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Aldeyra Therapeutics, Inc. Form 8-K March 08, 2019

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)

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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. would, objective, intend, should, could, can, expect, believe, anticipate, project, target, potential, plan or the negative of these terms, and similar expressions intended to identify forward-looking aim. 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

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No. Description
99.1 Aldevra 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.

By: <u>/s/ Joshua Reed</u> Joshua Reed Date: March 8, 2019

Chief Financial Officer