ALDER BIOPHARMACEUTICALS INC
Form 8-K
January 11, 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): January 5, 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		**98011**

Bothell, WA
(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 1.01 Entry into a Material Definitive Agreement.

Settlement and License Agreement

On January 5, 2018, Alder BioPharmaceuticals, Inc. (Alder) entered into a Settlement and License Agreement (the Settlement and License Agreement) with Teva Pharmaceuticals International GmbH (Teva). The Agreement resolves Alder s appeal following opposition proceedings before the European Patent Office related to Teva s European Patent No. 1957106 B1, with respect to calcitonin gene-related peptide (CGRP) antagonist antibodies, and provides clarity regarding Alder s freedom to develop, manufacture and commercialize eptinezumab, its lead product candidate for migraine prevention targeting CGRP.

Under the terms of the Settlement and License Agreement, Alder has received a non-exclusive license to Teva s CGRP patent portfolio to develop, manufacture and commercialize eptinezumab in the United States and worldwide, excluding Japan and Korea. In exchange, Alder has agreed to:

- Withdraw its appeal before the European Patent Office;
- Make an immediate one-time payment of $25 million to Teva;
- Make a second one-time payment of $25 million upon the approval of a Biologics License Application (BLA) for eptinezumab with the U.S. Food and Drug Administration (FDA) or of an earlier equivalent filing with a regulatory authority elsewhere in the license territory in which any Teva licensed patents exist; and
- Following commercial launch of eptinezumab, pay $75 million at each of two sales-related milestones (at the first $1 billion and $2 billion in net sales in a calendar year) and provide certain royalty payments on net sales at rates from 5% to 7%.

The foregoing summary of the Settlement and License Agreement is not intended to be complete and is qualified in its entirety by reference to the full text of the Settlement and License Agreement to be filed as an exhibit to Alder s Quarterly Report on Form 10-Q for the quarterly period ending March 31, 2018.

Preferred Stock Purchase Agreement for $250 Million Committed Equity Financing

On January 7, 2018, Alder entered into a Preferred Stock Purchase Agreement (the Purchase Agreement) with certain institutional and other accredited investors affiliated with or managed by Redmile Group, LLC (collectively, the Buyers), pursuant to which Alder has the right to sell to the Buyers from time to time up to $250,000,000 in shares of Alder s non-voting Class A Preferred Stock (Preferred Stock) over the next three years (the Facility Term), subject to certain limitations and conditions set forth in the Purchase Agreement. The Preferred Stock is initially convertible into shares of Alder s common stock on a one for ten basis.

Upon execution of the Purchase Agreement, and subject to certain conditions, Alder agreed to sell to the Buyers 725,268 shares of Preferred Stock (the Initial Purchase Shares) at $137.88 per share (the Initial Purchase Price) for gross proceeds of approximately $100,000,000 (the Initial Purchase). The proceeds to Alder will be reduced by an initial commitment fee of $2,000,000 and certain applicable expense amounts. The aggregate of all applicable expense amounts under the Purchase Agreement to be reimbursed by Alder shall not exceed $250,000. The closing of the Initial Purchase is expected to occur on January 12, 2018, subject to the satisfaction of customary closing conditions.

The Initial Purchase Price was calculated on the basis of the average of the volume-weighted average price (the VWAP) for Alder s common stock traded on the Nasdaq Global Market for each of January 4, 2018 ($13.2319), January 5, 2018 ($13.2353) and January 8, 2018 ($14.8966), multiplied by ten.

Under the Purchase Agreement, in addition to the Initial Purchase Shares, on any trading day selected by Alder beginning after the 90-day period following the date of the Initial Purchase, Alder has the right, in its sole discretion, to present the Buyers with a purchase notice (each, a VWAP Purchase Notice), directing the Buyers or their designees or assignees to purchase up to $150,000,000 of Alder s Preferred Stock in the aggregate (each such purchase, a VWAP Purchase). The purchase price per share for each VWAP Purchase (the VWAP Purchase Price) shall equal the product of (1) ten times the lower of (2) ninety percent (90%) of (a) the VWAP for the thirty trading days immediately preceding the date of the Buyers receipt of the VWAP Purchase Notice or (b) the closing sales price of Alder s common stock, on the last trading day immediately preceding the date of the Buyers receipt of the VWAP Purchase Notice, less applicable expense amounts. On the date of the first VWAP Purchase, the VWAP Purchase Price will be reduced by an access fee of $7,500,000.

Alder may deliver multiple VWAP Purchase Notices to the Buyers from time to time during the term of the Purchase Agreement, so long as (1) the most recent purchase has been completed, (2) a registration statement registering for sale by the Buyers the shares of Alder s common stock issuable upon conversion of the Preferred Stock issued pursuant to the Purchase Agreement or upon exercise of a warrant that may be issued pursuant to the Purchase Agreement (as described below) is continuously effective, and (3) certain other conditions set forth in the Purchase Agreement are met. No VWAP Purchase Amount (as defined below) may exceed, together with all other VWAP Purchase Amounts set forth in any VWAP Purchase Notice within the same calendar month, without the written consent of the Buyers that will purchase at least a majority of the Purchase Shares pursuant to such VWAP Purchase Notice, the lesser of (1) $13,500,000 and (2) an amount equal to 2% of Alder s market capitalization, determined by taking the product of (a) the number of shares of the Alder s common stock outstanding as of the last day of the preceding calendar month multiplied by (b) the closing sales price of the Common Stock on the last trading day of the preceding calendar month. The VWAP Purchase Amount means, with respect to any particular VWAP Purchase Notice, the amount set forth in such VWAP Purchase Notice.

Pursuant to the Purchase Agreement, the total number of shares of Preferred Stock that may be issued to the Buyers shall not exceed such number of shares of Preferred Stock that are convertible into an aggregate of 13,561,804 shares of Alder s common stock (the Exchange Cap), representing 19.99% of Alder s outstanding shares of common stock as of the date of execution of the Purchase Agreement, unless stockholder approval is obtained to issue more shares, in which case the Exchange Cap will not apply. In addition, the Exchange Cap will not apply if at any time, the Exchange Cap is reached and at all times thereafter the price paid for all shares issued under the Purchase Agreement is equal to or greater than $129.50 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction) per share. Additionally, at no time will Alder issue any Preferred Stock to the Buyers under the Purchase Agreement if the Buyers and their affiliates would own more than 19.99% of the outstanding shares of Alder s common stock or voting power, unless Alder has received approval from the listing market or obtained any required stockholder approval. The Buyers have no right to require Alder to sell any shares of Preferred Stock to the Buyers, but are obligated to make purchases from Alder as directed by Alder in accordance with the Purchase Agreement, subject to the satisfaction of customary closing conditions, including that no event of default has occurred.

During the Facility Term, the Buyers shall have the right to submit to the managing underwriter(s) in any public offering of securities by Alder a non-binding indication of interest to participate in such offering by purchasing that number of securities equal to such Buyer s pro rata ownership of Alder.

In addition, pursuant to the Purchase Agreement, in the event a deemed liquidation occurs within 24 months of the date of the Purchase Agreement, Alder will issue the Buyers or their designees or assignees a warrant to purchase an aggregate of 75,000 shares of Preferred Stock at a purchase price per share equal to the Initial Purchase Price (share number and exercise price each subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split, reverse stock split or other similar transaction).

The Purchase Agreement may be terminated (1) by the Buyers in the event of an event of default under the Purchase Agreement or (2) by Alder at any time, at its discretion, without any cost to Alder. In addition, the Purchase Agreement will automatically terminate (1) on the date that Alder sells the Buyers the full $250,000,000 of Preferred Stock, (2) on the date Alder raises in one or more financing transactions for aggregate proceeds to Alder of at least $100,000,000 during the Facility Term (excluding amounts raised under the Purchase Agreement) or (3) upon a deemed liquidation.

Each holder of Preferred Stock is entitled to receive in a liquidation (including any deemed liquidation) an amount equal to the greater of the original purchase price plus all accrued but unpaid dividends thereon or the amount to which such holder would be entitled to receive if such shares had been converted to Alder s common stock immediately prior to such liquidation or deemed liquidation as set forth in the applicable Certificate of Designation. The Preferred Stock shall be entitled to receive dividends, at a rate of 5% per annum, accrued, accumulated and payable semi-annually in arrears. Dividends may be payable in cash or in shares of Preferred Stock, at the option of Alder.

No holder of Preferred Stock may convert shares of Preferred Stock into Alder s common stock if, after giving effect to an attempted conversion, such conversion would result in the holder, together with its affiliates, beneficially owning more than 9.99% of the shares of Alder s common stock then issued and outstanding, which percentage may be changed at a holder s election upon 61 days notice to Alder.

The offer and sale of the foregoing securities are being made in a transaction not involving a public offering and have not been registered under the Securities Act of 1933, as amended (the Securities Act), or applicable state securities laws. Accordingly, the securities may not be reoffered or resold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Securities Act and such applicable state securities laws. As part of the transaction, Alder will enter into a registration rights agreement

pursuant to which it will agree to file one or more registration statements with the Securities and Exchange Commission for the purpose of registering the resale of shares of common stock issued or issuable to the Buyers upon conversion of the Preferred Stock.

The foregoing summary of the Purchase Agreement is not intended to be complete and is qualified in its entirety by reference to the full text of the Purchase Agreement filed as Exhibit 10.1 to this Current Report on Form 8-K, and is incorporated herein by reference. The press release announcing the execution of the Purchase Agreement, dated January 8, 2018, is filed as Exhibit 99.1 hereto.

Item 3.02. Unregistered Sales of Equity Securities.

The information set forth under the caption Preferred Stock Purchase Agreement for $250 Million Committed Equity Financing in Item 1.01 of this report is incorporated by reference into this Item 3.02. The offer and sale of securities are being made in reliance on the exemption afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act.

Item 8.01 Other Events.

Top-Line Results for PROMISE 2 Phase 3 Pivotal Clinical Trial

On January 8, 2018, Alder announced that eptinezumab, its lead investigational product candidate for migraine prevention targeting CGRP, met primary and all key secondary endpoints with very high statistical significance vs. placebo in PRevention Of Migraine via Intravenous ALD403 Safety and Efficacy 2 (PROMISE 2), a Phase 3 pivotal clinical trial evaluating eptinezumab for the prevention of chronic migraine. PROMISE 2 commenced in November 2016 and is evaluating the safety and efficacy of eptinezumab administered at two dose levels (300mg and 100mg) and placebo via infusion once every 3 months for six months in 1,072 patients with chronic migraine, defined as 15 or more headache days per month, with features of migraine on at least eight days per month.

The primary endpoint, demonstrating statistically significant reductions in mean monthly migraine days from baseline (average of approximately 16.1 days) over weeks 1 through 12 was met with a reduction of 8.2 monthly migraine days for 300mg ($p<0.0001$) and 7.7 days for 100mg ($p<0.0001$) compared to a reduction of 5.6 days for placebo.

The key secondary endpoints and other endpoints met include:

- Migraine prevalence Day One post-infusion: 52 percent reduction (300mg, $p<0.0001$) and 51 percent reduction (100mg, $p=0.0001$) in migraine risk beginning Day One post-infusion compared to 27 percent for placebo (p-values reflect Day One prevalence rate comparison between eptinezumab vs. placebo).

- 50% responder rates for weeks 1 through 12: 61 percent (300mg, $p<0.0001$) and 58 percent (100mg, $p<0.0001$) of patients achieved 50 percent or greater reduction in migraine days from baseline compared to 39 percent for placebo.

- 75% responder rates for weeks 1 through 4: 37 percent (300mg, $p<0.0001$) and 31 percent (100mg, $p<0.0001$) of patients achieved a 75 percent or greater reduction in migraine days from baseline, compared to 16 percent for placebo.

- 75% responder rates for weeks 1 through 12: 33 percent (300mg, $p<0.0001$) and 27 percent (100mg, $p=0.0001$) of patients achieved a 75 percent or greater reduction in migraine days from baseline, compared to 15 percent for placebo.

- 100% responder rates for weeks 1 through 12 (post hoc analysis): an average 15 percent (300mg, $p<0.0001$, unadjusted) and 11 percent (100mg, $p<0.0001$, unadjusted) of the patient population had no migraines for months 1 to 3, compared to 5 percent for placebo.

All other pre-specified key secondary endpoints were met with very high statistical significance.

The observed safety profile in PROMISE 2, to date, is consistent with previously reported eptinezumab studies. Adverse event rates among eptinezumab-treated subjects were similar to placebo-treated subjects. The most commonly reported adverse events for eptinezumab, occurring at an incidence of 2.0% or greater, were nasopharyngitis (common cold) (6.3 percent), upper respiratory infection (4.0 percent), nausea (3.4 percent) and urinary tract infection (3.1 percent), arthralgia (joint pain) (2.3 percent), dizziness (2.6 percent), anxiety (2.0 percent) and fatigue (2.0 percent). Full safety data will be available at the completion of the trial.

Additional results from the trial are expected to be presented at future medical meetings.

Alder plans to submit a BLA to the FDA for the infusion formulation of eptinezumab in the second half of 2018.

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements relating to: the anticipated benefits to Alder under the Settlement and License Agreement with Teva and the

obligations of the parties thereunder; planned and future sales of securities under the Purchase Agreement, the anticipated benefits to Alder therefrom, and the obligations of the parties thereunder; the closing of the preferred stock financing; the continued development and clinical, therapeutic and commercial potential of eptinezumab; the availability of clinical trial data; future data presentations; and the planned BLA submission for eptinezumab. Words such as will, future, expected, plans, or other similar words or expressions, identify forward-looking statements, bu 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 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 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
10.1	Preferred Stock Purchase Agreement by and among Alder BioPharmaceuticals, Inc. and the Buyers set forth therein dated January 7, 2018
99.1	Press Release of Alder BioPharmaceuticals, Inc. dated January 8, 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: January 11, 2018

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