

**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 5, 2021

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

Not Applicable
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	ALDX	The Nasdaq Stock Market LLC

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 5, 2021, Aldeyra Therapeutics, Inc. (“Aldeyra”) issued a press release and is holding a conference call regarding its financial results for the quarter ended June 30, 2021 and recent business highlights. The press release (other than the sections incorporated by reference pursuant to Item 8.01) 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 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,” “on track,” “scheduled,” “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; delay in or failure to obtain regulatory approval of Aldeyra’s product candidates; the ability to maintain regulatory approval of Aldeyra’s product candidates, and the labeling for any approved products; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Aldeyra’s product candidates in clinical trials focused on the same or on different indications; the scope, progress, expansion, and costs of developing and commercializing Aldeyra’s product candidates; the current and potential future impact of the COVID-19 pandemic on Aldeyra’s business, results of operations and financial position; uncertainty as to Aldeyra’s ability to commercialize (alone or with others) Aldeyra’s product candidates following regulatory approval, if any; 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; political, economic, legal, social and health risks, including the recent COVID-19 outbreak and subsequent public health measures, that may affect Aldeyra’s business or the global economy; 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 limited sales and marketing infrastructure; Aldeyra’s ability to establish and maintain development partnerships; Aldeyra’s ability to successfully integrate acquisitions into its business; 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, 2020 and Aldeyra’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, 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, 2021, expected to be filed with the SEC in the third quarter of 2021. 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 8.01. Other Events.

In the press release dated August 5, 2021, the Company also provided a business update. The information set forth under the heading “Recent Corporate Highlights and Program Updates” together with the “Safe Harbor Statement” at the end of the press release, are incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

The portions of the press release incorporated by reference into Item 8.01 of this Current Report on Form 8-K are being filed pursuant to Item 8.01. The remaining portions of the press release are being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed “filed” for purposes of Section 18 of 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, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated August 5, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 5, 2021



Aldeyra Therapeutics Reports Second-Quarter 2021 Financial Results and Recent Corporate Highlights

- *Top-Line Results from Phase 3 TRANQUILITY and TRANQUILITY-2 Clinical Trials of Reproxalap in Dry Eye Disease Expected in Fourth Quarter of 2021*
- *U.S. FDA Grants Orphan Drug Designation to ADX-2191 for the Treatment of Primary Vitreoretinal Lymphoma and Retinitis Pigmentosa*
- *Initial Results from Phase 2 Clinical Trials of Oral RASP Inhibitor ADX-629 in Multiple Systemic Indications Anticipated in Fourth Quarter of 2021 or First Quarter of 2022*
- *Cash and Cash Equivalents of \$249.7 Million as of June 30, 2021; Projected Cash Runway Through 2023, Including Potential New Drug Applications; Initial Commercialization of Reproxalap, if Approved; and Continued Development of Compounds for Retinal and Systemic Diseases*
- *Management to Host Conference Call at 8:00 a.m. ET Today*

LEXINGTON, Mass., August 5, 2021 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company developing novel immune-modulating therapies to treat ocular and systemic diseases, today reported financial results for the quarter ended June 30, 2021 and recent corporate highlights.

“We continue to make meaningful strides toward our goal of developing effective and highly differentiated new therapies to treat ocular and systemic diseases with significant unmet medical need,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “We remain on schedule to report top-line results from the Phase 3 TRANQUILITY and TRANQUILITY-2 dry eye disease clinical trials in the fourth quarter of this year, and we look forward to releasing results of our Phase 2 clinical trials of ADX-629 in systemic immunological diseases by the end of the year or early 2022.”

Recent Corporate Highlights and Program Updates

- **Phase 3 TRANQUILITY and TRANQUILITY-2 Dry Eye Disease Clinical Trial Results Expected in the Fourth Quarter of 2021:** Enrollment is ongoing in the dry eye chamber Phase 3 TRANQUILITY Trial of reproxalap. An identical trial, TRANQUILITY-2, is expected to begin enrollment this quarter. Ocular redness is the primary endpoint of the TRANQUILITY trials, which include tear RASP levels, Schirmer's test, and dry-eye symptoms as secondary endpoints. Top-line results are expected in the fourth quarter of this year. In addition, the company has initiated a multi-center, double-masked, randomized, vehicle-controlled, parallel-group Phase 2 clinical trial of reproxalap in dry eye disease. The Phase 2 trial is designed to optimize the measurement of tear RASP levels, with approximately 75 patients expected to be enrolled per arm. Similar to TRANQUILITY, ocular redness is the primary endpoint in the trial.
- **Orphan Drug Designation Granted for ADX-2191 in Two Additional Retinal Disease Indications:** The U.S. Food and Drug Administration (FDA) granted orphan drug designation to ADX-2191 (methotrexate for intravitreal injection) for the treatment of two rare retinal diseases: primary vitreoretinal lymphoma, an aggressive, high-grade cancer; and retinitis pigmentosa (RP), a clinical group of rare genetic eye diseases characterized by retinal cell death and loss of vision. Aldeyra plans to initiate a Phase 2 clinical trial of ADX-2191 in patients with RP this year. The FDA's orphan drug designation program is designed to provide financial incentives to sponsors for developing drugs and biologics for rare diseases and conditions, in part defined as affecting fewer than 200,000 people in the United States. Sponsors of designated orphan drugs are eligible for partial tax credits for clinical trial costs, waiver of the user fee for marketing applications and, upon approval, consideration for seven years of marketing exclusivity.
- **Phase 2 Clinical Trial Results from ADX-629, an Orally Available, Systems-Based RASP Inhibitor, Expected in the Fourth Quarter of 2021 or First Quarter of 2022:** Initial Phase 2 clinical trial results from ADX-629, a novel orally available RASP inhibitor currently undergoing testing in asthma, psoriasis, and COVID-19, are expected in the fourth quarter of 2021 or first quarter of 2022. ADX-629 represents a first-in-class systems-based therapeutic approach for the potential treatment of a myriad of immune-mediated diseases that today are treated with single-target drugs that can lead to serious toxicity.

Second-Quarter 2021 Financial Results

Cash and cash equivalents as of June 30, 2021 were \$249.7 million. Based on Aldeyra's current operating plan, the company believes that existing cash and cash equivalents will be sufficient to fund currently projected operating expenses through the end of 2023, including potential New Drug Application submissions for reproxalap; initial commercialization of reproxalap, if approved; and continued development of the company's product candidates in ocular and systemic immune-mediated diseases.

For the quarter ended June 30, 2021, Aldeyra reported a net loss of \$14.9 million, compared with a net loss of \$7.5 million for the quarter ended June 30, 2020. Net loss per share was \$0.28 for the quarter ended June 30, 2021, compared with \$0.25 for the same period in 2020. Losses have resulted from the costs of clinical trials and research and development programs, as well as from general and administrative expenses.

Research and development expenses were \$11.5 million for the quarter ended June 30, 2021, compared with \$4.9 million for the same period in 2020. The increase of \$6.6 million is primarily related to the increase in clinical research and development expenditures.

General and administrative expenses were \$3.1 million for the quarter ended June 30, 2021, compared with \$2.2 million for the quarter ended June 30, 2020. The increase of \$0.9 million is primarily due to an increase in personnel-related costs and other miscellaneous administrative expenses.

For the quarter ended June 30, 2021, total operating expenses were \$14.5 million, compared with total operating expenses of \$7.1 million for the same period in 2020.

Conference Call & Webcast Information

Aldeyra will host a conference call at 8:00 a.m. ET today to discuss second-quarter 2021 financial results and recent corporate highlights. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID number is 4968588. Due to expected high demand, please dial in at least 15 minutes prior to the start time.

A live webcast of the conference call will also be available on the Investor Relations page of the company's website at <https://ir.aldeyra.com>. After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for 90 days.

About Aldeyra Therapeutics, Inc.

Aldeyra Therapeutics is a biotechnology company developing novel immune-modulating therapies to treat ocular and systemic diseases. Two of the company's lead product candidates, reproxalap and ADX-629, target RASP, which are pre-cytokine, systems-based mediators of inflammation. Reproxalap is being evaluated in Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. The company's clinical pipeline also includes ADX-2191 (methotrexate for intravitreal injection), a drug candidate in Phase 3 testing for the prevention of proliferative vitreoretinopathy. For more information, visit <https://www.aldeyra.com/> and follow us on [LinkedIn](#), [Facebook](#), and [Twitter](#).

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding submission of potential New Drug Applications; the anticipated timing of results from Aldeyra's clinical trials; and Aldeyra's projected cash runway. 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, but not limited to, "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "on track," "scheduled," "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; delay in or failure to obtain regulatory approval of Aldeyra's product candidates; the ability to maintain regulatory approval of Aldeyra's product candidates, and the labeling for any approved products; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical or clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Aldeyra's product candidates in clinical trials focused on the same or on different indications; the risk that the results from smaller clinical trials or portions of clinical trials may not accurately predict results of larger scale trials or the remainder of a clinical trial; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; uncertainty as to Aldeyra's ability to commercialize (alone or with others) Aldeyra's product candidates following regulatory approval, if any; 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; political, economic, legal, social and health risks, including the recent COVID-19 outbreak and subsequent public health measures, that may affect Aldeyra's business or the global economy; 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 limited sales and marketing infrastructure; Aldeyra's ability to establish and maintain development partnerships; Aldeyra's ability to successfully integrate acquisitions into its business; 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, 2020, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at <https://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, 2021, expected to be filed with the SEC in the third quarter of 2021.

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.

ALDEYRA THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS

	<u>June 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
ASSETS	(Unaudited)	
Current assets:		
Cash and cash equivalents	\$ 124,739,010	\$ 52,858,311
Cash equivalent - reverse repurchase agreements	125,000,000	25,000,000
Prepaid expenses and other current assets	6,521,718	5,200,957
Total current assets	<u>256,260,728</u>	<u>83,059,268</u>
Right-of-use assets	118,401	233,310
Fixed assets, net	48,083	59,925
Total assets	<u>\$ 256,427,212</u>	<u>\$ 83,352,503</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,094,461	\$ 381,638
Accrued expenses	6,196,300	8,134,765
Current portion of credit facility	—	3,659,776
Current portion of operating lease liabilities	118,401	233,310
Total current liabilities	<u>7,409,162</u>	<u>12,409,489</u>
Long-term debt	15,338,105	11,434,456
Total liabilities	<u>22,747,267</u>	<u>23,843,945</u>
Commitments and contingencies		
Stockholders' equity:		
Common stock, voting, \$0.001 par value; 150,000,000 authorized and 57,997,345 and 38,667,491 shares issued and outstanding, respectively	57,997	38,667
Additional paid-in capital	496,764,448	296,385,619
Accumulated deficit	<u>(263,142,500)</u>	<u>(236,915,728)</u>
Total stockholders' equity	<u>233,679,945</u>	<u>59,508,558</u>
Total liabilities and stockholders' equity	<u>\$ 256,427,212</u>	<u>\$ 83,352,503</u>

ALDEYRA THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Operating expenses:				
Research and development	\$ 11,474,446	\$ 4,885,875	\$ 19,200,788	\$ 11,519,478
General and administrative	3,068,652	2,220,003	6,173,355	5,224,844
Loss from operations	<u>(14,543,098)</u>	<u>(7,105,878)</u>	<u>(25,374,143)</u>	<u>(16,744,322)</u>
Other income (expense):				
Interest income	39,665	71,710	63,427	281,809
Interest expense	<u>(433,477)</u>	<u>(486,048)</u>	<u>(916,056)</u>	<u>(925,863)</u>
Total other income (expense), net	<u>(393,812)</u>	<u>(414,338)</u>	<u>(852,629)</u>	<u>(644,054)</u>
Net loss	<u><u>\$(14,936,910)</u></u>	<u><u>\$(7,520,216)</u></u>	<u><u>\$(26,226,772)</u></u>	<u><u>\$(17,388,376)</u></u>
Net loss per share - basic and diluted	<u>\$ (0.28)</u>	<u>\$ (0.25)</u>	<u>\$ (0.52)</u>	<u>\$ (0.59)</u>
Weighted average common shares outstanding - basic and diluted	<u>54,280,393</u>	<u>30,118,456</u>	<u>49,979,545</u>	<u>29,586,148</u>

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