

ALDEYRA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

Filed 08/08/17 for the Period Ending 08/08/17

Address	131 HARTWELL AVENUE SUITE 320 LEXINGTON, MA 02421
Telephone	781-761-4904
CIK	0001341235
Symbol	ALDX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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 8, 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 August 8, 2017, Aldeyra Therapeutics, Inc. (“Aldeyra”) issued a press release and is holding a conference call regarding its financial results for the quarter ended June 30, 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,” “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 Aldeyra’s 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 and Aldeyra’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC’s website at www.sec.gov.

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 8, 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: August 8, 2017

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Aldeyra Therapeutics, Inc. Press Release dated August 8, 2017



Aldeyra Therapeutics Announces Second Quarter 2017 Financial Results

Lexington, MA, August 8, 2017 – Aldeyra Therapeutics, Inc. (Nasdaq:ALDX) (Aldeyra or the Company), a clinical-stage biotechnology company devoted to treating inflammation, inborn errors of metabolism, and other diseases related to aldehydes, today announced its financial results for the quarter ended June 30, 2017.

“With the release of allergic conjunctivitis Phase 2b clinical trial results in the second quarter, we were pleased to announce our third Phase 3 clinical program,” commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “We are determined to continue to advance our novel aldehyde trap platform toward commercialization, with the goal of providing a novel pharmacologic approach to patients with limited safe and effective therapeutic options for severe inflammation or inborn errors of aldehyde metabolism.”

Corporate Updates and Expected Milestones:

- Phase 3 Clinical Testing of ADX-102 in Allergic Conjunctivitis Planned Following End of Phase 2 Meeting with Regulatory Authorities.** Based on the results of Aldeyra’s Phase 2b clinical trial in allergic conjunctivitis reported in June 2017, Aldeyra plans to begin Phase 3 clinical testing of ADX-102 following an End of Phase 2 Meeting with regulatory authorities in the second half of 2017. The randomized, dose-ranging, parallel-group, double-masked, saline-controlled, multi-center Phase 2b clinical trial of topical ocular ADX-102 in 154 allergic conjunctivitis patients demonstrated statistically significant improvement in ocular itch relative to control. Consistent with Phase 2a clinical results, the sustained clinical activity of ADX-102 in the Phase 2b clinical trial was distinct from the activity of antihistamines, a commonly used therapy that is only partially effective in many allergic conjunctivitis patients. Aldeyra believes that the differentiated mechanism of action of ADX-102 could apply to millions of allergic conjunctivitis patients in the United States.
- Data from Phase 2a Clinical Trial in Dry Eye Disease (DED) Expected to be Announced in September 2017.** The Phase 2a clinical trial is a single-center, double-blind, randomized trial testing three formulations of topical ocular ADX-102 (ADX-102 0.5% ophthalmic solution, ADX-102 0.1% ophthalmic solution, and ADX-102 0.5% ophthalmic lipid solution) over 28 days of treatment. Endpoints will include standard signs and symptoms characteristic of DED, a bothersome and generally poorly treated inflammatory condition that represents one of the largest ophthalmic markets worldwide.
- Noninfectious Anterior Uveitis (NAU) Phase 3 Clinical Results Expected to be Announced in the Second Half of 2018.** In April 2017, Aldeyra initiated a randomized, parallel-group, double-masked, vehicle-controlled, multi-center Phase 3 clinical trial of ADX-102 0.5% ophthalmic solution in up to 100 patients with active NAU. The primary endpoint is resolution of inflammation as measured by inflammatory cell count in the anterior chamber of the eye, the same endpoint assessed in the positive Phase 2 clinical trial of ADX-102 announced last year. NAU is a potentially blinding inflammatory ocular disease that is typically treated with topical corticosteroids, which can result in glaucoma, cataracts, and other serious ocular toxicities.

-
- **Initial Results from Phase 3 Trial in Sjögren-Larsson Syndrome (SLS) Expected in the Second Half of 2018.** The Phase 3 clinical trial in SLS, an inborn error of aldehyde metabolism characterized by severe skin and neurological disease, is expected to be performed in two parts: a randomized and controlled assessment over six months of treatment, followed by a crossover design to evaluate change from baseline in drug-treated patients. Data from the first part of the trial will be used to confirm statistical power for the second part. In coordination with the start of the Phase 3 clinical trial, Aldeyra has launched the SLS Patient Registry with the intention of increasing the Company's profile among SLS patients, caregivers, physicians, researchers, and other members of the SLS community. The results from part one of the Phase 3 SLS trial are expected in the second half 2018. There is no FDA-approved therapy for the treatment of SLS.
 - **Novel Data on the Anti-Inflammatory Mechanism and Activity of ADX-102 Presented at the World Congress on Inflammation 2017 Annual Meeting.** In July 2017, Aldeyra presented the differentiated effects of ADX-102 on the down-regulation of inflammatory cell migration and activation in a mouse model of endotoxin-induced lung injury. The data demonstrate that the anti-inflammatory effects of ADX-102 differ from that of corticosteroids, building on existing evidence that aldehyde sequestration represents a novel anti-inflammatory therapeutic approach.

Second Quarter 2017 Financial Results

For the quarter ended June 30, 2017, Aldeyra reported a net loss of approximately \$5.3 million, compared to a net loss of approximately \$4.3 million for the quarter ended June 30, 2016. Basic and diluted net loss per share was \$0.35 for the quarter ended June 30, 2017, compared to basic and diluted net loss of \$0.41 per share for the quarter ended June 30, 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 \$3.8 million for the three months ended June 30, 2017, compared to \$2.8 million for the three months ended June 30, 2016. The increase of \$1.0 million is primarily related to the increases in our external research and development expenditures, including clinical and pre-clinical activities, partially offset by a reduction in manufacturing expenses.

General and administrative expenses were \$1.5 million for the three months ended June 30, 2017, compared to \$1.5 million for the three months ended June 30, 2016.

Cash, cash equivalents, and marketable securities were \$25.8 million as of June 30, 2017.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Tuesday, August 8, 2017, at 8:00 a.m. eastern time to discuss the results. The dial-in numbers are 1-877-870-4263 for domestic callers and 1-412-317-0790 for international callers. 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 7, 2018.

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 Allergic Conjunctivitis

Allergic conjunctivitis is a common allergic disease that affects 20-40% of the worldwide population, and is thought to be mediated in part by pro-inflammatory aldehydes. Symptoms include ocular itching, excessive tear production, lid swelling, and redness. Approximately one-third of allergic conjunctivitis patients do not adequately respond to standard-of-care therapy.

About Dry Eye Disease

Dry Eye Disease (DED) 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 DED, aldehydes may contribute to ocular inflammation as well as the impairment of lipids (fats) that lubricate the surface of the eye. Therapy for DED is generally considered by physicians and patients to be inadequate.

About Noninfectious Anterior Uveitis

Noninfectious anterior uveitis (NAU) 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. The only approved therapy for NAU is topical corticosteroids, which can cause serious ocular side effects, including glaucoma, cataracts, and infection.

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.

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 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. 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.

Corporate Contact:

Stephen Tulipano
Aldeyra Therapeutics, Inc.
Tel: +1 781-761-4904 Ext. 205
stulipano@aldeyra.com

Investor Contact:

Chris Brinzey
Westwicke Partners
Tel: 339-970-2843
Chris.brinzey@westwicke.com

Media Contact:

Cammy Duong
MacDougall Biomedical Communications
Tel: 781-591-3443
cduong@macbiocom.com

ALDEYRA THERAPEUTICS, INC.
BALANCE SHEETS

	June 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 14,609,742	\$ 12,015,061
Marketable securities	11,210,796	12,897,584
Prepaid expenses and other current assets	521,483	218,682
Total current assets	26,342,021	25,131,327
Deferred offering costs	77,942	—
Fixed assets, net	47,981	56,352
Total assets	\$ 26,467,944	\$ 25,187,679
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 762,681	\$ 275,441
Accrued expenses	1,038,905	1,946,251
Current portion of credit facility	310,185	77,546
Total current liabilities	2,111,771	2,299,238
Credit facility, net of current portion and debt discount	1,016,377	1,238,624
Total liabilities	3,128,148	3,537,862
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 15,150,176 and 12,576,325 shares issued and outstanding, respectively	15,150	12,576
Additional paid-in capital	111,030,501	98,938,446
Accumulated other comprehensive income (loss)	(4,640)	129
Accumulated deficit	(87,701,215)	(77,301,334)
Total stockholders' equity	23,339,796	21,649,817
Total liabilities and stockholders' equity	\$ 26,467,944	\$ 25,187,679

ALDEYRA THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(UNAUDITED)

	<u>Three Months ended June 30,</u>		<u>Six Months ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Operating expenses:				
Research and development	\$ 3,848,889	\$ 2,834,523	\$ 7,217,912	\$ 6,346,037
General and administrative	1,481,792	1,462,227	3,208,670	2,917,750
Loss from operations	<u>(5,330,681)</u>	<u>(4,296,750)</u>	<u>(10,426,582)</u>	<u>(9,263,787)</u>
Other income (expense):				
Interest income	48,384	21,951	80,002	46,671
Interest expense	<u>(26,463)</u>	<u>(27,817)</u>	<u>(53,301)</u>	<u>(52,853)</u>
Total other income (expense), net	21,921	(5,866)	26,701	(6,182)
Net loss	<u>\$ (5,308,760)</u>	<u>\$ (4,302,616)</u>	<u>\$ (10,399,881)</u>	<u>\$ (9,269,969)</u>
Net loss per share - basic and diluted	<u>\$ (0.35)</u>	<u>\$ (0.41)</u>	<u>\$ (0.72)</u>	<u>\$ (0.91)</u>
Weighted average common shares outstanding - basic and diluted	<u>15,136,399</u>	<u>10,622,411</u>	<u>14,470,555</u>	<u>10,167,466</u>

###