

November 14, 2016

# Aldeyra Therapeutics Announces Third Quarter 2016 Financial Results

## On Track to Initiate Two Phase II and Two Phase III Trials in 2017

LEXINGTON, MA -- (Marketwired) -- 11/14/16 -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to aldehydes, today reported third quarter 2016 financial results.

"We are extremely pleased with the progress we have made this year with our novel aldehyde trap, ADX-102," said Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "We have reported favorable Phase II clinical data in three diseases, which include ocular inflammation and inborn errors of metabolism. In addition, we expect to initiate a new clinical program in dry eye syndrome, a common disease where existing treatments have shown limited efficacy." Dr. Brady continued, "In aggregate, the clinical trial results announced this year validate ADX-102 and the aldehyde trap platform as a potentially important therapeutic approach in inflammation and inborn errors of aldehyde metabolism. We look forward to continuing the development of ADX-102 and other aldehyde traps in these and other clinical indications with unmet medical need."

# Recent Highlights

- 2016 Research & Development Day. On September 11, 2016, Aldeyra hosted a Research & Development Day featuring presentations by key ocular inflammation and metabolic disease opinion leaders on the therapeutic potential of Aldeyra's aldehyde trap platform. A webcast of the event can be found under the Events section of Aldeyra's investor website.
- Clinical Pipeline Advancement. Following positive data from Phase II clinical trials in Sjögren-Larsson Syndrome, noninfectious anterior uveitis, and allergic conjunctivitis, Aldeyra announced plans to initiate three late-stage clinical trials in addition to a clinical program in dry eye syndrome:
  - Phase III vehicle-controlled trial in noninfectious anterior uveitis, expected to be initiated in the first half of 2017
  - Phase III clinical trial in Sjögren-Larsson Syndrome ichthyosis, expected to be initiated in the second half of 2017 following U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) regulatory feedback
  - i Phase IIb clinical trial in allergic conjunctivitis, expected to be initiated in the first half of 2017
  - Phase IIa clinical trial in dry eye syndrome, expected to be initiated in the first half of 2017
- Organizational Update. In September 2016, Aldeyra announced the appointment of Richard H. Douglas to its Board of Directors. Dr. Douglas is the former Senior Vice President, Corporate Development at Genzyme Corporation where he led Genzyme's Corporate Development team, until the acquisition of Genzyme by Sanofi (now Sanofi Genzyme), in numerous acquisitions, licenses, financings, joint ventures, and strategic alliances.

## Third Quarter 2016 Financial Review

For the quarter ended September 30, 2016, Aldeyra reported a net loss of approximately \$4.8 million compared to a net loss of approximately \$3.4 million for the quarter ended September 30, 2015. Basic and diluted net loss per share was \$0.38 for the quarter ended September 30, 2016, compared to basic and diluted net loss of \$0.35 per share for the quarter ended September 30, 2015. Losses have resulted from the costs of Aldeyra's clinical trials and research and development programs, as well as from general and administrative expenses.

Research and development expenses were approximately \$3.4 million for the quarter ended September 30, 2016, compared to approximately \$2.1 million for the quarter ended September 30, 2015. The increase of approximately \$1.3 million is primarily related to the increase in Aldeyra's external research and development expenditures, including preclinical, manufacturing, and clinical development activities, and an increase in personnel costs, including stock-based compensation due to an increase in headcount.

General and administrative expenses were approximately \$1.4 million for the quarter ended September 30, 2016, compared to approximately \$1.3 million for the quarter ended September 30, 2015. The increase of approximately \$100,000 was primarily related to an increase in legal and personnel costs, including stock-based compensation due to an increase in headcount.

Cash, cash equivalents and marketable securities were approximately \$28.9 million at September 30, 2016.

#### Conference Call and Webcast Information

The Company will hold a conference call on Monday, November 14, 2016 at 8:00 a.m. EST to discuss the results and operational updates. The dial-in numbers are 1-888-740-6116 for domestic callers and 1-913-312-0958 for international callers. The conference ID number for both is 2931479. A live webcast of the conference call will also be available on the investor relations page of the Aldeyra Therapeutics corporate website at <a href="https://www.aldeyra.com">www.aldeyra.com</a>.

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 November 13, 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 2931479.

#### 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. Aldeyra's lead product candidate, ADX-102, 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. ADX-102 has not been approved for sale in the U.S. or elsewhere.

# About Sjögren-Larsson Syndrome

Sjögren-Larsson Syndrome is a rare inborn error of aldehyde metabolism caused by mutations in fatty acid aldehyde dehydrogenase, leading to elevated toxic fatty aldehyde levels that are thought to contribute to severe ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. There is no therapy for SLS that has been approved by the U.S. Food and Drug Administration.

### **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 Dry Eye Syndrome

Dry eye syndrome is a common inflammatory disease characterized by insufficient moisture and lubrication in the anterior surface of the eye. Symptoms may include ocular irritation, burning or stinging, and severe cases may lead to decreased vision. In patients with dry eye syndrome, aldehydes may contribute to ocular inflammation as well as the impairment of lipids (fats) that lubricate the surface of the eye.

## 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. 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 June 30, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>. Additional factors may be set forth in Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, to be filed with the SEC in the fourth quarter of 2016.

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

		eptember 30, 2016 (Unaudited)	December 31, 2015	
ASSETS		-		
Current assets:				
Cash and cash equivalents	\$	14,568,508	\$	14,648,866
Marketable securities		14,307,073		12,941,776
Prepaid expenses and other current assets		250,206		497,552
Total current assets		29,125,787		28,088,194
Deferred offering costs		-		36,236
Fixed assets, net		65,690		80,334
Total assets	\$	29,191,477	\$	28,204,764
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	733,560	\$	851,160
Accrued expenses		1,476,592		1,186,429
Current portion of credit facility		426,505		77,546
Total current liabilities		2,636,657		2,115,135
Credit facility, net of current portion and debt discount		883,282		1,211,310
Total liabilities		3,519,939		3,326,445
Commitments and contingencies				
Stockholders' equity:				
Preferred stock, \$0.001 par value, 15,000,000 shares authorized, none issued and				
outstanding as of September 30, 2016 and December 31, 2015		-		-
Common stock, voting, \$0.001 par value; 150,000,000 authorized and 12,568,563				
shares issued and outstanding as of September 30, 2016 and 9,712,521 shares				
issued and outstanding as of December 31, 2015		12,569		9,713
Additional paid-in capital		98,302,346		83,478,851
Accumulated other comprehensive income (loss), net of tax		6,528		(8,361)
Accumulated deficit		(72,649,905)		(58,601,884)
Total stockholders' equity		25,671,538		24,878,319
Total liabilities and stockholders' equity	<u>\$</u>	29,191,477	<u>\$</u>	28,204,764

### STATEMENT OF OPERATIONS

# (unaudited)

# Three Months Ended September 30,

# Nine Months Ended September 30,

		2016		2015		2016		2015
Operating expenses:								
Research and development	\$	3,379,711	\$	2,076,410	\$	9,728,494	\$	4,461,941
General and administrative		1,396,734		1,261,196		4,314,483		3,188,176
Loss from operations	_	(4,776,445)	_	(3,337,606)	_	(14,042,977)		(7,650,117)
Other income (expense):								
Interest income		27,792		-		74,463		-
Interest expense	_	(26,654)	_	(28,081)	_	(79,507)	_	(84,314)
Total other income (expense),		4.400		(00,004.)		(5.044)		(04.044)
net	_	1,138	_	(28,081)	_	(5,044)	_	(84,314)
Net loss	\$	(4,775,307)	\$	(3,365,687)	\$	(14,048,021)	\$	(7,734,431)
Net loss per share - basic and diluted	\$	(0.38)	\$	(0.35)	\$	(1.28)	\$	(0.94)
Weighted average common shares outstanding - basic and diluted	=	12,474,609	=	9,712,521	_	10,942,127	_	8,270,405

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