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ALDEYRA THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 05/15/18 for the Period Ending 05/15/18

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, 2018

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 May 15, 2018, Aldeyra Therapeutics, Inc. ("Aldeyra") issued a press release and is holding a conference call regarding its financial results for the quarter ended March 31, 2018. 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 strategy, future operations, future, prospects, plans, and objectives and Aldeyra's plans and expectations 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. 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. 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 of 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 and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use 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, 2017, 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, 2018, expected to be filed with the SEC in the second quarter of 2018.

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 May 15, 2018

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: May 15, 2018

Exhibit 99.1

Aldeyra Therapeutics Announces First Quarter 2018 Financial Results

LEXINGTON, Mass., May 15, 2018 /PRNewswire/ — Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) (Aldeyra), a biotechnology company devoted to development of next-generation medicines to improve the lives of patients with immune-mediated diseases, today announced financial results for the first quarter ended March 31, 2018.

"We are pleased with our progress in the first quarter, as we continued to advance our product pipeline for the treatment of immunological diseases," stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. "Our research collaboration with Johnson & Johnson Innovation to develop novel drug candidates for systemic inflammatory diseases, the initiation of late-stage clinical testing in dry eye disease and allergic conjunctivitis, and the poster presentations of our ocular inflammation programs, all highlight the promise of our platform across a number of product candidates and indications. We look forward to multiple milestones over the next year, including Phase 2b and Phase 3 clinical results in dry eye disease and allergic conjunctivitis, respectively."

Recent Highlights

- **Reproxalap, a novel late-stage product candidate focused on a broad spectrum of inflammatory diseases, continued to progress.**
  - In January 2018, Aldeyra initiated the enrollment of a Phase 2b clinical trial in patients with dry eye disease (DED). The trial will assess two concentrations of topical reproxalap (0.1% and 0.25%) against vehicle over 12 weeks of treatment in 300 patients with moderate DED. Consistent with Aldeyra's Phase 2a DED clinical trial, endpoints will include standard signs and symptoms characteristic of the disease. Results from the trial are expected to be announced in the second half of 2018.
  - In April 2018, Aldeyra enrolled the first patient in a Phase 3 allergic conjunctivitis clinical trial. The multi-center, double-masked, parallel-group, vehicle-controlled trial is expected to enroll 300 patients, randomized equally to receive either topical ocular 0.25% reproxalap, 0.5% reproxalap, or vehicle in a conjunctival allergen challenge model of acute allergic conjunctivitis. The primary outcome measure will be patient-reported ocular itching. Results from the trial are expected in the second half of 2018, or early 2019.
- **Research collaboration initiated with Johnson & Johnson Innovation to advance immune-modulating drugs for systemic inflammatory diseases.** In February 2018, Aldeyra entered into an agreement with Janssen Research & Development, LLC (Janssen), one of the Janssen Pharmaceutical Companies of Johnson & Johnson, to collaborate with Janssen on the development of novel product candidates designed to sequester pro-inflammatory reactive aldehyde species (RASP). The agreement is intended to advance existing analogs of reproxalap for the treatment of systemic inflammatory diseases.

- **Reproxalap and ADX-103, novel RASP scavengers, featured in a podium presentation and three posters at the 2018 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting.** In May 2018, Aldeyra held a podium presentation on the Phase 2a clinical trial results of reproxalap in DED. In addition, Aldeyra presented a poster on the Phase 2b clinical trial results of reproxalap in allergic conjunctivitis, as well as two posters demonstrating activity of reproxalap and ADX-103 in preclinical models of pan-ocular and retinal inflammation, diabetic macular edema, and dry age-related macular degeneration.
- **David McMullin joins Aldeyra as Senior Vice President Corporate Development and Strategy.** In May 2018, Aldeyra hired David McMullin to oversee Aldeyra's commercial planning, corporate development, and business development activities. Formerly of Shire plc, GlaxoSmithKline plc, and Novartis AG, Mr. McMullin brings extensive experience leading business development, strategic planning, commercial, and operational activities in the biopharmaceutical industry.

Quarter Ended March 31, 2018 Financial Review

For the quarter ended March 31, 2018, Aldeyra reported a net loss of approximately $8.4 million, compared to a net loss of approximately $5.1 million for the quarter ended March 31, 2017. Basic and diluted net loss per share was $0.43 for the quarter ended March 31, 2018, compared to $0.37 per share for the same period in 2017. 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 $6.6 million for the quarter ended March 31, 2018, compared to $3.4 million for the same period in 2017. The increase of $3.2 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 $1.9 million for the quarter ended March 31, 2018, compared to $1.7 million for the quarter ended 2017. The increase of $0.2 million is primarily related to an increase in legal and patent-related costs, rent, consulting costs, and personnel costs.

For the quarter ended March 31, 2018, total operating expenses were approximately $8.5 million, compared to total operating expenses of approximately $5.1 million for the same period in 2017.

Cash, cash equivalents, and marketable securities were $38.9 million as of March 31, 2018.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Tuesday, May 15, 2018, at 8:00 a.m. Eastern Daylight 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 is developing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead product candidate, reproxalap, is a first-in-class treatment in late-stage development for dry eye disease and other forms of ocular inflammation. Aldeyra is leveraging its experience in ocular inflammation to develop other product candidates for systemic inflammatory disease. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

About Dry Eye Disease

Dry eye disease is a common and chronic inflammatory disease estimated to affect approximately 20 million people in the United States, and is characterized by insufficient moisture 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.

About Allergic Conjunctivitis

Allergic conjunctivitis is a common allergic disease that affects 20% or more of the population worldwide. The disease 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. Antihistamines are commonly used to treat allergic conjunctivitis, but use is limited by lack of durable activity and ocular dryness.

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 strategy, future operations, future, prospects, plans, and objectives and Aldeyra's plans and expectations 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. 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. 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 of 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 and pricing for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency or use 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, 2017, 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, 2018, expected to be filed with the SEC in the second quarter of 2018.

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ALDEYRA THERAPEUTICS, INC.
BALANCE SHEETS
(UNAUDITED)

	March 31, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	$ 20,963,541	$ 20,023,337
Marketable securities	17,974,600	22,923,462
Prepaid expenses and other current assets	1,666,898	1,018,967
Total current assets	40,605,039	43,965,766
Deferred offering costs	—	165,930
Fixed assets, net	170,862	43,262
Total assets	$ 40,775,901	$ 44,174,958
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,618,889	$ 1,000,963
Accrued expenses	1,815,428	2,236,465
Current portion of credit facility	232,639	116,319
Total current liabilities	3,666,956	3,353,747
Credit facility, net of current portion and debt discount	1,107,741	1,220,192
Total liabilities	4,774,697	4,573,939
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 19,664,921 and 19,137,639 shares issued and outstanding, respectively	19,665	19,138
Additional paid-in capital	144,036,909	139,241,635
Accumulated other comprehensive loss	(16,385)	(17,831)
Accumulated deficit	(108,038,985)	(99,641,923)
Total stockholders' equity	36,001,204	39,601,019
Total liabilities and stockholders' equity	$ 40,775,901	$ 44,174,958

ALDEYRA THERAPEUTICS, INC.
STATEMENT OF OPERATIONS
(UNAUDITED)

	Three Months ended March 31,	
	2018	**2017**
Operating expenses:		
Research and development	$ 6,600,106	$ 3,369,023
General and administrative	1,891,303	1,726,878
Loss from operations	(8,491,409)	(5,095,901)
Other income (expense):		
Interest income	122,390	31,617
Interest expense	(28,044)	(26,837)
Total other income, net	94,346	4,780
Net loss	$ (8,397,063)	$ (5,091,121)
Net loss per share — basic and diluted	$ (0.43)	$ (0.37)
Weighted average common shares outstanding — basic and diluted	19,366,790	13,797,312