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): October 28, 2021

ALDEYRA THERAPEUTICS, INC.
(Exact name of Registrant as specified in its charter)

Delaware	001-36332	20-1968197
(State or other jurisdiction of incorporation)	(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

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 October 28, 2021, Aldeyra Therapeutics, Inc. ("Aldeyra") issued a press release and is holding a conference call regarding its financial results for the quarter ended September 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 COVID-19 pandemic and related 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 June 30, 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 September 30, 2021, expected to be filed with the SEC in the fourth 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 October 28, 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 October 28, 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 October 28, 2021

Exhibit 99.1

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

- ***Company Expects to Report Top-Line Results from Phase 3 TRANQUILITY and TRANQUILITY-2 Clinical Trials of Reproxalap in Dry Eye Disease in the Fourth Quarter of 2021***
- ***Phase 2 Clinical Trial of ADX-2191 in Retinitis Pigmentosa On Track to Initiate in the Fourth Quarter of 2021***
- ***Phase 2 Clinical Trial Results of ADX-629 in Multiple Systemic Indications Expected in the Fourth Quarter of 2021 or the First Quarter of 2022***
- ***Cash and Cash Equivalents of $241.4 Million as of September 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.--(BUSINESS WIRE)--October 28, 2021--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company developing novel immune-modulating therapies to treat ocular and systemic diseases, today reported recent corporate highlights and financial results for the quarter ended September 30, 2021.

“We continue to make important progress in developing safe and effective treatments for ocular and systemic diseases to improve the lives of patients who have significant unmet medical needs,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer of Aldeyra. “Among key clinical milestones, we expect to release top-line results from the Phase 3 TRANQUILITY and TRANQUILITY-2 dry eye disease clinical trials in the fourth quarter of this year and are on track to report top-line results from Phase 2 clinical trials of ADX-629 in psoriasis, atopic asthma, and COVID-19 by the end of the year or early 2022. We also look forward to the planned initiation of our Phase 2 clinical trial of ADX-2191 in retinitis pigmentosa this quarter.”

Recent Corporate Highlights and Program Updates

- **Top-Line Results from the Phase 3 TRANQUILITY and TRANQUILITY-2 Trials in Dry Eye Disease Expected in the Fourth Quarter of 2021.** Ocular redness is the primary endpoint of the TRANQUILITY trials, which include tear RASP levels, Schirmer's test, and dry eye disease symptoms as secondary endpoints. In addition, enrollment has completed in a multi-center, double-masked, randomized, vehicle-controlled, parallel-group Phase 2 clinical trial of reproxalap in dry eye disease. The Phase 2 trial was designed to optimize the measurement of tear RASP levels.
- **Phase 2 Clinical Trial of ADX-2191 in Retinitis Pigmentosa Scheduled to Initiate in the Fourth Quarter of 2021.** The primary endpoint of the trial is the safety and tolerability of ADX-2191 in patients with retinitis pigmentosa. Secondary endpoints are visual acuity, central retinal sensitivity, dark-adapted retinal sensitivity, and retinal morphometry.
- **Phase 2 Clinical Trial Results from ADX-629, an Orally Administered RASP Inhibitor, Expected in the Fourth Quarter of 2021 or First Quarter of 2022.** ADX-629 is in proof-of-concept Phase 2 clinical trials for the treatment of psoriasis, atopic asthma, and COVID-19. ADX-629 represents a first-in-class systems-based therapeutic approach for the potential treatment of many immune-mediated diseases that today are treated with single-target drugs that can lead to toxicity.
- **Post-Acute Ocular Tolerability Comparison of Topical Reproxalap 0.25% and Lifitegrast 5% in Patients with Dry Eye Disease Paper Published in Peer-Reviewed Journal.** *Clinical Ophthalmology* published the results of a clinical trial comparing the subjective eye drop experience of patients with dry eye disease over one hour after a single dose of two formulations of reproxalap versus lifitegrast.

Third-Quarter 2021 Financial Results

Cash and cash equivalents as of September 30, 2021 were $241.4 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; 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 September 30, 2021, Aldeyra reported a net loss of $15.8 million, compared with a net loss of $8.9 million for the quarter ended September 30, 2020. Net loss per share was $0.27 for the quarter ended September 30, 2021, compared with $0.23 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 $12.9 million for the quarter ended September 30, 2021, compared with $6.1 million for the same period in 2020. The increase of $6.8 million is primarily related to increases in our clinical research and development expenditures and consulting costs, partially offset by decreases in personnel related costs, including stock-based compensation, and manufacturing activities.

General and administrative expenses were $2.5 million for the quarter ended September 30, 2021, compared with $2.3 million for the quarter ended September 30, 2020. The increase of $0.2 million is primarily due to an increase in miscellaneous administrative costs.

For the quarter ended September 30, 2021, total operating expenses were $15.4 million, compared with total operating expenses of $8.4 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 third-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 8891298. 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 COVID-19 pandemic and related 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2021, which are 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 September 30, 2021, expected to be filed with the SEC in the fourth 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

	September 30, 2021	December 31, 2020
ASSETS	**(Unaudited)**	
Current assets:		
Cash and cash equivalents	$ 116,368,688	$ 52,858,311
Cash equivalent - reverse repurchase agreements	125,000,000	25,000,000
Prepaid expenses and other current assets	5,403,261	5,200,957
Total current assets	246,771,949	83,059,268
Right-of-use assets	406,014	233,310
Fixed assets, net	39,607	59,925
Total assets	$ 247,217,570	$ 83,352,503
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 467,932	$ 381,638
Accrued expenses	11,252,075	8,134,765
Current portion of credit facility	—	3,659,776
Current portion of operating lease liabilities	222,158	233,310
Total current liabilities	11,942,165	12,409,489
Operating lease liabilities, long-term	184,599	—
Long-term debt	15,420,904	11,434,456
Total liabilities	27,547,668	23,843,945
Stockholders' equity:		
Common stock, voting, $0.001 par value; 150,000,000 authorized and 58,045,432 and 38,667,491 shares issued and outstanding, respectively	58,045	38,667
Additional paid-in capital	498,549,312	296,385,619
Accumulated deficit	(278,937,455)	(236,915,728)
Total stockholders’ equity	219,669,902	59,508,558
Total liabilities and stockholders’ equity	$ 247,217,570	$ 83,352,503

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 12,894,344	$ 6,133,580	$ 32,095,132	$ 17,653,058
General and administrative	2,546,807	2,255,617	8,720,161	7,480,461
Loss from operations	(15,441,151)	(8,389,197)	(40,815,293)	(25,133,519)
Other income (expense):				
Interest income	59,306	5,215	122,732	287,025
Interest expense	(413,110)	(489,191)	(1,329,166)	(1,415,055)
Total other income (expense), net	(353,804)	(483,976)	(1,206,434)	(1,128,030)
Net loss	$(15,794,955)	$ (8,873,173)	$(42,021,727)	$(26,261,549)
Net loss per share - basic and diluted	$ (0.27)	$ (0.23)	$ (0.80)	$ (0.81)
Weighted average common shares outstanding - basic and diluted	58,019,099	37,796,946	52,688,846	32,395,217

Contacts

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