

## Alder BioPharmaceuticals Reports Second Quarter 2016 Financial and Operating Results

*Positive 24-Week Clinical Data for ALD403 in Chronic Migraine Continues to Demonstrate a Best-In-Class Profile as Company Advances Toward a BLA Submission*

*Advances Second Program Directed at Migraine Prevention, ALD1910, into IND-Enabling Studies*

BOTHELL, Wash., July 26, 2016 (GLOBE NEWSWIRE) -- Alder BioPharmaceuticals, Inc. (NASDAQ:ALDR), a clinical-stage biopharmaceutical company developing monoclonal antibody therapeutics, today provided a corporate update and reported its financial and operating results for the second quarter ended June 30, 2016.

"Led by the positive top-line 24 week data in chronic migraine announced yesterday, we continue to execute successfully against our plan to advance ALD403 toward an FDA submission and the goal of marketing a best-in-class migraine prevention antibody therapy," said Randall C. Schatzman, Ph.D., president and chief executive officer of Alder. "We are on schedule to initiate our second pivotal study of ALD403, PROMISE 2, later this year and to advance our alternate ALD403 formulation suitable for administration as a single quarterly sub-cutaneous or intra-muscular injection into advanced studies. Lastly, we are doubling our efforts to meet the needs of millions of people living with migraine by bringing forward a second drug candidate directed at migraine prevention, ALD1910, our PACAP-38 directed antibody. This action further reinforces our strategy to build a specialty sales force capable of successfully marketing multiple agents in the CNS arena, thereby increasing shareholder value."

### Recent Pipeline and Corporate Highlights

**ALD403** — Pivotal-stage monoclonal antibody candidate inhibiting the calcitonin gene-related peptide (CGRP) and being evaluated for migraine prevention

- | Reported positive top-line 24-week data yesterday from a Phase 2b study of ALD403 demonstrating persistent migraine prevention in patients with chronic migraine.
  - | The 24-week data confirm and extend the 12-week data reported previously, which included the 75% reduction in migraine days over 12 weeks and the mean reduction in migraine days from baseline, the primary efficacy and secondary endpoints, respectively.
- | Presented previously announced positive clinical data from Phase 2b and Phase 1 clinical trials of ALD403 for the prevention of migraine, and preclinical data from a case study comparing the binding kinetics of ALD403 to two other anti-CGRP monoclonal antibodies at the 58<sup>th</sup> Annual Scientific Meeting of the American Headache Society in San Diego, CA.
- | Announced an increase in the target patient enrollment in PROMISE 1, the first of two planned pivotal clinical trials of ALD403, to 800 patients from 600.

**Clazakizumab** — Monoclonal antibody, discovered by Alder, designed to block interleukin-6 (IL-6), which plays a key role in the inflammatory cascade

- | In May, licensed exclusive worldwide rights to clazakizumab to Vitaeris, Inc. In exchange for the rights to clazakizumab, Alder has received an equity stake in Vitaeris and is eligible to receive royalties and certain other payments. Vitaeris is a newly formed company that will pursue innovative therapeutic indications in chronic inflammatory diseases.

### Preclinical Programs

- | Advanced ALD1910 as a drug development candidate for the prevention of migraine. ALD1910 is a monoclonal antibody targeting pituitary adenylate cyclase-activating polypeptide-38 (PACAP-38), a protein that is active in mediating the initiation of migraine that Alder believes holds potential as a treatment for migraineurs who have an inadequate response to therapeutics directed at CGRP or its receptor.
- | Terminated development of ALD1613 based on preclinical studies identifying novel target specific toxicology findings that may limit human clinical utility.

### Corporate

- | Completed a public offering in April 2016 of 6,182,795 shares of Alder's common stock at a public offering price of \$23.25 per share. Net proceeds, after underwriting discounts and commissions and offering expenses, were \$134.9 million.
- | Expanded the leadership team to support advancement of ALD403 through late-stage trials including:
  - | Appointed Timothy Whitaker, M.D. as Chief Medical Officer
  - | Appointed Roger Cady M.D. as Vice President of Neurology
  - | Appointed Iqbal Husain Ph.D as Vice President of Program and Portfolio Management
  - | Promoted Dauphine S. Barone to Vice President of Manufacturing Logistics
  - | Promoted Barbara A. Schaeffler, MBA to Vice President of Clinical Operations

## **Expected Upcoming Events and Milestones**

- | Initiate PROMISE 2 (PRevention Of Migraine via Intravenous ALD403 Safety and Efficacy 2) in patients with chronic migraine in the second half of 2016 as the second pivotal clinical trial intended to support a Biologics License Application (BLA) submission to the U.S. Food and Drug Administration (FDA) for ALD403.
- | Advance Alder's alternate ALD403 formulation suitable for self-administration, as a single sub-cutaneous or intramuscular injection, with the objective of initiating a late stage study in 2016 or early 2017.
- | Announce top-line data from PROMISE 1 (PRevention Of Migraine via Intravenous ALD403 Safety and Efficacy 1), the first pivotal trial of ALD403, in the first half of 2017.

## **Second Quarter Ended June 30, 2016 Financial Results**

For the second quarter ended June 30, 2016, Alder recorded approximately \$0.1 million of revenue under license agreement with Vitaeris relating to a sale of clazakizumab inventory to Vitaeris at cost. Alder did not record any revenue in the second quarter of 2015.

Research and development expenses for the second quarter ended June 30, 2016, totaled \$33.8 million, compared to \$14.1 million for the same period in 2015. The increase in spending was primarily due to the ALD403 development program, and consisted of costs related to PROMISE 1 and other ongoing clinical trials and manufacturing costs of drug supplies in support of existing and planned pivotal clinical trials. In addition, Alder incurred increased compensation costs due to an increase in Alder's research and development headcount to support the pivotal trial program for ALD403 and an increase in stock-based compensation.

General and administrative expenses for the second quarter ended June 30, 2016, totaled \$6.5 million, compared to \$3.9 million for the same period in 2015. The increase was primarily due to compensation costs as a result of an increase in stock-based compensation and general and administrative headcount, as well as increases in market research and other administrative costs.

Alder recognized a gain of \$1.1 million on licensing clazakizumab to Vitaeris in the second quarter ended June 30, 2016.

Net loss for the second quarter ended June 30, 2016, totaled \$38.9 million, or \$0.79 per share, compared to a net loss of \$17.7 million, or \$0.46 per share, on a fully-diluted basis, for the same period in 2015.

As of June 30, 2016, Alder had \$450.1 million in cash, cash equivalents and investments which included net proceeds from Alder's April 2016 public offering, compared to \$353.3 million as of March 31, 2016.

## **Conference Call and Webcast**

Alder will host a conference call today at 5:00 p.m. ET to discuss these financial results and provide a general business update. 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 29548578. The webcast will be broadcast live on the Events & Presentations page of 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 therapeutic antibodies with the potential to meaningfully transform current treatment paradigms. ALD403, Alder's lead pivotal-stage product candidate being evaluated for migraine prevention, is a genetically engineered monoclonal antibody that inhibits calcitonin gene-related peptide. Alder is additionally evaluating ALD1910, a preclinical product candidate also in development as a migraine prevention therapy. ALD1910 is a monoclonal antibody targeting pituitary adenylate cyclase-activating polypeptide-38 (PACAP-38), a protein that is active in mediating the initiation of

migraine. Clazakizumab, Alder's third program, is a monoclonal antibody candidate designed to block 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 ALD403 and ALD1910; the initiation of future clinical trials and studies; future regulatory filings; the anticipated commercialization of ALD403; Alder's marketing strategy and expected increase in shareholder value; and Alder's potential receipt of royalties and other payments under the license agreement with Vitaeris. Words such as "continues," "demonstrate," "advance," "plan," "toward," "goal," "on schedule," "initiate," "meet," "bringing forward," "directed," "strategy," "build," "value," "confirm," "extend," "eligible," "will," "believes," "potential," "may," "expected," "upcoming," "intended," "support," "objective," "announce," 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 ALD403 and ALD1910 to demonstrate safety and efficacy in clinical testing; Alder's ability to conduct clinical trials of ALD403 and ALD1910 sufficient to achieve a positive completion; the availability of data at the expected times; the clinical, therapeutic and commercial value of ALD403 and ALD1910; risks and uncertainties related to regulatory application, review and approval processes and Alder's compliance with applicable legal and regulatory requirements; the uncertain timing and level of expenses associated with the development of ALD403 and ALD1910; the sufficiency of Alder's capital and other resources; Alder's reliance on Vitaeris for the development of clazakizumab; 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, 2016, which was filed with the Securities and Exchange Commission (SEC) on July 26, 2016, 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 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>2016</u>	<u>December 31,</u> <u>2015</u>
Cash, cash equivalents and investments	\$450,107	\$ 381,012
Prepaid expenses and other assets	24,270	19,015
Total assets	\$474,377	\$ 400,027
Total liabilities	\$ 16,310	\$ 12,510
Total stockholders' equity	458,067	387,517
Total liabilities and stockholders' equity	\$474,377	\$ 400,027

## Condensed Consolidated Statements of Operations (Unaudited)

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

	<u>Three Months Ended</u> <u>June 30,</u>		<u>Six Months Ended</u> <u>June 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
<b>Revenues</b>				
Revenue under license agreement	\$ 113	\$ —	\$ 113	\$ —

**Operating expenses**

Cost of sales	113	—	113	—
Research and development	33,833	14,088	61,480	25,123
General and administrative	6,466	3,930	12,511	7,607
Total operating expenses	40,412	18,018	74,104	32,730
Gain on license of clazakizumab	1,050	—	1,050	—
Loss from operations	(39,249)	(18,018)	(72,941)	(32,730)
Other income, net	383	363	712	422
Net loss	\$ (38,866)	\$ (17,655)	\$ (72,229)	\$ (32,308)
Net loss per share - basic and diluted	\$ (0.79)	\$ (0.46)	\$ (1.55)	\$ (0.86)
Weighted average number of common shares used in net loss per share - basic and diluted	49,284,573	38,162,226	46,519,045	37,536,331

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