
**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): September 14, 2017

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 7.01 Regulation FD.

On September 14, 2017, Alder BioPharmaceuticals, Inc. will provide to certain of its stockholders and securities analysts a written update regarding recent presentations and feedback from the 18th Congress of the International Headache Society. A copy of the communication is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information in this Current Report on Form 8-K, including the attached Exhibit 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.*(d) Exhibits.*

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>“Notes from the Road” Communication dated September 14, 2017.</u>

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: September 14, 2017

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



ALDER'S NOTES FROM THE ROAD

A RECAP FROM IHC

September 14, 2017

Dear Recipient,

We are just finishing up in Vancouver and are writing to share some of the positive news and feedback from the 18th Congress of the International Headache Society ("IHC"). As you may know, IHC is an international organization that brings together colleagues, industry partners and international scientists and clinicians to showcase advancements in headache science, education and management.

We had a number of encouraging individual meetings at IHC with migraine thought leaders to solicit expert understanding and feedback on attributes that positively differentiate eptinezumab for migraine prevention. We are pleased that they share our enthusiasm about the benefits of eptinezumab and its potential to change the current migraine treatment paradigm. Many expressed significant support for the infusion mode of administration, particularly the inherent advantages associated with the procedure. This included migraine specialists who are "interventionalists" that are familiar with infusion administration and prefer procedures that promote patient adherence and maximize product control and consistency of delivery. All of this reinforced eptinezumab's highly competitive and differentiated profile.

Here are some examples of what we are hearing from the physician experts:

"Today's treatment options are limited by safety, tolerability and efficacy limitations. The anti-CGRP class of products is a significant advancement in the treatment of migraine prevention and, if approved, will provide physicians with better options to improve our patients' outcomes and quality of life. For highly impacted patients, the advantage of eptinezumab delivered via infusion administration is that it provides 100% bioavailability of the drug and avoids the delayed absorption associated with therapeutics delivered subcutaneously. Eptinezumab's Day 1 preventative clinical benefit observed in the Phase 2b data in chronic migraine and the PROMISE 1 Phase 3 data in frequent episodic migraine underscores the rapid onset of sustained benefit associated with intravenous infusion. Infusion therapy is also an important option for those patients in my practice who will benefit from the product control consistency and treatment adherence associated with supervised medication administration, and eptinezumab is currently the only anti-CGRP delivered via infusion being developed for migraine prevention."

Dr. Steve Silberstein

Professor of Neurology and
Director of the Jefferson Headache Center
Thomas Jefferson University, Philadelphia

"My patients have been coping with their migraine disease for many years (often decades), and most will find an infusion therapy very desirable for managing their migraine vs. having to give themselves or find another person to give them multiple subcutaneous injections at home. In fact, at the Diamond Headache Clinic, we are currently assessing our infusion capabilities in anticipation of eptinezumab's entry into the market, if approved. The Phase 2b and Phase 3 data, which, for many patients, demonstrate preventative benefit on Day 1 post infusion and 75% responder rates achieved and sustained for three months, would represent a vast improvement in the standard of care and quality of life for my patients."

Dr. Merle Diamond

President and Managing Director
Diamond Headache Clinic

"I have many patients who have been severely impacted by their migraine for many years. They've cycled through many oral therapies with limited benefit because of safety and tolerability issues. They are at serious risk of medication overuse and further chronification of their disease. If eptinezumab receives regulatory approval, these patients would greatly benefit from eptinezumab's preventative benefit on Day 1 with efficacy that is sustained and from one infusion dose for three months and further improved after the second dose, as have been demonstrated in clinical testing to date. This would give me the opportunity to implement other behavioral modifications to their treatment regimens, which they haven't been able to comply with because we haven't been able to address the progression of their migraine disease."

Dr. Andrew Blumenfeld

Director at the Headache Center of Southern California



At IHC, Alder BioPharmaceuticals® made seven presentations that highlighted key clinical data and analyses for eptinezumab, our monoclonal antibody and investigational product candidate for migraine prevention. Eptinezumab is the only monoclonal antibody administered by quarterly infusion in development that allows for 100% of the dose available to selectively and potently inhibit CGRP.ⁱ Eptinezumab is currently in Phase 3 clinical trials, including PROMISE 1 and PROMISE 2, to assess its efficacy and safety in migraine prevention. To date, more than 1,600 people have been treated with eptinezumab in clinical trials.

Alder also sponsored a satellite symposium, “Expert Perspectives: Migraine Prevention for Highly Impacted Patients”, led by luminaries in migraine including Drs. Richard Lipton, Merle Diamond and Stewart Tepper and chaired by our own Dr. Roger Cady. Key highlights from the symposium, which was extremely well-attended, included:

- Current preventive migraine treatments are associated with safety, efficacy and tolerability limitations and fail to meet the need of most patients^{ii,iii}. In fact, over two-thirds of patients who are candidates for prophylactic therapy don’t receive it,^{iv} and of those patients on prophylactic therapy, over 80% discontinue after one year due to these limitations.^v
- The current standard for success is a 50% responder rate, which is defined by what current treatments can deliver.^{vi} Patients would prefer greater reductions in migraine days and the ability to achieve that outcome more rapidly.
- Alder’s 75% responder rate is associated with the more meaningful improvements in HIT-6 outcomes, a patient-reported tool used to assess headache impact on quality of life.^{vii}
- There is a significant need for more efficacious, rapidly acting, and well-tolerated treatment options.^{viii,v}

The presentation materials for the symposium are available on the Investors section of Alder’s website at this [link](#).

As the only anti-CGRP administered by quarterly infusion in development, eptinezumab has the opportunity to address this significant unmet need for highly impacted migraine patients. The data presented from both Alder’s Phase 3 PROMISE 1 study and its Phase 2b study support eptinezumab’s clinical profile as a potential first-of-its-kind, highly differentiated infusion therapy to prevent migraine, including:

- **Preventive benefit achieved on the first day post-infusion:** >50% reduction in the proportion of patients experiencing a migraine on Day 1 post-infusion;^{ix,x}
- **Significant days of migraine freedom sustained for three months after first dose:** ~1/3 of patients attained a □ 75% reduction in migraine days through one month and sustained through three months (300mg dose)^{xi}, building on the benefit achieved on Day 1; these changes were coupled with an improvement in patient-reported outcomes^{xii} and reduction in triptan use through three months post-infusion;^{xiii}
- **Migraine freedom further improved through three months after the second dose:** An average of 1 in 5 patients had no migraines in any given month^{xiv}; and
- **Safety profile similar to placebo:** Consistent with previously reported eptinezumab studies.^{xi}

With the close of another successful IHC, we are more excited than ever and reiterate our commitment to transforming the treatment of migraine. Importantly, we remain on track to complete our BLA submission in the second half of 2018 and look forward to providing additional updates as we continue to make progress in anticipation of a commercial launch of eptinezumab.

As always, please feel free to reach out if you have any questions or would like to discuss any of the above in greater detail.

Thank you for your continued support.

Best,

Randy
Randall C. Schatzman, Ph.D.
President and Chief Executive Officer

Roger
Roger Cady, M.D.,
Vice President, Neurology



- i Baker B, Schaeffler B, Cady R, et al; Rational design of a monoclonal antibody (mAb) inhibiting calcitonin gene-related peptide, ALD403 (eptinezumab), intended for the prevention of migraine. Poster presented at the American Academy of Neurology (AAN) 2017 Annual Meeting.
- ii Lipton RB, Silberstein SD. Episodic and chronic migraine headache: breaking down barriers to optimal treatment and prevention. *Headache*. 2015;55(S2):103-122.
- iii Bigal ME, Krymchantowski AV, Lipton RB. Barriers to satisfactory migraine outcomes. What have we learned, where do we Stand? *Headache*. 2009;49(7):1028–1041.
- iv Blumenfeld AM, Varon SF, Wilcox TK et al. Disability, HRQoL, and resource use among chronic and episodic migraineurs: results from the International Burden of Migraine Study (IBMS). *Cephalalgia*. 2011;31:301–315.
- v Hepp, Z, Dodick DW, Varon SF, et al. Adherence to oral migraine-preventive medications among patients with chronic migraine. *Cephalalgia* 2015;35(6):477-88.
- vi Estemalik E, Tepper S. Preventive treatment in migraine and the new US guidelines. *Neuropsychiatr Dis Treat*. 2013;9:709-720.
- vii Lipton RB et. al; Responders to ALD403 (eptinezumab) Show Significant Reduction in Headache Impact at Weeks 4 through 12 Following a Single Infusion in Chronic Migraine. Poster presented at the American Headache Society (AHS) June 2017.
- viii Bigal ME, Krymchantowski AV, Lipton RB. Barriers to satisfactory migraine outcomes. What have we learned, where do we Stand? *Headache*. 2009;49(7):1028–1041.
- ix Cady R et. al; Eptinezumab Infusion Associated With Meaningful Reductions in Daily Migraine Activity on Day 1 and Over Weeks 1 Through 4 in Patients With Frequent Episodic Migraine: Results of the PROMISE-1 (PREvention Of Migraine via Intravenous eptinezumab Safety and Efficacy–1) Trial. Presented at the 18th Congress of International Headache Society (IHC) September 2017.
- x Goadsby PJ et. al; Migraine Preventive Benefits of ALD403 (eptinezumab) Begin on the First Day Following Intravenous Administration. Presented at the 18th Congress of International Headache Society (IHC) September 2017.
- xi Saper J et. al; A Phase 3, Randomized, Double-blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Eptinezumab in Frequent Episodic Migraine Prevention: Primary Results of the PROMISE-1 (PREvention Of Migraine via Intravenous eptinezumab Safety and Efficacy–1) Trial. Presented at the 18th Congress of International Headache Society (IHC) September 2017.
- xii Lipton RB et. al; 75% Migraine Responder Rate to a Single Infusion of ALD403 (eptinezumab) Provides Greater Improvement in SF-36 Domain Scores Than Historically Accepted 50% Responder Rate. Presented at the 18th Congress of International Headache Society (IHC) September 2017.
- xiii Dodick D et. al; A Single Intravenous Administration of ALD403 (Eptinezumab) Reduces Use of Triptans Among Patients with Chronic Migraine. Presented at the 18th Congress of International Headache Society (IHC) September 2017.
- xiv Alder BioPharmaceuticals Inc. (2017, June 27). *Alder BioPharmaceuticals Announces Positive Eptinezumab Phase 3 Results for Prevention of Frequent Episodic Migraine* [Press release]. Retrieved September 11, 2017, from <http://investor.alderbio.com/releasedetail.cfm?releaseid=1031418>.

Forward Looking Statements: This communication contains forward-looking statements, including, without limitation, statements relating to: the continued development and clinical, therapeutic and commercial potential of eptinezumab; the limitations of existing preventive migraine treatment options and the need for new effective preventive migraine treatment options; the impact of the data and results presented at IHC, including the potential benefits of eptinezumab and belief that the referenced results may represent a new standard for migraine prevention; the advantages of eptinezumab's infusion mode of administration; Alder's commitment to transforming the treatment of migraine; the planned regulatory submission for eptinezumab and the timing thereof; future updates; and the anticipated commercialization of eptinezumab. Words such as "will," "would," "encouraging," "anticipation," "potential," "change," "opportunity," "support," "need," "improvement," "address," "change," "towards," "continue," "benefits," "advantages," "on track," "look forward," 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 communication 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, 2017, which was filed with the Securities and Exchange Commission (SEC) on August 8, 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 communication speak only as of the date of this communication. 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.