Aldeyra Therapeutics Announces Third Quarter 2018 Financial Results

November 14, 2018

- **Reported Positive Data from Phase 2b Clinical Trial of Topical Ocular Reproxalap in Dry Eye Disease**
- **Announced Positive Top-Line Data from Investigator-Sponsored Phase 1/2 Clinical Trial of ADX-1612 in Malignant Mesothelioma**
- **Raised $67.6 Million, Operations Expected to be Funded Through 2020**

LEXINGTON, Mass., Nov. 14, 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 immune-mediated diseases, today announced financial results for the third quarter ended September 30, 2018.

"The third quarter was highlighted by positive results from our Phase 2b clinical trial of reproxalap in dry eye disease and an investigator-sponsored Phase 1/2 clinical trial of ADX-1612 in malignant mesothelioma," commented Todd C. Brady, M.D., Ph.D. "In addition, we completed a successful financing to support a broad and diversified clinical development plan that includes Phase 3 clinical trials in dry eye disease, noninfectious anterior uveitis, allergic conjunctivitis, and Sjögren-Larsson Syndrome. We look forward to the announcement of our next major milestone, results from the ALLEVIATE Phase 3 clinical trial in allergic conjunctivitis, in early 2019."

Recent Highlights and Corporate Updates

- **Announced positive results from a randomized, vehicle-controlled, parallel-group, multi-center, double-masked Phase 2b clinical trial of topical ocular reproxalap in dry eye disease.** In September 2018, Aldeyra announced that reproxalap was observed to be statistically superior to vehicle across multiple dry eye disease symptoms and signs in a Phase 2b clinical trial. The results demonstrated activity versus vehicle as early as two weeks, supportive of a differentiated product profile relative to current standard of care. Aldeyra plans to initiate a Phase 3 clinical trial in 2019, following discussions with regulatory authorities.

- **Announced positive top-line results from the MESO-2 investigator-sponsored Phase 1/2 clinical trial of ADX-1612 (ganetespib) in patients with pleural malignant mesothelioma.** Results of the clinical trial were presented at the International Association for the Study of Lung Cancer (ASLC) 19th World Conference on Lung Cancer (Abstract #11921). ADX-1612, when combined with standard pemetrexed and platinum therapy, resulted in partial response rates that exceeded that of historical standard of care (pemetrexed and platinum therapy). A Phase 2 clinical trial of ADX-1612 in mesothelioma, a disease with no known cure and a poor prognosis, is expected to be initiated in 2019, pending discussion with regulatory authorities.

- **Strengthened balance sheet.** In October 2018, Aldeyra completed an underwritten public offering that raised net proceeds of $67.6 million after deducting underwriting discounts, commissions, and estimated expenses. The proceeds are expected to fund operations through 2020, including the currently planned announcements of top-line data from Phase 3 clinical trials in allergic conjunctivitis, noninfectious anterior uveitis, Sjögren-Larsson Syndrome (Part 1), and dry eye disease.

Upcoming Milestones and Events

- Phase 3 results from the ALLEVIATE Trial, a randomized, multi-center, double-masked, parallel-group, vehicle-controlled Phase 3 clinical trial of topical ocular reproxalap in an allergen challenge model of allergic conjunctivitis, expected in early 2019
- Phase 3 results from the SOLACE Trial, a randomized, multi-center, double-masked, parallel-group, vehicle-controlled Phase 3 clinical trial of topical ocular reproxalap in noninfectious anterior uveitis, expected in the second half of 2019
- Results from the first part of the RESET Trial, a two-part, pivotal, randomized, multi-center, double-masked Phase 3 clinical trial of topical dermal reproxalap for the treatment of ichthyosis (scaly, thickened, dry skin) associated with Sjögren-Larsson Syndrome, expected in the second half of 2019
- Initiation of a Phase 3 clinical trial of topical ocular reproxalap in dry eye disease expected in 2019
- Phase 1 clinical trial of ADX-629, for the treatment of systemic autoimmune disease, expected to be initiated in 2019
- Investigator-sponsored Phase 2 clinical trial of ADX-1612 in ovarian cancer (EUDARIO) expected to be initiated in 2018
- Phase 2 clinical trial of ADX-1612 in post-transplant lymphoproliferative syndrome expected to be initiated in 2019
- Phase 2 clinical trial of ADX-1612 in mesothelioma expected to be initiated in 2019, pending discussion with regulatory

authorities

Quarter Ended September 30, 2018 Financial Review

For the quarter ended September 30, 2018, Aldeyra reported a net loss of approximately $10.8 million, compared to a net loss of approximately $5.0 million for the quarter ended September 30, 2017. Basic and diluted net loss per share was $0.52 for the quarter ended September 30, 2018, compared to $0.32 per share for the same period in 2017. 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 $7.9 million for the quarter ended September 30, 2018, compared to $3.5 million for the same period in 2017. The increase of $4.4 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 $3.1 million for the quarter ended September 30, 2018, compared to $1.5 million for the quarter ended September 30, 2017. The increase of $1.6 million is primarily related to an increase in legal and patent-related costs, consulting costs, and personnel costs.

For the quarter ended September 30, 2018, total operating expenses were approximately $10.9 million, compared to total operating expenses of approximately $5.0 million for the same period in 2017.

Cash, cash equivalents, and marketable securities were $35.1 million as of September 30, 2018. In October 2018, $67.6 million of net proceeds was raised in a public offering of Aldeyra's common stock.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Wednesday, November 14, 2018, at 8:00 a.m. Eastern Standard Time. 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 immune-mediated 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. The company is also developing other product candidates for autoimmune disease, post-transplant lymphoproliferative disease, retinal inflammation, metabolic disease, and cancer. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

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 strategy, future operations, future, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans to initiate further clinical testing. 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, 2017 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018, both of 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 Quarterly Report on Form 10-Q for the quarter ended September 30,2018, expected to be filed with the SEC in the fourth 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)

	September 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,008,652	$ 2,023,337
Cash equivalent- reverse repurchase agreements	11,000,000	18,000,000
Marketable securities	17,133,925	22,923,462
Prepaid expenses and other current assets	1,702,533	1,018,967
Total current assets	36,845,110	43,965,766
Deferred offering costs	43,000	165,930
Fixed assets, net	243,483	43,262
Total assets	$ 37,131,593	$ 44,174,958
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,442,370	$ 1,000,963
Accrued expenses	3,746,037	2,236,465
Current portion of credit facility	465,278	116,319
Total current liabilities	7,653,685	3,353,747
Credit facility, net of current portion and debt discount	882,841	1,220,192
Total liabilities	8,536,526	4,573,939
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 20,989,302 and 19,137,639 shares issued and outstanding, respectively	20,989	19,138
Additional paid-in capital	156,481,258	139,241,635
Accumulated other comprehensive income (loss)	(5,196)	(17,831)
Accumulated deficit	(127,901,984)	(99,641,923)
Total stockholders' equity	28,595,067	39,601,019
Total liabilities and stockholders' equity	$ 37,131,593	$ 44,174,958

ALDEYRA THERAPEUTICS, INC.
STATEMENT OF OPERATIONS
(UNAUDITED)

Three Months ended September 30,		Nine Months ended September 30,	
2018	**2017**	**2018**	**2017**

Operating expenses:				
Research and development	$ 7,880,822	$ 3,539,368	$ 21,274,032	$ 10,757,279
General and administrative	3,065,912	1,475,904	7,330,142	4,684,574
Loss from operations	(10,946,734)	(5,015,272)	(28,604,174)	(15,441,853)
Other income (expense):				
Interest income	163,015	56,651	427,361	136,652
Interest expense	(28,846)	(27,578)	(83,248)	(80,878)
Total other income (expense), net	134,169	29,073	344,113	55,774
Net loss	$ (10,812,565)	$ (4,986,199)	$ (28,260,061)	$ (15,386,079)
Net loss per share - basic and diluted	$ (0.52)	$ (0.32)	$ (1.40)	$ (1.04)
Weighted average common shares outstanding - basic and diluted	20,969,913	15,581,426	20,168,633	14,844,914

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