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 12, 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 March 12, 2020, Aldeyra Therapeutics, Inc. (the "Company") issued a press release and is holding a conference call regarding its financial results for the year ended December 31, 2019. 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 the Company's plans and expectations for its product candidates. In some cases, you can identify forward looking statements by terms such as, but not limited to, "may," "might," "will," "objective," "intend," "should," "could," "can," "would," "expect," "believe," "anticipate," "project," "target," "design," "estimate," "predict," "potential," "aim," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties.

The Company is at an early stage of development and may not ever have any products that generate significant revenue. All of the Company'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 the Company's forward-looking statements include, among others, the timing of enrollment, commencement and completion of the Company's clinical trials, the timing and success of preclinical studies and clinical trials conducted by the Company and its development partners; delay in or failure to obtain regulatory approval of the Company's product candidates; the Company's ability to maintain regulatory approval of the Company'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 our product candidates; the scope, progress, expansion, and costs of developing and commercializing the Company's product candidates; uncertainty as to the Company's ability to commercialize (alone or with others) the Company's product candidates following regulatory approval, if any; the size and growth of the potential markets and pricing for the Company's product candidates and the ability to serve those markets; the Company's expectations regarding the Company's expenses and revenue, the sufficiency or use of the Company's cash resources and needs for additional financing; political, economic, legal, and social risks that may affect the Company's business or the global economy; the rate and degree of market acceptance of any of the Company's product candidates; the Company's expectations regarding competition; the Company's anticipated growth strategies; the Company's ability to attract or retain key personnel; the Company's limited sales and marketing infrastructure; the Company's ability to establish and maintain development partnerships; the Company's ability to successfully integrate acquisitions into our business; the Company's expectations regarding federal, state and foreign regulatory requirements; regulatory developments in the United States and foreign countries; the Company's ability to obtain and maintain intellectual property protection for the Company's product candidates; the anticipated trends and challenges in the Company'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 the Company's Annual Report on Form 10-K for the year ended December 31, 2018 and the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2019, both of which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at www.sec.gov. Additional factors are expected to be described in those sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2019, expected to be filed with the SEC in the first quarter of 2020.

In addition to the risks described above and in the Company's other filings with the SEC, other unknown or unpredictable factors also could affect the Company'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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b) On March 12, 2020, the Company announced that David Clark, M.D., the Company's former Chief Medical Officer, had transitioned to a consulting role.

Dr. Clark's separation from the Company as Chief Medical Officer is treated as a termination without "cause" within the meaning of that certain offer letter, dated December 14, 2015, between the Company and Dr. Clark (which agreement has previously been filed with the SEC). The Company entered into a separation letter with Dr. Clark dated March 9, 2020, which, among other things, provides that, pursuant to Dr. Clark's offer letter, Dr. Clark will receive (i) continued payment of his base salary for 9 months; (ii) a lump-sum cash payment equal to $148,556; and (iii) payment by the Company of the monthly premiums under COBRA for him and his eligible dependents for up to 9 months following the termination of his employment. In connection with the execution of the separation letter, the Company and Dr. Clark entered into a consulting agreement pursuant to which Dr. Clark will provide consulting services to the Company for a period of at least 9 months in exchange for the continued vesting of his outstanding options to purchase shares of the Company's common stock and his time-based restricted stock unit awards.

The foregoing description of the terms and conditions of the separation letter and consulting agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the separation letter and consulting agreement, which will be filed as exhibits to the Company's Quarterly Report on Form 10-Q for the period ending March 31, 2020.

Item 8.01. Other Events.

On March 12, 2020, the Company announced a near-term strategic prioritization of its late-stage ocular disease programs in allergic conjunctivitis, dry eye disease, and proliferative vitreoretinopathy. A copy of the press release announcing the strategic prioritization is attached hereto as Exhibit 99.2.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aldeyra Therapeutics, Inc. Press Release dated March 12, 2020.
99.2	Aldeyra Therapeutics, Inc. Press Release dated March 12, 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.

Date: March 12, 2020

By: /s/ Joshua Reed
Joshua Reed
Chief Financial Officer

Exhibit 99.1

Aldeyra Therapeutics Reports Full-Year 2019 Financial Results and Provides Updates on Anticipated Clinical Milestones

- INVIGORATE Phase 3 Trial of Reproxalap in Allergic Conjunctivitis Expected to be Completed in Second Half of 2020
- Based on Achievement of Symptom Endpoint in Two Clinical Trials, Subsequent Development Plans for Reproxalap in Dry Eye Disease Pending FDA Feedback, Expected in the Second Half of 2020
- GUARD Phase 3 Trial of ADX-2191 in Proliferative Vitreoretinopathy Initiated
- Strategic Prioritization of Late-Stage Ocular Pipeline Expected to Extend Company's Cash Runway Through the End of 2021
- Management to Host Conference Call at 8:00 a.m. ET Today

Lexington, Mass., March 12, 2020 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases, today reported financial results for the year ended December 31, 2019 and provided an update on anticipated clinical milestones.

"2019 was a year of continued momentum for our lead programs, as we reported statistically significant and clinical relevant data that underscored the potential of reproxalap as a first-line therapy in allergic conjunctivitis and dry eye disease, conditions that in the aggregate affect more than one billion people worldwide," stated Todd C. Brady, M.D., President and CEO of Aldeyra. "Reproxalap potentially represents a highly differentiated mechanism of action compared with existing therapies. We are excited about the market opportunities for reproxalap as we continue to advance towards the completion of clinical development."

Recent Highlights and Upcoming Milestones

- **Allergic Conjunctivitis:** Aldeyra expects to complete the INVIGORATE Phase 3 clinical trial of topical ocular reproxalap in the second half of 2020. In 2019, Aldeyra announced achievement of the primary endpoint of the Phase 3 ALLEVIATE Trial in allergic conjunctivitis, as well as statistically significant reductions in ocular itching and redness in an allergen chamber clinical trial.

- **Dry Eye Disease:** Based on the achievement of symptom endpoints in two well-controlled clinical trials, Aldeyra plans to meet with the U.S. Food and Drug Administration (FDA) prior to initiating Part 2 of the RENEW Trial, and plans to provide an update on future development in dry eye disease following FDA feedback, expected in the second half of 2020.
- **Proliferative Vitreoretinopathy (PVR):** Aldeyra is currently enrolling patients in the GUARD Phase 3 Trial of ADX-2191, a novel anti-inflammatory and anti-proliferative agent for the prevention of PVR, a rare sight-threatening condition with no approved treatment. The GUARD Trial is a two-part, multi-center, randomized, controlled, adaptive clinical trial evaluating the efficacy of intravitreal injections of ADX-2191 versus standard-of-care for the prevention of PVR. The trial will compare recurrent retinal detachment rates over a 24-week period following surgical repair of retinal detachment due to PVR or open globe injury. Enrollment is currently expected to be completed in 2021.
- **Systemic Autoimmune Disease:** A single and multiple ascending dose Phase 1 clinical trial has been completed for ADX-629, a novel orally administered RASP inhibitor in development for the treatment of systemic autoimmune disease and potentially other serious medical conditions. Top-line results are expected in the second quarter of this year. Initiation of Phase 2 clinical testing is planned for the second half of 2020.

Strategic Prioritization of Late-Stage Programs in Ocular Disease

In a separate news release issued earlier today, Aldeyra announced strategic prioritization of late-stage ocular disease programs in allergic conjunctivitis, dry eye disease, and proliferative vitreoretinopathy. In conjunction with the strategic prioritization, Aldeyra appointed ophthalmology drug development expert James A. Gow, M.D., as Senior Vice President of Clinical Development.

Aldeyra has elected to place on hold its clinical development of topical dermal reproxalap for the treatment of ichthyosis associated with Sjogren-Larsson Syndrome and ADX-1612 for the treatment of post-transplant lymphoproliferative disorder. The initiatives to prioritize the portfolio are expected to extend the company’s cash runway through the end of 2021.

Year Ended December 31, 2019 Financial Review

Aldeyra reported a net loss of $60.8 million for the year ended December 31, 2019, compared with a net loss of $38.9 million in 2018. Basic net loss per share was $2.24 for the year ended December 31, 2019, compared with $1.79 per share in 2018. 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 approximately $44.4 million for the year ended December 31, 2019, compared with approximately $29.8 million for the year ended December 31, 2018. The increase of $14.6 million is primarily related to the increase in clinical and preclinical development and manufacturing costs; an increase in personnel costs; and non-cash compensation costs related to a portion of upfront acquisition consideration that is subject to vesting based on continued service.

Acquired in-process research and development expenses were $6.6 million for the year ended December 31, 2019. Aldeyra did not have acquired in-process research and development expenses for the year ended December 31, 2018. The $6.6 million increase is related to the in-process research and development expenses associated with the January 2019 acquisition of Helio Vision.

General and administrative expenses were approximately $12.2 million for the year ended December 31, 2019, compared with $9.9 million for the year ended December 31, 2018. The increase of $2.3 million is primarily related to an increase in personnel costs and public company costs related to compliance with the Sarbanes-Oxley Act of 2002.

Total operating expenses were approximately $63.1 million for the year ended December 31, 2019, compared with total operating expenses of approximately $39.7 million for the year ended December 31, 2018.

Cash, cash equivalents, and marketable securities were $73.4 million as of December 31, 2019.

Conference Call & Webcast Information

Aldeyra will host a conference call today at 8:00 a.m. ET to discuss its full-year 2019 financial results and provide a corporate update. The dial-in numbers are (866) 211-4098 for domestic callers and (647) 689-6613 for international callers. The Conference ID number is 9984588.

A live webcast of the conference call will also be available on the Investors Relations section of the Aldeyra Therapeutics website at https://ir.aldeyra.com. After the live webcast, the event will remain archived on the Aldeyra Therapeutics website for 90 days.

About Reproxalap

Reproxalap is a novel, small-molecule immune-modulating covalent inhibitor of RASP (reactive aldehyde species), which are elevated in ocular and systemic inflammatory disease, and lead to activation of intracellular inflammatory factors, including NF-kB, inflammasomes, and Scavenger Receptor A. Reproxalap's mechanism of action has been validated with the demonstration of statistically significant and clinically relevant activity in multiple physiologically distinct late-phase clinical indications. Topical ocular reproxalap has now been studied in more than 1,100 patients with no observed safety concerns reported; mild instillation site irritation is the most commonly reported adverse event in clinical trials.

About ADX-2191

ADX-2191, an intravitreal formulation of methotrexate, has received orphan drug and fast track designations from the FDA for the prevention of PVR. The observed clinical activity of ADX-2191 in patients with PVR is believed to be the result of down-regulation of aberrant retinal cell proliferation and activity, thereby leading to reduced retinal scarring that is characteristic of PVR. Aldeyra retains an exclusive license to certain patents related to the use of ADX-2191 for the prevention of PVR.

About Aldeyra Therapeutics

Aldeyra Therapeutics is a biotechnology company devoted to developing and commercializing next-generation medicines to improve the lives of patients with immune-mediated diseases. Aldeyra's lead investigational drug product candidates are potential first-in-class treatments in development for dry eye disease, allergic conjunctivitis, and proliferative vitreoretinopathy. The company is also developing other product candidates for retinal and systemic inflammatory diseases.

Safe Harbor Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding Aldeyra's strategy, future operations, future financial position and cash runway, projected costs and expenses, prospects, plans, and objectives and Aldeyra's plans and expectations for its product candidates, including plans relating to current or future clinical development and its strategic prioritization. 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

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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, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,425,830	$ 3,357,472
Cash equivalent- reverse repurchase agreements	28,000,000	44,000,000
Marketable securities	28,938,545	46,242,220
Prepaid expenses and other current assets	1,804,450	1,169,594
Total current assets	75,168,825	94,769,286
Deferred offering costs	—	86,644
Property and equipment, net	148,449	235,225
Right-of-use assets	201,007	—
Total assets	$ 75,518,281	$ 95,091,155
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 808,302	$ 3,051,678
Accrued expenses	11,873,122	5,421,498
Current portion of operating lease liabilities	226,328	—
Total current liabilities	12,907,752	8,473,176
Long-term debt	14,528,212	—
Total liabilities	27,435,964	8,473,176
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value, 15,000,000 shares authorized, none issued and outstanding	—	—
Common stock, voting, $0.001 par value; 150,000,000 authorized and 28,656,832 and 26,244,435 shares issued and outstanding, respectively	28,657	26,244
Additional paid-in capital	247,409,793	225,136,127
Accumulated other comprehensive income (loss)	5,866	(9,224)
Accumulated deficit	(199,361,999)	(138,535,168)
Total stockholders' equity	48,082,317	86,617,979
Total liabilities and stockholders' equity	$ 75,518,281	$ 95,091,155

ALDEYRA THERAPEUTICS, INC.
CONSOLIDATED STATEMENT OF OPERATIONS

	Years ended December 31,	
	2019	2018
Operating expenses:		
Research and development	$ 44,351,851	$ 29,823,007
Acquired in-process research and development	6,567,754	—
General and administrative	12,154,702	9,876,144
Loss from operations	(63,074,307)	(39,699,151)
Other income (expense):		
Interest income	1,541,349	952,698
Interest expense	(603,846)	(146,792)
Total other income (expense), net	937,503	805,906
Loss before income taxes	(62,136,804)	(38,893,245)
Income tax benefit	1,309,973	—
Net loss	$(60,826,831)	$(38,893,245)
Net loss per share - basic and diluted	$ (2.24)	$ (1.79)
Weighted average common shares outstanding - basic and diluted	27,111,840	21,685,642

Corporate Contact:

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Investor & Media Contact:

Scott Solomon
Sharon Merrill Associates, Inc.
Tel: 617-542-5300
ALDX@investorrelations.com

Exhibit 99.2

Aldeyra Announces Strategic Prioritization of Late-Stage Clinical Pipeline in Ocular Disease

- *Plans to Focus on Phase 3 Programs in Allergic Conjunctivitis, Dry Eye Disease, and Proliferative Vitreoretinopathy Expected to Extend Company's Cash Runway Through the End of 2021*
- *Ophthalmology Drug Development Expert James A. Gow, M.D., Named Senior Vice President of Clinical Development*

LEXINGTON, Mass., March 12, 2020 – Aldeyra Therapeutics, Inc. (Nasdaq: ALDX) (Aldeyra), today announced strategic prioritization of late-stage ocular disease programs in allergic conjunctivitis, dry eye disease, and proliferative vitreoretinopathy. In conjunction with the strategic prioritization, Aldeyra appointed ophthalmology drug development expert James A. Gow, M.D., as Senior Vice President of Clinical Development.

Aldeyra has elected to place on hold clinical development of topical dermal reproxalap for the treatment of ichthyosis associated with Sjogren-Larsson Syndrome and ADX-1612 for the treatment of post-transplant lymphoproliferative disorder. The initiatives to prioritize Aldeyra's ocular portfolio are expected to extend the company's cash runway through the end of 2021.

"Our renewed focus on late-stage ophthalmic programs is expected to enable considerable financial flexibility as we continue to advance novel therapies for conditions with unmet medical need," stated Todd Brady, M.D., Ph.D., President and CEO of Aldeyra. "Consistent with our strategic prioritization of ocular disease, we are pleased to welcome Dr. Gow, an established leader in the development of ophthalmic therapeutics, as our new Senior Vice President of Clinical Development."

Prior to joining Aldeyra, Dr. Gow served as Vice President, Global Development Lead for lifitegrast (Xiidra®) on global clinical development projects at Novartis AG. He also served in similar roles at Shire Pharmaceuticals Inc. and at Takeda Pharmaceutical Company Ltd. following Takeda's acquisition of Shire in January 2019. During his career, Dr. Gow has held leadership positions of increasing responsibility at ISTA Pharmaceuticals (acquired by Bausch and Lomb, Inc.), Bausch and Lomb, Inc. (acquired by Valeant Pharmaceuticals International, Inc., now Bausch Health Companies Inc.), Alcon Research, Ltd., and Inotek Pharmaceuticals Corporation (merged with Rocket Pharmaceuticals, Inc.). He received his M.D. from the University of Manitoba, Winnipeg in Canada.

Aldeyra also announced that David J. Clark, M.D., its former Chief Medical Officer, has transitioned to a consulting role. "On behalf of Aldeyra and our Board of Directors, I would like to thank Dr. Clark for his significant contributions to our company over the past four years," said Dr. Brady. "Under Dr. Clark's leadership, Aldeyra has generated positive results from a number of novel and late-stage clinical programs across a variety of clinical indications."

About Aldeyra Therapeutics

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