March 29, 2018

Aldeyra Therapeutics Announces Year End 2017 Financial Results

LEXINGTON, Mass., March 29, 2018 /PRNewswire/ -- Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company devoted to development of next-generation medicines to improve the lives of patients with inflammatory diseases, today announced financial results for the year ended December 31, 2017.

"2017 was a productive year for Aldeyra, highlighted by favorable clinical results in dry eye disease and allergic conjunctivitis, initiation of a Phase 3 clinical trial in noninfectious anterior uveitis, and receipt of orphan drug designation for reproxalap in Sjögren-Larsson Syndrome," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Our progress has continued in 2018, having recently enrolled the first patient into our Phase 2b dry eye disease clinical trial, and with the signing of our development partnership with Janssen Research & Development, a Johnson & Johnson company. We look forward to sharing important milestones across multiple pipeline programs in 2018."

Key 2017 Highlights and Upcoming Events

- **Reported favorable Phase 2a clinical data in dry eye disease and initiated enrollment of Phase 2b clinical trial.** In September 2017, Aldeyra reported positive results from a randomized, dose-ranging, parallel-group, double-masked Phase 2a clinical trial of topical ocular reproxalap in dry eye disease patients. Reproxalap demonstrated statistically and clinically significant improvement across multiple sign and symptom scores. Improvements in dry eye disease signs and symptoms were evident within one week of therapy and effect sizes increased over the duration of therapy, supportive of rapid drug activity relative to standard of care. Aldeyra enrolled its first patient into a Phase 2b clinical trial of reproxalap in dry eye disease in January 2018, and expects to report results in the second half of 2018.

- **Planned initiation of Phase 3 clinical trial in allergic conjunctivitis.** Based on an End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) following favorable results from Aldeyra's Phase 2b clinical trial in allergic conjunctivitis, Aldeyra plans to begin a Phase 3 allergic conjunctivitis clinical trial of topical ocular reproxalap in the first half of 2018. Results of the Phase 3 clinical trial are expected in the second half of 2018, or early 2019.

- **Presented Phase 2 clinical results in noninfectious anterior uveitis (NAU) at ophthalmic medical conferences and initiated Phase 3 clinical trial.** In May 2017, Dr. John Sheppard, an internationally recognized expert in anterior ocular inflammation, presented the results of Aldeyra's Phase 2 clinical trial of topical ocular reproxalap in NAU as an Emerging Treatments paper at the Association for Research in Vision and Ophthalmology (ARVO) 2017 Annual Meeting. Data from the trial demonstrated activity comparable to Pred Forte®, a standard-of-care topical ocular corticosteroid, in reducing anterior chamber inflammatory cell count in patients with active NAU, without increasing intraocular pressure, a major side effect of corticosteroids. In November 2017, Dr. Sheppard presented additional analyses of Aldeyra's Phase 2 clinical trial at the American Uveitis Society held at the American Academy of Ophthalmology 2017 Annual Meeting. The results of the analyses demonstrated formal statistical non-inferiority of 0.5% reproxalap ophthalmic solution to Pred Forte® in reducing anterior chamber inflammatory cell count. The results also demonstrated that the combination of reproxalap and sub-therapeutic (twice-daily) Pred Forte® administration was also statistically non-inferior to Pred Forte® monotherapy (four-times-daily).

  In April 2017, Aldeyra initiated a Phase 3 clinical trial of topical ocular reproxalap in patients with NAU. Results of the trial are expected to be announced in 2019.

- **Planned initiation of Phase 3 clinical trial in Sjögren-Larsson Syndrome (SLS) and receipt of Orphan Drug Designation.** Based on an End of Phase 2 meeting with the FDA following favorable results from a Phase 2 clinical trial in SLS, Aldeyra plans to initiate a global, double-blind, two-part Phase 3 clinical trial of topical dermatologic reproxalap in the first half of 2018. Additionally, in April 2017, the FDA granted reproxalap orphan drug designation for the treatment of congenital ichthyosis, a severe skin disease characteristic of SLS. There are no FDA-approved therapies specifically indicated for the treatment of SLS, and reproxalap is believed to be the only potential SLS therapy in clinical development. Results from part one of the Phase 3 clinical trial are expected to be announced in 2019.

Year Ended December 31, 2017 Financial Review

For the year ended December 31, 2017, Aldeyra reported a net loss of approximately $22.3 million, compared to a net loss of approximately $18.7 million for the year ended December 31, 2016. Basic and diluted net loss per share was $1.40 for the year ended December 31, 2017, compared to $1.65 per share for the same period in 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 $16.3 million for the year ended December 31, 2017, compared to $13.2 million for the same period in 2016. The increase of $3.1 million is primarily related to the increase in research and development expenditures, including manufacturing, preclinical, and clinical development costs, and an increase in personnel costs.

General and administrative expenses were $6.2 million for the year ended December 31, 2017, compared to $5.5 million for the year ended 2016. The increase of $0.7 million is primarily related to an increase in legal costs, rent, consulting costs, and personnel costs.

In 2017, total operating expenses were approximately $22.5 million for the year, compared to total operating expenses of approximately $18.7 million in 2016.

Cash, cash equivalents, and marketable securities were $42.9 million as of December 31, 2017, including $26.9 million in net proceeds from the underwritten public offering of common stock that closed on September 21, 2017.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Thursday, March 29, 2018, at 8:00 a.m. eastern time to discuss the results. The dial-in numbers are 1-877-266-8979 for domestic callers and 1-412-317-5231 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.

About Aldeyra Therapeutics
Aldeyra Therapeutics is developing next-generation medicines to improve the lives of patients with inflammatory diseases. Aldeyra's lead product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease and other forms of ocular inflammation. Aldeyra is leveraging its experience in ocular inflammation to develop other product candidates for systemic inflammatory disease. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

About Dry Eye Disease
Dry eye disease is a common and chronic inflammatory disease estimated to affect approximately 20 million people in the United States, and is characterized by insufficient moisture in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, and, in severe cases, decreased vision. Among physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate.

About Allergic Conjunctivitis
Allergic conjunctivitis is a common allergic disease that affects 20% or more of the population worldwide. The disease 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. Antihistamines are commonly used to treat allergic conjunctivitis, but use is limited by lack of durable activity and ocular dryness.

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. Topical corticosteroid therapy is the only approved therapy for the resolution of inflammation associated with noninfectious anterior uveitis, but can lead to serious ocular complications, including glaucoma, infections, and cataracts.

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 ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. No therapy for SLS 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 and expectations 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. 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. 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; updated or refined data based on Aldeyra's continuing review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols and endpoints acceptable to applicable regulatory authorities, the ability to obtain and maintain regulatory approval of 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 and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, which are on file with the Securities and Exchange Commission(SEC) and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2017, expected to be filed with the SEC in the first quarter of 2018.

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
(UNAUDITED)

	December 31, 2017	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,023,337	$ 12,015,061
Marketable securities	22,923,462	12,897,584
Prepaid expenses and other current assets	1,018,967	218,682
Total current assets	43,965,766	25,131,327
Deferred offering costs	165,930	-

Fixed assets, net	43,262	56,352
Total assets	$ 44,174,958	$ 25,187,679
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,000,963	$ 275,441
Accrued expenses	2,236,465	1,946,251
Current portion of credit facility	116,319	77,546
Total current liabilities	3,353,747	2,299,238
Credit facility, net of current portion and debt discount	1,220,192	1,238,624
Total liabilities	4,573,939	3,537,862
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 19,137,639 and 12,576,325 shares issued and outstanding, respectively	19,138	12,576
Additional paid-in capital	139,241,635	98,938,446
Accumulated other comprehensive income (loss)	(17,831)	129
Accumulated deficit	(99,641,923)	(77,301,334)
Total stockholders' equity	39,601,019	21,649,817
Total liabilities and stockholders' equity	$ 44,174,958	$ 25,187,679

ALDEYRA THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(UNAUDITED)

	Years ended December 31,	
	2017	**2016**
Operating expenses:		
Research and development	$ 16,302,568	$ 13,175,670
General and administrative	6,185,820	5,520,308
Loss from operations	(22,488,388)	(18,695,978)
Other income (expense):		
Interest income	261,252	102,037
Interest expense	(113,454)	(105,509)
Total other income (expense), net	147,798	(3,472)
Net loss	$ (22,340,589)	$ (18,699,450)
Net loss per share - basic and diluted	$ (1.40)	$ (1.65)
Weighted average common shares outstanding - basic and diluted	15,921,884	11,352,230

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