Aldeyra Therapeutics Announces Second-Quarter 2020 Financial Results and Provides Corporate Update

August 6, 2020

− *Based on FDA Agreement that RASP is an Objective Sign of Dry Eye Disease, Assessment of Tear RASP Levels in Dry Eye Disease Patients Expected to Begin in the Fourth Quarter of 2020*

− *New Drug Application (NDA) Submission for Reproxalap in Dry Eye Disease Expected by the End of 2021*

− *Current Cash Expected to Support Operations Through 2022, Including Potential Approvals for Dry Eye Disease and Allergic Conjunctivitis*

− *Management to Host Conference Call at 8:00 a.m. ET Today*

LEXINGTON, Mass.--(BUSINESS WIRE)--Aug. 6, 2020-- Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a clinical-stage biotechnology company focused on the development of novel therapies with the potential to improve the lives of patients with immune-mediated diseases, today announced financial results for the second quarter of 2020 and provided a corporate update.

"We continue to make important progress in advancing a number of clinical-stage programs focused on the development of reproxalap and ADX-629, our first-in-class reactive aldehyde species (RASP) inhibitors," stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Following a successful meeting with the US Food and Drug Administration (FDA) in June, we are on track to initiate clinical trials assessing levels of RASP, a pro-inflammatory mediator, in the tears of patients with dry eye disease. Clinical development of ADX-629, an orally available RASP inhibitor, in COVID-19, psoriasis, and atopic asthma is expected to begin during the second half of this year."

"We also have enhanced our financial flexibility with recent common stock sales to Perceptive Advisors and Avidity Partners, transactions that generated gross proceeds of approximately $19.5 million and completed our previously announced at-the-market offering program," Dr. Brady continued. "We now expect to be able to fund operations through 2022, including potential approvals for reproxalap in dry eye disease and allergic conjunctivitis."

Recent Highlights

- **Use of RASP as an Objective Sign for Treatment of Dry Eye Disease:** In June 2020, Aldeyra announced agreement with the FDA for the use of RASP as an objective sign for the treatment of dry eye disease, marking the first new objective sign for the disease in more than a decade.
- **IND Submission for ADX-629:** Aldeyra completed an Investigational New Drug (IND) submission under the FDA's Coronavirus Accelerated Treatment Program to initiate a Phase 2 clinical trial of ADX-629 in patients with COVID-19.
- **Orphan Medicinal Product Designation for ADX-2191:** The European Commission designated ADX-2191 as an orphan medicinal product for the treatment of retinal detachment. ADX-2191, a novel and proprietary intravitreal formulation of methotrexate, is being evaluated in the Phase 3 GUARD Trial for prevention of recurrent retinal detachment due to proliferative vitreoretinopathy (PVR), the leading cause of failure of retinal detachment surgery. Drugs that receive the orphan medicinal product designation in the European Union (EU) are entitled to protocol assistance, research funding, and, upon approval, 10 years of EU market exclusivity.

Clinical-Stage Pipeline Updates

- **Reproxalap – A Novel Topical Ocular RASP Inhibitor for the Treatment of Dry Eye Disease and Allergic Conjunctivitis:** In the fourth quarter of this year, Aldeyra intends to initiate clinical testing to assess the activity of topical ocular reproxalap in reducing tear levels of RASP and other objective signs of dry eye disease, subject to finalization of trial design, RASP assay development, and potential disruptions due to the COVID-19 pandemic. In addition, a safety trial in dry eye disease patients is expected to be initiated in the fourth quarter of 2020. NDA submission is expected by the end of 2021, assuming positive clinical trial results and regulatory review. Top-line results from the Phase 3 INVIGORATE allergen chamber trial, the second Phase 3 trial of reproxalap in allergic conjunctivitis, are expected in the first half of 2021.
- **ADX-629 – A Novel Orally Available RASP Inhibitor for the Treatment of Systemic Inflammatory Diseases:** An IND for Phase 2 clinical testing of ADX-629 in patients with COVID-19 has been filed with the FDA. Additionally, in the fourth quarter of this year, the company expects to initiate Phase 2a clinical trials of ADX-629 in patients with psoriasis and atopic asthma.
- **ADX-2191 – An Intravitreal Methotrexate Injectable for Rare Proliferative Ocular Diseases:** Aldeyra has filed for

Orphan Drug Designation (ODD) with the FDA for ADX-2191 for the treatment of primary vitreoretinal lymphoma, a rare, aggressive, high-grade cancer that arises in the vitreous and retina. Additionally, an update on enrollment in the Phase 3 GUARD trial of ADX-2191 for the prevention of PVR, a rare but serious sight-threatening retinal disease with no approved treatment, is expected by the end of this year.

- **ADX-1612 – A Protein Chaperome Inhibitor for Systemic Disease:** Enrollment has been completed in the investigator-sponsored Phase 2 EUDARIO Trial of ADX-1612 in ovarian cancer. Regarding the ADX-1612 COVID-19 program, consistent with FDA feedback, additional preclinical antiviral testing of ADX-1612 against SARS-CoV-2, the virus that causes COVID-19, will be performed by the National Institute of Allergy and Infectious Diseases, which has accepted the company's request to evaluate ADX-1612 in in vivo models. Aldeyra expects to provide an update on the ADX-1612 COVID-19 program by the end of 2020.

Financial Results for the Quarter Ended June 30, 2020

For the quarter ended June 30, 2020, Aldeyra reported a net loss of $7.5 million, compared with a net loss of $13.3 million for the quarter ended June 30, 2019. Net loss per share was $0.25 for the quarter ended June 30, 2020, compared with $0.49 for the same period in 2019. 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 $4.9 million for the quarter ended June 30, 2020, compared with $10.7 million for the same period in 2019. The decrease of $5.8 million is primarily related to the decreases in clinical and preclinical development, manufacturing, and personnel costs.

General and administrative expenses were $2.2 million for the quarter ended June 30, 2020, compared with $3.1 million for the same period in 2019. The decrease of $0.9 million is due to decreases in personnel related costs, including stock-based compensation, and other miscellaneous administrative costs.

For the quarter ended June 30, 2020, total operating expenses were $7.1 million, compared with total operating expenses of $13.7 million for the same period in 2019.

As of June 30, 2020, cash, cash equivalents, and marketable securities were $66.2 million. Subsequent to June 30, 2020, $25.2 million in cash was received from at-the-market offering program sales to Perceptive Advisors, Avidity Partners, and other investors. Based on current operating plans, cash, cash equivalents, and marketable securities as of June 30, 2020, plus the additional at-the-market offering program proceeds, are expected to be sufficient to fund operations through the end of 2022, including potential NDA approvals for reproxalap in dry eye disease and allergic conjunctivitis, assuming positive clinical trial results, and planned NDA submissions, acceptances, and approvals. Use of Aldeyra's cash, cash equivalents, and marketable securities are also expected to include the continuation of Part 1 of the Phase 3 GUARD Trial in PVR, and Phase 2 clinical testing of ADX-629, an orally administered RASP inhibitor, in inflammatory diseases.

Conference Call & Webcast Information

Aldeyra will host a conference call today at 8:00 a.m. ET to discuss its second-quarter 2020 financial results. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID number is 9297174. Due to the expected high demand on our conference provider, please plan to dial in to the call at least 15 minutes prior to the start time.

A live webcast of the conference call will also be available on the investor relations page of the company's corporate website at https://ir.aldeyra.com. After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for 90 days.

About Aldeyra Therapeutics

Aldeyra Therapeutics is a clinical-stage biotechnology company focused on the development of novel therapies with the potential to improve the lives of patients with immune-mediated diseases. Two of the company's lead compounds, reproxalap and ADX-629, target reactive aldehyde species (RASP), which are elevated in ocular and systemic inflammatory disease and result in cytokine release via activation of a broad array of inflammatory factors, including NF-κB, inflammasomes, and Scavenger Receptor A. Reproxalap is being evaluated in Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. The company's clinical pipeline also includes ADX-2191, a dihydrofolate reductase inhibitor in Phase 3 testing for proliferative vitreoretinopathy, and ADX-1612, a chaperome inhibitor in Phase 2 testing for COVID-19 and ovarian cancer. For more information, visit https://www.aldeyra.com/ and follow us on LinkedIn, Facebook, and Twitter.

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, expected cash runway, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including reproxalap, ADX-629, ADX-2191, and ADX-1612. 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.

As a result of the COVID-19 pandemic, clinical site availability, staffing, and patient recruitment have been negatively affected and the timelines to complete our clinical trials may be delayed. 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 trials involving Aldeyra's product candidates; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the current and potential future impact of the COVID-19 pandemic on our business, results of operations and financial position; 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; political, economic, legal, social and health risks, including the recent COVID-19 outbreak and subsequent public health measures, that may affect Aldeyra's business or the global economy; 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, 2019 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, 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 set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, expected to be filed with the SEC in the third quarter of 2020.

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.
CONSOLIDATED BALANCE SHEETS

	June 30, 2020	December 31, 2019
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 50,688,834	$ 16,425,830
Cash equivalent - reverse repurchase agreements	10,000,000	$ 28,000,000
Marketable securities	5,500,975	28,938,545
Prepaid expenses and other current assets	5,232,717	1,804,450
Total current assets	71,422,526	75,168,825
Right-of-use assets	103,074	201,007
Fixed assets, net	101,695	148,449
Total assets	$ 71,627,295	$ 75,518,281
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 216,689	$ 808,302
Accrued expenses	3,693,594	11,873,122
Current portion of credit facility	894,042	—
Current portion of operating lease liabilities	116,124	226,328
Total current liabilities	4,920,449	12,907,752
Long-term debt	13,917,180	14,528,212
Total liabilities	18,837,629	27,435,964
Commitments and contingencies		
Stockholders' equity:		
Common stock, voting, $0.001 par value; 150,000,000 authorized and 32,997,346 and 28,656,832 shares issued and outstanding, respectively	32,997	28,657
Additional paid-in capital	269,502,290	247,409,793
Accumulated other comprehensive income	4,754	5,866
Accumulated deficit	(216,750,375)	(199,361,999)
Total stockholders' equity	52,789,666	48,082,317
Total liabilities and stockholders' equity	$ 71,627,295	$ 75,518,281

ALDEYRA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Operating expenses:				
Research and development	$ 4,885,875	$ 10,664,858	$ 11,519,478	$ 18,513,448
Acquired in-process research and development	—	(49,848)	—	6,547,703
General and administrative	2,220,003	3,116,414	5,224,844	6,101,452
Loss from operations	(7,105,878)	(13,731,424)	(16,744,322)	(31,162,603)
Other income (expense):				
Interest income	71,710	432,908	281,809	932,049
Interest expense	(486,048)	(28,649)	(925,863)	(30,612)
Total other income (expense), net	(414,338)	404,259	(644,054)	901,437
Loss before income taxes	(7,520,216)	(13,327,165)	(17,388,376)	(30,261,166)
Income tax benefit	—	—	—	1,309,973
Net loss	$ (7,520,216)	$ (13,327,165)	$ (17,388,376)	$ (28,951,193)
Net loss per share - basic and diluted	$ (0.25)	$ (0.49)	$ (0.59)	$ (1.08)
Weighted average common shares outstanding - basic and diluted	30,118,456	26,985,454	29,586,148	26,836,292

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