

ALDEYRA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 05/15/17 for the Period Ending 05/15/17

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): May 15, 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))

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 May 15, 2017, Aldeyra Therapeutics, Inc. (“Aldeyra”) issued a press release and is holding a conference call regarding its financial results for the quarter ended March 31, 2017. 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, 2016, which is 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, which will be filed with the SEC in the second 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.

SIGNATURES

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: May 15, 2017



Aldeyra Therapeutics Provides Corporate Update and Announces First Quarter 2017 Financial Results

Significant Platform Advancement Across Four Clinical Programs

Details Provided on 2017 and 2018 Catalysts

Lexington, MA, May 15, 2017 – Aldeyra Therapeutics, Inc. (Nasdaq:ALDX) (Aldeyra), a clinical-stage biotechnology company devoted to treating inflammation, inborn errors of metabolism, and other diseases related to aldehydes, today provided a corporate update and announced its financial results for the quarter ended March 31, 2017.

“We are pleased to update our progress with four clinical programs, three of which are now in late-stage development,” commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “We expect results from our Phase 2b clinical trial in allergic conjunctivitis in June of this year, results from our Phase 2a clinical trial in Dry Eye Syndrome in the third quarter of this year, results from our Phase 3 clinical trial in noninfectious anterior uveitis in the second half of next year, and initial top-line data from our Phase 3 clinical trial in Sjögren-Larsson Syndrome in the second half of next year. With the initiation of a Phase 3 clinical trial in noninfectious anterior uveitis, the advancement of our clinical pipeline across four clinical indications - coupled with the receipt of orphan designation for ichthyosis - highlights the productivity achieved in the first quarter.”

Corporate Updates:

- **Expected Timing of Results of Phase 2b Allergic Conjunctivitis Clinical Trial Ahead of Previous Guidance.** In April 2017, Aldeyra announced the completion of enrollment and dosing in a Phase 2b clinical trial of topical ocular ADX-102 in allergic conjunctivitis. The trial tested 0.1% and 0.5% concentrations of topical ocular ADX-102 against saline. Each of the three groups in the trial was comprised of 50 patients with a history of allergic conjunctivitis. Consistent with clinical trials used for registration of other drugs in allergic conjunctivitis, patients in the Phase 2b trial were treated with a single dose of drug or control solution in both eyes, followed by topically administered allergens. Patient-reported ocular itching will be assessed as the primary endpoint. Results from the trial are expected to be announced in June 2017.
- **Data Timeline for Phase 2a Clinical Trial in Dry Eye Syndrome Updated to Third Quarter of 2017.** The Phase 2a clinical trial in Dry Eye Syndrome will test three formulations of topical ocular ADX-102 over 28 days of dosing. Endpoints will include standard signs and symptoms characteristic of Dry Eye Syndrome. Results of the clinical trial are expected to be announced in the third quarter of 2017.
- **Phase 3 Clinical Trial in Noninfectious Anterior Uveitis Initiated in April 2017, Consistent with Previous Guidance.** The Phase 3 noninfectious anterior uveitis clinical trial is expected to enroll up to 100 patients with active disease, randomized equally to receive either 0.5% topical ocular ADX-102 or vehicle for four weeks. The primary endpoint will be the resolution of inflammation. Results of the trial are expected to be announced in the second half of 2018.

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- **Initial Data from Phase 3 Sjögren-Larsson Syndrome (SLS) Clinical Trial Expected in the Second Half of 2018.** The Phase 3 clinical trial in SLS is expected to be performed in two parts: a randomized and controlled assessment over six months of treatment, followed by a crossover design to assess change from baseline in drug-treated patients. Data from part one of the trial will be used to confirm statistical power for part two, and are expected to be available in the second half of next year. In coordination with the advancement of the SLS program to Phase 3 clinical testing, in February 2017, Aldeyra launched the SLS Patient Registry to unite SLS patients, caregivers, physicians, researchers, and other members of the SLS community.
 - **Orphan Drug Designation Granted for ADX-102 in Congenital Ichthyosis, a Debilitating Condition Characteristic of Sjögren-Larsson Syndrome.** In April 2017, Aldeyra announced that the United States Food and Drug Administration (FDA) granted ADX-102 orphan drug designation for the treatment of congenital ichthyosis, a severe skin disease in SLS patients. The FDA Office of Orphan Products Development designates orphan status to drugs intended to treat, diagnose, or prevent rare diseases that affect fewer than 200,000 people in the United States. Receiving Orphan Drug Designation provides Aldeyra with multiple benefits, including waiver of the Prescription Drug User Fee, post-approval marketing exclusivity for seven years, research tax credits, and assistance during the marketing registration process.

First Quarter 2017 Financial Results

For the quarter ended March 31, 2017, Aldeyra reported a net loss of approximately \$5.1 million, compared to a net loss of approximately \$5.0 million for the quarter ended March 31, 2016. Basic and diluted net loss per share was \$0.37 for the quarter ended March 31, 2017, compared to basic and diluted net loss of \$0.51 per share for the quarter ended March 31, 2016. 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 \$3.4 million for the quarter ended March 31, 2017, compared to approximately \$3.5 million for the quarter ended March 31, 2016. The decrease of \$0.1 million is primarily related to the decreases in external research and development expenditures, including manufacturing and pre-clinical activities.

General and administrative expenses were \$1.7 million for the three months ended March 31, 2017, compared to \$1.5 million for the three months ended March 31, 2016. The increase of \$0.2 million is primarily related to an increase in personnel costs, including stock-based compensation, and legal costs.

In February 2017, Aldeyra announced the closing of a \$10.5 million follow-on public offering, which included the full exercise of the underwriters' overallotment. The proceeds of the financing are expected to be used to facilitate clinical operations to support the ongoing clinical trials for its lead product, ADX-102, as well as other novel aldehyde traps, across multiple indications. Cash, cash equivalents, and marketable securities were \$31.2 million as of March 31, 2017.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Monday, May 15, 2017 at 8:00 a.m. ET to discuss the results. The dial-in numbers are 1-719-457-2600 for domestic callers and 1-888-283-6901 for international callers. The conference ID number for both is 6322395. 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 May 14, 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 6322395.

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 the Private Securities Litigation Reform Act of 1995, including statements regarding Aldeyra's plans for its product candidates. 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. 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, 2016, 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, 2017, to be filed with the SEC in the second 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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Aldeyra Therapeutics, Inc.
Balance Sheets

	March 31, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 19,302,850	\$ 12,015,061
Marketable securities	11,909,800	12,897,584
Prepaid expenses and other current assets	260,683	218,682
Total current assets	31,473,333	25,131,327
Fixed assets, net	58,284	56,352
Total assets	<u>\$ 31,531,617</u>	<u>\$ 25,187,679</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 694,922	\$ 275,441
Accrued expenses	1,520,322	1,946,251
Current portion of credit facility	193,866	77,546
Total current liabilities	2,409,110	2,299,238
Credit facility, net of current portion and debt discount	1,127,500	1,238,624
Total liabilities	<u>3,536,610</u>	<u>3,537,862</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 15,131,880 and 12,576,325 shares issued and outstanding, respectively	15,132	12,576
Additional paid-in capital	110,377,077	98,938,446
Accumulated other comprehensive income (loss)	(4,747)	129
Accumulated deficit	<u>(82,392,455)</u>	<u>(77,301,334)</u>
Total stockholders' equity	27,995,007	21,649,817
Total liabilities and stockholders' equity	<u>\$ 31,531,617</u>	<u>\$ 25,187,679</u>

Aldeyra Therapeutics, Inc.
Income Statement

	Three Months ended March 31,	
	2017	2016
Operating expenses:		
Research and development	\$ 3,369,023	\$ 3,511,477
General and administrative	1,726,878	1,455,559
Loss from operations	<u>(5,095,901)</u>	<u>(4,967,036)</u>
Other income (expense):		
Interest income	31,617	24,719
Interest expense	<u>(26,837)</u>	<u>(25,035)</u>
Total other income (expense), net	4,780	(316)
Net loss	<u>\$ (5,091,121)</u>	<u>\$ (4,967,352)</u>
Net loss per share - basic and diluted	<u>\$ (0.37)</u>	<u>\$ (0.51)</u>
Weighted average common shares outstanding - basic and diluted	<u>13,797,312</u>	<u>9,712,521</u>