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 25, 2019

ALDEYRA THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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).

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**ALDX**	**The Nasdaq Stock Market, LLC**

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 ☒

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. ☒

Item 7.01. Regulation FD Disclosure.

As reported under Item 8.01 of this Current Report on Form 8-K, on June 25, 2019, Aldeyra Therapeutics, Inc. (the "Company") issued a press release (the "Press Release") announcing results from the SOLACE Trial, a randomized, multi-center, double-masked, parallel-group, vehicle-controlled Phase 3 clinical trial of 0.5% topical ocular reproxalap in patients with noninfectious anterior uveitis. The Company is holding a conference call regarding the SOLACE Trial results on June 25, 2019. A copy of the supplemental presentation which will be referenced during this 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.

Item 8.01. Other Events.

On June 25, 2019, the Company announced in the Press Release results from the SOLACE Trial of 0.5% topical ocular reproxalap in patients with noninfectious anterior uveitis. 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

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Supplemental Presentation dated June 25, 2019.
99.2	Aldeyra Therapeutics, Inc. Press Release dated June 25, 2019.

SIGNATURES

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

Dated: June 25, 2019

ALDEYRA THERAPEUTICS, INC.

By: /s/ Joshua Reed
Name: Joshua Reed
Title: Chief Financial Officer

Exhibit 99.1

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June 2019

Nasdaq: ALDX

The SOLACE Trial in Noninfectious Anterior Uveitis

Top-Line Results

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, research and development plans or expectations, trends, 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 environment and potential growth opportunities, among other things. Forward-looking statements include all statements that are not historical facts and, in some cases, can be identified by terms such as "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "plan" or similar expressions and the negatives of those terms.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause Aldeyra's actual results, performance or achievements to be materially different from any future 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, clinical and regulatory plans or expectations for Aldeyra's product candidates and Aldeyra's continuing 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 timelines may be subject to adjustment depending on recruitment rate, regulatory review, preclinical and clinical results, and other factors that could delay the initiation, completion, or reporting of clinical trials.

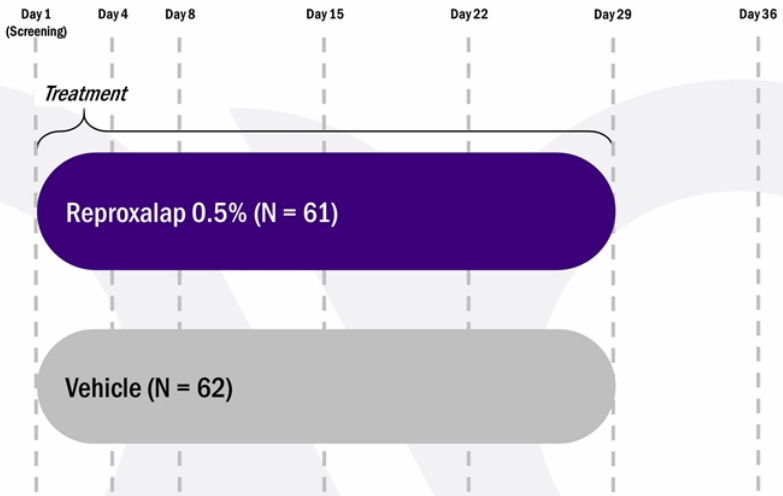
In addition to the risks described above and in Aldeyra's other filings with the SEC, other unknown or unpredictable factors also could affect Aldeyra's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information in this presentation is provided only **as of June 25, 2019**, 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.

Top-Line SOLACE Trial Results Summary

- No statistically significant difference was observed between the reproxalap group and the vehicle control group on the primary (time to cure) or secondary endpoints, due to high rates of disease resolution in vehicle-treated patients.
- For the primary and all time-to-event secondary endpoints, reproxalap was numerically favored over vehicle.
- The ocular inflammation improvement in the reproxalap group was consistent with Phase 2 trial results, which were statistically noninferior to corticosteroid therapy.
- Reproxalap activity in reducing ocular inflammation in patients with moderate disease, a pre-specified subgroup, was statistically superior to that of vehicle.
- Topical ocular reproxalap was observed to be safe and well tolerated, consistent with prior clinical trials.
- Aldeyra intends to discontinue the noninfectious anterior uveitis program in order to prioritize high-value Phase 3 ocular programs in dry eye disease, allergic conjunctivitis, and proliferative vitreoretinopathy.

The SOLACE Trial Design

- **Primary objective**
  - Evaluate efficacy of reproxalap ophthalmic solution (0.5%) on anterior chamber cell count (ACC) vs. vehicle
- **Inclusion highlights**
  - Acute endogenous noninfectious anterior uveitis with onset of symptoms within the previous 2 weeks
  - 6-50 ACC in the study eye
  - Intraocular pressure <21 mmHg
- **Dosing regimen**
  - Week 1 8x/day
  - Week 2 6x/day
  - Weeks 3-4 4x/day
  - Week 5 None
- **Endpoints**
  - Primary Endpoint: Time-to-cure (zero inflammatory cells in anterior chamber) without rescue
  - Secondary Time-to-Event Endpoints: one-point ACC grade reduction, flare cure, one-point flare grade reduction, requirement for rescue therapy



Further information can be found on www.clinicaltrials.gov: Trial #NCT03131154.

Primary and Secondary Time to Event Endpoints – Overall Population

Endpoint	Reproxalap	Vehicle	p value
Time to Cure (Anterior Cell Grade 0)	15 days	21 days	NS
Time to Anterior Cell Grade 1-Point Improvement	7 days	8 days	NS
Time to Flare Grade 0	8 days	15 days	NS
Time to Flare Grade 1-Point Improvement	5 days	6 days	NS
Time to Rescue Therapy	15 days	12 days	NS

Time to event represents 25th percentile Kaplan Meier estimates. Time to event p values represent log-rank tests. NS = Not Significant
Source: SOLACE noninfectious anterior uveitis clinical trial results

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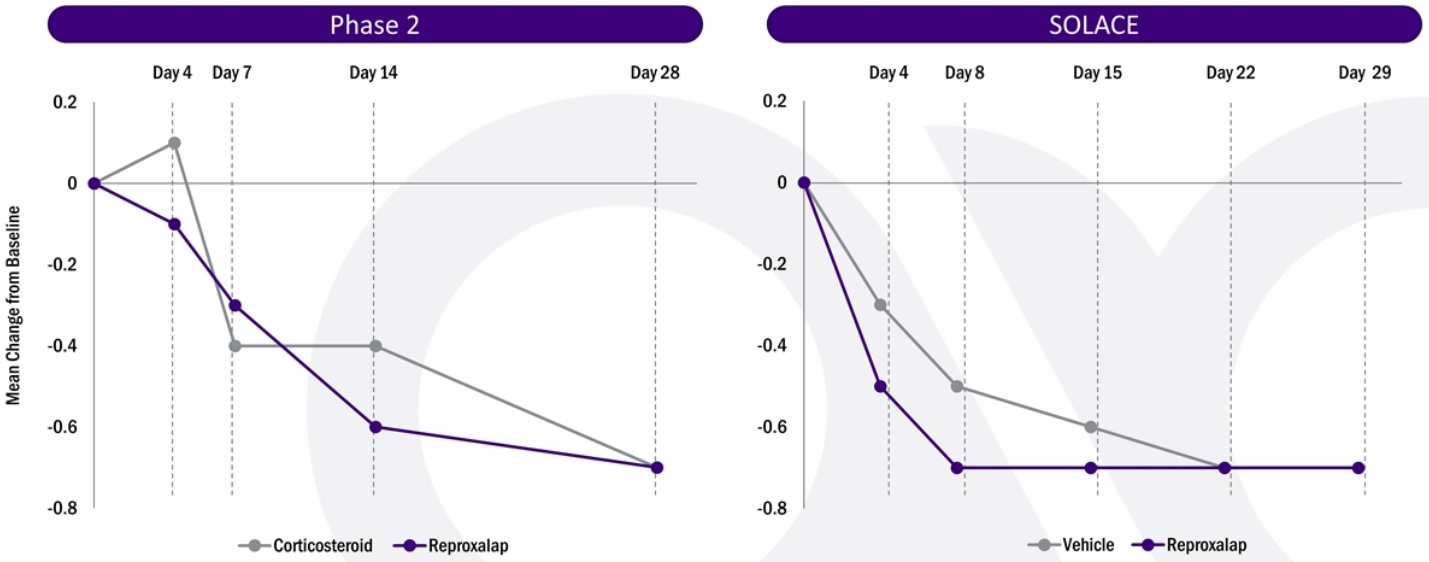
Immune-Modulating Activity Observed in SOLACE Consistent with Phase 2 Trial Results, Which Were Statistically Noninferior to Corticosteroid

Change from Baseline in Anterior Chamber Inflammatory Cell Grade
ITT Population with Last Observation Carried Forward



ITT = Intention-To-Treat
Source: SOLACE noninfectious anterior uveitis clinical trial results and Phase 2 noninfectious anterior uveitis clinical trial results

Primary and Secondary Time to Event Endpoints – Moderate Patients (a Pre-Specified Subgroup)

Endpoint	Reproxalap	Vehicle	p value
Time to Cure (Anterior Cell Grade 0)	15 days	31 days	0.08
Time to Anterior Cell Grade 1-Point Improvement	4 days	6 days	0.1
Time to Flare Grade 0	5 days	> 32 days	0.03
Time to Flare Grade 1-Point Improvement	5 days	20 days	0.1
Time to Rescue Therapy	15 days	7 days	0.06
Combined			0.0001

Moderate patients defined as patients with anterior chamber cell count grade of 2+.
Time to event represents 25th percentile Kaplan Meier estimates. Time to event p values represent log-rank tests. The combined p value is the fixed effect meta-analysis of log hazard ratios.
Source: SOLACE noninfectious anterior uveitis clinical trial results

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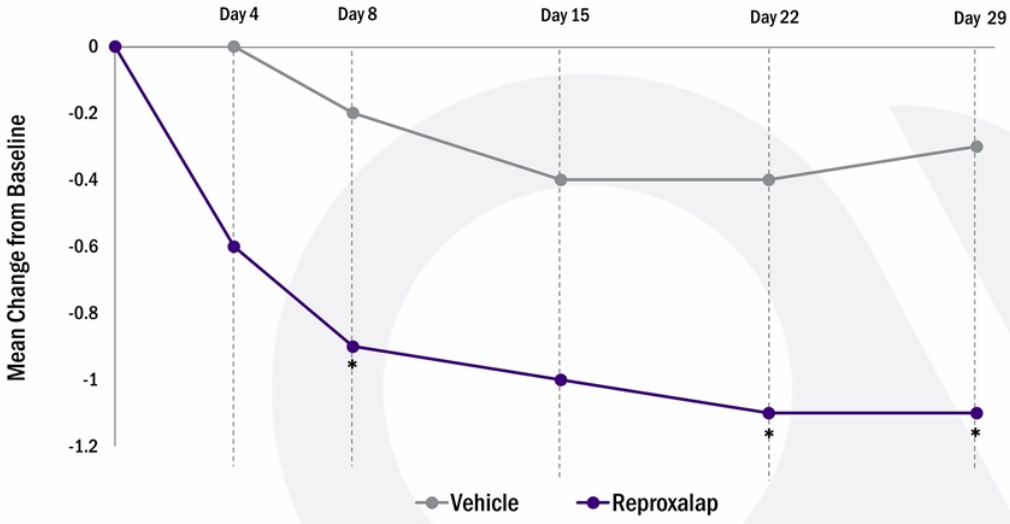
Immune-Modulating Activity of Reproxalap was Statistically Superior to that of Vehicle in Patients with Moderate Severity (a Pre-Specified Subgroup)

Change from Baseline in Anterior Chamber Inflammatory Cell Grade
Moderate Severity ITT Population with Last Observation Carried Forward



Proportion Cured (Grade 0 = no inflammatory cells observed)	
Week 4 Grade 0	Percent of Subjects
Reproxalap	53%
Vehicle	25%

MMRM p = 0.0489

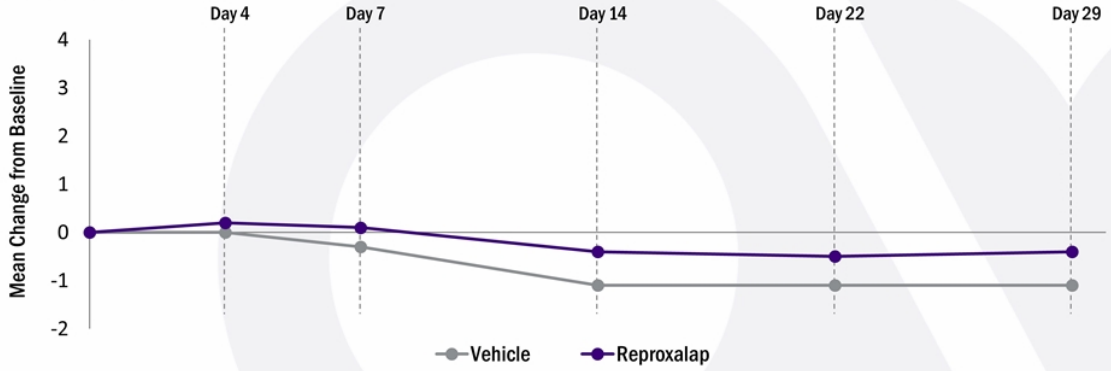
Moderate severity defined as patients with anterior chamber cell count grade of 2+.
Source: SOLACE noninfectious anterior uveitis clinical trial results

*p<0.05
MMRM = Mixed Effect Model Repeated Measures

Topical Ocular Reproxalap Was Generally Well Tolerated and No Safety Concerns Were Observed in SOLACE

- Now administered to over 800 patients across nine completed clinical trials
- No observed safety or tolerability concerns, consistent with previous clinical trials

Change from Baseline in Intraocular Pressure (mmHg)
Safety Population



Source: SOLACE noninfectious anterior uveitis clinical trial results

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Ocular Program Status

Aldeyra intends to prioritize high-value Phase 3 ocular programs

Dry Eye Disease

- **Positive Phase 2b** clinical trial results, announced September 2018
- **RENEW Phase 3 clinical trial program ongoing**

Allergic Conjunctivitis

- **Positive ALLEVIATE Phase 3** clinical trial results, announced March 2019
- **Positive allergen chamber** clinical trial results, announced June 2019
- **Subsequent Phase 3 trial expected to be confirmed H2 2019**

Proliferative Vitreoretinopathy

- **Phase 3 clinical program initiation expected H2 2019**

Aldeyra Therapeutics Announces Results from the SOLACE Trial in Noninfectious Anterior Uveitis

- Statistical Significance Not Achieved for Primary or Secondary Endpoints Due to High Rates of Disease Resolution in Vehicle-Treated Patients, but Activity of Reproxalap Observed to be Consistently Greater than Vehicle
- Noninfectious Anterior Uveitis Program to be Discontinued
- Company Plans to Prioritize Phase 3 Ocular Pipeline Programs in Dry Eye Disease, Allergic Conjunctivitis, and Proliferative Vitreoretinopathy

LEXINGTON, Mass., June 25, 2019 /BUSINESS WIRE/ — Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases, today announced results from the noninfectious anterior uveitis SOLACE Trial. Statistical significance was not achieved for the primary or secondary endpoints, due to high rates of disease resolution in vehicle-treated patients, but activity of reproxalap was consistently greater than that of vehicle.

“The results of the SOLACE Trial confirm the potential of reproxalap to treat ocular inflammation, and further validate the novel mechanism of action of reproxalap, which demonstrated highly statistically significant immune-modulating activity in the Phase 3 ALLEVIATE Trial and Phase 2b Dry Eye Disease trial,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “We look forward to aggressively prioritizing advancement of high-value ocular programs in dry eye disease, allergic conjunctivitis, and proliferative vitreoretinopathy.”

Topical ocular reproxalap was observed to be safe and well-tolerated. Reproxalap ophthalmic solution, in various concentrations, has now been administered to over 800 patients in nine clinical trials for ocular inflammation.

Conference Call

Aldeyra will hold a conference call on June 25, 2019 at 8:00 a.m. Eastern Time. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID is 8856138. A live, listen-only audio webcast of the conference call can be accessed on the investor relations page of Aldeyra’s corporate website at ir.aldeyra.com. After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for thirty days.

About Aldeyra Therapeutics

Aldeyra Therapeutics is a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra’s lead product candidates are first-in-class treatments in development for dry eye disease, allergic conjunctivitis, proliferative vitreoretinopathy, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for retinal and systemic inflammatory diseases. None of Aldeyra’s product candidates have been approved for sale in the U.S. or elsewhere.

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, future financial position, projected costs and expenses, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans to initiate further clinical testing, the timing of results from clinical programs, and its regulatory plans. 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 "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "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 trials involving Aldeyra's product candidates; 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; 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, 2018 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2019 which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at **www.sec.gov**.

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.

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