Aldeyra Therapeutics Reports Full-Year 2020 Financial Results and Recent Business Highlights

March 11, 2021

− Enrollment Completed in Phase 3 INVIGORATE Trial, with Top-Line Results Expected in the First Half of 2021

− Top-Line Results from Phase 3 TRANQUILITY and TRANQUILITY-2 Trials Expected in the Second Half of 2021

− Projected Cash Runway Through 2023, Including Potential New Drug Application Submissions for Dry Eye Disease and Allergic Conjunctivitis

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

LEXINGTON, Mass.--(BUSINESS WIRE)--Mar. 11, 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 business highlights and financial results for the year ended December 31, 2020.

“During the past year, we have worked diligently to advance our lead investigational compound reproxalap into pivotal Phase 3 clinical trials in dry eye disease and allergic conjunctivitis, two of the largest markets in ophthalmology,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “Based on clinical results to date, we believe reproxalap has the potential to be first-line therapy for the treatment of dry eye disease and an important alternative to corticosteroids for the treatment of allergic conjunctivitis. We look forward to the potential to further validate the opportunities for reproxalap with the results of the TRANQUILITY, TRANQUILITY-2, and INVIGORATE trials, as we begin 2021 in a strong financial position, with liquidity expected to fund our current clinical development plans and operations through 2023.”

Recent Highlights and Program Updates

- **Phase 3 INVIGORATE Allergic Conjunctivitis Trial Enrollment Completed:** Aldeyra has completed patient enrollment of its randomized, double-masked, crossover design, vehicle-controlled, allergen chamber Phase 3 INVIGORATE Trial of 0.25% reproxalap ophthalmic solution in patients with allergic conjunctivitis. The primary efficacy endpoint is patient-reported ocular itching score assessed on a 9-point scale. Investigator-assessed ocular redness is a key secondary endpoint. Top-line results are expected in the first half of 2021.
- **Phase 3 TRANQUILITY Dry Eye Disease Trial Design Finalized:** In February 2021, Aldeyra announced the finalization of the design of the multi-center, randomized, double-masked, parallel-group, vehicle-controlled Phase 3 TRANQUILITY Trial of 0.25% reproxalap ophthalmic solution for the treatment of dry eye disease. Approximately 150 dry eye disease patients are expected to be enrolled per arm. The primary endpoint is ocular redness over 90 minutes in a dry eye chamber. Tear RASP levels, Schirmer’s Test, and dry eye disease symptoms will be secondary endpoints. The protocol will utilize the two-day dosing paradigm, dry eye challenge design, and enrollment criteria of the run-in cohort. Results from the run-in cohort, announced in January 2021, demonstrated statistically significant improvement of reproxalap over vehicle in eye dryness score and other dry eye disease symptoms after a single day of dosing, and, during exposure to a dry eye chamber, statistically significant improvement of reproxalap over vehicle in eye dryness symptom score, ocular discomfort score, and ocular redness. TRANQUILITY and the confirmatory Phase 3 TRANQUILITY-2 Trial are on schedule to initiate enrollment in the first half of 2021. Top-line results from both trials are expected in the second half of 2021.
- **Phase 2 Clinical Testing of Novel Orally Administered RASP Inhibitor ADX-629 Initiated:** In the fourth quarter of 2020, Aldeyra announced the initiation of Phase 2 proof-of-concept clinical trials of ADX-629, a first-in-class orally administered RASP inhibitor for the treatment of psoriasis, atopic asthma, and COVID-19. The trials are part of a systematic strategy to assess the activity of ADX-629 across different types of systemic inflammatory disease. Top-line results from the trials are expected by the end of 2021.
- **Enrollment of Phase 3 GUARD Proliferative Vitreoretinopathy Trial of ADX-2191 Continues:** Completion of enrollment is expected in 2021 for Part 1 of the Phase 3 GUARD Trial of ADX-2191 (0.8% methotrexate intravitreal injection) for the prevention of proliferative vitreoretinopathy, a rare but serious sight-threatening retinal disease with no approved treatment.
- **Public Offering Completed:** Aldeyra announced the closing of an underwritten public offering of 7,868,421 shares of its common stock at a price of $9.50 per share, including 1,026,315 additional shares of common stock sold pursuant to the full exercise of the underwriters’ option to purchase additional shares. The underwritten offering generated gross proceeds of $74.7 million and net proceeds of $70.0 million after deducting underwriting discounts, commissions, and offering expenses.

Full-Year 2020 Financial Summary

Cash and cash equivalents as of December 31, 2020 were $77.9 million. Based on its current operating plan and including the net proceeds from the underwritten public offering completed in January 2021, Aldeyra believes that existing cash and cash equivalents will be sufficient to fund currently

anticipated operating expenses through the end of 2023, including the completion of the Phase 3 TRANQUILITY and TRANQUILITY-2 trials in dry eye disease; the completion of the Phase 3 INVIGORATE trial in allergic conjunctivitis; the Phase 2 clinical trials of ADX-629 in psoriasis, atopic asthma, and COVID-19; and the completion of Part 1 of the adaptive Phase 3 GUARD clinical trial in proliferative vitreoretinopathy.

The net loss for full-year 2020 was $37.6 million, or $1.11 per share, compared with a net loss of $60.8 million, or $2.24 per share, for full-year 2019.

Research and Development (R&D) expenses were $24.7 million for full-year 2020 compared with $44.4 million for full-year 2019. The decrease of $19.7 million in R&D expenses primarily reflected a reduction in clinical research and development expenditures, partially offset by an increase in non-cash compensation costs related to a portion of a contingent acquisition milestone.

Acquired in-process research and development expenses were $1.8 million for full-year 2020 compared with $6.6 million for full-year 2019. The $4.8 million decrease is related to lower in-process research and development expenses associated with the 2019 acquisition of Helio Vision.

General and administrative (G&A) expenses were $10.0 million for full-year 2020 compared with $12.2 million for full-year 2019. The decrease of $2.2 million in G&A expenses primarily reflected lower personnel costs, legal costs, public company costs related to continuing compliance with the Sarbanes Oxley Act of 2002, and miscellaneous administrative costs.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss its full-year 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 6253616. 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 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 investigational compounds, 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, 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, but not limited to, statements regarding: the timing of results from the company's Phase 3 INVIGORATE Trial for the treatment of allergic conjunctivitis; the timing of results from the company's Phase 3 TRANQUILITY and TRANQUILITY-2 Trials for the treatment of dry eye disease; the timing of results from the company's Phase 2 proof-of-concept clinical trials of ADX-629; the company's anticipated cash runway; the timing of potential New Drug Application submissions for dry eye disease and allergic conjunctivitis; and the completion of enrollment of Part 1 of the Phase 3 GUARD Trial of ADX-2191 for the treatment of proliferative vitreoretinopathy. 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 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, 2019 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020, which are 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 Annual Report on Form 10-K for the year ended December 31, 2020, expected to be filed with the SEC in the first 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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 52,858,311	$ 16,425,830
Cash equivalent - reverse repurchase agreements	25,000,000	28,000,000
Marketable securities	—	28,938,545
Prepaid expenses and other current assets	5,200,957	1,804,450
Total current assets	83,059,268	75,168,825
Fixed assets, net	59,925	148,449
Right-of-use assets	233,310	201,007
Total assets	$ 83,352,503	$ 75,518,281
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 381,638	$ 808,302
Accrued expenses	8,134,765	11,873,122
Current portion of credit facility	3,659,776	—
Current portion of operating lease liabilities	233,310	226,328
Total current liabilities	12,409,489	12,907,752
Long-term debt, net of current portion	11,434,456	14,528,212
Total liabilities	23,843,945	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 38,667,491 and 28,656,832 shares issued and outstanding, respectively	38,667	28,657
Additional paid-in capital	296,385,619	247,409,793
Accumulated other comprehensive income	—	5,866
Accumulated deficit	(236,915,728)	(199,361,999)
Total stockholders’ equity	59,508,558	48,082,317
Total liabilities and stockholders’ equity	$ 83,352,503	$ 75,518,281

ALDEYRA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years ended December 31,	
	2020	2019
Operating expenses:		
Research and development	$ 24,681,301	$ 44,351,851
Acquired in-process research and development	1,754,265	6,567,754
General and administrative	9,985,454	12,154,702
Loss from operations	(36,421,020)	(63,074,307)
Other income (expense):		
Interest income	292,224	1,541,349
Interest expense	(1,904,198)	(603,846)

Total other income (expense), net	(1,611,974)	937,503
Loss before income taxes	(38,032,994)	(62,136,804)
Income tax benefit	479,265	1,309,973
Net loss	$(37,553,729)	$(60,826,831)
Net loss per share - basic and diluted	$ (1.11)	$ (2.24)
Weighted average common shares outstanding - basic and diluted	33,965,955	27,111,840

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