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): March 8, 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).

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 March 8, 2019, Aldeyra Therapeutics, Inc. (the "Company") issued a press release and is holding a conference call regarding its financial results for the quarter and year ended December 31, 2018. 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 the Company'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.

The Company is at an early stage of development and may not ever have any products that generate significant revenue. All of the Company'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 the Company's forward-looking statements include, among others, the timing of enrollment, commencement and completion of the Company's clinical trials, the timing and success of preclinical studies and clinical trials conducted by the Company and its development partners; delay in or

failure to obtain regulatory approval of the Company's product candidates; the Company's ability to maintain regulatory approval of the Company'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 the Company's product candidates; uncertainty as to the Company's ability to commercialize (alone or with others) the Company's product candidates following regulatory approval, if any; the size and growth of the potential markets and pricing for the Company's product candidates and the ability to serve those markets; the Company's expectations regarding the Company's expenses and revenue, the sufficiency or use of the Company's cash resources and needs for additional financing; the rate and degree of market acceptance of any of the Company's product candidates; the Company's expectations regarding competition; the Company's anticipated growth strategies; the Company's ability to attract or retain key personnel; the Company's limited sales and marketing infrastructure; the Company's ability to establish and maintain development partnerships; the Company's ability to successfully integrate acquisitions into our business; the Company's expectations regarding federal, state and foreign regulatory requirements; regulatory developments in the United States and foreign countries; the Company's ability to obtain and maintain intellectual property protection for the Company's product candidates; the anticipated trends and challenges in the Company'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 the Company's Annual Report on Form 10-K for the year ended December 31, 2017 and the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, both of which are 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 the Company's Annual Report on Form 10-K for the year ended December 31, 2018, expected to be filed with the SEC in the first quarter of 2019.

In addition to the risks described above and in the Company's other filings with the SEC, other unknown or unpredictable factors also could affect the Company'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 March 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.

Date: March 8, 2019

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

Exhibit 99.1

Aldeyra Therapeutics Announces Year-End 2018 Financial Results

- *Results from the ALLEVIATE Phase 3 Clinical Trial in Allergic Conjunctivitis Expected in Early 2019*
- *The RENEW Adaptive Phase 3 Clinical Trial in Dry Eye Disease Expected to Begin in First Half of 2019*
- *Results from the SOLACE Phase 3 Clinical Trial in Noninfectious Anterior Uveitis Expected in Second Half of 2019*
- *Results from Part 1 of the RESET Phase 3 Clinical Trial in Sjögren-Larsson Syndrome Expected in Second Half of 2019*
- *Adaptive Phase 3 Clinical Trial of ADX-2191 in Proliferative Vitreoretinopathy Expected to Begin in Second Half of 2019*
- *Operations Expected to be Funded Through 2020*

LEXINGTON, Mass., March 8, 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 year ended December 31, 2018 financial results.

“2018 was a landmark year for Aldeyra, highlighted by positive results from our Phase 2b dry eye disease clinical trial, and the subsequent acquisition of Helio Vision in January of this year,” commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “We were pleased to add new Phase 3 clinical programs in dry eye disease and proliferative vitreoretinopathy, complementing our Phase 3 trials in allergic conjunctivitis, noninfectious anterior uveitis, and Sjögren-Larsson Syndrome**.** We look forward to updating investors on the progress of our late-stage development pipeline throughout 2019, as we continue our efforts to bring novel therapeutic options to market.”

Recent Highlights and Corporate Updates

- **Retinal Disease Pipeline Expanded with Acquisition of Helio Vision.** The acquisition of Helio Vision in January 2019 broadened Aldeyra’s development program in retinal disease with a Phase 3-ready product candidate, ADX-2191, for proliferative vitreoretinopathy (PVR). PVR, a rare inflammatory fibroproliferative disorder with no approved treatment, leads to severe retinal scarring and blindness. ADX-2191 has received Orphan Drug Designation from the U.S. Food and Drug Administration for the prevention of PVR. Following discussions with regulatory authorities, Aldeyra plans to initiate an adaptive Phase 3 clinical trial in PVR during the second half of 2019.

- **Positive Results Achieved in Dry Eye Disease Phase 2b Clinical Trial.** In September 2018, Aldeyra announced that 0.25% topical ocular reproxalap demonstrated statistical superiority over vehicle across multiple dry eye disease symptoms and signs. Based on the positive Phase 2b clinical results, in the first half of 2019, Aldeyra plans to initiate Part 1 of the RENEW adaptive Phase 3 clinical trial of 0.25% topical ocular reproxalap in patients with dry eye disease.

- **Results Expected from the ALLEVIATE Phase 3 Clinical Trial in Allergic Conjunctivitis in Early 2019.** The ALLEVIATE trial is a multi-center, double-masked, parallel-group, vehicle-

controlled, allergen-challenge Phase 3 clinical trial of 0.25% and 0.5% topical ocular reproxalap in patients with allergic conjunctivitis. Results from the ALLEVIATE trial are expected to be announced in early 2019.

- **Results from the SOLACE Phase 3 Clinical Trial in Noninfectious Anterior Uveitis Expected in Second Half of 2019.** The SOLACE trial is 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 to be announced in the second half of 2019.

- **Results from Part 1 of the RESET Phase 3 Clinical Trial in Sjögren-Larsson Syndrome Expected in the Second Half of 2019.** The RESET Trial is a 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, an orphan inborn error of metabolism. Results from Part 1 of the RESET trial are expected to be announced in the second half of 2019.

- **Organizational Changes Highlight Preparation for Commercialization.** As Aldeyra's pipeline continues to progress towards commercialization, in January 2019, Aldeyra announced the promotions of David McMullin to the position of Chief Commercial Officer and Stephen G. Machatha, Ph.D. to the position of Senior Vice President of Technical Operations. As the Chief Commercial Officer, Mr. McMullin will oversee Aldeyra's strategic initiatives, commercial planning activities, marketing, and commercial infrastructure development. As the Senior Vice President of Technical Operations, Dr. Machatha will lead chemistry, manufacturing and control activities, and develop Aldeyra's commercial supply infrastructure.

- **Financing Activity in 2018 Expected to Support Operations through 2020.** In October 2018, Aldeyra completed an underwritten public offering that raised net proceeds of $67.6 million after deducting underwriting discounts, commissions, and expenses. Based on Aldeyra's current operating plan, cash and cash equivalents as of December 31, 2018, including proceeds from the financing, are expected to fund currently anticipated operating expenses through 2020, including the planned announcements of top-line data from Phase 3 clinical trials in allergic conjunctivitis, noninfectious anterior uveitis, and Sjögren-Larsson Syndrome (RESET Part 1); the initiation of Phase 3 clinical trials in dry eye disease and PVR; and the initiation of multiple early-stage clinical programs.

- **Clinical Programs for Systemic Immune-Mediated Disease Expected to Begin in 2019.** A Phase 2 clinical trial of ADX-1612 in post-transplant lymphoproliferative disorder and an additional Phase 2 clinical trial of ADX-1612 in mesothelioma, pending discussions with regulatory authorities, are expected to initiate in 2019. A Phase 1 clinical trial of ADX-629 for the treatment of systemic autoimmune disease is expected to begin in the second half of 2019.

Year Ended December 31, 2018 Financial Review

Aldeyra reported a net loss of approximately $38.9 million for the year ended December 31, 2018, compared to a net loss of approximately $22.3 million in 2017. Basic and diluted net loss per share was $1.79 for the year ended December 31, 2018, compared to $1.40 per share in 2017. Losses have resulted from the costs of Aldeyra's clinical trials and research and development programs, as well as from general and administrative expenses.

Research and development expenses were approximately $29.8 million for the year ended December 31, 2018, compared to approximately $16.3 million in 2017. The increase of $13.5 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.

General and administrative expenses were approximately $9.9 million for the year ended December 31, 2018, compared to approximately $6.2 million in 2017. The increase of $3.7 million is primarily related to an increase in legal and patent-related costs, consulting costs, and personnel costs.

Total operating expenses were approximately $39.7 million for the year ended December 31, 2018, compared to total operating expenses of approximately $22.5 million in 2017.

Cash, cash equivalents, and marketable securities were $93.6 million as of December 31, 2018 which includes $67.6 million of net proceeds raised in an October 2018 public offering of Aldeyra's common stock.

Conference Call & Webcast Information
Aldeyra will hold a conference call on Friday, March 8, 2019, at 8:00 a.m. Eastern Standard 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 disorder, 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 "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, 2017 and Aldeyra’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, both of which are 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 Annual Report on Form 10-K for the year ended December 31, 2018, expected to be filed with the SEC in the first 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.

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

ALDEYRA THERAPEUTICS, INC.
BALANCE SHEETS

	December 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,357,472	$ 2,023,337
Cash equivalent- reverse repurchase agreements	44,000,000	18,000,000
Marketable securities	46,242,220	22,923,462
Prepaid expenses and other current assets	1,169,594	1,018,967
Total current assets	94,769,286	43,965,766
Deferred offering costs	86,644	165,930
Fixed assets, net	235,225	43,262
Total assets	$ 95,091,155	$ 44,174,958
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,051,678	$ 1,000,963
Accrued expenses	5,421,498	2,236,465
Current portion of credit facility	-	116,319
Total current liabilities	8,473,176	3,353,747
Credit facility, net of current portion and debt discount	-	1,220,192
Total liabilities	8,473,176	4,573,939
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 15,000,000 shares authorized, none issued and outstanding	-	-
Common stock, voting, $0.001 par value; 150,000,000 authorized and 26,244,435 and 19,137,639 shares issued and outstanding, respectively	26,244	19,138
Additional paid-in capital	225,136,127	139,241,635
Accumulated other comprehensive income (loss)	(9,224)	(17,831)
Accumulated deficit	(138,535,168)	(99,641,923)
Total stockholders' equity	86,617,979	39,601,019
Total liabilities and stockholders' equity	$ 95,091,155	$ 44,174,958

ALDEYRA THERAPEUTICS, INC.
STATEMENT OF OPERATIONS

	Years ended December 31,	
	2018	**2017**
Operating expenses:		
Research and development	$ 29,823,007	$ 16,302,568
General and administrative	9,876,144	6,185,820
Loss from operations	(39,699,151)	(22,488,388)
Other income (expense):		
Interest income	952,698	261,252
Interest expense	(146,792)	(113,453)
Total other income (expense), net	805,906	147,799
Net loss	$ (38,893,245)	$ (22,340,589)
Net loss per share - basic and diluted	$ (1.79)	$ (1.40)
Weighted average common shares outstanding - basic and diluted	21,685,642	15,921,884