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): May 9, 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

(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).

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. ☒

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**

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2019, Aldeyra Therapeutics, Inc. (“Aldeyra”) issued a press release and is holding a conference call regarding its financial results for the quarter ended March 31, 2019. 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; the delay in or failure to obtain regulatory approval of the 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 March 31, 2019, expected to be filed with the SEC in the second 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated May 9, 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: May 9, 2019

Exhibit 99.1

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

- *Reported Positive Results from Phase 3 ALLEVIATE Trial in Allergic Conjunctivitis*
- *Initiated Adaptive Phase 3 RENEW Trial in Dry Eye Disease*
- *Last Patient Dosed in Phase 3 SOLACE Trial in Noninfectious Anterior Uveitis*
- *Completion of Part 1 of the Phase 3 RESET Trial in Sjögren-Larsson Syndrome Expected in Second Half of 2019*
- *Initiation of Adaptive Phase 3 Clinical Trial in Proliferative Vitreoretinopathy Expected in Second Half of 2019*

LEXINGTON, Mass., May 9, 2019 /PRNewswire/ — 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 March 31, 2019 financial results and provided a corporate update.

“With the announcement of positive results from the Phase 3 ALLEVIATE Trial, the initiation of the Phase 3 RENEW Trial, and the completion of dosing in the Phase 3 SOLACE Trial, our progress in 2019 has been remarkable,” commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “We look forward to announcing results from the SOLACE Trial and completing Part 1 of the Phase 3 RESET Trial later this year, as we continue to advance our innovative pipeline towards commercialization across a variety of serious diseases.”

Recent Highlights and Corporate Updates

- **Reported Positive Results from the Phase 3 ALLEVIATE Trial in Allergic Conjunctivitis.** The double-masked, randomized, vehicle-controlled, multi-center, parallel-group conjunctival allergen challenge ALLEVIATE Trial assessed the efficacy and safety of 0.25% and 0.5% concentrations of reproxalap topical ophthalmic solutions compared to vehicle in 318 patients with seasonal allergic conjunctivitis. The primary endpoint of ocular itch score area under the curve was achieved for both concentrations ($p < 0.0001$ and $p = 0.0025$, respectively). The key secondary endpoint of clinically relevant two-point ocular itch score improvement was also achieved for both concentrations ($p = 0.0005$ and $p = 0.0169$, respectively). 0.25% reproxalap is expected to advance to additional Phase 3 clinical testing contingent upon successful completion of ongoing environmental allergen exposure method development studies and subsequent discussion with regulatory authorities.
- **Initiated Adaptive Phase 3 RENEW Trial in Dry Eye Disease, and Presented Phase 2b Dry Eye Disease Clinical Trial Results at the 2019 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting.** In September 2018, and at ARVO in May 2019, Aldeyra reported results from topical ocular reproxalap in a Phase 2b dry eye disease

clinical trial, which demonstrated statistically significant superiority of 0.25% reproxalap over vehicle in ocular dryness symptom score and fluorescein nasal region ocular staining in pre-specified moderate to severe patients ($p = 0.0048$ and $p = 0.0007$, respectively). In April 2019, the first patient was enrolled in the Phase 3 RENEW trial, an adaptive, two-part, Phase 3 clinical trial of topical ocular 0.25% reproxalap. Following the completion of the first part of RENEW, assuming the results support advancement to further testing, Aldeyra expects to report the endpoints, dosing regimen, and sample size for the second part of the trial. Aldeyra expects to report full clinical results following the completion of RENEW.

- **Dosed Last Patient in the Phase 3 SOLACE Trial in Noninfectious Anterior Uveitis.** In April 2019, dosing was completed in 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, a serious ocular inflammatory disease that can lead to loss of vision. Results from the SOLACE Trial are expected in the second half of 2019.
- **Completion of Part 1 of the Phase 3 RESET Trial in Sjögren-Larsson Syndrome Expected in the Second Half of 2019.** The RESET Trial is an adaptive, two-part, pivotal, randomized, multi-center, double-masked Phase 3 clinical trial of 1% topical dermal reproxalap for the treatment of ichthyosis associated with Sjögren-Larsson Syndrome. Following the completion of RESET Part 1, assuming the results support advancement to further testing, Aldeyra expects to report the endpoints, dosing regimen, and sample size for RESET Part 2. Aldeyra expects to report full clinical results following the completion of RESET.
- **Phase 3 Adaptive Clinical Trial of ADX-2191 in Proliferative Vitreoretinopathy Expected to Initiate in the Second Half of 2019.** In January 2019, Aldeyra expanded its pipeline in retinal disease with the addition ADX-2191 for the treatment of proliferative vitreoretinopathy, a rare inflammatory disorder that leads to severe retinal scarring and blindness. An adaptive, two-part Phase 3 clinical trial is expected to begin in the second half of 2019. Following the completion of the initial part of the trial, expected in 2020, and assuming the results support advancement to further testing, Aldeyra expects to report the endpoints, dosing regimen, and sample size for the remainder of the trial. Aldeyra expects to report full clinical results following the completion of the trial.
- **Programs in Systemic Immune-Mediated Diseases Expected to Begin Clinical Testing in 2019.** 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 disease are expected to initiate in the second half of 2019.

Quarter Ended March 31, 2019 Financial Review

For the quarter ended March 31, 2019, Aldeyra reported a net loss of approximately $15.6 million, compared to a net loss of approximately $8.4 million for the quarter ended March 31, 2018. Basic and diluted net loss per share was $0.58 for the quarter ended March 31, 2019,

compared to $0.43 per share for the same period in 2018. Losses have resulted from the costs of research and development programs; non-cash charges in connection with Aldeyra's January 2019 stock-for-stock acquisition of Helio Vision, Inc. (Helio); and general and administrative expenses.

Research and development expenses were $7.8 million for the quarter ended March 31, 2019, compared to $6.6 million for the same period in 2018. The increase of $1.2 million is primarily related to the increase in research and development expenditures, including manufacturing, preclinical, and clinical development costs; and an increase in personnel costs; and non-cash compensation costs related to a portion of the upfront consideration paid to the founders of Helio.

In connection with the Helio acquisition, in-process research and development expenses were $6.6 million for the quarter ended March 31, 2019. There was no such expense for the three months ended March 31, 2018. The acquired in-process research and development expensed during the quarter was comprised of a non-cash charge related to the fair value of consideration issued to the Helio non-founders, a cash charge related to Helio acquisition transaction expenses, and a non-cash charge related to the deferred tax liability arising from the accounting differences for book and tax purposes resulting from the acquisition.

General and administrative expenses were $3.0 million for the quarter ended March 31, 2019, compared to $1.9 million for the quarter ended March 31, 2018. The increase of $1.1 million is primarily related to an increase in personnel, legal, and patent-related costs.

For the quarter ended March 31, 2019, total operating expenses were approximately $17.4 million, compared to total operating expenses of approximately $8.5 million for the same period in 2018.

Cash, cash equivalents, and marketable securities were $82.1 million as of March 31, 2019. In March 2019, Aldeyra entered into a Loan and Security Agreement, which provides up to $60 million in non-dilutive financing. The facility advances capital at Aldeyra's option based upon certain funding conditions. Aldeyra elected not to draw the initial term loan advance, which expired on April 15, 2019. An additional term loan advance of $15.0 million is expected to be available, and may be drawn at Aldeyra's option, through September 30, 2019.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Thursday, May 9, 2019, at 8:00 a.m. Eastern Time. The dial-in numbers are 1-877-266-8979 for domestic callers and 1-412-317-5231 for international callers. 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 product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease, allergic conjunctivitis, noninfectious anterior uveitis, and Sjögren-Larsson Syndrome. The company is also developing other product candidates for proliferative vitreoretinopathy and other retinal diseases, post-transplant lymphoproliferative disease, autoimmune disease, metabolic disease, and cancer. 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. 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 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, 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 March 31, 2019 expected to be filed in the second 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 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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ALDEYRA THERAPEUTICS, INC.
BALANCE SHEETS
(UNAUDITED)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,297,555	$ 3,357,472
Cash equivalent - Reverse Repurchase Agreements	39,000,000	$ 44,000,000
Marketable securities	37,826,635	46,242,220
Prepaid expenses and other current assets	4,872,067	1,169,594
Total current assets	86,996,257	94,769,286
Deferred offering costs	—	86,644
Debt issuance costs	538,038	—
Right-of-use assets	377,920	—
Fixed assets, net	215,908	235,225
Total assets	$ 88,128,123	$ 95,091,155
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,013,362	$ 3,051,678
Accrued expenses	5,257,071	5,421,498
Current portion of operating lease liabilities	221,112	—
Total current liabilities	9,491,545	8,473,176
Operating lease liabilities, long-term	156,808	—
Total liabilities	9,648,353	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 26,910,355 and 26,244,435 shares issued and outstanding, respectively	26,910	26,244
Additional paid-in capital	232,605,244	225,136,127
Accumulated other comprehensive income (loss)	6,812	(9,224)
Accumulated deficit	(154,159,196)	(138,535,168)
Total stockholders' equity	78,479,770	86,617,979
Total liabilities and stockholders' equity	$ 88,128,123	$ 95,091,155

ALDEYRA THERAPEUTICS, INC.
STATEMENT OF OPERATIONS
(UNAUDITED)

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	$ 7,848,590	$ 6,600,106
Acquired in-process research and development	6,597,551	—
General and administrative	2,985,038	1,891,303
Loss from operations	(17,431,179)	(8,491,409)
Other income (expense):		
Interest income	499,140	122,390
Interest expense	(1,962)	(28,044)
Total other income (expense), net	497,178	94,346
Loss before income taxes	(16,934,001)	(8,397,063)
Income tax benefit	1,309,973	—
Net loss	$(15,624,028)	$ (8,397,063)
Net loss per share - basic and diluted	$ (0.58)	$ (0.43)
Weighted average common shares outstanding - basic and diluted	27,053,842	19,366,790