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

November 5, 2020

− *Initiation of Phase 3 Objective Sign Trial in Dry Eye Disease Planned for the Fourth Quarter 2020*

− *Phase 2 Clinical Trials of ADX-629 in COVID-19, Atopic Asthma, and Psoriasis Expected to Initiate in the Fourth Quarter of 2020*

− *Top-line Results from the Phase 3 INVIGORATE Clinical Trial in Allergic Conjunctivitis Expected in the First Half of 2021*

− *Cash, Cash Equivalents, and Marketable Securities of $86.2 Million as of September 30, 2020, Expected to Support Operations Through 2022*

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

LEXINGTON, Mass.--(BUSINESS WIRE)--Nov. 5, 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 third quarter of 2020 and provided a corporate update.

“Our novel RASP inhibitor reproxalap continues to progress toward New Drug Application (NDA) submissions for dry eye disease and allergic conjunctivitis, two of the largest markets in ophthalmology,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “Among a number of key clinical milestones planned for the fourth quarter of 2020, we expect to initiate a pivotal Phase 3 objective sign clinical trial of reproxalap for the treatment of dry eye disease, and Phase 2 clinical trials of ADX-629 in COVID-19, atopic asthma, and psoriasis.”

“We concluded the third quarter in a strong financial position, with cash, cash equivalents, and marketable securities of $86.2 million as of September 30,” Dr. Brady continued. “Based on our current operating plans, we expect to have sufficient capital to fund operations through 2022, including NDA submissions for reproxalap in dry eye disease and allergic conjunctivitis, assuming positive clinical trial results and regulatory review.”

Recent Highlights

- **American Academy of Ophthalmology 2020:** Aldeyra announced the presentation of new clinical utility data from the Phase 2 allergen chamber clinical trial of reproxalap in allergic conjunctivitis. The data will be presented in a poster at the American Academy of Ophthalmology 2020 Virtual Annual Meeting from November 11 through November 15, 2020.

- **Phase 2 Clinical Trial Data Published in Journal of Ocular Pharmacology and Therapeutics:** The peer-reviewed *Journal of Ocular Pharmacology and Therapeutics* published the positive results of a randomized, corticosteroid-controlled Phase 2 clinical trial of reproxalap in patients with noninfectious anterior uveitis, a sight-threatening ocular inflammatory condition typically treated with topical corticosteroids.

- **Regulatory Clearance for Phase 2 Clinical Trial in COVID-19:** In September 2020, Aldeyra announced receipt of a Study May Proceed letter from the U.S. Food and Drug Administration to begin a Phase 2 clinical trial evaluating ADX-629, a novel orally available RASP inhibitor, for the treatment of adult patients hospitalized for COVID-19.

Clinical-Stage Pipeline Updates

- **Reproxalap – A Novel Topical Ocular RASP Inhibitor for the Treatment of Dry Eye Disease and Allergic Conjunctivitis:** Aldeyra plans to initiate a Phase 3 clinical trial in the fourth quarter of 2020 to assess the activity of reproxalap in objective signs of dry eye disease, including tear RASP levels, after single and multiple doses of drug. The trial initiation timing is subject to the finalization of trial design, assay development, and potential disruptions due to the COVID-19 pandemic. Enrollment is ongoing in the Phase 3 INVIGORATE Trial of reproxalap for the treatment of patients with allergic conjunctivitis. INVIGORATE is a randomized, double-masked, crossover, vehicle-controlled clinical trial to assess the efficacy and safety of reproxalap compared to vehicle using an allergen chamber. Consistent with prior allergic conjunctivitis trials, the primary endpoint will be subject-reported ocular itching score, as agreed with FDA. Aldeyra expects top-line results in the first half of 2021. NDA submission in dry eye disease and allergic conjunctivitis is expected by the end of 2021, assuming positive clinical trial results and regulatory review.

- **ADX-629 – A Novel Orally Available RASP Inhibitor for the Treatment of Systemic Inflammatory Diseases:** Phase 2 clinical testing of ADX-629 for the treatment of COVID-19, atopic asthma, and psoriasis is expected to begin by the end of this year.

- **ADX-2191 – 0.8% Methotrexate Intravitreal Injection for Rare Proliferative Ocular Diseases:** Completion of enrollment in Part 1 of the Phase 3 GUARD Trial of ADX-2191 for the prevention of proliferative vitreoretinopathy (PVR), a rare but serious sight-threatening retinal disease with no approved treatment, is expected in 2021.

Financial Results for the Quarter Ended September 30, 2020

For the quarter ended September 30, 2020, Aldeyra reported a net loss of $8.9 million, compared with a net loss of $18.7 million for the quarter ended September 30, 2019. Net loss per share was $0.23 for the quarter ended September 30, 2020, compared with $0.69 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 $6.1 million for the quarter ended September 30, 2020, compared with $16.2 million for the same period in 2019. The decrease of $10.1 million is primarily related to decreases in clinical research and development expenditures and lower personnel related costs, partially offset by increases in manufacturing and preclinical development costs.

General and administrative expenses were $2.3 million for the quarter ended September 30, 2020, compared with $2.8 million for the same period in 2019. The decrease of $0.5 million is due to decreases in personnel related costs and other miscellaneous administrative costs.

For the quarter ended September 30, 2020, total operating expenses were $8.4 million, compared with total operating expenses of $19.0 million for the same period in 2019.

As of September 30, 2020, cash, cash equivalents, and marketable securities were $86.2 million. Based on current operating plans, Aldeyra’s cash, cash equivalents, and marketable securities as of September 30, 2020 are expected to be sufficient to fund operations through the end of 2022, including potential NDA submissions for reproxalap in dry eye disease and allergic conjunctivitis, assuming positive clinical trial results and regulatory review. Use of Aldeyra’s cash, cash equivalents, and marketable securities is 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.

Conference Call & Webcast Information

Aldeyra will host a conference call today at 8:00 a.m. ET to discuss its third-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 5472726. 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 development 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 Aldeyra’s 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 Aldeyra's 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 June 30, 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 September 30, 2020, expected to be filed with the SEC in the fourth 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

	September 30, 2020	December 31, 2019
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 71,175,507	$ 16,425,830
Cash equivalent - reverse repurchase agreements	15,000,000	28,000,000
Marketable securities	—	28,938,545
Prepaid expenses and other current assets	2,017,273	1,804,450
Total current assets	88,192,780	75,168,825
Right-of-use assets	52,195	201,007
Fixed assets, net	79,455	148,449
Total assets	$ 88,324,430	$ 75,518,281
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 123,900	$ 808,302
Accrued expenses	4,018,635	11,873,122
Current portion of credit facility	2,259,417	—
Current portion of operating lease liabilities	58,720	226,328
Total current liabilities	6,460,672	12,907,752
Long-term debt	12,693,311	14,528,212
Total liabilities	19,153,983	27,435,964
Commitments and contingencies		
Stockholders' equity:		
Common stock, voting, $0.001 par value; 150,000,000 authorized and 38,631,709 and 28,656,832 shares issued and outstanding, respectively	38,632	28,657
Additional paid-in capital	294,755,363	247,409,793
Accumulated other comprehensive income	—	5,866
Accumulated deficit	(225,623,548)	(199,361,999)
Total stockholders' equity	69,170,447	48,082,317
Total liabilities and stockholders' equity	$ 88,324,430	$ 75,518,281

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 6,133,580	$ 16,223,972	$ 17,653,058	$ 34,737,420
Acquired in-process research and development	—	(47,102)	—	6,500,602
General and administrative	2,255,617	2,839,319	7,480,461	8,940,771
Loss from operations	(8,389,197)	(19,016,189)	(25,133,519)	(50,178,793)
Other income (expense):				
Interest income	5,215	330,329	287,025	1,262,378
Interest expense	(489,191)	(29,154)	(1,415,055)	(59,766)
Total other income (expense), net	(483,976)	301,175	(1,128,030)	1,202,612
Loss before income taxes	(8,873,173)	(18,715,014)	(26,261,549)	(48,976,181)
Income tax benefit	—	—	—	1,309,973
Net loss	$ (8,873,173)	$ (18,715,014)	$ (26,261,549)	$ (47,666,208)
Net loss per share - basic and diluted	$ (0.23)	$ (0.69)	$ (0.81)	$ (1.77)
Weighted average common shares outstanding - basic and diluted	37,796,946	27,111,600	32,395,217	26,928,725

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Source: Aldeyra Therapeutics, Inc.