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): May 2, 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:

☐ 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. ☐

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, $0.0001 par value per share	ALDR	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

Item 2.02 Results of Operations and Financial Condition.

On May 2, 2019, Alder BioPharmaceuticals, Inc. (“Alder”) issued a press release announcing financial results for the quarter ended March 31, 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 May 2, 2019.

INDEX TO EXHIBITS

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99.1	Press Release of Alder BioPharmaceuticals, Inc. issued May 2, 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 hereunto duly authorized.

Alder BioPharmaceuticals, Inc.

Dated: May 2, 2019

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

Exhibit 99.1

Alder BioPharmaceuticals® Reports First Quarter 2019 Financial and Operating Results

- FDA sets eptinezumab PDUFA date of February 21, 2020; launch expected in first quarter of 2020 -

- Acute study planned for potential eptinezumab label expansion -

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

BOTHELL, Wash., May 2, 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 first quarter ended March 31, 2019.

"The recent acceptance by the U.S. Food and Drug Administration (FDA) of our Biologics License Application (BLA) for eptinezumab was another major milestone for Alder and moves us one step closer to making the first quarterly infusion prevention therapy available to the millions of patients debilitated by episodic and chronic migraine," said Bob Azelby, Alder's president and chief executive officer. "We are in a strong position as we continue to prepare to commercialize eptinezumab in the first quarter of 2020, by building commercial inventory and expanding our commercial infrastructure. Additionally, in pursuit of Alder's mission to forever change migraine treatment, we are excited to announce today that we plan to initiate a Phase 3 clinical trial of eptinezumab for the acute treatment of migraine in the second half of 2019."

First Quarter 2019 Highlights

- On April 22, 2019, Alder announced its BLA submission for eptinezumab, the company's investigational monoclonal antibody (mAb) for migraine prevention targeting the calcitonin gene-related peptide (CGRP) and lead commercial candidate, was accepted by the FDA. The FDA has set the Prescription Drug User Fee Act (PDUFA) target action date of February 21, 2020. The BLA includes, and is supported by, positive data from Alder's PROMISE 1 and PROMISE 2 Phase 3 clinical trials, open-label safety study, pharmacokinetic (PK) comparability study and chemistry, manufacturing, and controls (CMC) data packages.
- In April, Alder announced the appointment of Nadia Dac as chief commercial officer. Ms. Dac brings more than two decades of U.S. and global commercial experience in neurology with both large and small publicly traded biopharmaceutical companies, with extensive expertise across all commercial functions including marketing, market access and promotion, sales, pipeline management, business development and partnerships. She joins Alder from AbbVie, where she served as vice president of global specialty commercial development.

- In March, Alder closed an underwritten public offering and concurrent private placement in which the company received net proceeds of $159.3 million (which included the exercise of an over-allotment option granted to the underwriters in the public offering).
- In January, Alder announced the appointment of Dr. Paul Streck, M.D. as chief medical officer. He brings more than 25 years of experience in drug development, regulatory and medical affairs leadership across both large and small publicly traded biopharmaceutical companies. Dr. Streck previously served as chief medical officer at Insmed Incorporated, where he played an instrumental role as a member of the executive leadership team and successfully led the Arikayce® regulatory filing, approval and launch.
- In January, an amendment to Alder's contract manufacturing agreement with Sandoz GmbH for the production of eptinezumab became effective. Pursuant to this amendment, Sandoz will manufacture and supply guaranteed quantities of eptinezumab drug substance for a five year term, running through 2023. Alder anticipates the guaranteed quantities will be sufficient to supply U.S. and ex-U.S. markets beyond 2023, if eptinezumab is approved.

Upcoming Anticipated Milestones

- Alder plans to initiate a Phase 3 clinical trial evaluating eptinezumab as a treatment for acute migraine 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 and positioning eptinezumab as the only anti-CGRP monoclonal antibody for the treatment and prevention of migraine, if approved for these indications.
- Alder remains on track for the potential commercial launch of eptinezumab in the first quarter of 2020, and continues to advance its manufacturing and commercial readiness activities in anticipation of launch. Currently, Alder is advancing its supply chain, building commercial inventory, continuing to build out its commercial and operational infrastructure, and executing against other key pre-launch initiatives.
- Alder continues to advance its pre-clinical candidate, ALD1910, a monoclonal antibody targeting PACAP-38 (pituitary adenylate cyclase-activating peptide-38). ALD1910 is currently undergoing Investigational New Drug (IND)-enabling preclinical studies and Alder expects to initiate a first in-human clinical study by the end of 2019.

First Quarter 2019 Financial Results

- As of March 31, 2019, Alder had $498.5 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 first quarter ended March 31, 2019 totaled $69.6 million, compared to $74.0 million for the same period in 2018. The year-over-year decrease was primarily due to lower clinical trial costs, partially offset by expenses related to securing

manufacturing capacity and the initial build of commercial inventory in preparation for the launch of eptinezumab.

- General and administrative expenses for the first quarter ended March 31, 2019 totaled $44.5 million, compared to $11.6 million for the same period in 2018. The year-over-year increase reflects a $26 million loss contingency provision relating to a dispute over a contract we terminated for breach by the other party, as well as Alder's continued ramp-up of the commercial organization and infrastructure required for the anticipated commercialization of eptinezumab.
- Net loss applicable to common stockholders for the first quarter ended March 31, 2019 totaled $119.2 million, or $1.63 per share, compared to net loss of $117.6 million, or $1.73 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 8162289. 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 accompanying slides are available now at 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 the migraine treatment paradigm through the discovery, development and commercialization of novel therapeutic antibodies. Alder's lead product candidate, eptinezumab, is an investigational monoclonal antibody (mAb) that inhibits calcitonin gene-related peptide (CGRP) and is currently in late-stage clinical development for the prevention of migraine. If approved by the U.S. Food and Drug Administration, eptinezumab will be the first infusion therapy for migraine prevention. Alder is also developing ALD1910, a preclinical mAb that inhibits pituitary adenylate cyclase-activating polypeptide-38 (PACAP-

38), as a potential new therapeutic option for migraine. 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 anticipated commercial launch of eptinezumab and Alder's progress with advancing manufacturing, commercial readiness and other activities and initiatives to prepare for such launch; Alder's mission to forever change migraine treatment; the planned Phase 3 clinical trial of eptinezumab for the acute treatment of migraine and Alder's objective relating thereto; Alder's contract manufacturing agreement with Sandoz GmbH, including the sufficiency and duration of the supply produced thereunder; the clinical, therapeutic and commercial potential of eptinezumab and ALD1910; the development of ALD1910, including the planned initiation of a first in human clinical trial; and Alder's financial outlook, including the expected range of full-year 2019 net cash used in operating activities and purchases of property and equipment and 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. Words such as "expected," "planned," "potential," "moves," "available," "continue," "prepare," "mission," "initiate," "will," "anticipates," "sufficient," "objective," "on track," "advance," "outlook," "believes," "projected," 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 the build of Alder's commercialization infrastructure; risks and uncertainties relating to the manufacture and supply of eptinezumab; risks related to the potential failure of eptinezumab and ALD1910 to demonstrate safety and efficacy in clinical testing; Alder's ability to conduct clinical trials and studies of eptinezumab and ALD1910 sufficient to achieve a positive completion; the availability of data at the expected times; Alder's ability to obtain and protect intellectual property rights, and operate without infringing on the intellectual property rights of others; risks and uncertainties relating to ongoing and potential future legal proceedings; 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 March 31, 2019, which was filed with the Securities and Exchange Commission (SEC) on May 2, 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)

	March 31, 2019	December 31, 2018
Cash, cash equivalents, investments and restricted cash	$ 498,508	$ 412,369
Prepaid expenses and other assets	14,660	13,870
Total assets	$ 513,168	$ 426,239
Convertible notes, net of discount	$ 185,146	$ 182,104
Other liabilities	67,214	30,404
Convertible preferred stock	103,755	103,755
Total stockholders' equity	157,053	109,976
Total liabilities, convertible preferred stock and stockholders' equity	$ 513,168	$ 426,239

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

	Three Months Ended March 31,	
	2019	**2018**
Revenues		
Collaboration and license agreements	$ —	$ —
Operating expenses		
Research and development	69,589	74,048
General and administrative	44,498	11,553
Total operating expenses	114,087	85,601
Loss from operations	(114,087)	(85,601)
Other income (expense), net	(3,847)	(1,430)
Net loss	$ (117,934)	$ (87,031)
Dividends on convertible preferred stock	(1,311)	(1,083)
Deemed dividend on convertible preferred stock related to accretion of beneficial conversion feature	—	(29,460)
Net loss applicable to common stockholders	$ (119,245)	$ (117,574)
Net loss per share applicable to common stockholders - basic and diluted	$ (1.63)	$ (1.73)
Weighted average number of common shares used in net loss per share - basic and diluted	73,056,907	67,844,872

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