

ALDEYRA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 03/30/17 for the Period Ending 03/30/17

Address	131 HARTWELL AVENUE SUITE 320 LEXINGTON, MA 02421
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**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 30, 2017

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

Delaware
(State or other jurisdiction of incorporation)

001-36332
(Commission
File No.)

20-1968197
(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))
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Item 2.02. Results of Operations and Financial Condition.

On March 30, 2017, Aldeyra Therapeutics, Inc. (“Aldeyra”) issued a press release and is holding a conference call regarding its financial results for the year ended December 31, 2016. 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 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,” “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. 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 ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra’s product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra’s product candidates; the size and growth of the potential markets for Aldeyra’s product candidates and the ability to serve those markets; Aldeyra’s expectations regarding Aldeyra’s expenses and revenue, the sufficiency 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; 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, 2015 and Aldeyra’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC’s website at www.sec.gov. Additional information will also be set forth in those sections of Aldeyra’s Annual Report on Form 10-K for the year ended December 31, 2016, which will be filed with the SEC in the first quarter of 2017.

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Aldeyra Therapeutics, Inc. dated March 30, 2017

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/ Todd C. Brady, M.D., Ph.D.

Name: Todd C. Brady, M.D., Ph.D.

Title: President and Chief Executive Officer

Dated: March 30, 2017

EXHIBIT INDEX

**Exhibit
No.**

Description

99.1 Press Release of Aldeyra Therapeutics, Inc. dated March 30, 2017



Aldeyra Therapeutics Reports Full Year 2016 Financial Results

Lexington, MA, March 30, 2017 – Aldeyra Therapeutics, Inc. (Nasdaq:ALDX) (Aldeyra), a biotechnology company focused primarily on the development of new products for inflammation, inborn errors of metabolism, and other diseases that are thought to be related to endogenously generated toxic and pro-inflammatory chemical species known as aldehydes, today announced its financial results for the year ended December 31, 2016.

“2016 was a productive year for Aldeyra, highlighted by positive data from our late-stage clinical programs in allergic conjunctivitis, noninfectious anterior uveitis, and Sjögren-Larsson Syndrome,” commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “We look forward to building upon our accomplishments from last year as we advance our clinical programs, two of which are expected to commence Phase 3 studies in 2017. In addition, we expect to initiate a new clinical program in Dry Eye Syndrome.”

Key 2016 Clinical Program Highlights and Upcoming Events

- **Topical Dermatologic ADX-102 in Sjögren-Larsson Syndrome**. In August 2016, Aldeyra announced positive results from a randomized, double-blind, vehicle-controlled Phase 2 clinical trial of ADX-102 in SLS patients. ADX-102 was statistically superior to vehicle and demonstrated clinically relevant activity in diminishing the severity of ichthyosis, a serious dermatologic disease that afflicts patients with Sjögren-Larsson Syndrome. Following an End of Phase 2 meeting held with the U.S. Food and Drug Administration (FDA), Aldeyra expects to initiate enrollment of a Phase 3 trial in the second half of 2017.
- **Topical Ocular ADX-102 in Noninfectious Anterior Uveitis**. In May 2016, Aldeyra announced positive results from a randomized, parallel-group, investigator-masked, active-controlled Phase 2 clinical trial of ADX-102 in noninfectious anterior uveitis patients. ADX-102 reduced inflammatory cell count in the anterior chamber of the eye to a degree similar to that of standard-of-care corticosteroid therapy (which may lead to cataracts and glaucoma in some patients), but without the intraocular pressure elevations that were observed in subjects treated with corticosteroids. Following meetings held with the FDA, Aldeyra expects to initiate a vehicle-controlled Phase 3 clinical trial in the second quarter of 2017.
- **Topical Ocular ADX-102 in Allergic Conjunctivitis**. In February 2016, Aldeyra announced positive results from a randomized, parallel-group, double-masked, vehicle-controlled Phase 2a clinical trial of ADX-102 in allergic conjunctivitis patients. ADX-102 demonstrated statistically and clinically significant activity over vehicle in reducing ocular itching and tearing. Following a meeting held with the FDA, Aldeyra initiated enrollment in February 2017 of a saline-controlled Phase 2b clinical trial. Results from the trial are expected to be reported in the second half of 2017.
- **Topical Ocular ADX-102 and Topical Ocular ADX-103 in Dry Eye Syndrome**. In November 2016, Aldeyra announced the addition of a Phase 2a clinical program in Dry Eye Syndrome, a common and painful ocular disease caused by inflammation and insufficient lipids (fats) in tears.

By diminishing inflammation and protecting lipids from aldehyde-mediated damage, Aldeyra's aldehyde trap platform may represent a novel dual-acting approach for the treatment of Dry Eye Syndrome. Aldeyra plans to initiate a Phase 2a clinical trial of topical ocular ADX-102 in the second quarter of 2017. Contingent on preclinical results, regulatory feedback, and other factors, Aldeyra may also subsequently initiate a Phase 2a clinical trial of ADX-103. Results from the ADX-102 trial are expected to be reported in the second half of 2017.

Year Ended December 31, 2016 Financial Review

For the year ended December 31, 2016, Aldeyra reported a net loss of approximately \$18.7 million compared to a net loss of approximately \$12.1 million for the year ended December 31, 2015. Basic and diluted net loss per share was \$1.65 for the year ended December 31, 2016 compared to \$1.40 per share for the same period in 2015. 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 \$13.2 million for the year ended December 31, 2016 compared to \$7.6 million for the same period in 2015. The increase of \$5.6 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 \$5.5 million for the year ended December 31, 2016, compared to \$4.4 million for the year ended 2015. The increase of \$1.1 million is primarily related to an increase in legal costs, rent, consulting costs, and personnel costs.

In 2016, total operating expenses were approximately \$18.7 million for the year compared to total operating expenses of approximately \$12 million in the prior year.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Thursday, March 30, 2017 at 8:30 a.m. ET to discuss the results. The dial-in numbers are 1-877-419-6590 for domestic callers and 1-719-325-4778 for international callers. The conference ID number for both is 7824349. 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. In addition, a telephonic replay of the call will be available until March 29, 2018. The replay dial-in numbers are 1-888-203-1112 for domestic callers and 1-719-457-0820 for international callers. Please use event passcode 7824349.

About Aldeyra Therapeutics

Aldeyra Therapeutics, Inc. is a biotechnology company devoted to improving lives by inventing, developing and commercializing products that treat diseases thought to be related to endogenous aldehydes, a naturally occurring class of pro-inflammatory and toxic molecules. Aldeyra's lead product candidate, ADX-102, is an aldehyde trap in development for ocular inflammation, as well as for Sjögren-Larsson Syndrome and Succinic Semi-Aldehyde Dehydrogenase Deficiency, two inborn errors of aldehyde metabolism. ADX-102 has not been approved for sale in the U.S. or elsewhere.

About Sjögren-Larsson Syndrome

Sjögren-Larsson Syndrome is a rare inborn error of aldehyde metabolism caused by mutations in fatty acid aldehyde dehydrogenase, leading to elevated toxic fatty aldehyde levels that are thought to contribute to severe ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. There is no therapy for SLS that has been approved by the U.S. Food and Drug Administration.

About Noninfectious Anterior Uveitis

Noninfectious anterior uveitis is a rare, potentially blinding disease that may be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation in the front of the eye, pain, impaired vision, and photophobia.

About Allergic Conjunctivitis

Allergic conjunctivitis is a common allergic disease that is thought to be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in ocular itching, excessive tear production, lid swelling, and redness.

About Dry Eye Syndrome

Dry Eye Syndrome is a common inflammatory disease characterized by insufficient moisture and lubrication in the anterior surface of the eye. Symptoms may include ocular irritation, burning or stinging, and, in severe cases, decreased vision. In patients with Dry Eye Syndrome, aldehydes may contribute to ocular inflammation as well as the impairment of lipids (fats) that lubricate the surface of the eye.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's plans for its product candidates. 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. 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 ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency 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 ability to establish and maintain development partnerships; 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, 2015 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, 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 set forth in Aldeyra's Annual Report on Form 10-K for the year ended December 31, 2016, to be filed with the SEC in the first quarter of 2017. 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.

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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(Financial Statements to follow.)

ALDEYRA THERAPEUTICS, INC.
BALANCE SHEETS

	<u>December 31,</u> <u>2016</u>	<u>December 31,</u> <u>2015</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 12,015,061	\$ 14,648,866
Marketable securities	12,897,584	12,941,776
Prepaid expenses and other current assets	<u>218,682</u>	<u>497,552</u>
Total current assets	25,131,327	28,088,194
Deferred offering costs	—	36,236
Fixed assets, net	<u>56,352</u>	<u>80,334</u>
Total assets	<u>\$ 25,187,679</u>	<u>\$ 28,204,764</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 275,441	\$ 851,160
Accrued expenses	1,946,251	1,186,429
Current portion of credit facility	<u>77,546</u>	<u>77,546</u>
Total current liabilities	2,299,238	2,115,135
Credit facility, net of current portion and debt discount	<u>1,238,624</u>	<u>1,211,310</u>
Total liabilities	<u>3,537,862</u>	<u>3,326,445</u>
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 12,576,325 and 9,712,521 shares issued and outstanding, respectively	12,576	9,713
Additional paid-in capital	98,938,446	83,478,851
Accumulated other comprehensive income (loss)	129	(8,361)
Accumulated deficit	<u>(77,301,334)</u>	<u>(58,601,884)</u>
Total stockholders' equity	21,649,817	24,878,319
Total liabilities and stockholders' equity	<u>\$ 25,187,679</u>	<u>\$ 28,204,764</u>

ALDEYRA THERAPEUTICS, INC.

STATEMENTS OF OPERATIONS

	Years ended December 31,	
	2016	2015
Operating expenses:		
Research and development	\$ 13,175,670	\$ 7,574,398
General and administrative	5,520,308	4,414,709
Loss from operations	<u>(18,695,978)</u>	<u>(11,989,107)</u>
Other income (expense):		
Interest income	102,037	11,126
Interest expense	<u>(105,509)</u>	<u>(112,306)</u>
Total other expense, net	<u>(3,472)</u>	<u>(101,180)</u>
Net loss	<u>(18,699,450)</u>	<u>(12,090,287)</u>
Net loss per share - basic and diluted	\$ (1.65)	\$ (1.40)
Weighted average common shares outstanding - basic and diluted	<u>11,352,230</u>	<u>8,633,897</u>