ALDEYRA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

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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): November 9, 2017

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**

(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 November 9, 2017, Aldeyra Therapeutics, Inc. ("Aldeyra") issued a press release and is holding a conference call regarding its financial results for the quarter ended September 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. Additional information will also be set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, which will be filed with the SEC in the fourth 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

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated November 9, 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: November 9, 2017

Exhibit 99.1

Aldeyra Therapeutics Announces Third Quarter 2017 Financial Results

LEXINGTON, Mass., November 9, 2017 /PRNewswire/ — 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 endogenous aldehyde toxicity, today announced financial results for the quarter ended September 30, 2017.

"The announcement of clinical results in dry eye disease in the third quarter marks the fifth positive Phase 2 clinical trial of our lead aldehyde trap, reproxalap, formerly known as ADX-102," commented Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Given the consistent clinical activity of reproxalap across large-market and orphan diseases, we now look to expand our pipeline with new molecules in new indications, and, last quarter, we were pleased to announce development of ADX-103 for retinal disease."

Third Quarter Highlights:

- **Reported Positive Results from Phase 2a Clinical Trial in Dry Eye Disease** . In September 2017, Aldeyra reported positive results from a Phase 2a clinical trial of reproxalap in dry eye disease, a common and sub-optimally treated chronic ocular disorder. The results demonstrated statistically and clinically significant improvement across multiple sign and symptom endpoints, and onset of action was observed within one week of therapy, markedly faster than standard of care. Supportive of drug activity, reduction in levels of pro-inflammatory aldehydes was correlated with improvement in ocular staining scores and tear osmolarity.
- **Announced New Results from Phase 2b Allergic Conjunctivitis Clinical Trial Demonstrating Clinically Relevant Activity of Reproxalap.** Analysis of the previously reported Phase 2b results demonstrated that patients treated with reproxalap were more than three times more likely than vehicle-treated patients ($p<0.05$) to improve in ocular itch score (range 0 to 4) by one point, an amount consistent with U.S. Food and Drug Administration standards for regulatory approval and clinical relevance. Additionally, time to clinical response was more rapid in drug groups than in the vehicle group ($p<0.01$). Allergic conjunctivitis is a persistently disturbing and common ocular disease affecting 20% or more of the worldwide population.
- **Introduced Novel Aldehyde Trap ADX-103 as a Product Candidate for the Treatment of Retinal Disease.** In preclinical retinal disease models of macular degeneration, uveitis, and diabetic macular edema, ADX-103 (a novel aldehyde trap that is structurally distinct from reproxalap) demonstrated consistent activity that was at least as potent as that of reproxalap. Additional results are expected to be released at a major scientific meeting in 2018.
- **Adoption of Reproxalap as Generic Name for ADX-102.** Reproxalap, the generic name for the first-in-class aldehyde trap, formerly known as ADX-102, has been adopted by the United States Adopted Names Council and the International Nonproprietary Names Expert Group. The name incorporates a new stem for aldehyde traps, "-alap", and recognizes aldehyde traps as a novel class of drug.

- **2017 Research & Development Day.** On October 10, 2017, Aldeyra hosted its Research & Development Day, which featured presentations from key ocular inflammation opinion leaders on the therapeutic and market potential of Aldeyra's late-stage aldehyde trap platform in dry eye disease and allergic conjunctivitis, two closely related ocular inflammatory conditions that, in aggregate, represent one of the largest topical ophthalmic markets worldwide. An archived webcast of the event can be found under the Events section of Aldeyra's investor website.

Expected Clinical Milestones:

- Phase 3 Allergic Conjunctivitis Expected to Begin in the First Half of 2018; Results Expected to be Announced in the Second Half of 2018
- Phase 2b Dry Eye Disease Expected to Begin in the First Half of 2018; Results Expected to be Announced in the Second Half of 2018
- Phase 3 Noninfectious Anterior Uveitis Results Expected to be Announced in the Second Half of 2018
- Phase 3 Sjögren-Larsson Syndrome Expected to Begin in the First Half of 2018; Initial Results Expected to be Announced in the Second Half of 2018

Third Quarter 2017 Financial Results

For the third quarter, Aldeyra reported a net loss of approximately $5.0 million, compared to a net loss of approximately $4.8 million for the quarter ended September 30, 2016. Basic and diluted net loss per share was $0.32 for the quarter ended September 30, 2017, compared to basic and diluted net loss of $0.38 per share for the quarter ended September 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 $3.5 million for the three months ended September 30, 2017, compared to $3.4 million for the three months ended September 30, 2016. The increase of $0.1 million is primarily related to the increases in external research and development expenditures, including clinical, preclinical, and manufacturing expenses.

General and administrative expenses were $1.5 million for the three months ended September 30, 2017, compared to $1.4 million for the three months ended September 30, 2016.

Cash, cash equivalents, and marketable securities were $47.9 million as of September 30, 2017, including $26.9 million in net proceeds from the underwritten public offering of common stock that closed on September 21, 2017.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Thursday, November 9, 2017, at 8:00 a.m. eastern time to discuss the results. The dial-in numbers are 1-877-266-8979 for domestic callers and 1-412-317-5231 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.

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, reproxalap, formerly known as ADX-102, is an aldehyde trap in development as topical eye drops for the treatment of ocular inflammation. Reproxalap has now been tested in over 250 patients in Phase 2 clinical trials in dry eye disease, allergic conjunctivitis, and noninfectious anterior uveitis. A dermatologic formulation of reproxalap is in late-stage clinical development for the treatment of ichthyosis due to Sjögren-Larsson Syndrome, an inborn error of aldehyde metabolism. Reproxalap has not been approved for sale in the U.S. or elsewhere.

About Dry Eye Disease

Dry eye disease is a common inflammatory disease estimated to affect approximately 20 million people in the United States, and is characterized by insufficient moisture and lubrication in the anterior surface of the eye, leading to dryness, inflammation, pain, discomfort, irritation, and in severe cases, decreased vision. Among physicians and patients, existing therapy for dry eye disease is generally regarded as inadequate. In patients with dry eye disease, pro-inflammatory aldehyde mediators may contribute to ocular inflammation. By diminishing aldehyde levels, Aldeyra's topical ocular aldehyde trap platform represents a novel and differentiated approach for the treatment of dry eye disease.

About Allergic Conjunctivitis

Allergic conjunctivitis is a common allergic disease that affects 20% or more of the population worldwide. The disease 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 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 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 ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. No therapy for SLS 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 and expectations for the development of Reproxalap and ADX-103; and the potential of Reproxalap as an agent for the treatment of dry eye disease and allergic conjunctivitis and ADX-103 as an agent for the treatment of retinal disease. 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; updated or refined data based on Aldeyra's continuing review and quality control analysis of clinical data, Aldeyra's ability to design clinical trials with protocols and endpoints acceptable to applicable regulatory authorities, 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 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. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, to be filed with the SEC in the fourth 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

	September 30, 2017 (unaudited)	December 31, 2016
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,103,849	$ 12,015,061
Marketable securities	14,807,166	12,897,584
Prepaid expenses and other current assets	1,141,727	218,682
Total current assets	49,052,742	25,131,327
Deferred offering costs	138,661	—
Fixed assets, net	38,017	56,352
Total assets	$ 49,229,420	$ 25,187,679
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 485,267	$ 275,441
Accrued expenses	1,507,458	1,946,251
Current portion of credit facility	426,505	77,546
Total current liabilities	2,419,230	2,299,238
Credit facility, net of current portion and debt discount	905,253	1,238,624
Total liabilities	3,324,483	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 19,117,676 and 12,576,325 shares issued and outstanding, respectively	19,118	12,576
Additional paid-in capital	138,574,234	98,938,446
Accumulated other comprehensive income (loss)	(1,002)	129
Accumulated deficit	(92,687,413)	(77,301,334)
Total stockholders' equity	45,904,937	21,649,817
Total liabilities and stockholders' equity	$ 49,229,420	$ 25,187,679

ALDEYRA THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three Months ended September 30,		Nine Months ended September 30,	
	2017	2016	2017	2016
Operating expenses:				
Research and development	$ 3,539,368	$ 3,379,711	$ 10,757,279	$ 9,728,494
General and administrative	1,475,904	1,396,734	4,684,574	4,314,483
Loss from operations	(5,015,272)	(4,776,445)	(15,441,853)	(14,042,977)
Other income (expense):				
Interest income	56,651	27,792	136,652	74,463
Interest expense	(27,578)	(26,654)	(80,878)	(79,507)
Total other income (expense), net	29,073	1,138	55,774	(5,044)
Net loss	$ (4,986,199)	$ (4,775,307)	$ (15,386,079)	$ (14,048,021)
Net loss per share - basic and diluted	$ (0.32)	$ (0.38)	$ (1.04)	$ (1.28)
Weighted average common shares outstanding - basic and diluted	15,581,426	12,474,609	14,844,914	10,942,127

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