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): August 6, 2019

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 (see General Instructions A.2. below):

☐ 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock (Par Value $0.0001)	ALDR	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

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 2.02 Results of Operations and Financial Condition.

On August 6, 2019, Alder BioPharmaceuticals, Inc. (“Alder”) issued a press release announcing financial results for the quarter ended June 30, 2019 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.		Description
99.1		Press Release of Alder BioPharmaceuticals, Inc. issued August 6, 2019.

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 thereunto duly authorized.

Alder BioPharmaceuticals, Inc.

Dated: August 6, 2019

By: /s/ Robert W. Azelby
Robert W. Azelby
President and Chief Executive Officer

Exhibit 99.1

Alder BioPharmaceuticals® Reports Second Quarter 2019 Financial and Operating Results

- *Data presented at American Academy of Neurology and American Headache Society Annual Meetings continue to support eptinezumab's differentiated clinical profile and impact on quality of life measures –*

- *Core commercial leadership team secured, including field payer team, in anticipation of expected eptinezumab U.S. launch in 1Q 2020, assuming FDA approval –*

- *Key milestones anticipated in 2H 2019, including completed commercial footprint, start of acute study and advancement of second product candidate, ALD1910, into clinical development –*

- *Conference call today at 5:00 p.m. ET -*

BOTHELL, Wash., August 6, 2019 -- Alder BioPharmaceuticals, Inc. (NASDAQ: ALDR), a biopharmaceutical company focused on developing novel therapeutic antibodies for the treatment of migraine, today provided a corporate update and reported its financial results for the second quarter ended June 30, 2019.

"We continue to make significant progress toward the potential launch of eptinezumab in the U.S. in the first quarter of 2020. We have our commercial leadership team in place, with experienced personnel leading sales, marketing and market access. The team is sharpening our go-to-market strategy and expects to complete our commercial footprint later this year. We recently presented additional data further confirming eptinezumab's differentiated clinical profile and benefits in patient-reported outcomes at the 2019 American Headache Society and American Academy of Neurology Annual Meetings," said Bob Azelby, Alder's president and chief executive officer. "Looking forward, we believe there is a large opportunity to build value at Alder in the latter half of the year, with the initiation of eptinezumab's acute study and the advancement of our product candidate, ALD1910, into the clinic. These collective activities align with our mission to forever change the migraine treatment landscape and give people with migraines their lives back."

Second Quarter 2019 Highlights and Recent Developments

- **Commercial readiness activities ongoing under the leadership of recently appointed chief commercial officer, Nadia Dac:** As Alder prepares for the potential commercial launch of eptinezumab in the U.S. in the first quarter of 2020, the company has conducted new market research that further confirms eptinezumab's differentiated profile and is prepared to begin account-level engagement with payers. The company plans to focus its marketing efforts on the high-prescribing headache specialist population and accounts, where eptinezumab fits well into their treatment protocols of quarterly patient visits with its short, 30-minute IV administration and its well-tolerated safety profile, as demonstrated in the company's clinical trials. The company plans to utilize a specialty sales organization sized between 75 and 100 sales representatives.
- **New migraine-free months, migraine severity and quality of life data presented at AHS Annual Meeting:** In July 2019, Alder presented new data from post-hoc analyses from its PROMISE 1 and PROMISE 2 Phase 3 clinical trials for eptinezumab at the American Headache Society's (AHS) 61st Annual Scientific Meeting in Philadelphia, PA from July 11-14, 2019. Key

highlights from the new data presented show 18.1% of episodic migraine patients treated with 100 mg of eptinezumab experienced no migraine days for at least half of the study period (≥six months), compared with 12.6% of placebo-treated patients, and 14.0% of chronic migraine patients treated with 100 mg of eptinezumab experienced no migraine days for at least half of the study period (≥three months), compared with 4.9% of placebo-treated patients. Data presented from PROMISE 2 also showed consistent clinically significant improvements in migraine severity in chronic migraine patients, a large contributor to impact on quality of life, starting at Month 1. Eptinezumab treatment resulted in clinically meaningful improvements in Headache Impact Test (HIT-6) scores in chronic migraine patients as early as Month 1 after treatment, which were maintained or further improved throughout the six-month study period, compared to placebo, which did not achieve a clinically meaningful improvement until Month 6. In addition, eptinezumab treatment resulted in clinically meaningful improvements greater than placebo in the 36-item Short-Form Health Survey (SF-36) scores in chronic migraine patients as early as Month 1 after treatment and through the six-month study period. From a safety perspective, longer-term exposure has demonstrated no change in the overall safety profile for eptinezumab.

- **Data showing consistency of rapid onset of migraine prevention and improvements in most bothersome migraine symptoms and patient reported outcomes data presented at AAN Annual Meeting:** In May 2019, Alder presented efficacy data highlighting the consistency of the rapid onset of migraine prevention across four clinical trials with eptinezumab at the 71st American Academy of Neurology (AAN) Annual Meeting in Philadelphia, PA from May 4-10, 2019. Across the Phase 2 and Phase 3 clinical trials, it was observed that eptinezumab, with its 100% bioavailability at the end of infusion, showed a rapid onset of migraine prevention. The rapid response observed on both Day 1 and through Month 1 in PROMISE 1 and PROMISE 2 was also sustained through the first quarter following a single eptinezumab infusion, and was maintained or further increased through subsequent infusions. Alder also presented a new analysis of patient-reported outcomes data from the PROMISE 2 Phase 3 clinical trial of eptinezumab for the prevention of chronic migraine, showing improvements in the most bothersome migraine symptoms and patients' global impression of change in their migraine status by Month 1 after treatment, with improvements sustained in overall response through the first and second quarterly infusions.

Upcoming Anticipated Milestones

- **Eptinezumab PDUFA target action date set for early 2020:** The U.S. Food and Drug Administration (FDA) accepted the Biologics License Application (BLA) filing for eptinezumab in April 2019, and set a Prescription Drug User Fee Act (PDUFA) target action date of February 21, 2020. If approved, eptinezumab will be the first-to-market IV therapy for migraine prevention, providing rapid and sustained prevention that begins on Day 1.
- **Acute study for eptinezumab to begin in 2H 2019:** Alder plans to initiate a Phase 3 clinical trial evaluating eptinezumab as a treatment for acute migraine in patients who are candidates for prevention therapy in the second half of 2019. The trial will seek to leverage eptinezumab's 100% bioavailability and rapid onset of prevention demonstrated in clinical testing, with the objective of securing an indication for the acute treatment of migraine for patients and positioning eptinezumab as the first anti-CGRP monoclonal antibody for both the treatment and prevention of migraine, if approved for both these indications.

- **ALD1910 to enter clinical development in 2019:** Alder continues to advance its preclinical candidate, ALD1910, a monoclonal antibody targeting PACAP (pituitary adenylate cyclase-activating peptide) for migraine prevention. ALD1910 is currently undergoing Investigational New Drug (IND)-enabling preclinical studies. Alder expects to initiate a first in-human clinical study by the end of 2019.

Second Quarter 2019 Financial Results

- As of June 30, 2019, Alder had $440.7 million in cash, cash equivalents, investments and restricted cash, compared to $412.4 million as of December 31, 2018.
- Research and development expenses for the second quarter ended June 30, 2019 totaled $34.1 million, compared to $52.8 million for the same period in 2018. The year-over-year decrease was primarily due to a decrease in process development costs and a decrease in clinical trial costs due to the completion of patient treatments for several of the company's clinical trials.
- General and administrative expenses for the second quarter ended June 30, 2019 totaled $21.6 million, compared to $11.9 million for the same period in 2018. The year-over-year increase reflects efforts to support commercial readiness activities for eptinezumab.
- Net loss applicable to common stockholders for the second quarter ended June 30, 2019 totaled $59.9 million, or $0.72 per share, compared to net loss of $70.7 million, or $1.04 per share on a fully-diluted basis, for the same period in 2018.

Financial Outlook

Alder continues to expect that full-year 2019 net cash used in operating activities and purchases of property and equipment will be in the range of $285 to $315 million. The majority of the spend is focused on ensuring that Alder is prepared for the potential launch of eptinezumab in the first quarter of 2020, including advancing eptinezumab's supply chain, building commercial inventory, continuing to build out Alder's commercial footprint and other pre-launch market readiness activities.

Alder believes its available cash, cash equivalents, investments and restricted cash will be sufficient to meet its projected operating requirements through the anticipated launch of eptinezumab and into the latter part of 2020.

Conference Call and Webcast
Alder will host a conference call today at 5:00 p.m. ET 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 6561825. The webcast will be broadcast live and can be accessed from the Events & Presentations page in the Investors section of Alder's website at www.alderbio.com. The webcast will be available for replay following the call for at least 30 days.

About Alder BioPharmaceuticals, Inc.
Alder BioPharmaceuticals is a clinical-stage biopharmaceutical company focused on transforming migraine treatment through the discovery, development and commercialization of novel therapeutic antibodies. The company's mission is to forever change migraine treatment and give people with migraine

their lives back. In 2019, Alder was ranked 19th among the top 100 fastest growing companies in Seattle by Growjo.

Eptinezumab, Alder's lead product candidate for migraine prevention, is an investigational monoclonal antibody (mAb) that is delivered via IV and designed for 100% bioavailability with high specificity and strong binding for suppression of calcitonin gene-related peptide (CGRP). If approved by the U.S. Food and Drug Administration, it will be the first IV therapy for migraine prevention. Alder is also developing ALD1910, a preclinical mAb designed to inhibit pituitary adenylate cyclase-activating polypeptide (PACAP) for migraine prevention. For more information, please visit www.alderbio.com.

Forward-Looking Statements
This press release contains forward-looking statements, including, without limitation, statements relating to: the potential approval by the FDA of the BLA for eptinezumab; the continued development of eptinezumab and the development of ALD1910, including the planned initiation of a first in human clinical trial; the clinical, therapeutic and commercial potential of eptinezumab and ALD1910; the anticipated commercial launch of eptinezumab and Alder's commercialization plans and readiness activities to prepare for such launch; the planned Phase 3 clinical trial of eptinezumab for the acute treatment of migraine and Alder's objective relating thereto; the belief that eptinezumab has the potential to be a compelling treatment option; the belief that there is a large opportunity to create value at Alder; Alder's financial outlook, including the expected range of full-year 2019 net cash used in operating activities and purchases of property and equipment; Alder's belief that its available cash, cash equivalents, investments and restricted cash will be sufficient to meet the company's projected operating requirements through the anticipated launch of eptinezumab and into the latter part of 2020 and Alder's mission to forever change migraine treatment and give people with migraine their lives back. Words such as "will," "expected," "anticipated", "differentiated", "compelling", "benefits," "build," "continue," "prepare," "mission," "initiate," "sufficient," "objective," "advance," "outlook," "projected," "potential," "option," "can," "plan", "believe," "looking 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 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: the clinical, therapeutic and commercial value of eptinezumab and ALD1910; 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 build out of Alder's commercialization infrastructure; risks and uncertainties relating to the manufacture and supply 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, 2019, which was filed with the Securities and Exchange Commission (SEC) on August 6, 2019, 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 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)

	June 30, 2019	December 31, 2018
Cash, cash equivalents, investments and restricted cash	$ 440,652	$ 412,369
Prepaid expenses and other assets	21,915	13,870
Total assets	$ 462,567	$ 426,239
Convertible notes, net of discount	$ 188,323	$ 182,104
Other liabilities	57,393	30,404
Convertible preferred stock	106,546	103,755
Total stockholders' equity	110,305	109,976
Total liabilities, convertible preferred stock and stockholders' equity	$ 462,567	$ 426,239

Condensed Consolidated Statements of Operations
(Unaudited)
(Amounts in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues				
Collaboration and license agreements	$ —	$ —	$ —	$ —
Operating expenses				
Research and development	34,125	52,818	103,714	126,866
General and administrative	21,633	11,911	66,131	23,464
Total operating expenses	55,758	64,729	169,845	150,330
Loss from operations	(55,758)	(64,729)	(169,845)	(150,330)
Other income (expense), net	(2,653)	(3,660)	(6,500)	(5,090)
Net loss	$ (58,411)	$ (68,389)	$ (176,345)	$ (155,420)
Dividends on convertible preferred stock	(1,480)	(2,302)	(2,791)	(3,385)
Deemed dividend on convertible preferred stock related to accretion of beneficial conversion feature	—	—	—	(29,460)
Net loss applicable to common stockholders	$ (59,891)	$ (70,691)	$ (179,136)	$ (188,265)
Net loss per share applicable to common stockholders - basic and diluted	$ (0.72)	$ (1.04)	$ (2.29)	$ (2.77)
Weighted average number of common shares used in net loss per share - basic and diluted	83,479,867	67,966,066	78,297,180	67,905,804

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