October 27, 2016

Alder BioPharmaceuticals Announces Third Quarter 2016 Financial and Operating Results

Company Finalizes ALD403 Pivotal Program Design and Confirms Planned Initiation of PROMISE 2 Phase 3 Study in 2016

Top-Line ALD403 PROMISE 1 Phase 3 Data Expected in First Half of 2017

BOTHELL, Wash., Oct. 27, 2016 (GLOBE NEWSWIRE) -- Alder BioPharmaceuticals, Inc. (NASDAQ:ALDR), a clinical-stage biopharmaceutical company developing monoclonal antibody therapeutics, today announced its financial results for the third quarter ended Sept. 30, 2016, and provided a corporate and clinical update.

As part of this update, the company reported positive outcomes from discussions with the U.S. Food and Drug Administration (FDA) regarding ALD403, the company's lead candidate being developed as a migraine prevention treatment for patients with chronic and frequent episodic migraine. Following consultation with the FDA, Alder finalized the basic design and endpoints for the pivotal clinical trial program of ALD403.

"We are very pleased with the outcome of our FDA discussions and the resulting finalization of our clinical path to a BLA submission for ALD403. If ALD403 is approved, we believe the selected Phase 3 endpoints will support a competitive label that emphasizes the product's unique clinical characteristics to treat frequent episodic and chronic migraine patients," said Randall C. Schatzman, Ph.D., president and chief executive officer of Alder. "ALD403 has potential as a unique and important therapeutic option for physicians in the treatment of their patients with migraine."

The basic elements of the ALD403 pivotal clinical studies have been finalized as follows:

- The PROMISE 2 (**PR**evention **O**f **M**igraine via **I**ntravenous ALD403 **S**afety and **E**fficacy 2) pivotal study will begin in 2016 and will evaluate the safety and efficacy of ALD403 in patients with chronic migraine. The study will be a double-blind, placebo-controlled Phase 3 clinical trial enrolling approximately 1,050 patients randomized to either one of two dose levels of ALD403 or placebo administered via infusion once every 12 weeks across sites in the United States and Europe.
    - The PROMISE 2 study primary endpoint will be the mean reduction in migraine days from baseline over weeks 1 to 12.
    - The PROMISE 2 study key secondary endpoints will be the 75% responder rate over weeks 1 to 12 as determined by the change in migraine days between ALD403 and placebo, and the 75% responder rate over weeks 1 to 4 as determined by the change in migraine days between ALD403 and placebo.
- As a further outcome from the FDA consultations, Alder is aligning the primary and key secondary endpoints of PROMISE 1 (**PR**evention **O**f **M**igraine via **I**ntravenous ALD403 **S**afety and **E**fficacy 1), the company's ongoing pivotal study that is evaluating the safety and efficacy of ALD403 administered once every 12 weeks in approximately 800 patients with frequent episodic migraine, with the PROMISE 2 study endpoints for consistency between the two Phase 3 studies. The modification of the endpoints will not affect the conduct of the trial, including the expected top-line PROMISE 1 data readout in the first half of 2017.
- Patient recruitment for PROMISE 1 is complete.
- Both the PROMISE 1 and PROMISE 2 study protocols were developed to be consistent with current standards for evaluating new investigational drug therapies for migraine prevention while also highlighting ALD403's clinical attributes observed to date, including significant benefit achieved in the first month, sustained 12-week efficacy after a single treatment and robust efficacy as determined by the 75% responder rate.
- No additional studies were requested by the FDA beyond the PROMISE 1 and PROMISE 2 pivotal studies and a planned open-label study.
- The planned timing for the availability of top-line data from PROMISE 2 is the first half of 2018.
- The planned timing for the submission of the Company's Biologics License Application (BLA) to the FDA remains the

second half of 2018.

Timothy Whitaker, M.D., chief medical officer of Alder, added, "We have made great progress in the ALD403 clinical program as demonstrated by our successful dialogue with the FDA. Finalization of the design of our Phase 3 clinical program will enable us to continue to advance the development of ALD403 rapidly toward a BLA submission. Further, we are also pleased to have completed recruitment for PROMISE 1, keeping us on track to achieve top-line data in the first half of 2017."

Additional Pipeline and Corporate Highlights:

ALD403 — Pivotal-stage monoclonal antibody candidate inhibiting the calcitonin gene-related peptide (CGRP) that Alder is evaluating for migraine prevention

- In July 2016, Alder reported positive top-line 24-week data from a Phase 2b study of ALD403. The 24-week data confirmed and extended the previously reported 12-week data, which included the mean reduction in migraine days from baseline and the 75% reduction in migraine days over 12 weeks.
- In September 2016, Alder presented data from Phase 2b and Phase 1 clinical trials of ALD403 for the prevention of migraine as well as preclinical data from a case study of ALD403 and other CGRP-antibodies at the 5th European Headache and Migraine Trust International Congress (EHMTIC 2016) in Glasgow, Scotland.
- Completed recruiting for PROMISE 1; top-line PROMISE 1 data readout continues on track for the first half of 2017.
- Continued to plan to progress the alternate ALD403 formulation suitable for self-administration, as a single subcutaneous or intramuscular injection, to more advanced studies in 2017.

ALD1910 — Preclinical monoclonal antibody targeting pituitary adenylate cyclase-activating polypeptide-38 (PACAP-38), a protein that is active in mediating the initiation of migraine. Alder believes ALD1910 holds potential as a treatment for migraine patients who have an inadequate response to therapeutics directed at CGRP or its receptor

- The company is advancing ALD1910 through IND-enabling studies.

Corporate — Expanded the leadership team to support advancement of ALD403 through late-stage trials and continue pre-commercial activities.

- In October 2016, Alder promoted Larry Benedict to executive vice president and principal accounting officer.
- In September 2016, the company appointed Elisabeth A. Sandoval as chief commercial officer.
- Also in September 2016, Alder appointed Nancy L. Boman M.D., Ph.D., as senior vice president of regulatory affairs and pharmacovigilance.

Financial Results for the Third Quarter Ended Sept. 30, 2016

For the third quarters ended Sept. 30, 2016, and 2015, Alder did not record any revenues.

Research and development expenses for the third quarter ended Sept. 30, 2016, totaled $29.5 million, compared to $22.9 million for the same period in 2015. The increase in spending was primarily due to an increase in ALD403 manufacturing costs for drug supply in support of planned and ongoing pivotal clinical trials. The company also had an increase in salaries and stock-based compensation expenses as a result of an increase in research and development headcount to support programs under development.

General and administrative expenses for the third quarter ended Sept. 30, 2016, totaled $6.2 million, compared to $4.3 million for the same period in 2015. The increase was primarily due to an increase in stock-based compensation expense and salaries expense as a result of an increase in headcount over the prior year period.

Net loss for the third quarter ended Sept. 30, 2016, totaled $35.1 million, or $0.70 per share, compared to a net loss of $27.0 million, or $0.62 per share, on a fully-diluted basis, for the same period in 2015.

As of Sept. 30, 2016, Alder had $403.4 million in cash, cash equivalents and investments, compared to $450.1 million as of June 30, 2016.

Conference Call and Webcast

Alder will host a conference call at 5 p.m. ET today 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 94584081. The webcast may be accessed from the Events & Presentations page on the Investors section of Alder's website at 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, ALD403, is being evaluated for migraine prevention. ALD403 is a monoclonal antibody that inhibits calcitonin gene-related peptide (CGRP), a protein that is active in mediating the initiation of 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 ALD403 and ALD1910; the availability of results from clinical trials; the initiation and enrollment of future clinical trials; future regulatory filings and potential regulatory approval of ALD403. Words such as "planned," "initiation," "expected," "will," "believe," "support," "approved," "enable," "advance," "on track," "continue," "demonstrated," "potential," 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 and studies 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; 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 September 30, 2016, which was filed with the Securities and Exchange Commission (SEC) on October 27, 2016, 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)

	September 30, 2016	December 31, 2015
Cash, cash equivalents and investments	$ 403,389	$ 381,012
Prepaid expenses and other assets	40,214	19,015
Total assets	$ 443,603	$ 400,027
Total liabilities	$ 16,867	$ 12,510
Total stockholders' equity	426,736	387,517
Total liabilities and stockholders' equity	$ 443,603	$ 400,027

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues				
Revenue under license agreement	$ —	$ —	$ 113	$ —
Operating expenses				
Cost of sales	—	—	113	—
Research and development	29,491	22,852	90,971	47,975
General and administrative	6,239	4,318	18,750	11,925
Total operating expenses	35,730	27,170	109,834	59,900
Gain on license of clazakizumab	—	—	1,050	—
Loss from operations	(35,730)	(27,170)	(108,671)	(59,900)
Other income, net	596	173	1,308	595
Net loss	$ (35,134)	$ (26,997)	$ (107,363)	$ (59,305)
Net loss per share - basic and diluted	$ (0.70)	$ (0.62)	$ (2.25)	$ (1.50)
Weighted average number of common shares used in net loss per share - basic and diluted	50,226,588	43,525,888	47,763,913	39,554,790

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