## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

#### FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 27, 2023

#### ALDEYRA THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation) 001-36332 (Commission File No.) 20-1968197 (IRS Employer Identification No.)

131 Hartwell Avenue, Suite 320 Lexington, MA 02421 (Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 761-4904

Not Applicable (Former Name or Former Address, if Changed Since Last Report)

	Common Stock \$0.001 par value per chare	AI DY	The Nacdag Stock Market LLC	
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered	
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ecurit	ties registered pursuant to Section 12(b) of the Act:			
]	Pre-commencement communications pursuant to Rule 13e-4(c) under the Excha	ange Act (17 CFR 240.13e-4(c))		
]	Pre-commencement communications pursuant to Rule 14d-2(b) under the Excha	mencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))		
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 24	40.14a-12)		
]	Written communications pursuant to Rule 425 under the Securities Act (17 CFR	R 230.425)		
Check	k the appropriate box below if the Form 8-K filing is intended to simu	ultaneously satisfy the filing obligation of the registrant	t under any of the following provisions:	
	_			

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter)

Emerging growth company  $\square$ 

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

#### Item 7.01.

#### Regulation FD Disclosure.

As reported under Item 8.01 of this Current Report on Form 8-K, on June 27, 2023, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing positive top-line results from the Phase 2 clinical trial of ADX-629 in patients with chronic cough. The Company is holding a conference call regarding the announcement on June 27, 2023. A copy of the supplemental presentation which will be referenced during the conference call and posted on the Company's website is furnished herewith as Exhibit 99.1 and is incorporated by reference herein.

This information in this Item 7.01 of this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in any such filing.

The Press Release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

	No.	Description
<u>99.1</u>		Aldeyra Therapeutics, Inc. Presentation dated June 27, 2023
99.2		Aldeyra Therapeutics, Inc. Press Release dated June 27, 2023
104		Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALDEYRA THERAPEUTICS, INC.

By:

/s/ Todd C. Brady Name: Todd C. Brady, M.D., Ph.D. Title: Chief Executive Officer

Dated June 27, 2023



### **Disclaimers and Forward-Looking Statements**

This presentation and various remarks which may be made during this presentation contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's possible or assumed future results of operations, expenses and financing needs, business strategies and plans, statements regarding Aldeyra's future expectations, plans and prospects, including, without limitation, statements regarding: Aldeyra's belief in the adequacy of the data it has submitted or plans to submit in the NDAs for reproxalap and ADX-2191; the potential timing for FDA review of such NDAs or the potential for FDA acceptance of such NDAs; the potential for regulatory approval and commencement of commercialization of reproxalap and ADX-2191 and Aldeyra's goals as to timing; the potential profile and benefit of reproxalap in dry eye disease and allergic conjunctivitis and its other product candidates in the indications for which they are developed; and other statements regarding the goals, opportunity and potential for reproxalap, anticipated clinical or regulatory milestones for ADX-2191. ADX-246, ADX-248, and ADX-629 including expectations regarding the results of scheduled FDA meetings, clinical trial initiations and completions and submissions to the FDA; and other statements regarding the goals, opportunity and potential for reproxalap, ADX-2191, ADX-246, ADX-248, ADX-629 and Aldeyra's other product candidates, and for Aldeyra's business, research, development and regulatory plans or expectations, political, economic, legal, social and health risks, including the COVID-19 pandemic and related public health measures and other responses to it, that may affect Aldeyra's business or the global economy, the structure, timing and success of Aldeyra's planned or pending clinical trials, expected milestones, market sizing, pricing and reimbursement, competitive position, regulatory matters, industry environ

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Aldeyra's actual results, performance or achievements expressed or implied by the forward-looking statements. These statements reflect Aldeyra's current views with respect to future events and are based on assumptions and subject to risks and uncertainties, including the development of, and clinical and regulatory plans or expectations for Aldeyra's investigational new drugs (including ADX-629 and ADX-2191), and systems-based approaches, later developments with the FDA that may be inconsistent with Aldeyra's expectations and beliefs, including the risk that the results from earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent trials or the remainder of a clinical trial for the same or different indications, inconsistent expectations regarding FDA acceptance and review of the company's filings and submitted data sets, and Aldeyra's continuing or post-hoc review and quality control analysis of clinical data. Important factors that could cause actual results to differ materially from those reflected in Aldeyra's forward-looking statements are described in Aldeyra's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, as well as Aldeyra's subsequent filings with the Securities and Exchange Commission. All of Aldeyra's development plans and timelines may be subject to adapt subject to change based on the regulator's workload and other potential review issues, preclinical and clinical results, and other factors any of which could result in changes to Aldeyra's development plans and programs or delay the initiation, enrolment, completion, or reporting of clinical trials.

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 presentation is provided only as of June 27, 2023, and Aldeyra undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.





## The Phase 2 Clinical Trial of ADX-629 in Chronic Cough **Demonstrated Statistically Significant Reduction in Cough** Frequency vs. Placebo

The primary endpoint of safety was met: ADX-629 was well tolerated with no identified safety concerns.

Statistical significance was achieved for all assessed continuous cough reduction endpoints:

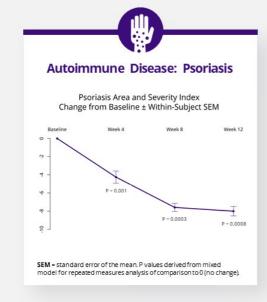
- awake cough frequency (P=0.01), the key secondary endpoint;
- the secondary endpoint of 24-hour cough frequency (P=0.001); and
- related post-hoc assessments of awake cough count (P=0.001) and 24-hour cough count (P=0.001).

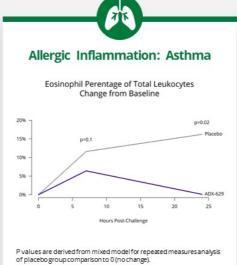
The results from the Phase 2 clinical trial in chronic cough are **consistent** with activity demonstrated in previously disclosed clinical trials of ADX-629, including Phase 2 clinical trials in psoriasis, asthma, and COVID-19, adding to a growing body of evidence supportive of the activity of ADX-629 in systemic diseases associated with inflammation.

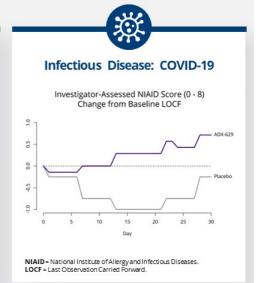
ADX-629 is an investigational drug candidate

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## ADX-629, a First-in-Class Orally Administered RASP Modulator, Has **Demonstrated Activity in Phase 2 Clinical Trials**



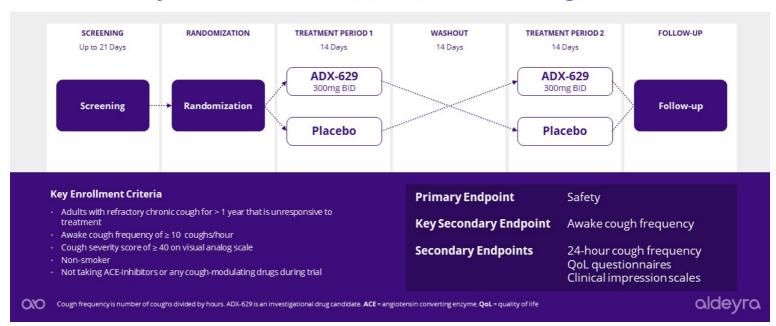




ADX-629 is an investigational drug candidate.

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# A Phase 2, Multicenter, Randomized-Sequence, Double-Blind, Placebo-Controlled, Crossover Clinical Trial to Evaluate the Safety and Efficacy of ADX-629 in Adults with Chronic Cough



## Baseline Characteristics Were Similar Across Sequences

	ADX-629 to Placebo (n=26) Mean (SD) or %	Placebo to ADX-629 (n=25) Mean (SD) or %
Mean Age (years)	65.3 (9.5)	65.2 (7.1)
BMI (kg/m²)	29.4 (9.5)	28.4 (4.7)
Gender	Male (19%), Female (81%)	Male (16%), Female (84%)
Awake Cough Frequency	51.8 (44.4)	44.7 (32.4)
Chronic Cough History (years)	18.8 (15.7)	11.2 (9.2)



ADX-629 is an investigational drug candidate. Awake cough frequency is number of coughs while awake divided by hours awake. BMI = body mass index; SD = standard deviation.



## ADX-629 Was Well Tolerated and No Safety Signals Were Identified

51 patients were enrolled, and all patients completed both treatment periods.

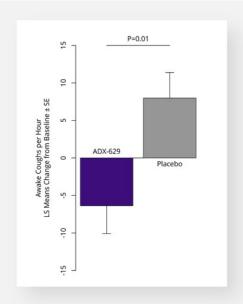
	Placebo (n=51)	ADX-629 (n=51)
Serious Adverse Events	0	0
Severe	0	0
Moderate	2 (3.9%)	4 (7.8%)
Mild	8 (15.7%)	10 (19.6%)
Caused Discontinuation	0	0

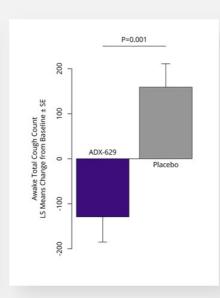


ADX-629 is an investigational drug candidate. Severity summary reflects treatment-emergent adverse events.



## ADX-629 Achieved the Key Secondary Endpoint of Reduction in Awake Cough Frequency in the Phase 2 Chronic Cough Clinical Trial





#### **KEY RESULTS**

**Key secondary endpoint** of awake cough frequency reduction **achieved** 

Reduction of awake cough frequency (coughs perhour) following ADX-629 treatment statistically significantly superior (P=0.01) to that following treatment with placebo

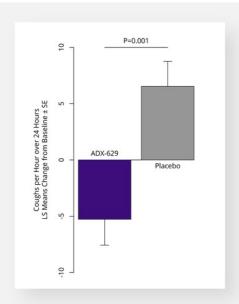
Key secondary endpoint results consistent with statistically significant (P=0.001) reduction in total awake cough count in favor of ADX-629 over placebo

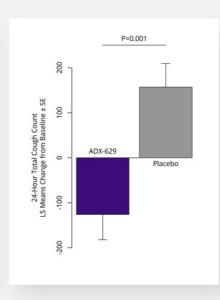
OXO

LS means and P values derived from mixed effect model of repeated measures analysis that adjusted for baseline and prior treatment to account for carryover effect. Awake cough frequency is number of coughs while awake divided by hours awake. ADX-629 is an investigational drug candidate. SE = standard error; LS = least squares.



## ADX-629 Achieved the Secondary Endpoint of Reduction in 24-Hour Cough Frequency in the Phase 2 Chronic Cough Clinical Trial





#### **KEY RESULTS**

**Secondary endpoint** of 24-hour cough frequency reduction **achieved** 

Reduction of 24-hour cough frequency (coughs per hour) following ADX-629 treatment statistically significantly superior (P=0.001) to that following treatment with placebo

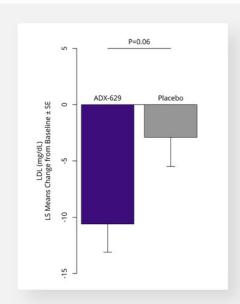
24-hour cough frequency endpoint results consistent with statistically significant (P=0.001) reduction in total 24-hour cough count in favor of ADX-629 over placebo

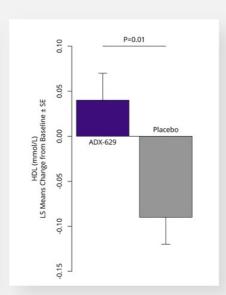


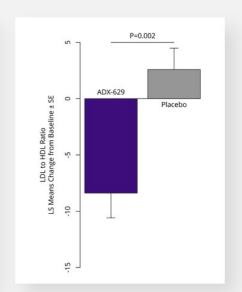
LS means and P values derived from mixed effect model of repeated measures analysis that adjusted for baseline and prior treatment to account for carryover effect. Twenty-four cough frequency is number of coughs over 24 hours divided by 24. ADX-629 is an investigational drug candidate. SE = standard error; LS = least squares.



## Lipid Profiles Improved Following ADX-629 Treatment in the Phase 2 Chronic Cough Clinical Trial





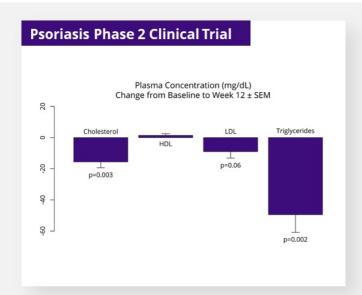


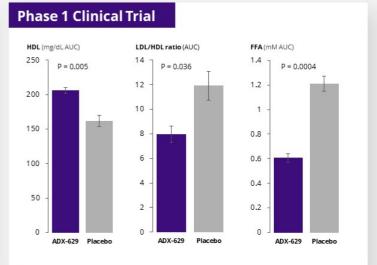
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LS means and P values derived from mixed effect model of repeated measures analysis that adjusted for baseline and prior treatment to account for carryover effect. ADX-629 is an investigational drug candidate. SE = standard error; LDL = low-densitylipoprotein cholesterol; HDL = high-densitylipoprotein cholesterol; LS = least squares.

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## Lipid Profiles Improved Following ADX-629 Treatment in Previously Completed Phase 1 and Phase 2 Psoriasis Clinical Trials





OXO

P values derived from mixed effect model of repeated measures analysis that adjusted for baseline. Phase 1 results derived from assessments following ingestion of a fatty meal. ADX-629 is an investigational drug candidate. SEM = standard error of measurement; LDL = low-density lipoprotein cholesterol; HDL = high-density lipoprotein cholesterol; AUC = area under the curve.





#### **Dry Eye Disease**

PDUFA date of November 23, 2023†

#### **Proliferative Vitreoretinopathy**

Type C meeting with FDA to discuss completion of clinical development planned for H2 2023

#### **Retinitis Pigmentosa**

Phase 2 clinical trial top-line results expected in June 2023<sup>‡</sup>

## Atopic Dermatitis (Part 1), Idiopathic Nephrotic Syndrome (Part 1), and Sjögren-Larsson Syndrome\*

Phase 2 clinical trial top-line results expected in H2 2023<sup>‡</sup>

#### **Moderate Alcohol-Associated Hepatitis**

Initiation of Phase 2 clinical trial expected in H2 2023<sup>‡</sup>

<sup>†</sup>Regulatory review timelines are flexible and subject to change based on the regulator's workload and other potential review issues. <sup>‡</sup>The timing of ongoing clinical trials depends, in part, on the availability of clinical research facilities and staffing, and the ability to recruit patients. <sup>†</sup>Investigator sponsored.



### Aldeyra Therapeutics Announces Statistically Significant Reduction in Cough Frequency in Phase 2 Clinical Trial of ADX-629 in Patients With Chronic Cough

- Relative to Placebo, Statistical Significance Achieved for Reduction in Awake Cough Frequency (P=0.01), 24-Hour Cough Frequency (P=0.001), Awake Cough Count (P=0.001), and 24-Hour Cough Count (P=0.001)
- ADX-629 Was Well Tolerated and No Safety Concerns Were Identified
- · Company to Discuss Results in Conference Call and Webcast at 8:00 a.m. ET Today

LEXINGTON, Mass.--(BUSINESS WIRE)--June 27, 2023--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to discovering and developing innovative therapies designed to treat immune-mediated diseases, today announced positive top-line results from the Phase 2 clinical trial of orally administered ADX-629, an investigational new drug, in patients with chronic cough. The clinical trial demonstrated statistically significant reduction in cough frequency following administration of ADX-629 relative to placebo.

"Consistent with previously demonstrated activity in clinical trials of patients with psoriasis, asthma, and COVID-19, the reduction in cough frequency observed in the Phase 2 clinical trial in chronic cough supports the potentially broad-based activity of ADX-629 as a novel, immune-modulating therapeutic approach," stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "We look forward to discussing the results with regulatory authorities as we consider the expansion of clinical testing to include patients with co-morbid conditions of frequent coughing and active inflammation"

The multicenter, randomized, double-blind, placebo-controlled, two-period Phase 2 crossover trial enrolled 51 patients with refractory or unexplained chronic cough, which is often defined as a cough that persists for more than eight weeks and is unresponsive to treatment. Patients were randomized to receive ADX-629 or placebo twice daily for 14 days, followed by a 14-day washout period prior to crossing over to 14 days of treatment with ADX-629 or placebo, whichever was not received in the first period. The primary endpoint of the clinical trial was safety. Secondary endpoints included awake cough frequency (the key secondary endpoint), 24-hour cough frequency, quality of life, and clinical impression scales.

Fifty-one patients were enrolled, and all patients completed both treatment periods. Relative to placebo, statistical significance was achieved for the key secondary endpoint of reduction in awake cough frequency (P=0.01), the secondary endpoint of 24-hour cough frequency (P=0.001), and the related post-hoc analyses of awake cough count (P=0.001) and 24-hour cough count (P=0.001). Quality of life and clinical impression scales did not consistently change between treatment groups over the two-week treatment periods. ADX-629 was well tolerated, and no safety concerns were identified following administration of either ADX-629 or placebo. No serious adverse events were reported, adverse event frequencies were similar across treatment groups, and no patients discontinued due to adverse events.

"Frequent coughing, which is characteristic of a number of inflammatory pulmonary diseases, represents a persistently disturbing condition for patients," stated Gary N. Gross, MD., Clinical Professor of Internal Medicine at Southwestern Medical School and a Board-certified allergist and immunologist with the Dallas Allergy & Asthma Center. "The difficulty in treating chronic coughing highlights the medical need for new therapies."

Consistent with a Phase 1 clinical trial and the Phase 2 clinical trial in psoriasis, improvement in LDL and HDL levels was observed following treatment with ADX-629 relative to treatment with placebo. ADX-629, an investigational new drug, is a novel, orally administered RASP (reactive aldehyde species) modulator for the potential treatment of systemic immune-mediated diseases. ADX-629 is also currently in development for atopic dermatitis, idiopathic nephrotic syndrome, and Sjögren-Larsson Syndrome. Initial results from each trial are expected in the second half of 2023. A Phase 2 clinical trial of ADX-629 in moderate alcohol-associated hepatitis is expected to initiate in the second half of 2023.

#### Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss top-line results of the Phase 2 clinical trial of ADX-629 in chronic cough. The dial-in numbers are (888) 415-4305 for domestic callers and (646) 960-0336 for international callers. The access code is 5858366. A live webcast of the conference call will 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**

Aldeyra Therapeutics is a biotechnology company devoted to discovering innovative therapies designed to treat immune-mediated diseases. Our approach is to develop pharmaceuticals that modulate immunological systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity. Our product candidates include RASP (reactive aldehyde species) modulators ADX-629, ADX-246, ADX-248, and chemically related molecules for the potential treatment of systemic and retinal immune-mediated diseases. Our pre-commercial product candidates are reproxalap, a RASP modulator for the potential treatment of dry eye disease (under U.S. Food and Drug Administration New Drug Application Review) and allergic conjunctivitis, and ADX-2191, a novel formulation of intravitreal methotrexate for the potential treatment of proliferative vitreoretinopathy and retinitis pigmentosa.

#### 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 Aldeyra's future expectations, plans, and prospects, including without limitation statements regarding: the goals, opportunity and potential for ADX-629 and anticipated clinical or regulatory milestones for ADX-629. 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," "on schedule," "target," "design," "estimate," "predict," "contemplates," likely," "potential," "continue," "ongoing," "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, funding, and other factors that could delay the initiation, enrollment, or completion of clinical trials. Important factors that may cause actual results to differ materially from those reflected in Aldeyra's forwardlooking 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; delay in or failure to obtain regulatory approval of Aldeyra's product candidates, including as a result of the FDA not accepting Aldeyra's regulatory filings, requiring additional clinical trials or data prior to review or approval of such filings; 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 different indications; 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) and obtain reimbursement for 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 future revenue, the timing of future revenue, the sufficiency or use of Aldeyra's cash resources and needs for additional financing; 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 commercialization, marketing and manufacturing capabilities and strategy; 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; political, economic, legal, social, and health risks, including the COVID-19 pandemic and subsequent public health measures, and war or other military actions, that may affect Aldeyra's business or the global economy; 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, 2022, and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, expected to be filed with the SEC in the third quarter of 2023.

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.

#### Contacts

#### Investors & Media:

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