the Securities and Exchange Commission (SEC) on August 7, 2018, and is available on the SEC s website at www.sec.gov. 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. 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.

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: October 24, 2018

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