

# ALDER BIOPHARMACEUTICALS INC

## **FORM 8-K** (Current report filing)

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Address	11804 NORTH CREEK PARKWAY SOUTH BOTHELL, WA 98011
Telephone	425-205-2900
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Industry	Biotechnology & Medical Research
Sector	Healthcare
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): August 8, 2017**

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**Alder BioPharmaceuticals, Inc.**

(Exact name of registrant as specified in its charter)

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**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:

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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.

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**Item 2.02 Results of Operations and Financial Condition.**

On August 8, 2017, Alder BioPharmaceuticals, Inc. (“Alder”) issued a press release announcing financial results for the quarter ended June 30, 2017 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.

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**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

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Exhibit No.	Description
99.1	Press Release of Alder BioPharmaceuticals, Inc. issued August 8, 2017

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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: August 8, 2017

By: /s/ Randall C. Schatzman

Randall C. Schatzman, Ph.D.

President and Chief Executive Officer

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## INDEX TO EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Alder BioPharmaceuticals, Inc. issued August 8, 2017

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## Alder BioPharmaceuticals® Announces Second Quarter 2017 Financial and Operating Results

*– Positive top-line PROMISE 1 study results  
further support eptinezumab’s unique clinical profile –*

*– \$161.5 million from recent public offering expected to enable continued advancement of eptinezumab through pivotal studies, a planned Biologics License Application and achievement of other key activities –*

*– Conference call set for 5 p.m. EDT today –*

**BOTHELL, Wash., Aug. 8, 2017** – Alder BioPharmaceuticals, Inc. (NASDAQ: ALDR), a clinical-stage biopharmaceutical company developing monoclonal antibody therapeutics, today announced financial results for the second quarter ended June 30, 2017, and provided a corporate update.

“Migraine is a debilitating disease in which current preventative treatment options fail to meet the needs of severe migraine patients. There is a significant market need for new effective treatment options that we believe can be served by eptinezumab, our investigational migraine prevention candidate and one of a new class of anti-CGRP migraine treatments in development,” said Randall C. Schatzman, Ph.D., president and chief executive officer of Alder. “We were pleased to report positive top-line results from PROMISE 1, our first pivotal trial for eptinezumab, during the second quarter, which builds upon the robust clinical data we have observed to date. We believe that eptinezumab’s highly competitive and differentiated profile, coupled with the fact that it is the only anti-CGRP migraine treatment administered by infusion in development, will provide a distinct commercial advantage for Alder in the emerging CGRP-directed treatment market. We believe that this would translate to a U.S. market opportunity for eptinezumab infusion therapy, if approved, in the range of approximately \$1.5 to \$2.0 billion. With our balance sheet enhanced by our recently completed public offering and our disciplined spending plan, we are well-positioned to continue advancing eptinezumab and our goal of transforming the treatment of migraine.”

### Recent Corporate Highlights

*Eptinezumab – Pivotal-stage novel monoclonal antibody targeting the calcitonin gene-related peptide (CGRP) for the prevention of migraine*

- Reported top-line three and six month results from the PROMISE 1 ( **P**R evention **O**f **M** igraine via **I**ntravenous eptinezumab **S**afety and **E**fficacy **1** ) Phase 3 pivotal clinical trial on June 27, 2017. PROMISE 1 is evaluating the safety and efficacy of eptinezumab administered via infusion once every 3 months in 888 patients with frequent episodic migraine in the United States. The results demonstrated:

- **Eptinezumab met the primary endpoint:** highly statistically significant reductions in monthly migraine days from baseline through three months;
  - **Rapid speed to clinical benefit:** a statistically significant >50% reduction in the proportion of patients experiencing a migraine on Day 1 post dose;
  - **Statistically significant efficacy responses observed at all key time points:** ~ 1/3 of patients attained a  $\geq 75\%$  reduction in migraine days through 1 month and sustained through 3 months (300mg dose);
  - **Migraine free relief:** average 1 in 5 patients had 100% response (i.e., no migraines) in any given month (reduction from a baseline of >8 mean migraine days/month); and
  - **Safety profile similar to placebo:** consistent with previously reported eptinezumab studies.
- Completed public offering of common stock on July 18, 2017 resulting in net proceeds to Alder of approximately \$161.5 million, after underwriting discounts, commissions and estimated offering expenses.
  - Presented additional data in June 2017 at the 59th Annual Scientific Meeting of the American Headache Society from Alder's eptinezumab program, including additional positive data from the Phase 2b trial of eptinezumab for the prevention of chronic migraine and information describing the rational design objectives and selection of attributes that are important for supporting the desired clinical profile of a migraine prevention therapy.
  - In June 2017, submitted Alder's statement setting out the grounds of appeal with respect to the decision of the European Patent Office Opposition Division to maintain certain patent claims granted to Teva.

#### Upcoming Eptinezumab Milestones Expected in 2H-2017

- Presentation of additional data from Alder's eptinezumab program at the 18th Congress of the International Headache Society, to be held September 7-10, 2017.
- Completion of enrollment in PROMISE 2 ( **P**REVENTION **O**F **M**IGRAINE VIA **I**NTRAVENOUS **E**PTINEZUMAB **S**AFETY AND **E**FFICACY **2** ) study in the second half of 2017. PROMISE 2 is the company's ongoing pivotal study that is evaluating the safety and efficacy of eptinezumab administered via infusion once every 3 months in approximately 1,050 patients with chronic migraine.

#### Second Quarter 2017 Financial Results

**Research and development expenses** for the quarter ended June 30, 2017 totaled \$65.3 million, compared to \$33.8 million for the same period in 2016. The increase in expenses was primarily due to the eptinezumab program, with increased external manufacturing costs for commercial readiness activities and drug supply in support of planned and ongoing clinical trials and increased external clinical trial costs. Alder also experienced increased salaries expense and stock-based compensation expense because of headcount growth in research and development to support ongoing and planned clinical trials and other development activities.

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**General and administrative expenses** for the quarter ended June 30, 2017 totaled \$9.5 million, compared to \$6.5 million for the same period in 2016. The increases in spending were primarily due to an increase in stock-based compensation expense and salaries expense due to an increase in headcount, as well as increases in professional fees and other administrative costs to support commercial readiness activities.

**Net loss** for the quarter ended June 30, 2017 totaled \$74.6 million, or \$1.48 per share, compared to net loss of \$38.9 million, or \$0.79 per share on a fully-diluted basis, for the same period in 2016.

**Cash** and cash equivalents and short-term investments totaled \$224.5 million as of June 30, 2017, compared to \$289.6 million as of March 31, 2017.

### **Financial Outlook**

Alder estimates its available cash and cash equivalents and short-term investments totaling \$224.5 million as of June 30, 2017, together with the net proceeds of approximately \$161.5 million received from its July 2017 public offering, will be sufficient to meet the company's projected operating requirements through late 2018/early 2019 and enable it to achieve the following key activities:

- Read-out of top-line data from PROMISE 2;
- Completion of the eptinezumab infusion pivotal trial program;
- Planned submission of a Biologics License Application for the eptinezumab infusion formulation;
- Establishment of a commercial drug supply chain for the eptinezumab infusion formulation; and
- Advancement of the eptinezumab subcutaneous mode of administration.

### **Conference Call and Webcast**

Alder will host a conference call today at 5:00 p.m. EDT 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 51609769. The webcast and any accompanying slides can be accessed from the Events & Presentations page in the Investors section of Alder's website at [www.alderbio.com](http://www.alderbio.com) and will be available for replay following the call for 30 days.

### **About Alder BioPharmaceuticals, Inc.**

Alder BioPharmaceuticals, Inc., is a clinical-stage biopharmaceutical company that discovers, develops and seeks to commercialize genetically engineered therapeutic antibodies with the potential to meaningfully transform current treatment paradigms. Alder's lead pivotal-stage product candidate, eptinezumab, is being evaluated for migraine prevention. Eptinezumab is a monoclonal antibody that inhibits calcitonin gene-related peptide (CGRP), a protein that is active in mediating the initiation of

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migraine. Alder is additionally evaluating ALD1910, a preclinical product candidate also in development as a migraine prevention therapy. ALD1910 is a monoclonal antibody that inhibits pituitary adenylate cyclase-activating polypeptide-38 (PACAP-38), another protein that is active in mediating the initiation of migraine. Clazakizumab, Alder's third program, is a monoclonal antibody candidate that inhibits interleukin-6 and is licensed to Vitaeris, Inc. For more information, please visit <http://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 significant market need for new effective preventative migraine treatment options; the availability of results from clinical trials; future regulatory filings and the potential regulatory approval of eptinezumab; eptinezumab's competitive and differentiated profile and anticipated commercial advantage; the U.S. market opportunity for eptinezumab; Alder's goal of transforming the treatment of migraine; future data presentations; and Alder's financial outlook, including the sufficiency of Alder's cash resources to meet projected operating requirements and enable the achievement of key activities. Words such as "support," "expected," "enable," "continue," "advancement," "planned," "achieve," "need," "options," "believe," "can," "builds," "will," "advantage," "emerging," "would," "opportunity," "well-positioned," "goal," "presentation," "completion," "outlook," "estimates," "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 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](http://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

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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>June 30,</u> <u>2017</u>	<u>December 31,</u> <u>2016</u>
Cash, cash equivalents and investments	\$ 224,481	\$ 351,867
Prepaid expenses and other assets	29,487	57,287
Total assets	\$ 253,968	\$ 409,154
Total liabilities	\$ 34,547	\$ 26,371
Total stockholders' equity	219,421	382,783
Total liabilities and stockholders' equity	\$ 253,968	\$ 409,154

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

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
<b>Revenues</b>				
Collaboration and license agreements	\$ 683	\$ 113	\$ 683	\$ 113
<b>Operating expenses</b>				
Cost of sales	683	113	683	113
Research and development	65,276	33,833	155,965	61,480
General and administrative	9,548	6,466	19,529	12,511
Total operating expenses	75,507	40,412	176,177	74,104
Gain on license of clazakizumab	—	1,050	—	1,050
Loss from operations	(74,824)	(39,249)	(175,494)	(72,941)
Other income, net	195	383	537	712
Net loss	\$ (74,629)	\$ (38,866)	\$ (174,957)	\$ (72,229)
Net loss per share - basic and diluted	\$ (1.48)	\$ (0.79)	\$ (3.47)	\$ (1.55)
Weighted average number of common shares used in net loss per share - basic and diluted	50,427,865	49,284,573	50,411,837	46,519,045

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