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Aldeyra Therapeutics Announces Second Quarter 2017 Financial Results

LEXINGTON, Mass., Aug. 8, 2017 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra or the Company), a clinical-stage biotechnology company devoted to treating inflammation, inborn errors of metabolism, and other diseases related to aldehydes, today announced its financial results for the quarter ended June 30, 2017.

"With the release of allergic conjunctivitis Phase 2b clinical trial results in the second quarter, we were pleased to announce our third Phase 3 clinical program," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "We are determined to continue to advance our novel aldehyde trap platform toward commercialization, with the goal of providing a novel pharmacologic approach to patients with limited safe and effective therapeutic options for severe inflammation or inborn errors of aldehyde metabolism."

Corporate Updates and Expected Milestones:

- | **Phase 3 Clinical Testing of ADX-102 in Allergic Conjunctivitis Planned Following End of Phase 2 Meeting with Regulatory Authorities.** Based on the results of Aldeyra's Phase 2b clinical trial in allergic conjunctivitis reported in June 2017, Aldeyra plans to begin Phase 3 clinical testing of ADX-102 following an End of Phase 2 Meeting with regulatory authorities in the second half of 2017. The randomized, dose-ranging, parallel-group, double-masked, saline-controlled, multi-center Phase 2b clinical trial of topical ocular ADX-102 in 154 allergic conjunctivitis patients demonstrated statistically significant improvement in ocular itch relative to control. Consistent with Phase 2a clinical results, the sustained clinical activity of ADX-102 in the Phase 2b clinical trial was distinct from the activity of antihistamines, a commonly used therapy that is only partially effective in many allergic conjunctivitis patients. Aldeyra believes that the differentiated mechanism of action of ADX-102 could apply to millions of allergic conjunctivitis patients in the United States.
- | **Data from Phase 2a Clinical Trial in Dry Eye Disease (DED) Expected to be Announced in September 2017.** The Phase 2a clinical trial is a single-center, double-blind, randomized trial testing three formulations of topical ocular ADX-102 (ADX-102 0.5% ophthalmic solution, ADX-102 0.1% ophthalmic solution, and ADX-102 0.5% ophthalmic lipid solution) over 28 days of treatment. Endpoints will include standard signs and symptoms characteristic of DED, a bothersome and generally poorly treated inflammatory condition that represents one of the largest ophthalmic markets worldwide.
- | **Noninfectious Anterior Uveitis (NAU) Phase 3 Clinical Results Expected to be Announced in the Second Half of 2018.** In April 2017, Aldeyra initiated a randomized, parallel-group, double-masked, vehicle-controlled, multi-center Phase 3 clinical trial of ADX-102 0.5% ophthalmic solution in up to 100 patients with active NAU. The primary endpoint is resolution of inflammation as measured by inflammatory cell count in the anterior chamber of the eye, the same endpoint assessed in the positive Phase 2 clinical trial of ADX-102 announced last year. NAU is a potentially blinding inflammatory ocular disease that is typically treated with topical corticosteroids, which can result in glaucoma, cataracts, and other serious ocular toxicities.
- | **Initial Results from Phase 3 Trial in Sjögren-Larsson Syndrome (SLS) Expected in the Second Half of 2018.** The Phase 3 clinical trial in SLS, an inborn error of aldehyde metabolism characterized by severe skin and neurological disease, is expected to be performed in two parts: a randomized and controlled assessment over six months of treatment, followed by a crossover design to evaluate change from baseline in drug-treated patients. Data from the first part of the trial will be used to confirm statistical power for the second part. In coordination with the start of the Phase 3 clinical trial, Aldeyra has launched the SLS Patient Registry with the intention of increasing the Company's profile among SLS patients, caregivers, physicians, researchers, and other members of the SLS community. The results from part one of the Phase 3 SLS trial are expected in the second half 2018. There is no FDA-approved therapy for the treatment of SLS.
- | **Novel Data on the Anti-Inflammatory Mechanism and Activity of ADX-102 Presented at the World Congress on Inflammation 2017 Annual Meeting.** In July 2017, Aldeyra presented the differentiated effects of ADX-102 on the down-regulation of inflammatory cell migration and activation in a mouse model of endotoxin-induced lung injury. The data demonstrate that the anti-inflammatory effects of ADX-102 differ from that of corticosteroids, building on existing evidence that aldehyde sequestration represents a novel anti-inflammatory therapeutic approach.

Second Quarter 2017 Financial Results

For the quarter ended June 30, 2017, Aldeyra reported a net loss of approximately \$5.3 million, compared to a net loss of approximately \$4.3 million for the quarter ended June 30, 2016. Basic and diluted net loss per share was \$0.35 for the quarter ended June 30, 2017, compared to basic and diluted net loss of \$0.41 per share for the quarter ended June 30, 2016. 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 \$3.8 million for the three months ended June 30, 2017, compared to \$2.8 million for the three months ended June 30, 2016. The increase of \$1.0 million is primarily related to the increases in our external research and development expenditures, including clinical and pre-clinical activities, partially offset by a reduction in manufacturing expenses.

General and administrative expenses were \$1.5 million for the three months ended June 30, 2017, compared to \$1.5 million for the three months ended June 30, 2016.

Cash, cash equivalents, and marketable securities were \$25.8 million as of June 30, 2017.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Tuesday, August 8, 2017, at 8:00 a.m. eastern time to discuss the results. The dial-in numbers are 1-877-870-4263 for domestic callers and 1-412-317-0790 for international callers. 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 August 7, 2018.

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 Allergic Conjunctivitis

Allergic conjunctivitis is a common allergic disease that affects 20-40% of the worldwide population, and is thought to be mediated in part by pro-inflammatory aldehydes. Symptoms include ocular itching, excessive tear production, lid swelling, and redness. Approximately one-third of allergic conjunctivitis patients do not adequately respond to standard-of-care therapy.

About Dry Eye Disease

Dry Eye Disease (DED) 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, in severe cases, decreased vision. In patients with DED, aldehydes may contribute to ocular inflammation as well as the impairment of lipids (fats) that lubricate the surface of the eye. *Therapy for DED is generally considered by physicians and patients to be inadequate.*

About Noninfectious Anterior Uveitis

Noninfectious anterior uveitis (NAU) 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. The only approved therapy for NAU is topical corticosteroids, which can cause serious ocular side effects, including glaucoma, cataracts, and infection.

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.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Aldeyra's plans for its product candidates. Aldeyra intends such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. 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, 2016 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. All of Aldeyra's development timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation or completion of clinical trials.

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.

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ALDEYRA THERAPEUTICS, INC.
BALANCE SHEETS

	June 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,609,742	\$ 12,015,061
Marketable securities	11,210,796	12,897,584
Prepaid expenses and other current assets	521,483	218,682
Total current assets	26,342,021	25,131,327
Deferred offering costs	77,942	-
Fixed assets, net	47,981	56,352
Total assets	<u>\$ 26,467,944</u>	<u>\$ 25,187,679</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 762,681	\$ 275,441
Accrued expenses	1,038,905	1,946,251
Current portion of credit facility	310,185	77,546
Total current liabilities	<u>2,111,771</u>	<u>2,299,238</u>
Credit facility, net of current portion and debt discount	<u>1,016,377</u>	<u>1,238,624</u>
Total liabilities	<u>3,128,148</u>	<u>3,537,862</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 15,150,176 and 12,576,325 shares issued and outstanding, respectively	15,150	12,576
Additional paid-in capital	111,030,501	98,938,446
Accumulated other comprehensive income (loss)	(4,640)	129
Accumulated deficit	<u>(87,701,215)</u>	<u>(77,301,334)</u>
Total stockholders' equity	<u>23,339,796</u>	<u>21,649,817</u>
Total liabilities and stockholders' equity	<u>\$ 26,467,944</u>	<u>\$ 25,187,679</u>

ALDEYRA THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months ended June 30,		Six Months ended June 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	\$ 3,848,889	\$ 2,834,523	\$ 7,217,912	\$ 6,346,037
General and administrative	1,481,792	1,462,227	3,208,670	2,917,750
Loss from operations	<u>(5,330,681)</u>	<u>(4,296,750)</u>	<u>(10,426,582)</u>	<u>(9,263,787)</u>
Other income (expense):				
Interest income	48,384	21,951	80,002	46,671
Interest expense	<u>(26,463)</u>	<u>(27,817)</u>	<u>(53,301)</u>	<u>(52,853)</u>
Total other income (expense), net	<u>21,921</u>	<u>(5,866)</u>	<u>26,701</u>	<u>(6,182)</u>
Net loss	<u>\$ (5,308,760)</u>	<u>\$ (4,302,616)</u>	<u>\$ (10,399,881)</u>	<u>\$ (9,269,969)</u>
Net loss per share - basic and diluted	<u>\$ (0.35)</u>	<u>\$ (0.41)</u>	<u>\$ (0.72)</u>	<u>\$ (0.91)</u>
Weighted average common shares outstanding - basic and diluted	<u>15,136,399</u>	<u>10,622,411</u>	<u>14,470,555</u>	<u>10,167,466</u>

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