# 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): November 12, 2015

# **ALDEYRA THERAPEUTICS, INC.**

(Exact name of Registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

001-36332 (Commission File No.) 20-1968197 (IRS Employer Identification No.)

131 Hartwell Avenue, Suite 320 Lexington, MA 02421 (Address of principal executive offices and zip code)

Registrant's telephone number, including area code: (781) 761-4904

(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))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 2.02. Results of Operations and Financial Condition.

On November 12, 2015, Aldeyra Therapeutics, Inc. (the "Company") issued a press release and is holding a conference call to discuss its financial results for the quarter ended September 30, 2015. 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 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," "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. 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; the ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets for Aldeyra's product candidates and the ability to serve those markets; Aldeyra's expectations regarding Aldeyra's expenses and revenue, the sufficiency of Aldeyra's cash resources and needs for additional financing; 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; 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, 2014 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, which will be filed with the SEC in the fourth quarter of 2015.

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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Aldeyra Therapeutics, Inc. dated November 12, 2015

#### SIGNATURES

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/ Todd C. Brady, M.D., Ph.D.

Name: Todd C. Brady, M.D., Ph.D. Title: President and Chief Executive Officer

Dated: November 12, 2015

# EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release of Aldeyra Therapeutics, Inc. dated November 12, 2015



#### Aldeyra Therapeutics Reports Third Quarter and Year to Date 2015 Financial and Operating Results

**Lexington, MA, November 12, 2015** – Aldeyra Therapeutics, Inc. (Nasdaq:ALDX) (Aldeyra), a biotechnology company focused on the development of products to treat diseases related to aldehydes, today announced its financial and operating results for the third quarter and nine months ended September 30, 2015.

Todd C. Brady, M.D., Ph.D., President and CEO of Aldeyra, commented, "We continue to advance the development of NS2 in multiple clinical indications. Most recently, we began a Phase II clinical trial in patients with allergic conjunctivitis, which is our third ongoing Phase II trial with NS2 and our second trial in an inflammatory ophthalmologic indication. Additionally, at the 2015 American Society of Human Genetics Annual Meeting, we presented novel preclinical data on the aldehyde trapping activity of NS2 in a knock-out mouse model of Succinic Semi-aldehyde Dehydrogenase Deficiency (SSADHD). We eagerly anticipate further exploration of the therapeutic potential of systemically administered NS2 in SSADHD and other diseases associated with elevated levels of toxic aldehydes."

Dr. Brady concluded, "We are looking forward to three significant clinical milestones in 2016. We continue to expect to complete enrollment of our Sjögren-Larsson Syndrome (SLS) dermatologic trial in the first quarter of 2016, and complete enrollment of our noninfectious anterior uveitis trial during the second quarter of 2016. We are also pleased to announce that we expect to complete enrollment in our allergic conjunctivitis trial in the second quarter of 2016."

#### Third Quarter and Nine Months Ended September 30, 2015 Financial Review

For the third quarter of 2015, Aldeyra reported a net loss attributable to common stockholders of approximately \$3.4 million compared to a net loss of approximately \$2.0 million for the third quarter of 2014. Basic and diluted net loss per share was \$0.35 for the three months ended September 30, 2015 compared to basic and diluted net loss per share of \$0.36 for the same period in 2014.

For the nine months ended September 30, 2015, Aldeyra reported a net loss attributable to common stockholders of approximately \$7.7 million compared to a net loss attributable to common stockholders of approximately \$7.1 million for the nine months ended September 30, 2014. Basic and diluted net loss per share was \$0.94 for the nine months ended September 30, 2015, compared to basic net loss per share of \$2.21 and diluted net loss per share of \$2.89 for the same period in 2014.

Research and development expenses totaled approximately \$2.1 million for the third quarter of 2015 compared to approximately \$1.2 million for the third quarter of 2014. For the nine months ended September 30, 2015, research and development expenses totaled approximately \$4.5 million compared to \$2.3 million for the nine months ended September 30, 2014.

For the third quarter of 2015, general and administrative expenses were approximately \$1.3 million compared to approximately \$800,000 for the third quarter of 2014. For the nine months ended September 30, 2015, general and administrative expenses totaled approximately \$3.2 million compared to \$2.6 million for the nine months ended September 30, 2014.

Total operating expenses for the third quarter of 2015 were approximately \$3.3 million compared to total operating expenses of approximately \$2.0 million for the third quarter of 2014. For the nine months ended September 30, 2015, total operating expenses totaled approximately \$7.7 million compared to \$4.9 million for the nine months ended September 30, 2014.

As of September 30, 2015, Aldeyra had cash and cash equivalents of \$30.6 million.

#### **Operational Highlights from the Third Quarter of 2015**

- Initiated enrollment in Phase II clinical trial (Clinicaltrials.gov identifier NCT02578914) of ophthalmic NS2 in patients with allergic conjunctivitis
- Announced expected completion of enrollment in allergic conjunctivitis Phase II clinical trial in the second quarter of 2016
- Reiteration of prior guidance on the expected completion of enrollment in two ongoing Phase II clinical trials:
  - SLS dermatologic Phase II clinical trial expected to complete enrollment in the first quarter of 2016
  - Noninfectious anterior uveitis Phase II clinical trial expected to complete enrollment in the second quarter of 2016
- Poster presentation held at the 2015 American Society of Human Genetics Annual Meeting, evidencing pre-clinical activity of NS2 in trapping succinic semi-aldehyde, the key toxic aldehyde in SSADHD, in a knock-out mouse model of SSADHD

#### About NS2

NS2 is an aldehyde-binding small molecule based on an innovative platform technology focused on trapping aldehydes, which are toxic and proinflammatory mediators of numerous diseases. By decreasing aldehyde load, NS2 may mitigate excessive inflammation and address diseases where aldehyde metabolism is impaired, including certain inborn errors of metabolism.

#### About Sjögren-Larsson Syndrome

Sjögren-Larsson Syndrome (SLS) is a rare disease caused by mutations in fatty acid aldehyde dehydrogenase, leading to elevated fatty aldehyde levels that are thought to contribute to severe ichthyosis (scaly, thickened, dry skin), neurological disorders, and retinal disease. There is no FDA-approved therapy for SLS.

#### **About Noninfectious Anterior Uveitis**

Noninfectious anterior uveitis is a rare disease that may be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation in the front of the eye, pain, impaired vision, and photophobia.

#### **About Allergic Conjunctivitis**

Allergic conjunctivitis is a common disease that is thought to be mediated in part by pro-inflammatory aldehydes, and is characterized by inflammation of the conjunctiva (a membrane covering part of the front of the eye), resulting in excessive tear production in addition to ocular swelling, redness, and itching.

#### About Succinic Semi-Aldehyde Dehydrogenase Deficiency

Succinic Semi-aldehyde Dehydrogenase Deficiency (SSADHD) is a rare disease caused by mutations in succinic semi-aldehyde dehydrogenase, leading to elevated levels of succinic semi-aldehyde that result in the formation of neurotoxic metabolites. SSADHD is characterized clinically by neurological compromise that includes cognitive and developmental delay, decreased muscle tone, and, in some cases, seizures. There is no FDA-approved therapy for SSADHD.

#### **About Aldeyra Therapeutics**

Aldeyra Therapeutics, Inc., is a biotechnology company focused primarily on the development of products to treat diseases thought to be related to endogenous aldehydes, a naturally occurring class of toxic molecules. The company has developed NS2, a product candidate designed to trap aldehydes. Aldeyra has initiated clinical testing of NS2 for the treatment of Sjögren-Larsson Syndrome, noninfectious anterior uveitis, and allergic conjunctivitis. NS2 has not been approved for sale in the U.S. or elsewhere. www.aldeyra.com

#### Safe Harbor Statement

This release contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding Aldeyra's plans for its product candidates and its financial guidance. In some cases, you can identify forward-looking statements by terms such as "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. Aldeyra is at an early stage of development and may not ever have any products that generate significant revenue. 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; the ability to obtain and maintain regulatory approval to conduct clinical trials and to commercialize Aldeyra's product candidates, and the labeling for any approved products; the scope, progress, expansion, and costs of developing and commercializing Aldeyra's product candidates; the size and growth of the potential markets for Aldevra's product candidates and the ability to serve those markets; Aldevra's expectations regarding Aldevra's expenses and revenue, the sufficiency of Aldeyra's cash resources and needs for additional financing; 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 ability to establish and maintain development partnerships; 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, 2014 and Aldeyra's Quarterly Report on Form 10-Q for the quarter ended June 30, 2015, which are on file with the Securities and Exchange Commission (SEC) and available on the SEC's website at <u>www.sec.gov</u>. Additional factors may also be set forth in those sections of Aldeyra's Quarterly Report on Form 10-Q for the quarter ended September 30, 2015 to be filed with the SEC in the fourth quarter of 2015.

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:

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#### **Investor Contact:**

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# ALDEYRA THERAPEUTICS, INC.

## BALANCE SHEETS (Unaudited)

	September 30, 2015	December 31, 2014
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 30,618,365	\$ 8,527,304
Prepaid expenses and other current assets	607,335	232,568
Total current assets	31,225,700	8,759,872
Deferred offering costs	36,236	14,238
Fixed assets, net	88,463	12,993
Total assets	\$ 31,350,399	\$ 8,787,103
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 743,623	\$ 341,294
Accrued expenses	630,325	908,724
Current portion of credit facility		77,546
Total current liabilities	1,373,948	1,327,564
Credit facility, net of current portion and debt discount	1,281,088	1,175,481
Total liabilities	2,655,036	2,503,045
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value, 15,000,000 shares authorized, none issued and outstanding as of September 30,		
2015 and December 31, 2014	_	_
Common stock, voting, \$0.001 par value; 150,000,000 authorized and 9,712,521 shares issued and outstanding as		
of September 30, 2015 and 5,565,415 shares issued and outstanding as of December 31, 2014	9,712	5,565
Additional paid-in capital	82,931,679	52,790,090
Accumulated deficit	(54,246,028)	(46,511,597)
Total stockholders' equity	28,695,363	6,284,058
Total liabilities and stockholders' equity	\$ 31,350,399	\$ 8,787,103

## ALDEYRA THERAPEUTICS, INC.

## STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS) (Unaudited)

		Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014	
Operating expenses:					
Research and development	\$ 2,076,410	\$ 1,195,668	\$ 4,464,941	\$ 2,303,854	
General and administrative	1,261,196	772,467	3,188,176	2,555,692	
Loss from operations	(3,337,606)	(1,968,135)	(7,650,117)	(4,859,546)	
Other income (expense):					
Change in fair value of preferred stock warrant liabilities	—	—	_	2,327,502	
Interest income	—			3	
Interest expense	(28,081)	(41,071)	(84,314)	(210,539)	
Total other income (expense), net	(28,081)	(41,071)	(84,314)	2,116,966	
Net loss and comprehensive loss	(3,365,687)	(2,009,206)	(7,734,431)	(2,742,580)	
Accretion of preferred stock	—		_	(333,082)	
Deemed dividend				(4,053,570)	
Net loss attributable to common stockholders	\$(3,365,687)	\$(2,009,206)	\$(7,734,431)	\$(7,129,232)	
Net loss per share attributable to common stockholders:					
Basic	\$ (0.35)	\$ (0.36)	\$ (0.94)	\$ (2.21)	
Diluted	\$ (0.35)	\$ (0.36)	\$ (0.94)	<u>\$ (2.89)</u>	
Weighted average common shares outstanding:					
Basic	9,712,521	5,565,415	8,270,405	3,229,338	
Diluted	9,712,521	5,565,415	8,270,405	3,272,730	