Aldeyra Therapeutics Reports First-Quarter 2021 Financial Results and Recent Business Highlights

May 6, 2021

- *Recently Announced Phase 3 INVIGORATE Clinical Trial Results Indicated Statistically Significant Activity of Reproxalap in Ocular Itching and Redness Associated with Allergic Conjunctivitis*
- *Top-Line Results from Phase 3 TRANQUILITY and TRANQUILITY-2 Trials of Reproxalap in Dry Eye Disease Expected in the Second Half of 2021*
- *Initial Phase 2 Clinical Trial Results for ADX-629, a Novel Orally Available Systems-Based RASP Inhibitor with Potential Broad Applicability Across Immune-Mediated Diseases, Expected in the Second Half of 2021*
- *Raised Gross Proceeds of $125 Million Before Deduction of Underwriting Discounts and Commissions, in Underwritten Public Offering*
- *Projected Cash Runway Through 2023, Including Potential New Drug Applications; Initial Commercialization of Reproxalap, if Approved; and Continued Pipeline Development*
- *Management to Host Conference Call at 8:00 a.m. ET Today*

LEXINGTON, Mass.--(BUSINESS WIRE)--May 6, 2021-- 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 quarter ended March 31, 2021 and provided recent business highlights.

“We expect 2021 to be a catalyst-rich year for Aldeyra as we continue to advance reproxalap, our lead program, toward potential commercialization in anterior ocular inflammatory disease,” stated President and CEO Todd C. Brady, M.D., Ph.D. “We recently completed the Phase 3 INVIGORATE Trial of reproxalap, achieving statistically significant superiority over vehicle across all assessed signs and symptoms of allergic conjunctivitis, including ocular itching and redness. We look forward to meeting with the U.S. Food and Drug Administration in the second half of this year to discuss the INVIGORATE results and the potential submission of a New Drug Application (NDA). In addition, we remain on track to report top-line results in the second half of this year from the Phase 3 TRANQUILITY and TRANQUILITY-2 clinical trials of reproxalap in dry eye disease.

“We believe we continue to operate from a position of financial strength,” Dr. Brady stated. “With the recent follow-on public offering, we expect to have sufficient capital to prepare reproxalap for NDA submission and a potential commercial launch, if approved, while investing in the clinical development of ADX-629, ADX-2191, and other product candidates in retinal and systemic immunological diseases with unmet medical need.”

Recent Highlights and Program Updates

- **Primary, Key Secondary, and All Secondary Endpoints Met in Phase 3 INVIGORATE Allergic Conjunctivitis Clinical Trial:** In the first-ever Phase 3 clinical trial of a novel investigational product in an allergen chamber, 0.25% reproxalap ophthalmic solution (reproxalap) demonstrated statistically significant improvement over vehicle for the primary endpoint of ocular itching ($p<0.0001$), the key secondary endpoint of ocular redness ($p<0.0001$), and the secondary endpoints of ocular tearing and total ocular severity score (each $p<0.0001$). The results of INVIGORATE, the second positive Phase 3 trial for reproxalap in allergic conjunctivitis, indicate potential clinical utility before and during exposure to moderate to high levels of pollen.
- **Phase 3 TRANQUILITY and TRANQUILITY-2 Dry Eye Disease Trial Results Expected in Second Half of 2021:** Patient enrollment has begun in the dry eye chamber Phase 3 TRANQUILITY Trial of reproxalap. The primary endpoint of the trial is ocular redness, which was statistically lower ($p=0.03$) for reproxalap relative to vehicle in the TRANQUILITY run-in cohort results announced in January 2021. Tear RASP (reactive aldehyde species) levels will also be assessed. Approximately 150 dry eye disease patients are expected to be enrolled per arm. Reproxalap will be administered four times the day prior to entry into the dry eye chamber, just before entry into the chamber, and 45 minutes after chamber entry. Enrollment in TRANQUILITY is ongoing, and enrollment in the confirmatory TRANQUILITY-2 Trial is expected to begin in the second quarter of 2021. Aldeyra plans to report top-line results from both trials in the second half of this year.
- **Phase 2 Clinical Trial Results from ADX-629, an Orally Available RASP Inhibitor, Expected Second Half of 2021:** Initial Phase 2 clinical results from ADX-629, a novel orally available RASP inhibitor currently undergoing testing in asthma, psoriasis, and COVID-19, are expected in the second half of 2021. ADX-629 represents a first-in-class systems-based therapeutic approach for an orally administered RASP inhibitor, the potential applicability of which could extend to a myriad of immune-mediated diseases that today are treated with single-target drugs that can lead to serious toxicity.
- **Public Offering Completed:** Aldeyra sold 10,000,000 shares of its common stock at a public offering price of $12.50 per share in an underwritten public offering. The offering generated gross proceeds of $125.0 million and net proceeds of $117.3 million after deducting underwriting discounts, commissions, and estimated offering expenses.

First-Quarter 2021 Financial Summary

Cash and cash equivalents as of March 31, 2021 were $138.4 million. Based on Aldeyra's current operating plan, the company believes that existing cash and cash equivalents, as of March 31, 2021, together with the net proceeds from the sale of common stock in the underwritten public offering in May 2021, will be sufficient to fund currently projected operating expenses through the end of 2023, including potential NDA submission for reproxalap; initial commercialization of reproxalap, if approved; and continued early and late-stage development of the company's product candidates in ocular and systemic immune-mediated diseases.

For the quarter ended March 31, 2021, Aldeyra reported a net loss of $11.3 million, compared with a net loss of $9.9 million for the quarter ended March 31, 2020. Net loss per share was $0.25 for the quarter ended March 31, 2021, compared with $0.34 for the same period in 2020. 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 (R&D) expenses were $7.7 million for the quarter ended March 31, 2021, compared with $6.6 million for the same period in 2020. The increase of $1.1 million is primarily related to clinical development and manufacturing costs, partially offset by lower personnel related costs and a decrease in preclinical costs.

General and administrative expenses were $3.1 million for the quarter ended March 31, 2021, compared with $3.0 million for the quarter ended March 31, 2020.

For the quarter ended March 31, 2021, total operating expenses were $10.8 million, compared with total operating expenses of $9.6 million for the same period in 2020.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss its first-quarter 2021 financial results and recent highlights. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID number is 6779202. Due to the expected high demand on our conference call 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 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, Inc.

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 product candidates, reproxalap and ADX-629, target RASP (reactive aldehyde species), 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. 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, but not limited to, statements regarding submission of potential New Drug Applications; the anticipated timing of results from Aldeyra's clinical trials; and Aldeyra's projected cash runway. 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 in clinical trials focused on the same or on different indications; the risk that the results from smaller clinical trials or portions of clinical trials may not accurately predict results of larger scale trials or the remainder of a clinical trial; 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; 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, 2020, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at https://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, 2021, expected to be filed with the SEC in the second quarter of 2021.

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, 2021	December 31, 2020
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 88,442,379	$ 52,858,311
Cash equivalent - reverse repurchase agreements	50,000,000	25,000,000
Prepaid expenses and other current assets	8,630,543	5,200,957
Total current assets	147,072,922	83,059,268
Right-of-use assets	175,619	233,310
Fixed assets, net	57,559	59,925
Total assets	$ 147,306,100	$ 83,352,503
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 448,591	$ 381,638
Accrued expenses	5,371,681	8,134,765
Current portion of credit facility	5,094,938	3,659,776
Current portion of operating lease liabilities	175,619	233,310
Total current liabilities	11,090,829	12,409,489
Long-term debt, net of current portion	10,140,799	11,434,456
Total liabilities	21,231,628	23,843,945
Commitments and contingencies		
Stockholders' equity:		
Common stock, voting, $0.001 par value; 150,000,000 authorized and 47,651,035 and 38,667,491 shares issued and outstanding, respectively	47,651	38,667
Additional paid-in capital	374,232,411	296,385,619
Accumulated deficit	(248,205,590)	(236,915,728)
Total stockholders' equity	126,074,472	59,508,558
Total liabilities and stockholders' equity	$ 147,306,100	$ 83,352,503

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

	Three Months Ended March 31,	
	2021	2020
Operating expenses:		
Research and development	$ 7,726,342	$ 6,633,603
General and administrative	3,104,702	3,004,841
Loss from operations	(10,831,044)	(9,638,444)
Other income (expense):		
Interest income	23,762	210,100
Interest expense	(482,580)	(439,816)
Total other income (expense), net	(458,818)	(229,716)
Net loss	$ (11,289,862)	$ (9,868,160)
Net loss per share - basic and diluted	$ (0.25)	$ (0.34)

Weighted average common shares outstanding - basic and diluted	45,630,910	29,210,889

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