



August 11, 2015

## **Aldeyra Therapeutics Reports Second Quarter and Year to Date 2015 Financial Results and Provides Development Updates**

LEXINGTON, Mass., Aug. 11, 2015 (GLOBE NEWSWIRE) -- Aldeyra Therapeutics, Inc. (Nasdaq:ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to free aldehydes, today announced its financial results for the second quarter and six months ended June 30, 2015.

Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra, commented, "During the recent quarter and entering the second half of the year, we have continued to focus on the development of our lead product candidate, NS2, a novel aldehyde trap. Importantly, we are excited to announce the addition of a new clinical program, allergic conjunctivitis, a common inflammatory ocular disease that is not adequately treated with currently available therapy in certain patients. The addition of the allergic conjunctivitis program provides the Company with yet another market opportunity, highlighting the breadth of potential indications for our platform technology. Also, during the second quarter we enrolled our first patient with noninfectious anterior uveitis, our previously announced ocular program in this rare disease.

"As we move forward, we are continuing to advance the development of new aldehyde trap compounds as well as a systemic formulation of NS2. We are pleased to announce that we expect to begin clinical testing of systemically administered NS2 in 2016."

Dr. Brady concluded, "In addition to advancing our product development programs, we have continued to demonstrate our ability to access the capital markets. In the second quarter, we raised approximately \$19.6 million in net proceeds with the completion of a follow-on public offering of common stock. By expanding our opportunities and maintaining a strong balance sheet, we believe we are well positioned to create long-term value for the Company and its stockholders."

### **Second Quarter and Six Months Ended June 30, 2015 Financial Review**

For the second quarter of 2015, Aldeyra reported a net loss attributable to common stockholders of approximately \$2.2 million compared to a net loss of approximately \$5.3 million for the second quarter of 2014. Basic and diluted net loss per share was \$0.27 for the three months ended June 30, 2015 compared to basic net loss per share of \$1.43 and diluted net loss per share of \$1.56 for the same period in 2014.

For the six months ended June 30, 2015, Aldeyra reported a net loss attributable to common stockholders of approximately \$4.4 million compared to a net loss of approximately \$5.1 million for the six months ended June 30, 2014. Basic and diluted net loss per share was \$0.58 for the six months ended June 30, 2015, compared to basic net loss per share of \$2.51 and diluted net loss per share of \$3.53 for the same period in 2014.

Research and development expenses totaled approximately \$1.2 million for the second quarter of 2015 compared to approximately \$664,000 for the second quarter of 2014. For the six months ended June 30, 2015, research and development expenses totaled approximately \$2.4 million compared to \$1.1 million for the six months ended June 30, 2014.

For the second quarter of 2015, general and administrative expenses were approximately \$955,000 compared to approximately \$983,000 for the second quarter of 2014. For the six months ended June 30, 2015, general and administrative expenses totaled approximately \$1.9 million compared to \$1.8 million for the six months ended June 30, 2014.

Total operating expenses for the second quarter of 2015 were approximately \$2.2 million compared to total operating expenses of approximately \$1.6 million for the second quarter of 2014. For the six months ended June 30, 2015, total operating expenses totaled approximately \$4.3 million compared to \$2.9 million for the six months ended June 30, 2014.

As of June 30, 2015, Aldeyra had cash and cash equivalents of \$33.6 million, which based on its current business plan is expected to fund operations into 2017.

### **Development Highlights and Update**

Aldeyra filed a Clinical Trial Authorization with Health Canada for a Phase IIa clinical trial of NS2 ophthalmic drops in patients with allergic conjunctivitis in late July 2015. Enrollment in the trial is expected to be completed in 2016. Updating guidance on its

current clinical programs, Aldeyra expects its ongoing Phase II clinical trial of NS2 in SLS to be fully enrolled by the end of the first quarter of 2016, and its ongoing Phase II clinical trial of NS2 in non-infectious anterior uveitis to complete enrollment in the second quarter of 2016.

Aldeyra continued progress on the design and synthesis of new aldehyde trap compounds, as well as a systemic formulation of NS2 that is expected to begin clinical testing in 2016. Potential clinical indications for the systemic formulation include SLS, Succinic Semi-aldehyde Dehydrogenase Deficiency, and autoimmune crises.

During the second quarter of 2015, novel data on the effects of NS2 in an animal model of radiation mucositis and fibrosis was accepted and presented at the 2015 Multinational Association of Supportive Care in Cancer - International Society of Oral Oncology Annual Meeting. Also during the second quarter, Aldeyra presented novel data on the effects NS2 ophthalmic drops, which in some measures exhibited efficacy comparable to topical steroids, in an animal model of ocular inflammation at the 2015 Annual Meeting of the Association for Research in Vision and Ophthalmology (ARVO). Additionally, at ARVO, Aldeyra presented novel data on the effects of NS2 in preventing the development of corneal fibrosis (haze) in an animal model.

## **About NS2**

NS2 is an aldehyde-binding small molecule based on an innovative platform technology focused on trapping free aldehydes, which are toxic and pro-inflammatory mediators of numerous diseases. By decreasing aldehyde load, NS2 may mitigate excessive inflammation and address diseases where aldehydes are thought to mediate pathology.

## **About Allergic Conjunctivitis**

Allergic conjunctivitis is a common 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 excessive tear production in addition to ocular swelling, redness, and itching.

## **About Sjögren-Larsson Syndrome**

Sjögren-Larsson Syndrome (SLS) 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.

## **About Noninfectious Anterior Uveitis**

Noninfectious anterior uveitis is a rare 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 Succinic Semi-Aldehyde Dehydrogenase Deficiency**

Succinic Semi-aldehyde Dehydrogenase (SSADH) Deficiency is a rare disease caused by mutations in SSADH, leading to elevated levels of succinic semi-aldehyde that are then converted to neurotoxic metabolites. SSADH Deficiency is characterized clinically by neurological compromise that includes cognitive and developmental delay, decreased muscle tone, and, in some cases, seizures.

## **About Aldeyra Therapeutics**

Aldeyra Therapeutics, Inc., is a biotechnology company focused primarily on the development of products to treat diseases thought to be related to endogenous free aldehydes, a naturally occurring class of toxic molecules. The company has developed NS2, a product candidate designed to trap free aldehydes. Aldeyra has initiated clinical testing of NS2 for the treatment of Sjögren-Larsson Syndrome and noninfectious anterior uveitis and intends to initiate clinical testing in allergic conjunctivitis. NS2 has not been approved for sale in the U.S. or elsewhere. [www.aldeyra.com](http://www.aldeyra.com)

## **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, 2014 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at [www.sec.gov](http://www.sec.gov). Additional information will also be set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, which will be filed with the SEC in the third quarter of 2015.

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 (Unaudited)**

	<b>June 30, 2015</b>	<b>December 31, 2014</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 33,569,784	\$ 8,527,304
Prepaid expenses and other current assets	266,850	232,568
Total current assets	33,836,634	8,759,872
Deferred offering costs	--	14,238
Fixed assets, net	40,868	12,993
Total assets	<u>\$ 33,877,502</u>	<u>\$ 8,787,103</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 629,346	\$ 341,294
Accrued expenses	451,641	908,724
Current portion of credit facility	310,185	77,546
Total current liabilities	1,391,172	1,327,564
Credit facility, net of current portion and debt discount	961,549	1,175,481
Total liabilities	<u>2,352,721</u>	<u>2,503,045</u>
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 15,000,000 shares authorized, none issued and outstanding as of June 30, 2015 and December 31, 2014	--	--
Common stock, voting, \$0.001 par value; 150,000,000 authorized and 9,712,521 shares issued and outstanding as of June 30, 2015 and 5,565,415 shares issued and outstanding as of December 31, 2014	9,712	5,565

Additional paid-in capital	82,395,410	52,790,090
Accumulated deficit	<u>(50,880,341)</u>	<u>(46,511,597)</u>
Total stockholders' equity	<u>31,524,781</u>	<u>6,284,058</u>
Total liabilities and stockholders' equity	<u>\$ 33,877,502</u>	<u>\$ 8,787,103</u>

**ALDEYRA THERAPEUTICS, INC.**  
**STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS) (Unaudited)**

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Operating expenses:				
Research and development	\$ 1,249,097	\$ 663,908	\$ 2,385,531	\$ 1,108,186
General and administrative	954,879	982,579	1,926,980	1,783,225
Loss from operations	<u>(2,203,976)</u>	<u>(1,646,487)</u>	<u>(4,312,511)</u>	<u>(2,891,411)</u>
Other income (expense):				
Change in fair value of preferred stock warrant liabilities	--	567,588	--	2,327,502
Interest income	--	--	--	3
Interest expense	<u>(28,210)</u>	<u>(56,246)</u>	<u>(56,234)</u>	<u>(169,467)</u>
Total other income (expense), net	<u>(28,210)</u>	<u>511,342</u>	<u>(56,234)</u>	<u>2,158,038</u>
Net loss and comprehensive loss	(2,232,186)	(1,135,145)	(4,368,745)	(733,373)
Accretion of preferred stock	--	(141,513)	--	(333,082)
Deemed dividend	<u>--</u>	<u>(4,053,570)</u>	<u>--</u>	<u>(4,053,570)</u>
Net loss attributable to common stockholders	<u>\$ (2,232,186)</u>	<u>\$ (5,330,228)</u>	<u>\$ (4,368,745)</u>	<u>\$ (5,120,025)</u>
Net loss per share attributable to common stockholders:				
Basic	<u>\$ (0.27)</u>	<u>\$ (1.43)</u>	<u>\$ (0.58)</u>	<u>\$ (2.51)</u>
Diluted	<u>\$ (0.27)</u>	<u>\$ (1.56)</u>	<u>\$ (0.58)</u>	<u>\$ (3.53)</u>
Weighted average common shares outstanding:				
Basic	<u>8,397,713</u>	<u>3,737,675</u>	<u>7,537,396</u>	<u>2,041,941</u>
Diluted	<u>8,397,713</u>	<u>3,769,360</u>	<u>7,537,396</u>	<u>2,107,389</u>

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