



May 9, 2016

Aldeyra Therapeutics Announces Positive Results From Phase II Clinical Trial in Subjects With Noninfectious Anterior Uveitis

Company to Provide Corporate Update and First Quarter Financial Results Announcement of the Second Positive Phase II Clinical Trial of NS2 in 2016 NS2 Has Now Demonstrated Clinical Activity in the Two Major Types of Ocular Inflammation

LEXINGTON, MA -- (Marketwired) -- 05/09/16 -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to aldehydes, today reported that a randomized, multi-center, investigator-masked, comparator-controlled, parallel-group Phase II clinical trial of topical ocular NS2, a first-in-class aldehyde trap, demonstrated activity comparable to standard-of-care topical ocular corticosteroids in reducing anterior chamber cell count in patients with active noninfectious anterior uveitis.

Topical corticosteroids are often associated with ocular toxicity, including cataract formation and glaucoma (elevated intra-ocular pressure). The data released today suggest that NS2 has the potential to reduce or replace corticosteroid use in noninfectious anterior uveitis.

Commenting on the results, Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra, said, "We are excited about these results, which, in combination with the positive data in allergic conjunctivitis that were released earlier this year, broaden the potential therapeutic applicability of topical ocular NS2 to many ocular inflammatory diseases. We look forward to continuing to develop aldehyde traps as a novel approach for the treatment of inflammation."

Forty-five subjects were randomized equally to receive NS2 0.5% four times daily, Pred Forte® 1% (a corticosteroid) four times daily (tapered), or NS2 0.5% four times daily and Pred Forte® 1% twice daily (tapered). There were no statistical differences among all groups in any clinical endpoint, including anterior chamber cell count and ocular flare. NS2 was generally well tolerated and there were no serious adverse events, consistent with previous Phase I and Phase II clinical trials.

NS2 produced clinically meaningful effects on anterior chamber cell counts (ACC) comparable to corticosteroid. At the week 2 study visit, grade 0 (cell count of zero or one) ACC treatment response was seen in 33% of NS2 patients, 31% of Pred Forte® patients, and 31% of patients on combination therapy. At the week 8 study visit, grade 0 ACC treatment response was seen in 40% of NS2 patients, 46% of Pred Forte® patients, and 44% of patients on combination therapy. For ACC improvement of at least one grade, treatment response was seen in 53% of NS2 patients, 46% of Pred Forte® patients, and 50% of patients on combination therapy. For subjects that did not respond to therapy, rescue medication rates were similar between NS2 and Pred Forte®, with rescue medication required in 20% of NS2 patients, 38% of Pred Forte® patients and 25% of patients on combination therapy.

The principal investigator of the trial, Dr. Stephen Foster, a leading expert in ocular inflammation, has described this study outcome as "very encouraging with NS2 demonstrating clear activity in anterior uveitis and no evidence of significant adverse effects. This suggests that NS2 may be an important future treatment option for anterior uveitis patients. Effectiveness equal to topical corticosteroids with the absence of eye pressure elevation or cataract production would make this anti-inflammatory therapy an attractive therapeutic option for treating uveitis."

Aldehydes are thought to mediate both major forms of inflammation, allergy (such as allergic conjunctivitis) and autoimmune disease (such as noninfectious anterior uveitis). In February 2016, Aldeyra reported positive Phase II data with topical ocular NS2 in allergic conjunctivitis. The Phase II results in noninfectious anterior uveitis released today suggest that NS2 is also active in autoimmune disease.

Additional Recent Highlights

- 1 ***Reported positive results from Phase II clinical trial in subjects with allergic conjunctivitis.*** Aldeyra reported that the results of a randomized, parallel-group, single-center, double-masked, vehicle-controlled Phase II clinical trial of topical ocular NS2 in subjects with induced allergic conjunctivitis demonstrated statistically significant and sustained activity of NS2 over vehicle in reducing ocular itching and tearing. NS2 was generally well tolerated and there were no

serious adverse events during the trial.

- 1 **Phase II clinical data in Sjögren-Larsson Syndrome expected in third quarter of 2016.** Aldeyra confirmed that the results of a Phase II clinical trial of dermatologic NS2 for the treatment of ichthyosis in Sjögren-Larsson Syndrome, an inborn error of aldehyde metabolism, are expected in the third quarter of 2016.
- 1 **Hired key employees for pipeline advancement.** In January 2016, Aldeyra hired David J. Clark, M.D. as Chief Medical Officer. Dr. Clark has 18 years of drug development experience at Pfizer, SmithKline Beecham, and several biotechnology companies focused on rare and common diseases. Aldeyra also hired Mary Taylor, MPH as the Senior Vice President, Regulatory Affairs in February 2016. Ms. Taylor's industry experience spans over 30 years in drug development and senior regulatory positions at Shire, Bayer, and multiple biotechnology companies. The additions of Dr. Clark and Ms. Taylor enhance the ability to advance multiple treatments through the clinic and to the market for a number of inflammatory diseases and inborn errors of aldehyde metabolism.

First Quarter 2016 Financial Review

For the quarter ended March 31, 2016, Aldeyra reported a net loss of approximately \$(5.0) million compared to a net loss of approximately \$(2.1) million for the quarter ended March 31, 2015. Basic and diluted net loss per share was \$(0.51) for the quarter ended March 31, 2016 compared to basic and diluted net loss of \$(0.32) per share for the quarter ended March 31, 2015. Losses have resulted from the costs of our clinical trials and research and development programs, as well as from general and administrative expenses.

Research and development expenses were approximately \$3.5 million for the quarter ended March 31, 2016 compared to approximately \$1.1 million for the quarter ended March 31, 2015. The increase of approximately \$2.4 million is primarily related to the increase in our external research and development expenditures, including preclinical, manufacturing and clinical efforts and an increase in personnel costs including stock based compensation due to an increase in headcount.

General and administrative expenses were approximately \$1.5 million for the quarter ended March 31, 2016, compared to approximately \$972,000 for the quarter ended March 31, 2015. The increase was primarily related to an increase in insurance costs, legal costs and personnel costs, including stock-based compensation due to an increase in headcount.

Cash, cash equivalents and marketable securities were \$23.0 million at March 31, 2016.

Conference Call and Webcast Information

The Company will hold a conference call on Monday, May 9, 2016 at 8:00 a.m. EDT to discuss the results and operational updates. The dial-in numbers are 1-888-438-5519 for domestic callers and 1-719-325-2308 for international callers. The conference ID number for both is 4012631. A live webcast of the conference call will also be available on the investor relations page of the Aldeyra Therapeutics corporate website at www.aldeyra.com.

After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for one year. In addition, a telephonic replay of the call will be available until May 9, 2017. The replay dial-in numbers are 1-888-203-1112 for domestic callers and 1-719-457-0820 for international callers. Please use event passcode 4012631.

About Aldeyra Therapeutics

Aldeyra Therapeutics, Inc., is a biotechnology company devoted to improving lives by inventing, developing and commercializing products that treat diseases thought to be related to endogenous aldehydes, a naturally occurring class of pro-inflammatory and toxic molecules. The company's lead product, NS2, is an aldehyde trap in development for ocular inflammation, as well as for Sjögren-Larsson Syndrome and Succinic Semi-Aldehyde Dehydrogenase Deficiency, two inborn errors of aldehyde metabolism. For more information regarding our novel therapeutic approaches, please visit www.aldeyra.com.

About Noninfectious Anterior Uveitis

Noninfectious anterior uveitis is a rare, potentially blinding disease that may be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation in the front of the eye, pain, impaired vision, and photophobia.

About Allergic Conjunctivitis

Allergic conjunctivitis is a common allergic disease that is thought to be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in ocular itching, excessive tear production, lid swelling and redness.

About Sjögren-Larsson Syndrome

Sjögren-Larsson Syndrome is a rare disease caused by mutations in fatty acid aldehyde dehydrogenase, leading to elevated fatty aldehyde levels that are thought to contribute to severe ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. There is no FDA-approved therapy for SLS.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's plans for its product candidates and its financial guidance. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "aim," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Aldeyra is at an early stage of development and may not ever have any products that generate significant revenue. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements include, among others, the timing of enrollment, commencement and completion of Aldeyra's clinical trials, the timing and success of preclinical studies and clinical trials conducted by Aldeyra and its development partners; the ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency of Aldeyra's cash resources and needs for additional financing; the rate and degree of market acceptance of any of Aldeyra's product candidates; Aldeyra's expectations regarding competition; Aldeyra's anticipated growth strategies; Aldeyra's ability to attract or retain key personnel; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's expectations regarding federal, state and foreign regulatory requirements; regulatory developments in the United States and foreign countries; Aldeyra's ability to obtain and maintain intellectual property protection for its product candidates; the anticipated trends and challenges in Aldeyra's business and the market in which it operates; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2015 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov.

In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this release is provided only as of the date of this release, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this release on account of new information, future events, or otherwise, except as required by law.

ALDEYRA THERAPEUTICS, INC. BALANCE SHEETS

	<u>March 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,148,524	\$ 14,648,866
Marketable securities	12,877,281	12,941,776
Prepaid expenses and other current assets	283,509	497,552
Total current assets	23,309,314	28,088,194
Deferred offering costs	45,986	36,236
Fixed assets, net	81,466	80,334
Total assets	<u>\$ 23,436,766</u>	<u>\$ 28,204,764</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 578,017	\$ 851,160
Accrued expenses	1,035,888	1,186,429
Current portion of credit facility	193,866	77,546
Total current liabilities	1,807,771	2,115,135
Credit facility, net of current portion and debt discount	1,101,968	1,211,310
Total liabilities	<u>2,909,739</u>	<u>3,326,445</u>
Commitments and contingencies		

Stockholders' equity:		
Preferred stock, \$0.001 par value, 15,000,000 shares authorized, none issued and outstanding	-	-
Common stock, voting, \$0.001 par value; 150,000,000 authorized and 9,712,521 shares issued and outstanding, respectively	9,713	9,713
Additional paid-in capital	84,084,750	83,478,851
Accumulated other comprehensive income (loss), net of tax	1,800	(8,361)
Accumulated deficit	<u>(63,569,236)</u>	<u>(58,601,884)</u>
Total stockholders' equity	<u>20,527,027</u>	<u>24,878,319</u>
Total liabilities and stockholders' equity	<u>\$ 23,436,766</u>	<u>\$ 28,204,764</u>

ALDEYRA THERAPEUTICS, INC.
STATEMENT OF OPERATIONS

	Three Months Ended March 31,	
	2016	2015
Operating expenses:		
Research and development	\$ 3,511,477	\$ 1,136,434
General and administrative	1,455,559	972,101
Loss from operations	<u>(4,967,036)</u>	<u>(2,108,535)</u>
Other income (expense):		
Interest income	24,719	-
Interest expense	<u>(25,035)</u>	<u>(28,024)</u>
Total other income (expense), net	<u>(316)</u>	<u>(28,024)</u>
Net loss	<u>\$ (4,967,352)</u>	<u>\$ (2,136,559)</u>
Net loss per share:		
Basic	<u>\$ (0.51)</u>	<u>\$ (0.32)</u>
Diluted	<u>\$ (0.51)</u>	<u>\$ (0.32)</u>
Weighted average common shares outstanding:		
Basic	<u>9,712,521</u>	<u>6,667,519</u>
Diluted	<u>9,712,521</u>	<u>6,667,519</u>

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