Aldeyra Therapeutics Reports First-Quarter 2020 Financial Results and Announces New Clinical Programs

May 7, 2020

- *ADX-629 Expected to Begin Phase 2 Clinical Trials in COVID-19 Respiratory Compromise, Atopic Asthma, and Psoriasis in 2020*
- *Type C Meeting Scheduled with FDA to Discuss Remaining NDA Requirements for Reproxalap in Dry Eye Disease*
- *Results from Phase 3 INVIGORATE Trial of Reproxalap in Allergic Conjunctivitis Expected in First Half of 2021*
- *Cash Runway Extended into 2022*
- *Management to Host Conference Call at 8:00 a.m. ET Today*

LEXINGTON, Mass.--(BUSINESS WIRE)--May 7, 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 reported financial results for the first quarter ended March 31, 2020, announced new clinical trials in systemic inflammatory diseases, and provided an update on ocular disease programs.

“Based on the success of the novel RASP inhibitor ADX-629 in Phase 1 clinical testing, we are pleased to announce a new comprehensive clinical initiative in systemic inflammatory diseases, complementing our late-stage pipeline in ocular disease,” said Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “Although the COVID-19 pandemic has affected clinical trial enrollment timelines, our cash position remains strong, and we are extending our projected cash runway guidance into 2022.”

New Clinical Programs in Systemic Inflammatory Diseases

Aldeyra plans to assess the activity of ADX-629 in three types of severe inflammation: cytokine release syndrome, autoimmune disease, and allergy. In preclinical models, ADX-629 treatment reduced levels of TH1, TH2, and TH17-related cytokines, suggesting potential activity across a broad array of inflammatory diseases. The timing of clinical trial initiation depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, and the ability to recruit patients.

- **COVID-19 Respiratory Compromise**: A Phase 2 clinical trial of ADX-629 is expected in subjects with COVID-19-associated respiratory compromise, defined as hypoxia and pulmonary radiographic involvement, immediately following admission to the hospital. Severe inflammation, characterized in part by cytokine release syndrome, leads to acute respiratory distress syndrome and other conditions that require mechanical ventilation. The clinical trial, contingent on FDA review of information submitted via the Coronavirus Treatment Acceleration Program (CTAP), is expected to begin in the third quarter of 2020.
- **Autoimmune Disease**: A Phase 2a clinical trial of ADX-629 in patients with psoriasis, an autoimmune condition associated with TH1 cytokines, is expected to begin in the second half of 2020.
- **Allergy**: A Phase 2a allergen-challenge clinical trial of ADX-629 in patients with atopic asthma, an allergic inflammatory disease associated with TH2 cytokines, is expected to begin in the second half of 2020.

Late-Stage Ocular Disease Programs

Reproxalap, a first-in-class RASP inhibitor for topical ocular administration, continues to advance towards a new drug application (NDA) filing in allergic conjunctivitis and dry eye disease. The Phase 3 GUARD Trial of ADX-2191, a novel formulation of methotrexate for intravitreal administration, in patients with proliferative vitreoretinopathy currently remains active, although enrollment has been significantly delayed due to the COVID-19 pandemic.

- **Dry Eye Disease**: A Type C meeting with the U.S. Food and Drug Administration (FDA) is scheduled for mid-2020 to discuss remaining NDA requirements for reproxalap in dry eye disease. Reproxalap has demonstrated clinically relevant improvement from baseline in two well-controlled clinical trials: Part 1 of the Phase 3 RENEW Trial announced late last year and a Phase 2 formulation trial announced earlier this year. Dry eye disease remains poorly served by available therapies, and represents one of the largest markets in ophthalmology, affecting an estimated 34 million patients in the United States. Aldeyra plans to provide an update on dry eye disease clinical development plans following receipt and review of FDA feedback.
- **Allergic Conjunctivitis**: Based on delays primarily associated with an extended allergy season, results from the Phase 3 INVIGORATE Trial of reproxalap are currently expected in the first half of 2021. Based on the successful Phase 3 ALLEVIATE Trial announced in 2019, and assuming continued clinical success and positive regulatory review, reproxalap has the potential to be the first new mechanistic approach in decades for the treatment of allergic conjunctivitis. The

current therapeutic landscape of allergic conjunctivitis is generally limited to antihistamines, which do not lead to satisfactory activity in up to one-third of patients, and corticosteroids, which cannot be used chronically due to potentially serious adverse events. Allergic conjunctivitis is one of most common ocular surface diseases, affecting an estimated 66 million patients in the United States, and is often associated with dry eye disease.

- **Proliferative Vitreoretinopathy (PVR)**: Patient enrollment in Part 1 of the adaptive the Phase 3 GUARD Trial of ADX-2191 for the prevention of PVR has been significantly delayed due to lack of clinical site availability and staffing resulting from the COVID-19 pandemic. PVR is a rare but vision-threatening retinal disease associated with recurrent retinal detachments. There is no approved therapy for PVR. Aldeyra expects to update the enrollment and completion timeline by year-end, and is also exploring additional indications for ADX-2191, including primary intraocular lymphoma, a rare but serious ocular cancer that can affect the retina, uvea, optic nerve, and other ocular structures.

Financial Review for the Quarter Ended March 31, 2020

For the quarter ended March 31, 2020, Aldeyra reported a net loss of $9.9 million, compared with a net loss of $15.6 million for the quarter ended March 31, 2019. Net loss per share was $0.34 for the quarter ended March 31, 2020, compared with $0.58 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 $6.6 million for the quarter ended March 31, 2020, compared with $7.8 million for the same period in 2019. The decrease of $1.2 million is primarily related to the decreases in clinical and preclinical development and manufacturing costs. Expenses for the 2019 period also included $6.6 million of in-process research and development expenses incurred in connection with the acquisition of Helio Vision.

General and administrative expenses were $3.0 million for each of the quarters ended March 31, 2020 and 2019. Increases in personnel related costs, including stock-based compensation, were offset by a decrease in legal and other miscellaneous administrative costs.

For the quarter ended March 31, 2020, total operating expenses were $9.6 million, compared with total operating expenses of $17.4 million for the same period in 2019.

Cash, cash equivalents, and marketable securities were $61.4 million as of March 31, 2020. Based on current operating plans, Aldeyra believes that its cash, cash equivalents, and marketable securities as of March 31, 2020 will be sufficient to fund currently anticipated operating expenses into 2022, including the completion of the Phase 3 INVIGORATE Trial for reproxalap, as well as the Phase 2 clinical trials of ADX-629 in COVID-19-associated respiratory compromise, atopic asthma, and psoriasis; the commencement of one or more additional clinical trials in dry eye disease, subject to the outcome of the FDA meeting scheduled for mid-year 2020; and the continuation of Part 1 of the adaptive Phase 3 clinical trial in PVR contingent on patient enrollment.

Conference Call & Webcast Information

Aldeyra will host a conference call today at 8:00 a.m. ET to announce new clinical trials in systemic inflammatory diseases, provide an update on ocular disease programs, and report first-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 6982314. Due to the expected high demand on our conference provider, please plan to dial in to the call at least 30 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, leading to elevated levels of 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. 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, which is 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 March 31, 2020, expected to be filed with the SEC in the second 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

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,542,971	$ 16,425,830
Cash equivalent - reverse repurchase agreements	23,000,000	28,000,000
Marketable securities	22,833,583	28,938,545
Prepaid expenses and other current assets	1,375,129	1,804,450
Total current assets	62,751,683	75,168,825
Right-of-use assets	152,666	201,007
Fixed assets, net	124,750	148,449
Total assets	$ 63,029,099	$ 75,518,281
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,072,897	$ 808,302
Accrued expenses	3,641,724	11,873,122
Current portion of operating lease liabilities	172,241	226,328
Total current liabilities	4,886,862	12,907,752

Long-term debt	14,669,717	14,528,212
Total liabilities	19,556,579	27,435,964
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 29,506,829 and 28,656,832 shares issued and outstanding, respectively	29,507	28,657
Additional paid-in capital	252,615,578	247,409,793
Accumulated other comprehensive income	57,594	5,866
Accumulated deficit	(209,230,159)	(199,361,999)
Total stockholders' equity	43,472,520	48,082,317
Total liabilities and stockholders' equity	$ 63,029,099	$ 75,518,281

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

	Three Months Ended March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 6,633,603	$ 7,848,590
Acquired in-process research and development	—	6,597,551
General and administrative	3,004,841	2,985,038
Loss from operations	(9,638,444)	(17,431,179)
Other income (expense):		
Interest income	210,100	499,140
Interest expense	(439,816)	(1,962)
Total other income (expense), net	(229,716)	497,178
Loss before income taxes	(9,868,160)	(16,934,001)
Income tax benefit	—	1,309,973
Net loss	$ (9,868,160)	$ (15,624,028)
Net loss per share - basic and diluted	$ (0.34)	$ (0.58)
Weighted average common shares outstanding - basic and diluted	29,210,889	27,053,842

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