
**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 9, 2018

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 9, 2018, Aldeyra Therapeutics, Inc. (“Aldeyra”) issued a press release and is holding a conference call regarding its financial results for the quarter ended June 30, 2018. The press release also detailed certain recent corporate updates. 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 successfully integrate its new senior management team members; 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 and quarter ended March 31, 2018, both of 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 June 30, 2018, expected to be filed with the SEC in the third 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 August 9, 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/ Joshua Reed

Name: Joshua Reed

Title: Chief Financial Officer

Dated: August 9, 2018

**Aldeyra Therapeutics Announces Second Quarter 2018 Financial Results
and Provides Corporate Update**

Phase 2b Results for Topical Ocular Reproxalap in Dry Eye Disease Expected in Late Third Quarter or Early Fourth Quarter 2018

Clinical Results from Investigator-Sponsored Trial of ADX-1612 in Mesothelioma Expected to be Released at the International Association for the Study of Lung Cancer Conference in September 2018

LEXINGTON, Mass., August 9, 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 second quarter ended June 30, 2018 and provided a corporate update.

“As our lead product candidate reproxalap has advanced to four late-stage clinical programs, our development pipeline continues to grow, and now features a number of novel compounds across multiple diseases and mechanisms of action,” stated Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “We look forward to announcing Phase 2b clinical results in dry eye disease late third quarter or early fourth quarter this year, Phase 3 clinical results in allergic conjunctivitis late this year or early next year, Phase 3 Part 1 clinical results in Sjögren-Larsson Syndrome next year, and Phase 3 results in noninfectious anterior uveitis next year. Additionally, in September, we expect to announce clinical results from an investigator-sponsored clinical trial with ADX-1612 in malignant mesothelioma.”

Recent Highlights and Corporate Updates

- **Phase 2b Clinical Results in Dry Eye Disease Expected in Late Third Quarter or Early Fourth Quarter 2018.** In July 2018, Aldeyra announced that the last patient completed dosing in a randomized, double-masked, vehicle-controlled, multi-center, parallel-group Phase 2b clinical trial of topical ocular reproxalap in dry eye disease. The clinical trial will measure the activity of reproxalap versus vehicle on standard dry eye disease signs and symptoms. Since reproxalap has not been previously tested against vehicle in patients with dry eye disease, the trial was not statistically powered, and the primary objective of the trial is to select the number of patients, the drug concentration, and the clinical endpoints for Phase 3 clinical testing.
- **Clinical Results from the MESO-2 Trial in Malignant Mesothelioma Expected to be Released at the International Association for the Study of Lung Cancer Conference September 23-26, 2018.** In combination with pemetrexed and cisplatin or carboplatin, ADX-1612, a novel Heat Shock Protein 90 (HSP90) inhibitor, was studied in the MESO-02 investigator-sponsored clinical trial for malignant mesothelioma. Results from the trial are expected to inform the feasibility of subsequent, pivotal clinical testing of ADX-1612 in malignant mesothelioma.

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- **Phase 3 Clinical Results from the ALLEVIATE Trial in Allergic Conjunctivitis Expected in Late 2018 or Early 2019.** In April 2018, Aldeyra announced that the first patient was enrolled in a multi-center, double-masked, parallel-group, vehicle-controlled Phase 3 clinical trial of topical ocular reproxalap in an allergen challenge model of allergic conjunctivitis. In addition, in preparation for a subsequent Phase 3 clinical trial, Aldeyra is conducting two clinical method development studies to assess the feasibility of measuring ocular itching following environmental exposure to allergen in subsequent Phase 3 clinical testing.
 - **Phase 3 Clinical Results from the RESET Part 1 Trial in Sjögren-Larsson Syndrome Expected in 2019.** In July 2018, Aldeyra enrolled the first patient in a two-part, pivotal, Phase 3 clinical trial of topical dermal reproxalap for the treatment of ichthyosis (scaly, thickened, dry skin) associated with Sjögren-Larsson Syndrome. The primary objective of the first part of the clinical trial is to confirm statistical power for part 2 of the trial, which is expected to assess improvement in ichthyosis in drug-treated patients over six months of therapy.
 - **Phase 3 Clinical Results from the SOLACE Trial in Noninfectious Anterior Uveitis Expected in 2019.** In April 2017, Aldeyra initiated a randomized, double-masked, vehicle-controlled Phase 3 clinical trial of topical ocular reproxalap in noninfectious anterior uveitis. The trial represents the first-ever significant vehicle-controlled study in noninfectious anterior uveitis, and will assess time to cure (zero inflammatory cells in the anterior chamber of the eye).
 - **New Clinical and Preclinical Programs Announced at 2018 Research Day.** ADX-629 for the treatment of non-alcoholic steatohepatitis, ADX-103 for the treatment of retinal disease, and ADX-1612 for the treatment of post-transplant lymphoproliferative disorder were announced at Aldeyra's Research Day update in June 2018. The new development programs are expected to begin clinical testing in 2019.
 - **New Collaborative Research Agreement in Ocular Inflammation Initiated with Large Pharmaceutical Company.** Aldeyra will collaborate with an undisclosed large pharmaceutical company on the development of novel therapeutics for the prevention and treatment of ocular inflammation. The collaboration will focus on an anti-inflammatory mechanism that is distinct from Aldeyra's RASP (Reactive Aldehyde Species) scavenger and HSP90 inhibition programs.
 - **Joshua Reed Appointed as Chief Financial Officer in July 2018.** Mr. Reed has more than 20 years of financial operations, strategy, and investment banking experience. Prior to joining Aldeyra, Mr. Reed served as Vice President and Head of Finance for Bristol-Myers Squibb's United States and Puerto Rico operations, a \$12 billion business unit.

Quarter Ended June 30, 2018 Financial Review

For the quarter ended June 30, 2018, Aldeyra reported a net loss of approximately \$9.1 million, compared to a net loss of approximately \$5.3 million for the quarter ended June 30, 2017. Basic and diluted net loss per share was \$0.46 for the quarter ended June 30, 2018, compared to \$0.35 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 \$6.8 million for the quarter ended June 30, 2018, compared to \$3.8 million for the same period in 2017. The increase of \$3.0 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 \$2.4 million for the quarter ended June 30, 2018, compared to \$1.5 million for the quarter ended June 30, 2017. The increase of \$0.9 million is primarily related to an increase in legal and patent-related costs, rent, consulting costs, and personnel costs.

For the quarter ended June 30, 2018, total operating expenses were approximately \$9.2 million, compared to total operating expenses of approximately \$5.3 million for the same period in 2017.

Cash, cash equivalents, and marketable securities were \$41.7 million as of June 30, 2018.

Conference Call & Webcast Information

Aldeyra will hold a conference call on Thursday, August 9, 2018, at 8:00 a.m. Eastern Daylight Time. 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. The company is also developing other product candidates for autoimmune disease, post-transplant lymphoproliferative disease, retinal inflammation, metabolic disease, and cancer. None of Aldeyra's product candidates have been approved for sale in the U.S. or elsewhere.

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 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, both of 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 June 30, 2018, expected to be filed with the SEC in the third quarter of 2018.

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ALDEYRA THERAPEUTICS, INC.
BALANCE SHEETS
(UNAUDITED)

	June 30, 2018	December 31, 2017
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 7,605,674	\$ 2,023,337
Cash equivalent—reverse repurchase agreements	17,000,000	18,000,000
Marketable securities	17,072,720	22,923,462
Prepaid expenses and other current assets	1,392,905	1,018,967
Total current assets	<u>43,071,299</u>	<u>43,965,766</u>
Deferred offering costs	—	165,930
Fixed assets, net	214,743	43,262
Total assets	<u>\$ 43,286,042</u>	<u>\$ 44,174,958</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 802,125	\$ 1,000,963
Accrued expenses	4,159,071	2,236,465
Current portion of credit facility	348,958	116,319
Total current liabilities	5,310,154	3,353,747
Credit facility, net of current portion and debt discount	995,291	1,220,192
Total liabilities	<u>6,305,445</u>	<u>4,573,939</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 20,842,198 and 19,137,639 shares issued and outstanding, respectively	20,842	19,138
Additional paid-in capital	154,051,733	139,241,635
Accumulated other comprehensive income (loss)	(2,559)	(17,831)
Accumulated deficit	<u>(117,089,419)</u>	<u>(99,641,923)</u>
Total stockholders' equity	<u>36,980,597</u>	<u>39,601,019</u>
Total liabilities and stockholders' equity	<u>\$ 43,286,042</u>	<u>\$ 44,174,958</u>

ALDEYRA THERAPEUTICS, INC.
STATEMENT OF OPERATIONS
(UNAUDITED)

	<u>Three Months ended June 30,</u>		<u>Six Months ended June 30,</u>	
	<u>2018</u>	<u>2017</u>	<u>2018</u>	<u>2017</u>
Operating expenses:				
Research and development	\$ 6,792,974	\$ 3,848,889	\$ 13,393,080	\$ 7,217,912
General and administrative	2,373,059	1,481,792	4,264,360	3,208,670
Loss from operations	<u>(9,166,033)</u>	<u>(5,330,681)</u>	<u>(17,657,440)</u>	<u>(10,426,582)</u>
Other income (expense):				
Interest income	141,956	48,384	264,346	80,002
Interest expense	<u>(26,358)</u>	<u>(26,463)</u>	<u>(54,402)</u>	<u>(53,301)</u>
Total other income (expense), net	115,598	21,921	209,944	26,701
Net loss	<u>\$ (9,050,435)</u>	<u>\$ (5,308,760)</u>	<u>\$ (17,447,496)</u>	<u>\$ (10,399,881)</u>
Net loss per share—basic and diluted	<u>\$ (0.46)</u>	<u>\$ (0.35)</u>	<u>\$ (0.88)</u>	<u>\$ (0.72)</u>
Weighted average common shares outstanding—basic and diluted	<u>19,761,352</u>	<u>15,136,399</u>	<u>19,761,352</u>	<u>14,470,555</u>