
**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): August 10, 2016

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 August 10, 2016, Aldeyra Therapeutics, Inc. (“Aldeyra”) issued a press release and is holding a conference call regarding its financial results for the quarter ended June 30, 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 March 31, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, which will be filed with the SEC in the third quarter of 2016.

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	Aldeyra Therapeutics, Inc. Press Release dated August 10, 2016

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: August 10, 2016

EXHIBIT INDEX

**Exhibit
No.**

Description

99.1 Aldeyra Therapeutics, Inc. Press Release dated August 10, 2016



Aldeyra Therapeutics Announces Second Quarter 2016 Financial Results and Provides Corporate Update

Three Positive Clinical Trials Announced in 2016

LEXINGTON, MA — (Marketwired) – 8/10/2016 — Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to aldehydes, today reported second quarter financial results and provided a corporate update.

“We are extremely pleased with our progress through the first half of the year with our novel aldehyde trap, NS2,” said Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “In February, we reported positive Phase II clinical trial results in allergic conjunctivitis, and in May, we reported positive Phase II clinical trial results in noninfectious anterior uveitis. Yesterday, we announced positive results from our randomized, double-blind, vehicle controlled clinical trial in patients with Sjögren-Larsson Syndrome, a rare inborn error of metabolism with no FDA-approved therapy.”

Dr. Brady continued, “In aggregate, the clinical trial results this year validate NS2 and the aldehyde trap platform as a potentially important therapeutic approach in inflammation and inborn errors of aldehyde metabolism. We look forward to continuing the development of NS2 in these and other clinical indications with unmet medical need.”

Recent Highlights

- **Reported positive results from a randomized, double-blind, vehicle controlled clinical trial in patients with Sjögren-Larsson Syndrome.** Aldeyra recently reported positive data from a randomized, parallel-group, double-blind, vehicle-controlled, multi-center clinical trial of topical NS2 for the treatment of the dermatologic manifestations of Sjögren-Larsson Syndrome (SLS). Patients with SLS, a rare inborn error of aldehyde metabolism, suffer from ichthyosis, a debilitating dermatologic disease characterized by dry, thickened, scaly skin. The symptoms of SLS are thought to be related to high levels of toxic fatty aldehydes due to genetic mutations in fatty aldehyde dehydrogenase, an enzyme critical for the normal function of skin and other organs. NS2 is specifically designed to reduce levels of toxic aldehydes, and is the first therapy to be directed at the putative cause of SLS. In the clinical trial, NS2 consistently produced clinically meaningful effects in reducing the severity of ichthyosis that exceeded vehicle response.
- **Reported positive results from Phase II clinical trial in patients with noninfectious anterior uveitis.** In May 2016, Aldeyra reported positive data from a randomized, parallel-group, multi-center, investigator-masked, active-controlled Phase II clinical trial in subjects with noninfectious anterior uveitis. Forty-five patients were randomized to receive either NS2 or Pred-Forte®, a standard-of-care corticosteroid that leads to elevations of intraocular pressure in some patients, or a combination of NS2 and Pred-Forte®. Results from this study demonstrated that NS2 was as clinically effective as Pred-Forte but did not increase intraocular pressure.

- **Reported positive results from Phase II clinical trial in subjects with allergic conjunctivitis.** In February 2016, Aldeyra reported that the results of a randomized, parallel-group, single-center, double-masked, vehicle-controlled Phase II clinical trial of topical ocular NS2 in subjects with induced allergic conjunctivitis demonstrated statistically significant and sustained activity of NS2 over vehicle in reducing ocular itching and tearing.

Second Quarter 2016 Financial Review

For the quarter ended June 30, 2016, Aldeyra reported a net loss of approximately \$4.3 million compared to a net loss of approximately \$2.2 million for the quarter ended June 30, 2015. Basic and diluted net loss per share was \$0.41 for the quarter ended June 30, 2016 compared to basic and diluted net loss of \$0.27 per share for the quarter ended June 30, 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 approximately \$2.8 million for the quarter ended June 30, 2016 compared to approximately \$1.2 million for the quarter ended June 30, 2015. The increase of approximately \$1.6 million is primarily related to the increase in Aldeyra's external research and development expenditures, including preclinical, manufacturing and clinical development activities and an increase in personnel costs, including stock-based compensation due to an increase in headcount.

General and administrative expenses were approximately \$1.5 million for the quarter ended June 30, 2016, compared to approximately \$955,000 for the quarter ended June 30, 2015. The increase of approximately \$507,000 was primarily related to an increase in insurance costs, legal costs and personnel costs, including stock-based compensation due to an increase in headcount.

During the quarter, Aldeyra sold in an underwritten public offering 2,760,000 shares of its common stock, including 360,000 shares sold in connection with the exercise in full by the underwriter of its option to purchase additional shares. The net proceeds of the offering, including the full exercise of the option, were approximately \$12.6 million, after deducting the underwriting discounts and commissions and the other estimated offering expenses payable by Aldeyra.

Cash, cash equivalents and marketable securities were approximately \$32.5 million at June 30, 2016.

Conference Call and Webcast Information

The Company will hold a conference call on Wednesday, August 10, 2016 at 8:00 a.m. EDT to discuss the results and operational updates. The dial-in numbers are 1-800-211-3767 for domestic callers and 1-719-325-2493 for international callers. The conference ID number for both is 6212040. 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 August 10, 2017. 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 6212040.

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, NS2, 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. NS2 has not been approved for sale in the U.S. or elsewhere.

About NS2

NS2 is an aldehyde-binding small molecule based on an innovative platform technology focused on trapping aldehydes, which are toxic and pro-inflammatory mediators of numerous diseases. By decreasing aldehyde load, NS2 may mitigate excessive inflammation and address diseases where aldehyde metabolism is impaired, including certain inborn errors of metabolism.

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.

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 March 31, 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, to be filed with the SEC in the third quarter of 2016.

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ALDEYRA THERAPEUTICS, INC.
BALANCE SHEETS

	<u>June 30,</u> <u>2016 (Unaudited)</u>	<u>December 31,</u> <u>2015</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 17,607,522	\$ 14,648,866
Marketable securities	14,940,912	\$ 12,941,776
Prepaid expenses and other current assets	260,087	497,552
Total current assets	32,808,521	28,088,194
Deferred offering costs	—	36,236
Fixed assets, net	75,027	80,334
Total assets	<u>\$ 32,883,548</u>	<u>\$ 28,204,764</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 823,301	\$ 851,160
Accrued expenses	1,084,591	1,186,429
Accrued deferred offering costs	155,122	—
Current portion of credit facility	310,185	77,546
Total current liabilities	2,373,199	2,115,135
Credit facility, net of current portion and debt discount	992,625	1,211,310
Total liabilities	<u>3,365,824</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 as of June 30, 2016 and December 31, 2015	—	—
Common stock, voting, \$0.001 par value; 150,000,000 authorized and 12,472,521 shares issued and outstanding as of June 30, 2016 and 9,712,521 shares issued and outstanding as of December 31, 2015	12,473	9,713
Additional paid-in capital	97,372,402	83,478,851
Accumulated other comprehensive income (loss), net of tax	4,703	(8,361)
Accumulated deficit	(67,871,854)	(58,601,884)
Total stockholders' equity	29,517,724	24,878,319
Total liabilities and stockholders' equity	<u>\$ 32,883,548</u>	<u>\$ 28,204,764</u>

ALDEYRA THERAPEUTICS, INC.
STATEMENT OF OPERATIONS
(unaudited)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Operating expenses:				
Research and development	\$ 2,834,523	\$ 1,249,097	\$ 6,346,037	\$ 2,385,531
General and administrative	1,462,227	954,879	2,917,750	1,926,980
Loss from operations	<u>(4,296,750)</u>	<u>(2,203,976)</u>	<u>(9,263,787)</u>	<u>(4,312,511)</u>
Other income (expense):				
Interest income	21,951	—	46,671	—
Interest expense	<u>(27,817)</u>	<u>(28,210)</u>	<u>(52,853)</u>	<u>(56,234)</u>
Total other income (expense), net	<u>(5,866)</u>	<u>(28,210)</u>	<u>(6,182)</u>	<u>(56,234)</u>
Net loss	<u>\$ (4,302,616)</u>	<u>\$ (2,232,186)</u>	<u>\$ (9,269,969)</u>	<u>\$ (4,368,745)</u>
Net loss per share - Basic and Diluted	<u>\$ (0.41)</u>	<u>\$ (0.27)</u>	<u>\$ (0.91)</u>	<u>\$ (0.58)</u>
Weighted average common shares outstanding - Basic and Diluted	<u>10,622,411</u>	<u>8,397,713</u>	<u>10,167,466</u>	<u>7,537,396</u>

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