UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 7, 2020

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 May 7, 2020, Aldeyra Therapeutics, Inc. (“Aldeyra”) issued a press release and is holding a conference call regarding its financial results for the quarter ended March 31, 2020. The press release also included a corporate update. 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 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,” “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. As a result of the COVID-19 pandemic, clinical site availability, staffing, and patient recruitment have been negatively affected and the timelines to complete our clinical trials may be delayed. 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; 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 our 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, 2019, which is on file with the Securities and Exchange Commission (SEC) and available on the SEC’s website at www.sec.gov. Additional factors may be described in those sections of Aldeyra’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, expected to be filed with the SEC in the second quarter of 2020. 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 May 7, 2020, the Company also provided a corporate update. The information set forth under the heading "New Clinical Programs in Systemic Inflammatory Diseases" and "Late-Stage Ocular Disease Programs" 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 May 7, 2020

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: May 7, 2020

Exhibit 99.1

Aldeyra Therapeutics Reports First-Quarter 2020 Financial Results and Announces New Clinical Programs

- *ADX-629 Expected to Begin Phase 2 Clinical Trials in COVID-19 Respiratory Compromise, Atopic Asthma, and Psoriasis in 2020*
- *Type C Meeting Scheduled with FDA to Discuss Remaining NDA Requirements for Reproxalap in Dry Eye Disease*
- *Results from Phase 3 INVIGORATE Trial of Reproxalap in Allergic Conjunctivitis Expected in First Half of 2021*
- *Cash Runway Extended into 2022*
- *Management to Host Conference Call at 8:00 a.m. ET Today*

Lexington, Mass., May 7, 2020 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a clinical-stage biotechnology company focused on the development of novel therapies with the potential to improve the lives of patients with immune-mediated diseases, today reported financial results for the first quarter ended March 31, 2020, announced new clinical trials in systemic inflammatory diseases, and provided an update on ocular disease programs.

“Based on the success of the novel RASP inhibitor ADX-629 in Phase 1 clinical testing, we are pleased to announce a new comprehensive clinical initiative in systemic inflammatory diseases, complementing our late-stage pipeline in ocular disease,” said Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra. “Although the COVID-19 pandemic has affected clinical trial enrollment timelines, our cash position remains strong, and we are extending our projected cash runway guidance into 2022.”

New Clinical Programs in Systemic Inflammatory Diseases

Aldeyra plans to assess the activity of ADX-629 in three types of severe inflammation: cytokine release syndrome, autoimmune disease, and allergy. In preclinical models, ADX-629 treatment reduced levels of TH1, TH2, and TH17-related cytokines, suggesting potential activity across a broad array of inflammatory diseases. The timing of clinical trial initiation depends, in part, on restrictions related to COVID-19, the availability of clinical research facilities and staffing, and the ability to recruit patients.

- **COVID-19 Respiratory Compromise**: A Phase 2 clinical trial of ADX-629 is expected in subjects with COVID-19-associated respiratory compromise, defined as hypoxia and pulmonary radiographic involvement, immediately following admission to the hospital. Severe inflammation, characterized in part by cytokine release syndrome, leads to acute respiratory distress syndrome and other conditions that require mechanical ventilation. The clinical trial, contingent on

FDA review of information submitted via the Coronavirus Treatment Acceleration Program (CTAP), is expected to begin in the third quarter of 2020.

- **Autoimmune Disease**: A Phase 2a clinical trial of ADX-629 in patients with psoriasis, an autoimmune condition associated with TH1 cytokines, is expected to begin in the second half of 2020.
- **Allergy**: A Phase 2a allergen-challenge clinical trial of ADX-629 in patients with atopic asthma, an allergic inflammatory disease associated with TH2 cytokines, is expected to begin in the second half of 2020.

Late-Stage Ocular Disease Programs

Reproxalap, a first-in-class RASP inhibitor for topical ocular administration, continues to advance towards a new drug application (NDA) filing in allergic conjunctivitis and dry eye disease. The Phase 3 GUARD Trial of ADX-2191, a novel formulation of methotrexate for intravitreal administration, in patients with proliferative vitreoretinopathy currently remains active, although enrollment has been significantly delayed due to the COVID-19 pandemic.

- **Dry Eye Disease**: A Type C meeting with the U.S. Food and Drug Administration (FDA) is scheduled for mid-2020 to discuss remaining NDA requirements for reproxalap in dry eye disease. Reproxalap has demonstrated clinically relevant improvement from baseline in two well-controlled clinical trials: Part 1 of the Phase 3 RENEW Trial announced late last year and a Phase 2 formulation trial announced earlier this year. Dry eye disease remains poorly served by available therapies, and represents one of the largest markets in ophthalmology, affecting an estimated 34 million patients in the United States. Aldeyra plans to provide an update on dry eye disease clinical development plans following receipt and review of FDA feedback.
- **Allergic Conjunctivitis**: Based on delays primarily associated with an extended allergy season, results from the Phase 3 INVIGORATE Trial of reproxalap are currently expected in the first half of 2021. Based on the successful Phase 3 ALLEVIATE Trial announced in 2019, and assuming continued clinical success and positive regulatory review, reproxalap has the potential to be the first new mechanistic approach in decades for the treatment of allergic conjunctivitis. The current therapeutic landscape of allergic conjunctivitis is generally limited to antihistamines, which do not lead to satisfactory activity in up to one-third of patients, and corticosteroids, which cannot be used chronically due to potentially serious adverse events. Allergic conjunctivitis is one of most common ocular surface diseases, affecting an estimated 66 million patients in the United States, and is often associated with dry eye disease.

- **Proliferative Vitreoretinopathy (PVR)**: Patient enrollment in Part 1 of the adaptive the Phase 3 GUARD Trial of ADX-2191 for the prevention of PVR has been significantly delayed due to lack of clinical site availability and staffing resulting from the COVID-19 pandemic. PVR is a rare but vision-threatening retinal disease associated with recurrent retinal detachments. There is no approved therapy for PVR. Aldeyra expects to update the enrollment and completion timeline by year-end, and is also exploring additional indications for ADX-2191, including primary intraocular lymphoma, a rare but serious ocular cancer that can affect the retina, uvea, optic nerve, and other ocular structures.

Financial Review for the Quarter Ended March 31, 2020

For the quarter ended March 31, 2020, Aldeyra reported a net loss of $9.9 million, compared with a net loss of $15.6 million for the quarter ended March 31, 2019. Net loss per share was $0.34 for the quarter ended March 31, 2020, compared with $0.58 for the same period in 2019. Losses have resulted from the costs of Aldeyra's clinical trials and research and development programs, as well as from general and administrative expenses.

Research and development expenses were $6.6 million for the quarter ended March 31, 2020, compared with $7.8 million for the same period in 2019. The decrease of $1.2 million is primarily related to the decreases in clinical and preclinical development and manufacturing costs. Expenses for the 2019 period also included $6.6 million of in-process research and development expenses incurred in connection with the acquisition of Helio Vision.

General and administrative expenses were $3.0 million for each of the quarters ended March 31, 2020 and 2019. Increases in personnel related costs, including stock-based compensation, were offset by a decrease in legal and other miscellaneous administrative costs.

For the quarter ended March 31, 2020, total operating expenses were $9.6 million, compared with total operating expenses of $17.4 million for the same period in 2019.

Cash, cash equivalents, and marketable securities were $61.4 million as of March 31, 2020. Based on current operating plans, Aldeyra believes that its cash, cash equivalents, and marketable securities as of March 31, 2020 will be sufficient to fund currently anticipated operating expenses into 2022, including the completion of the Phase 3 INVIGORATE Trial for reproxalap, as well as the Phase 2 clinical trials of ADX-629 in COVID-19-associated respiratory compromise, atopic asthma, and psoriasis; the commencement of one or more additional clinical trials in dry eye disease, subject to the outcome of the FDA meeting scheduled for mid-year 2020; and the continuation of Part 1 of the adaptive Phase 3 clinical trial in PVR contingent on patient enrollment.

Conference Call & Webcast Information

Aldeyra will host a conference call today at 8:00 a.m. ET to announce new clinical trials in systemic inflammatory diseases, provide an update on ocular disease programs, and report first-quarter 2020 financial results. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID number is 6982314. Due to the expected high demand on our conference provider, please plan to dial in to the call at least 30 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 corporate 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

Aldeyra Therapeutics is a clinical-stage biotechnology company focused on the development of novel therapies with the potential to improve the lives of patients with immune-mediated diseases. Two of the company's lead compounds, reproxalap and ADX-629, target reactive aldehyde species (RASP), which are elevated in ocular and systemic inflammatory disease, leading to elevated levels of cytokine release via activation of a broad array of inflammatory factors, including NF-kB, inflammasomes, and Scavenger Receptor A. 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, a dihydrofolate reductase inhibitor in Phase 3 testing for 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 statements regarding Aldeyra's strategy, future operations, expected cash runway, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including reproxalap, ADX-629, ADX-2191 and ADX-1612. 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. As a result of the COVID-19 pandemic, clinical site availability, staffing, and patient recruitment have been negatively affected and the timelines to complete our clinical trials may be delayed. 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 trials involving Aldeyra's product candidates; 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 our 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, 2019, which is on file with the Securities and Exchange Commission

(SEC) and available on the SEC's website at www.sec.gov. Additional factors may be described in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, expected to be filed with the SEC in the second quarter of 2020.

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.

Corporate Contact:

David McMullin

Aldeyra Therapeutics, Inc.

Tel: 781-761-4904 ext. 218

dmcmullin@aldeyra.com

Investor & Media Contact:

Scott Solomon

Sharon Merrill Associates, Inc.

Tel: 617-542-5300

ALDX@investorrelations.com