Aldeyra Therapeutics Reports Third-Quarter 2019 Financial Results and Provides Updates on Anticipated Clinical Milestones

November 7, 2019

- Part I of Adaptive RENEW Phase 3 Clinical Trial in Dry Eye Disease on Track for Completion in Fourth Quarter 2019
- Adaptive GUARD Phase 3 Clinical Trial of ADX-2191 in Proliferative Vitreoretinopathy to Initiate in Fourth Quarter 2019
- Initiation of INVIGORATE Phase 3 Clinical Trial of Reproxalap in Allergic Conjunctivitis Planned for First Half 2020
- Phase 1 Clinical Trial of Novel, Orally Administered RASP Inhibitor ADX-629 Initiated
- Management to Host Conference Call at 8:00 a.m. ET today

LEXINGTON, Mass.--(BUSINESS WIRE)--Nov. 7, 2019-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases, today reported financial results for the quarter ended September 30, 2019. In addition, the company updated investors on anticipated clinical milestones.

“Aldeyra continued to make significant progress during the quarter in advancing our immunology platform toward the goal of reducing the burden of disease and helping patients lead healthier lives,” said Aldeyra President and CEO Todd C. Brady, M.D., Ph.D. “We have reached agreement with the U.S. Food and Drug Administration (FDA) on the primary endpoint for our pivotal INVIGORATE Phase 3 clinical trial of reproxalap in allergic conjunctivitis. In addition, this quarter we expect to complete Part 1 of our adaptive RENEW Phase 3 clinical trial of reproxalap in dry eye disease, and initiate the first part of our adaptive GUARD Phase 3 clinical trial in proliferative vitreoretinopathy, representing the expansion of our ocular program from the front of the eye to the retina.”

Clinical Milestone Updates

- **Dry Eye Disease: Part 1 of Adaptive RENEW Phase 3 Clinical Trial Scheduled for Completion in the Fourth Quarter of 2019.** Part 1 of the two-part adaptive RENEW Phase 3 dry eye disease clinical trial of topical ocular reproxalap, the company’s lead reactive aldehyde species (RASP) inhibitor, is scheduled for completion in the fourth quarter of 2019, at which point Aldeyra plans to announce the endpoints, dosing regimen, and sample size planned for Part 2 of the trial. Dry eye disease affects more than 34 million adults in the U.S., and physicians and patients generally regard current therapeutic options as inadequate.

- **Allergic Conjunctivitis: INVIGORATE Phase 3 Clinical Trial Scheduled to Initiate in the First Half of 2020.** Aldeyra recently released expanded data from the completed allergen chamber clinical methods trial of topical ocular reproxalap and announced the design of the INVIGORATE Phase 3 clinical trial, which is expected to initiate in the first half of 2020. The primary endpoint of INVIGORATE is statistical significance versus vehicle in ocular itch (0-4 scale) at a majority of 11 time points between 110 and 210 minutes after chamber entry. In October, the company presented the results of the ALLEVIATE Phase 3 clinical trial in allergic conjunctivitis at the American Academy of Ophthalmology Annual Meeting in San Francisco. ALLEVIATE met the primary endpoint of reduction of ocular itch versus vehicle following conjunctival allergen challenge. Of the estimated 100 million allergic conjunctivitis sufferers in the U.S., up to 30 million do not respond adequately to, or are dissatisfied with, antihistamines.

- **Proliferative Vitreoretinopathy: Part 1 of the Adaptive GUARD Phase 3 Clinical Trial Scheduled to Initiate in the Fourth Quarter of 2019**. Patient enrollment in Part 1 of the adaptive GUARD Phase 3 Clinical Trial of ADX-2191 is expected to begin in the fourth quarter of 2019. GUARD will compare recurrence rates across patients treated with ADX-2191 or standard of care following surgical repair of retinal detachment due to proliferative vitreoretinopathy (PVR). In September, the FDA granted fast track designation to ADX-2191 for the prevention of PVR, a rare inflammatory disorder of the retina that leads to severe retinal scarring and blindness. There is no approved therapy for PVR. More than 50% of PVR cases result in severe uncorrectable vision loss, and 76% of patients suffer from at least moderate uncorrectable vision loss.

- **Systemic Autoimmune Disease: ADX-629 Phase 1 Clinical Trial Initiated.** Patient enrollment is underway in the Phase 1 clinical trial of ADX-629, a novel orally administered RASP inhibitor in development for the treatment of systemic autoimmune disease and potentially other serious medical conditions.

- **Post-transplant Lymphoproliferative Syndrome: Phase 2 Clinical Trial of ADX-1612 Scheduled to Initiate in the Fourth Quarter of 2019.** The Phase 2 clinical trial of ADX-1612, Aldeyra’s lead chaperome inhibitor, is slated to start in the fourth quarter of 2019 in patients with post-transplant lymphoproliferative syndrome, a rare and potentially fatal

immunological disease that can occur following solid organ transplant.

Outlook

“We expect our clinical momentum to accelerate as we move through the fourth quarter of this year and into 2020,” Dr. Brady said. “We believe that reproxalap has the potential to be the next novel entrant in dry eye disease and allergic conjunctivitis, part of a spectrum of conditions estimated to affect more than four in ten Americans. Our ocular programs represent the initial step of our mission to develop therapies for a broad category of systemic immune-mediated diseases.”

Quarter Ended September 30, 2019 Financial Review

For the quarter ended September 30, 2019, Aldeyra reported a net loss of approximately $18.7 million, compared with a net loss of approximately $10.8 million for the quarter ended September 30, 2018. Basic and diluted net loss per share was $0.69 for the quarter ended September 30, 2019, compared with $0.52 per share for the same period in 2018. Losses resulted from the costs of research and development programs, as well as from general and administrative expenses.

Research and development expenses were $16.2 million for the quarter ended September 30, 2019, compared with $7.9 million for the same period in 2018. The increase of $8.3 million is primarily related to an increase in clinical and preclinical development and manufacturing costs; an increase in personnel costs; and non-cash compensation costs related to a portion of upfront acquisition consideration that is subject to vesting based on continued service.

General and administrative expenses were $2.8 million for the quarter ended September 30, 2019, compared with $3.1 million for the quarter ended September 30, 2018. The decrease of $0.3 million is primarily related to lower consulting costs.

For the quarter ended September 30, 2019, total operating expenses were approximately $19.0 million, compared with total operating expenses of approximately $10.9 million for the same period in 2018.

As of September 30, 2019, cash, cash equivalents, and marketable securities were $76.2 million, which includes $15.0 million drawn from the company’s debt facility in September 2019.

Conference Call & Webcast Information

Aldeyra will host a conference call today at 8:00 a.m. ET to discuss its third-quarter financial results and provide a corporate update. The dial-in numbers are 1-866-211-4098 for domestic callers and 1-647-689-6613 for international callers. The conference ID number for the live call will be 9487086.

A live webcast of the conference call will also be available on the Investors Relations section of the Aldeyra Therapeutics website at https://ir.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 a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead investigational drug product candidates are first-in-class potential treatments in development for dry eye disease, allergic conjunctivitis, proliferative vitreoretinopathy, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for retinal and systemic inflammatory diseases.

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 financial position, projected costs and expenses, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans relating to current or future clinical development. 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, but not limited to, "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "on track," "scheduled," "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; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; the ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Aldeyra's product candidates; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra’s ability to commercialize (alone or with others) Aldeyra's product candidates following regulatory approval, if any; 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 limited sales and marketing infrastructure; Aldeyra's ability to establish and maintain development partnerships; Aldeyra’s ability to successfully integrate acquisitions into its business; 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, 2018 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, 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, 2019 expected to be filed in the fourth quarter of 2019.

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

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,604,203	$ 3,357,472
Cash equivalent - Reverse Repurchase Agreements	26,000,000	$ 44,000,000
Marketable securities	24,567,074	46,242,220
Prepaid expenses and other current assets	849,087	1,169,594
Total current assets	77,020,364	94,769,286
Deferred offering costs	—	86,644
Right-of-use assets	248,165	—
Fixed assets, net	172,470	235,225
Total assets	$ 77,440,999	$ 95,091,155
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 572,363	$ 3,051,678
Accrued expenses	11,324,963	5,421,498
Current portion of operating lease liabilities	218,953	—
Total current liabilities	12,116,279	8,473,176
Non-current liabilities:		
Long-term debt	14,386,706	—
Operating lease liabilities, net of current portion	58,720	—
Total liabilities	26,561,705	8,473,176
Stockholders' equity:		

Common stock, voting, $0.001 par value; 150,000,000 authorized and 27,151,775 and 26,244,435 shares issued and outstanding, respectively	27,152	26,244
Additional paid-in capital	237,047,752	225,136,127
Accumulated other comprehensive income (loss)	5,766	(9,224)
Accumulated deficit	(186,201,376)	(138,535,168)
Total stockholders' equity	50,879,294	86,617,979
Total liabilities and stockholders' equity	$ 77,440,999	$ 95,091,155

ALDEYRA THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Operating expenses:				
Research and development	$ 16,223,972	$ 7,880,822	$ 34,737,420	$ 21,274,032
Acquired in-process research and development	(47,102)	—	6,500,602	—
General and administrative	2,839,319	3,065,912	8,940,771	7,330,142
Loss from operations	(19,016,189)	(10,946,734)	(50,178,793)	(28,604,174)
Other income (expense):				
Interest income	330,329	163,015	1,262,378	427,361
Interest expense	(29,154)	(28,846)	(59,766)	(83,248)
Total other income (expense), net	301,175	134,169	1,202,612	344,113
Loss before income taxes	(18,715,014)	(10,812,565)	(48,976,181)	(28,260,061)
Income tax benefit	—	—	1,309,973	—
Net loss	$ (18,715,014)	$ (10,812,565)	$ (47,666,208)	$ (28,260,061)
Net loss per share - basic and diluted	$ (0.69)	$ (0.52)	$ (1.77)	$ (1.40)
Weighted average common shares outstanding - basic and diluted	27,111,600	20,969,913	26,928,725	20,168,633

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