Aldeyra Therapeutics, Inc.
Form 8-K
September 25, 2018

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): September 25, 2018

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 8.01. Other Events.

On September 25, 2018, Aldeyra Therapeutics, Inc. (the Company) issued a press release announcing the presentation of clinical results from the MESO-2 investigator-sponsored clinical trial of ADX-1612, a novel Heat Shock Protein 90 (HSP90) inhibitor, in combination with pemetrexed and cisplatin or carboplatin for the treatment of pleural malignant mesothelioma at the International Association for the Study of Lung Cancer Conference. A copy of the Company s press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The Company is developing ADX-1612 pursuant to a License Agreement between the Company and Madrigal Pharmaceuticals, Inc. (Madrigal), entered into on December 26, 2016 (the Agreement). Pursuant to the Agreement, the Company obtained an exclusive, worldwide license from Madrigal under certain patents and patent applications, and other licenses to intellectual property, to develop and commercialize HSP90 Inhibitors, including ADX-1612 (investigated in oncology under the name ganetespib) (Agreement Products). The Company has agreed to use its commercially reasonable efforts to develop Agreement Products.

In consideration for the rights licensed under the Agreement, the Company paid Madrigal an upfront license fee of $250,000 and is obligated to make future regulatory and development and sales-dependent milestone payments to Madrigal of less than $340 million in the aggregate (over 80% of such amount being tied to the Company s achievement of increasingly greater annual worldwide net sales milestones), as well as royalty payments to Madrigal at a rate which, as a percentage of net sales, is in the high single digits for products containing ADX-1612 and mid-single digits for any other HSP90 Inhibitor product. The Company is also obligated under the Agreement to pay Madrigal a percentage of certain sublicense revenue that the Company receives in connection with the Company entering into any sublicensing arrangements with any third parties, at a percentage rate which tiers downward from the mid-twenties to low-single digits based on the development stage of the product at the time of the sublicense.

The Agreement will remain in effect until all payment obligations under the Agreement expire. The Company may terminate the Agreement in its entirety or on an Agreement Product-by-Agreement Product basis with timely notice to Madrigal. Either party may terminate the Agreement for uncured material breach by the other party or upon certain insolvency or bankruptcy proceedings involving the other party, both with timely notice to the other party. In addition, Madrigal has the right to terminate the Agreement if the Company, its affiliates, or sublicensees interferes with, challenges the validity or enforceability of, opposes the extension of or grant of a supplementary protection certificate with respect to any of the Company s licensed patents under the Agreement. In the event of an early termination of the Agreement, all rights licensed and developed by the Company under the Agreement may revert back to Madrigal. Each party has agreed to indemnify the other party for certain third party claims arising under the Agreement.

The foregoing description of the Agreement is qualified in its entirety by reference to the Agreement. In connection with the announcement of clinical results from the MESO-2 investigator-sponsored clinical trial of ADX-1612, a copy of the Agreement is attached as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference. The Company intends to submit a Freedom of Information Act confidential treatment request to the Securities and Exchange Commission pursuant to Rule 24b-2 under the Securities Exchange Act of 1934, as amended, requesting that it be permitted to redact certain portions of the Agreement. The omitted material will be included in the request for confidential treatment.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No.	**Description**
99.1	Press Release of Aldeyra Therapeutics, Inc. dated September 25, 2018.
99.2*	License Agreement, dated as of December 26, 2016, by and between Aldeyra Therapeutics, Inc. and Madrigal Pharmaceuticals, Inc.

* Certain confidential portions of this exhibit were omitted by means of redacting a portion of the text. An application has been made to the Securities and Exchange Commission seeking confidential treatment of such confidential portions under Rule 24b-2 under the Securities Exchange Act of 1934, as amended. This exhibit has been filed separately with the Securities and Exchange Commission without redactions in connection with Aldeyra Therapeutics, Inc. s confidential treatment request.

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.

ALDEYRA THERAPEUTICS, INC.

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

Dated: September 25, 2018