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): August 8, 2019

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

Delaware	001-36332	20-1968197
(State or other jurisdiction of incorporation)	(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

(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))

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 2.02. Results of Operations and Financial Condition.

On August 8, 2019, Aldeyra Therapeutics, Inc. ("Aldeyra") issued a press release and is holding a conference call regarding its financial results for the quarter ended June 30, 2019. The press release also included a corporate update. The press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Various statements to be made during the conference call are "forward-looking statements" under the securities laws, including, but not limited to, statements regarding Aldeyra's plans and expectations for its product candidates. 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," "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; the delay in or failure to obtain regulatory approval of Aldeyra's product candidates; Aldeyra's 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 our 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 Aldeyra's 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, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at 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, 2019, expected to be filed with the SEC in the third quarter of 2019.

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 conveyed on the conference call is provided only as of the date of the call, and Aldeyra undertakes no obligation to update any forward-looking statements presented on the call on account of new information, future events, or otherwise, except as required by law.

The information in Item 2.02 of this Current Report on Form 8-K and the Exhibit attached hereto 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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

In the press release dated August 8, 2019, the Company also provided a corporate update. The information set forth under the heading "Recent Highlights and Corporate Updates" together with the forward-looking statement disclaimer at the end of the press release, are incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

The portions of the press release incorporated by reference into Item 8.01 of this Current Report on Form 8-K are being filed pursuant to Item 8.01. The remaining portions of the press release are being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated August 8, 2019

EXHIBIT INDEX

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99.1	Aldeyra Therapeutics, Inc. Press Release dated August 8, 2019

SIGNATURE

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

Dated: August 8, 2019

Exhibit 99.1

Aldeyra Therapeutics Announces Second Quarter 2019 Financial Results and Provides Corporate Update

- *Part 1 of Adaptive Phase 3 RENEW Trial in Dry Eye Disease Expected to be Completed in Fourth Quarter 2019*
- *Meeting with FDA Scheduled in Fourth Quarter 2019 to Confirm Design of Second Phase 3 Trial in Allergic Conjunctivitis*
- *Initiation of the Adaptive Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy Planned for Fourth Quarter 2019*
- *Part 1 of Adaptive Phase 3 RESET Trial in Sjögren-Larsson Syndrome Completed*

LEXINGTON, Mass. – (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 quarter ended June 30, 2019 financial results and provided a corporate update.

"With Part 1 of our first Phase 3 trial in dry eye disease expected to be completed later this year, Aldeyra continues to advance reproxalap, the lead product candidate in our novel RASP inhibitor platform, towards commercialization," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "In addition, in the fourth quarter of 2019, we expect to confirm the design of our second Phase 3 trial of reproxalap in allergic conjunctivitis and initiate Phase 3 clinical testing of ADX-2191 in our first retinal indication, proliferative vitreoretinopathy, a rare and potentially blinding inflammatory disorder with no approved therapies."

Recent Highlights and Corporate Updates

- **Dry Eye Disease – Part 1 of the Adaptive Phase 3 RENEW Trial Expected to be Completed in Fourth Quarter of 2019.** Aldeyra announced completion of enrollment in Part 1 of the two-part adaptive Phase 3 RENEW Trial of topical ocular reproxalap in dry eye disease. Following completion of Part 1 of RENEW, expected in the fourth quarter of 2019, Aldeyra plans to report the endpoints, dosing regimen, and sample size for Part 2 of the trial. Top-line results of the RENEW Trial are expected to be announced following completion of Part 2.
- **Allergic Conjunctivitis – FDA Meeting Scheduled for Fourth Quarter to Confirm Design of Second Phase 3 Clinical Trial.** In March 2019, Aldeyra reported positive top-line results from the Phase 3 ALLEVIATE Trial of topical ocular reproxalap in allergic conjunctivitis, and plans to present full results of ALLEVIATE at the American Academy of Ophthalmology 2019 Annual Meeting in October 2019. In addition, in June of 2019, Aldeyra announced results of topical ocular reproxalap in an allergen chamber trial, which demonstrated that ocular itching and redness in reproxalap-treated patients were statistically lower than that of vehicle-treated patients. A meeting with the U.S. Food and Drug Administration (FDA) has been scheduled in the fourth quarter of 2019 to confirm the design of a second Phase 3 trial.
- **Proliferative Vitreoretinopathy – the Adaptive Phase 3 GUARD Clinical Trial of ADX-2191 Expected to Initiate in the Fourth Quarter of 2019.** Later this year, Aldeyra expects to initiate the adaptive Phase 3 GUARD Trial of ADX-2191 for the prevention of proliferative vitreoretinopathy (PVR). The trial will compare recurrence rates across patients treated with ADX-2191 or standard of care following surgical repair of retinal detachment due to PVR. PVR is expected to be the first indication in Aldeyra's retinal disease platform to begin clinical testing.

- **Sjögren-Larsson Syndrome – Part 1 of the Phase 3 RESET Trial Completed.** In Part 1 of the two-part adaptive Phase 3 RESET trial in Sjögren-Larsson Syndrome, investigator-assessed dermal scaling scores in the six patients treated with 1% reproxalap topical dermatologic formulation were statistically lower than pre-treatment values over six months of therapy, an improvement that was numerically greater than that observed in the three patients treated with vehicle, when adjusted for baseline score. Prior to initiating subsequent clinical testing, Aldeyra plans to discuss the RESET Part 1 results with regulatory authorities. The RESET Trial is a randomized, multi-center, double-masked Phase 3 clinical trial of 1% topical dermal reproxalap for the treatment of ichthyosis, a severe skin disease associated with Sjögren-Larsson Syndrome.
- **Programs in Systemic Immune-Mediated Diseases Expected to Begin Clinical Testing in 2019.** As Aldeyra expands to the development of therapies for the treatment of systemic immune-mediated disease, a Phase 2 clinical trial of ADX-1612 in post-transplant lymphoproliferative disorder and a Phase 1 clinical trial of ADX-629 for the treatment of systemic autoimmune and metabolic disease remain on track to be initiated in the second half of 2019.

Quarter Ended June 30, 2019 Financial Review

For the quarter ended June 30, 2019, Aldeyra reported a net loss of approximately $13.3 million, compared to a net loss of approximately $9.1 million for the quarter ended June 30, 2018. Basic and diluted net loss per share was $0.49 for the quarter ended June 30, 2019, compared to $0.46 per share for the same period in 2018. Losses have resulted from the costs of research and development programs, as well as from general and administrative expenses.

Research and development expenses were $10.7 million for the quarter ended June 30, 2019, compared to $6.8 million for the same period in 2018. The increase of $3.9 million is primarily related to an increase in manufacturing, preclinical, and clinical development costs; an increase in personnel costs; and non-cash compensation costs related to a portion of upfront acquisition consideration that is subject to vesting based on continued service.

General and administrative expenses were $3.1 million for the quarter ended June 30, 2019, compared to $2.4 million for the quarter ended June 30, 2018. The increase of $0.7 million is primarily related to an increase in personnel costs.

For the quarter ended June 30, 2019, total operating expenses were approximately $13.7 million, compared to total operating expenses of approximately $9.2 million for the same period in 2018.

Cash, cash equivalents, and marketable securities were $69.5 million as of June 30, 2019.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Thursday, August 8, 2019, at 8:00 a.m. Eastern Time. The dial-in numbers are 1-877-211-4098 for domestic callers and 1-647-689-6613 for international callers. The conference ID number for the live call will be 9329328. A live webcast of the conference call will also be available on the investor relations page of the Aldeyra Therapeutics corporate website at www.aldeyra.com. After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for one year.

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 investigational drug product candidates are first-in-class potential 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.

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 relating to current or future clinical development. 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," "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

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ALDEYRA THERAPEUTICS, INC.
BALANCE SHEETS

	June 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,399,564	$ 3,357,472
Cash equivalent - Reverse Repurchase Agreements	32,000,000	$ 44,000,000
Marketable securities	30,057,408	46,242,220
Prepaid expenses and other current assets	3,398,930	1,169,594
Total current assets	72,855,902	94,769,286
Deferred offering costs	—	86,644
Debt issuance costs	492,448	—
Right-of-use assets	294,173	—
Fixed assets, net	196,491	235,225
Total assets	$ 73,839,014	$ 95,091,155
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,773,987	$ 3,051,678
Accrued expenses	3,403,789	5,421,498
Current portion of operating lease liabilities	211,744	—
Total current liabilities	6,389,520	8,473,176
Operating lease liabilities, long-term	116,124	—
Total liabilities	6,505,644	8,473,176
Commitments and contingencies (Notes 14 and 15)		
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 26,986,936 and 26,244,435 shares issued and outstanding, respectively	26,987	26,244
Additional paid-in capital	234,779,291	225,136,127
Accumulated other comprehensive income (loss)	13,453	(9,224)
Accumulated deficit	(167,486,361)	(138,535,168)
Total stockholders' equity	67,333,370	86,617,979
Total liabilities and stockholders' equity	$ 73,839,014	$ 95,091,155

ALDEYRA THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	$ 10,664,858	$ 6,792,974	$ 18,513,448	$ 13,393,080
Acquired in-process research and development	(49,848)	—	6,547,703	—
General and administrative	3,116,414	2,373,059	6,101,452	4,264,360
Loss from operations	(13,731,424)	(9,166,033)	(31,162,603)	(17,657,440)
Other income (expense):				
Interest income	432,908	141,956	932,049	264,346
Interest expense	(28,649)	(26,358)	(30,612)	(54,402)
Total other income (expense), net	404,259	115,598	901,437	209,944
Loss before income taxes	(13,327,165)	(9,050,435)	(30,261,166)	(17,447,496)
Income tax benefit	—	—	1,309,973	—
Net loss	$(13,327,165)	$ (9,050,435)	$(28,951,193)	$(17,447,496)
Net loss per share - basic and diluted	$ (0.49)	$ (0.46)	$ (1.08)	$ (0.88)
Weighted average common shares outstanding - basic and diluted	26,985,454	19,761,352	26,836,292	19,761,352

Corporate Contact:
David McMullin
Aldeyra Therapeutics, Inc.
Tel: 781-761-4904 ext. 218
dmcmullin@aldeyra.com

Investor Contact:
Chris Brinzey
Westwicke, an ICR Company
Tel: 339-970-2843
Chris.brinzey@westwicke.com