# 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): March 17, 2022**

# 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 March 17, 2022, Aldeyra Therapeutics, Inc. (“Aldeyra” or the “Company”) issued a press release (the “Press Release”) and is holding a conference call regarding its financial results for the year ended December 31, 2021 and recent corporate 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 risk that the results from earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent 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, and war or other military actions, 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 September 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 Annual Report on Form 10-K for the year ended December 31, 2021, expected to be filed with the SEC in the first quarter of 2022. 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 March 17, 2022, the Company also provided a corporate update. The information set forth under the headings “Recent Corporate Highlights” and “Upcoming Planned Clinical and Regulatory Milestones,” 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 March 17, 2022 |
| 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 March 17, 2022

# Aldeyra Therapeutics Reports Full-Year 2021 Financial Results and Recent Corporate Highlights

- ***Top-Line Data from Proof-of-Concept Clinical Trials of ADX-629 in Multiple Systemic Indications Expected by the End of March 2022***
- ***Results from Phase 3 TRANQUILITY-2 Trial of Reproxalap in Dry Eye Disease Expected Mid-2022***
- ***Results from Part 1 of Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy Expected in the Second Half of 2022***
- ***Phase 2 Clinical Trial of ADX-2191 in Retinitis Pigmentosa Initiated in the First Quarter of 2022; Results Expected in the Second Half of 2022***
- ***Cash and Cash Equivalents of $229.8 Million as of December 31, 2021; Projected Cash Runway Through 2023***
- ***Management to Host Conference Call at 8:00 a.m. ET Today***

LEXINGTON, Mass.--(BUSINESS WIRE)--March 17, 2022--Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company discovering and developing innovative therapies for the treatment of immune-mediated diseases, today reported recent corporate highlights and financial results for the year ended December 31, 2021.

“In addition to our planned completion of clinical development for reproxalap in dry eye disease, 2022 is expected to highlight data milestones for our systemic and retinal disease platforms,” stated Todd C. Brady, M.D., Ph.D., President and Chief Executive Officer. “We are excited about the planned release this month of top-line data from our proof-of-concept clinical trials of ADX-629, a first-in-class RASP modulator, across a variety of systemic inflammatory diseases, and we look forward to reporting results of our recently initiated clinical trial of ADX-2191 in retinitis pigmentosa in the second half of this year.”

**Recent Corporate Highlights**

- **Initiated Phase 2 Clinical Trial of ADX-2191 in Retinitis Pigmentosa.** Aldeyra initiated a Phase 2 clinical trial of ADX-2191 (intravitreal methotrexate 0.8%), an investigational new drug product, in retinitis pigmentosa, a rare, sight-threatening retinal disease with no approved therapy. The trial is being conducted at Duke University Medical Center.
- **Reported Positive Results from Phase 2 Dry Eye Chamber Clinical Trial of Reproxalap Compared to Xiidra®.** In a Phase 2 dry eye chamber clinical trial, ocular discomfort and ocular itching symptom scores were assessed following treatment with either reproxalap or Xiidra (lifitegrast ophthalmic solution 5%). Both ocular discomfort ($p=0.002$) and ocular itching ($p=0.01$) were statistically lower after treatment with reproxalap than with Xiidra.
- **Reported Results from Phase 3 TRANQUILITY Trial of Reproxalap in Dry Eye Disease.** Although the primary endpoint of ocular redness was not met in the TRANQUILITY Trial, statistical significance ($p=0.0001$) was achieved for the dry eye disease sign of Schirmer test, a secondary endpoint. The Schirmer test has been accepted by the U.S. Food and Drug Administration as an approvable objective sign that can be used to support a New Drug Application (NDA) for dry eye disease.
- **Continued Enrollment in Phase 3 TRANQUILITY-2 Trial of Reproxalap.** Patient enrollment continued in the Phase 3 TRANQUILITY-2 Trial of reproxalap in dry eye disease. The primary endpoint of the trial will be met if either Schirmer test or ocular redness achieves statistical significance in favor of reproxalap over vehicle.
- **Completed Enrollment in Part 1 of Phase 3 GUARD Trial of ADX-2191 in Proliferative Vitreoretinopathy.** Patient enrollment concluded in Part 1 of the Phase 3 GUARD Trial of ADX-2191 in patients with proliferative vitreoretinopathy, a rare, sight-threatening retinal disease with no approved therapy.
- **Initiated Enrollment in Phase 3 INVIGORATE-2 Trial of Reproxalap in Allergic Conjunctivitis.** Patient enrollment began in the Phase 3 INVIGORATE-2 Trial of reproxalap in allergic conjunctivitis. The protocol of INVIGORATE-2 is substantially identical to that of the Phase 3 INVIGORATE Trial, which, relative to vehicle, demonstrated statistically significant reductions in patient-reported ocular itching ($p<0.0001$) and investigator-assessed ocular redness ($p<0.0001$) following treatment with reproxalap in an allergen chamber. Results from INVIGORATE-2 are expected in 2023.
- **Announced the Publication of Phase 2 Clinical Trial of Reproxalap in Allergen Chamber Model.** The peer-reviewed journal *Clinical Ophthalmology* published results from the randomized, double-masked, vehicle-controlled, crossover Phase 2 clinical trial of reproxalap versus vehicle in an allergen chamber model. Relative to vehicle, reproxalap treatment statistically reduced patient-reported ocular itching ($p<0.0001$), patient-reported ocular tearing ($p<0.0001$), and investigator-assessed ocular redness ($p<0.0001$).

**Upcoming Planned Clinical and Regulatory Milestones**

- **Systemic Disease:** Top-line data from the Phase 2 proof-of-concept trials of ADX-629 in psoriasis, asthma, and COVID-19 are expected by the end of March 2022.
- **Dry Eye Disease:** Results from the Phase 3 TRANQUILITY-2 Trial of reproxalap in dry eye disease are expected mid-2022, followed by NDA submission, pending the outcome of TRANQUILITY-2 and enrollment in the 12-month safety trial of reproxalap in dry eye disease patients.
- **Retinal Disease:** Results from Part 1 of the Phase 3 GUARD Trial of ADX-2191 in proliferative vitreoretinopathy, and from the Phase 2 clinical trial of ADX-2191 in retinitis pigmentosa, are expected in the second half of 2022.

**Full-Year 2021 Financial Results**

Cash and cash equivalents as of December 31, 2021 were $229.8 million. Based on its current operating plan, Aldeyra believes that existing cash and cash equivalents will be sufficient to fund currently projected operating expenses through the end of 2023, including potential NDA submissions; initial commercialization of reproxalap, if approved; and continued development of Aldeyra's product candidates in ocular and systemic immune-mediated diseases.

Net loss for the year ended December 31, 2021 was $57.8 million, or $1.07 per share, compared with a net loss of $37.6 million, or $1.11 per share, for the comparable period of 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 for the year ended December 31, 2021 were $44.9 million, compared with $24.7 million for the same period in 2020. The increase of $20.2 million is primarily related to increases in clinical research and development expenditures.

General and administrative expenses for the year ended December 31, 2021 were $11.3 million, compared with $10.0 million for the same period in 2020. The increase of $1.3 million is primarily due to increases in legal, insurance, and consulting costs.

Total operating expenses for the year ended December 31, 2021 were $56.2 million, compared with total operating expenses of $36.4 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 recent corporate highlights and financial results for the year ended December 31, 2021. The dial-in numbers are (844) 200-6205 for domestic callers and (929) 526-1599 for international callers. The access code is 132077. Due to expected high demand, please dial in at least 15 minutes prior to the start time.

A live webcast of the conference call can be accessed via the Investors & Media page of the Aldeyra website at https://ir.aldeyra.com. After the live webcast, the event will remain archived on the website for 90 days.

**About Aldeyra**

Aldeyra Therapeutics discovers and develops innovative therapies designed to treat immune-mediated diseases. Our approach is to develop therapies that modulate immunological systems, instead of directly inhibiting or activating single protein targets, with the goal of optimizing multiple pathways at once while minimizing toxicity. Two of our lead product candidates, reproxalap and ADX-629, target pre-cytokine, systems-based mediators of inflammation known as RASP (reactive aldehyde species). Reproxalap is in Phase 3 clinical trials in patients with dry eye disease and allergic conjunctivitis. ADX-629, an orally administered RASP modulator, is in Phase 2 proof-of-concept clinical trials in psoriasis, asthma, and COVID-19. Our pipeline also includes ADX-2191 (intravitreal methotrexate 0.8%), in development for the prevention of proliferative vitreoretinopathy and the treatment of retinitis pigmentosa and primary vitreoretinal lymphoma. 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 earlier clinical trials, portions of clinical trials, or pooled clinical data may not accurately predict results of subsequent 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, and war or other military actions, 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 September 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 Annual Report on Form 10-K for the year ended December 31, 2021, expected to be filed with the SEC in the first quarter of 2022.

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**

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 104,790,989 | $ 52,858,311 |
| Cash equivalent - reverse repurchase agreements | 125,000,000 | 25,000,000 |
| Prepaid expenses and other current assets | 2,961,781 | 5,200,957 |
| Total current assets | 232,752,770 | 83,059,268 |
| Fixed assets, net | 32,487 | 59,925 |
| Right-of-use assets | 351,863 | 233,310 |
| Total assets | $ 233,137,120 | $ 83,352,503 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 1,019,702 | $ 381,638 |
| Accrued expenses | 10,523,353 | 8,134,765 |
| Current portion of long-term debt | — | 3,659,776 |
| Current portion of operating lease liabilities | 229,607 | 233,310 |
| Total current liabilities | 11,772,662 | 12,409,489 |
| Operating lease liabilities, long-term | 125,232 | — |
| Long-term debt, net of current portion | 15,503,703 | 11,434,456 |
| Total liabilities | 27,401,597 | 23,843,945 |
| Stockholders' equity: | | |
| Common stock, voting, $0.001 par value; 150,000,000 authorized and 58,081,215 and 38,667,491 shares issued and outstanding, respectively | 58,081 | 38,667 |
| Additional paid-in capital | 500,369,444 | 296,385,619 |
| Accumulated other comprehensive income | — | — |
| Accumulated deficit | (294,692,002) | (236,915,728) |
| Total stockholders’ equity | 205,735,523 | 59,508,558 |
| Total liabilities and stockholders’ equity | $ 233,137,120 | $ 83,352,503 |

**ALDEYRA THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS**

| | Years ended December 31, | |
|---|---|---|
| | **2021** | **2020** |
| Operating expenses: | | |
| Research and development | $ 44,936,532 | $ 24,681,301 |
| Acquired in-process research and development | — | 1,754,265 |
| General and administrative | 11,283,004 | 9,985,454 |
| Loss from operations | (56,219,536) | (36,421,020) |
| Other income (expense): | | |
| Interest income | 185,363 | 292,224 |
| Interest expense | (1,742,101) | (1,904,198) |
| Total other income (expense), net | (1,556,738) | (1,611,974) |
| Loss before income taxes | (57,776,274) | (38,032,994) |
| Income tax benefit | — | 479,265 |
| Net loss | $(57,776,274) | $(37,553,729) |
| Net loss per share - basic and diluted | $ (1.07) | $ (1.11) |
| Weighted average common shares outstanding - basic and diluted | 54,042,103 | 33,965,955 |

## Contacts

**Corporate Contact**
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