

## Aldeyra Therapeutics (ALDX - \$4.15)

### Robust ADX-102 in Dry Eye Disease Phase IIa Results Place ALDX in a Comfortable Position Advancing Forward

This morning, ALDX reported positive ADX-102 in dry eye disease (DED) Phase IIa results and they have chosen two doses to be tested for the upcoming Phase IIb study, likely to start in 1H18.

- Details.** ALDX reported positive Phase IIa results as the treatment (data pooled from three doses) achieved a statistically significant outcome vs. baseline over 28 days in multiple measurements: Symptom Assessment in Dry Eye (SANDE) Score (p=0.003), Ocular Discomfort Score (p=0.00002), Overall Four-Symptom Score (p=0.0004), Schirmer (tear volume) Test (p=0.008), tear osmolarity (p=0.003), and Lissamine Green ocular surface staining score (p=0.002). ALDX observed reduction of malondialdehyde (p=0.009) in the tears. It is a pro-inflammatory aldehyde mediator and the reduction is consistent with mechanism of action of aldehyde trapping. ALDX has decided to choose two doses (0.1% and 0.25%) to be tested in a Phase IIb trial (n=225, vehicle controlled and 12-week treatment) with multiple standard dry eye disease signs and symptoms as endpoints. The trial will be started in 1Q18 with data readout potentially in early 3Q18. For one of the doses (0.1%) that ALDX will choose for the Phase IIb trial, the data readout from the Phase IIa study remains robust: Ocular Discomfort Score (p=0.002), the dryness component of the Four-Symptom Score (p=0.01), Overall Four-Symptom Score (p=0.048), SANDE Score (p=0.09), Schirmer Test (p=0.04), tear osmolarity (p=0.06), and tear aldehyde levels (p=0.007). Efficacy across the three doses (0.1%, 0.5%, and 0.5% lipid formulation) of Phase IIa trial are similar, and the 0.1% dose is best tolerated. Further, adding lipid did not have initially anticipated benefits.
- Implications.** We view the news a very positive development given the robust clinical responses across multiple measurements; and as such, it should bode well for potential positive outcome of the upcoming Phase IIb controlled study. Potential approval might only require success of one sign and symptom endpoint. We also view the rapid drug responses and the well differentiated MOA could set ADX-102 apart from all other marketed DED products. Further, we believe the consistent successes of clinical studies across several ocular and in rare disease indications further validate the pathological impacts of excess aldehyde and the notion that aldehyde trapping is an effective treatment modality. The Phase IIb outcome would be highly critical given it would sort out the placebo effect and potentially determine the best endpoints to be used going forward for pivotal trials.
- Action.** We are reiterating our Buy rating and our \$30 target price based on peer comparable probability adjusted DCF analyses.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-17E</b>	-0.37A	-0.35A	-0.37	-0.39	-1.48	N.A.
<b>FY-16A</b>	-0.51	-0.41	-0.38	-0.37	-1.65	N.A.
<b>FY-15A</b>	-0.32	-0.27	-0.35	-0.45	-1.40	N.A.
<b>FY-14A</b>	-0.04	-1.43	-0.36	-0.39	-2.51	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	<b>ALDX</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$30.00</b>

#### Trading Data:

Last Price (9/11/2017)	\$4.15
52-Week High (9/27/2016)	\$8.19
52-Week Low (5/9/2017)	\$3.80
Market Cap. (MM)	\$64
Shares Out. (MM)	11.352

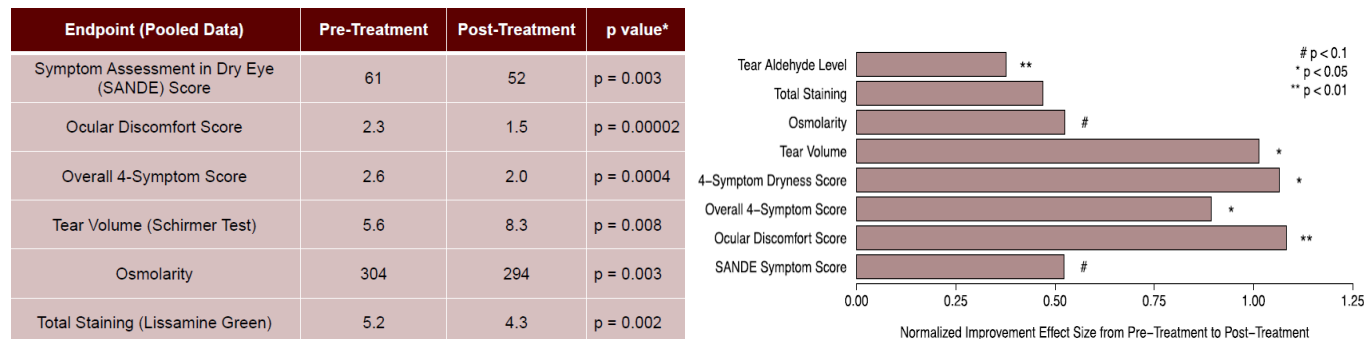
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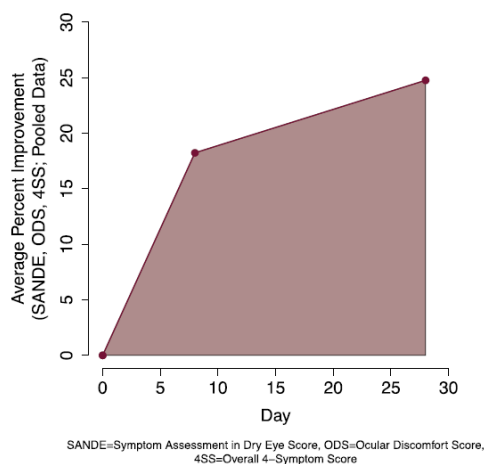
- **R&D day is scheduled for October 10<sup>th</sup>.** ALDX will host a R&D day on 10/10/2017. The agenda will focus on ocular developments with topics include the potential approvable endpoint adjustment for the allergic conjunctivitis Phase III studies, and more details and insight of dry eye disease development.

**Figure 1: ADX-102 in DED topline (n=51) (left) and 0.1% cohort (n=17) results (right)**



Source: Company report

**Figure 2: ADX-102 showed rapid and accumulative response**



Source: Company report

**Figure 3: Proposed ADX-102 in DED Phase IIb trial design**

<b>Groups</b>	0.1% ADX-102, 0.25% ADX-102, and Control
<b>Randomization</b>	1:1:1 Double-Masked
<b>Treatment Time</b>	12 Weeks
<b>Enrollment</b>	225 Patients with Dry Eye Disease
<b>Endpoints</b>	Standard Dry Eye Disease Signs and Symptoms

Source: Company report

## Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
ADX-102 cream	Sjögren-Larsson Syndrome (SLS)	Start Phase III study	4Q17	***
		Potentially interim Phase III study results	2H18	****
		Potentially Phase III study results	2019	****
ADX-102 eyedrop	Noninfectious anterior uveitis	Potentially report Phase III study top-line results	4Q18	****
		Potentially start 2nd Phase III trial	2019	***
	Allergic conjunctivitis	Potentially EOP2 discussion with the FDA	2H17	***
		Potential to start next clinical trial	1H18	***
	Dry eye syndrome	Potentially start Phase IIb trial	1H18	***
	Oral ADX-102 or new trapper	Succinic Semi-aldehyde Dehydrogenase (SSADH)	Potentially to start safety Phase I study	1Q18
Potentially to start Phase IIa study			2H18	***
Potentially to report Phase IIa study results			2019	****
Sjögren-Larsson Syndrome (SLS) CNS disorders		Potentially to start Phase I study	2H18	***
New aldehyde trapper		Provide more updates	2H17	***
		R&D day	10-Oct-17	***

\*\*\*\* / \*\*\*\*\* Major catalyst event that could impact share price very significantly while \*\*\* event is more informative

Source: Laidlaw & Company and company presentation

## Major Risks

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**Risks of clinical study failure could have a major impact on ALDX share value.** Although promising aspects of the company's lead products, ADX-102 in the two indications under clinical trials; it remains too early to predict the safety and efficacy from the two ongoing and upcoming clinical studies. The clinical validation for these programs has not been established. The success of each study could illustrate ADX-102 treatment potential of separate disease areas. It is important that one or both studies demonstrate a positive outcome in order to increase the company's assets and shareholder value. Negative results of either of the clinical studies could impair shareholder value. Further, should these programs further advance into later clinical stage development, it remains too early to predict any potential success of such clinical trials. In SLS, it is possible that elevated fatty alcohol, instead of elevated aldehyde, affects the progression of the disease. If so, ADX-102 might not have the therapeutic effect on of elevated fatty alcohol levels. We view this to be a very modest risk, however.

**Products may not be approved or reach anticipated sales.** Aldeyra's current pipeline products have exhibited the potential to generate positive clinical outcomes from current and future trials. However, it remains too early to project whether any of these products will be approved by regulatory agencies. Even if the products were to enter the market, sales could be significantly below projections due to the specific product label under approval, physician consensus for prescribing the drug, changes of treatment paradigms, entrance of competitors, and possibly the changes in pricing flexibility and payer reimbursement. A revenue outlook below expectations could also negatively affect ALDX shareholder value.

**Limited product offering and further validation of technology represent limited diversification to investors.** The major technology platform of ALDX is aldehyde trapping and the company currently has only one drug, ADX-102, in two different delivery forms, in clinical studies. As such, ALDX has a very concentrated product offering portfolio and hence, exhibits limited diversification for investors. In addition, although aldehyde trapping is a novel and logical approach in drug development, it remains too early to gain greater buy-in within medical and investor communities since clinical validation remains very limited.

**Additional financings could dilute shareholder value.** Although the company had ~\$26MM cash at the end of 2Q17, ALDX could need more financial resources going forward if it wants to expand and further develop its pipeline. Should the product not receive FDA approval, or product revenue does not reach expectations; the company might need to issue new equity to raise additional cash. Under such a scenario, the share value of existing shareholders could be diluted.

**Limited trading liquidity limits shareholder options.** Given ALDX shares only entered the public market recently; daily trading volume and name recognition are relatively modest. With relatively illiquid trading volume, shareholders wanting to increase or reduce their positions in a volatile stock market may face constraints.

Figure 1: Income Statement

Aldeyra Therapeutics – Income Statement											
(\$'000)	2014	2015	2016	1Q17	2Q17	3Q17E	4Q17E	2017E	2018E	2019E	2020E
<b>Revenue</b>											
Product revenue	0	0	0	-	-	-	-	0	0	0	2,944
Other revenue	0	0	0	-	-	-	-	0	0	0	0
Total revenue	0	0	0	-	-	-	-	0	0	0	2,944
Costs of goods				-	0	0	-	0	0	0	265
Gross sales				-	0	0	-	0	0	0	2,679
Research and development	3,708	7,574	13,176	3,369	3,849	4,157	4,406	15,781	17,201	18,749	20,249
General and administrative	3,563	4,415	5,520	1,727	1,482	1,497	1,542	6,247	6,559	6,887	7,231
Marketing and sales									16,500	16,500	16,500
<b>Total Operating Expenses</b>	7,271	11,989	18,696	5,096	5,331	5,653	5,948	22,028	40,260	42,136	43,981
<b>Operating Incomes (losses)</b>	(7,271)	(11,989)	(18,696)	(5,096)	(5,331)	(5,653)	(5,948)	(22,028)	(40,260)	(42,136)	(41,301)
Change in fair value of preferred stock warrant liabilities	2,328	0	0	-	-	-	-	0	0	0	0
Change in fair value of convertible preferred stock rights and rights	0	0	0	-	-	-	-	0	0	0	0
Value provided in excess of issuance price of Series B convertible	0	0	0	-	-	-	-	0	0	0	0
Interest income	0	11	102	32	48	27	27	134	147	162	162
Other expenses				-	-	-	-	0	0	0	0
Interest expense	(244)	(113)	(106)	(27)	(26)	(27)	(27)	(107)	(107)	(107)	(107)
Total Other Income (Expense)	2,083	(102)	(3)	5	22	0	0	27	40	55	55
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(5,091)	(5,309)	(5,653)	(5,948)	(22,001)	(40,220)	(42,082)	(41,247)
Accretion of preferred stock	(333)	0	0	-	-	-	-	0	0	0	0
Allocation of undistributed earnings to preferred stockholders	0	0	0	-	-	-	-	0	0	0	0
Deemed dividend	(4,054)	0	0	-	-	-	-	0	0	0	0
Tax	0	0	0	-	-	-	-	0	0	0	0
<b>Net Income (Loss)</b>	(9,574)	(12,091)	(18,699)	(5,091)	(5,309)	(5,653)	(5,948)	(22,001)	(40,220)	(42,082)	(41,247)
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(18,699)	(5,091)	(5,309)	(5,653)	(5,948)	(22,001)	(40,220)	(42,082)	(41,247)
Net Earnings (Losses) Per Share—Basic	(\$2.51)	(\$1.40)	(\$1.65)	(\$0.37)	(\$0.35)	(\$0.37)	(\$0.39)	(\$1.48)	(\$2.53)	(\$2.49)	(\$2.30)
Net Earnings (Losses) Per Share—Diluted	(\$3.09)	(\$1.40)	(\$1.65)	(\$0.37)	(\$0.35)	(\$0.37)	(\$0.39)	(\$1.48)	(\$2.53)	(\$2.49)	(\$2.30)
Shares outstanding—basic	3,818	8,634	11,352	13,797	15,136	15,286	15,436	14,914	15,914	16,914	17,914
Shares outstanding—diluted	3,851	8,634	11,352	13,797	15,136	15,286	15,436	14,914	15,914	16,914	17,914
<b>Margin Analysis (% of Sales/Revenue)</b>											
Costs of goods										9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	688%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	246%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1403%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1401%
<b>Financial Indicator Growth Analysis (YoY%)</b>											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	140%	104%	74%	-4%	36%	23%	28%	20%	9%	9%	8%
SG&A	67%	24%	25%	19%	1%	7%	28%	13%	5%	5%	5%
Marketing and sales											
Operating Income (Losses)	98%	65%	56%	3%	24%	18%	28%	18%	83%	5%	-2%
Pretax Income	-140%	133%	55%	2%	23%	18%	28%	18%	83%	5%	-2%
Net Income	-963%	26%	55%	2%	23%	18%	28%	18%	83%	5%	-2%
EPS	-172%	-44%	18%	-28%	-13%	-3%	4%	-10%	71%	-2%	-7%
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Source: Bloomberg LP; Company reports; Laidlaw &amp; Company estimates

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Date	Rating	Closing Price (\$)
01/26/2015	Buy (B)	9.86

**3 Year Price Change History**

Date	Target Price (\$)	Closing Price, (\$)
01/26/2015	30.00	9.86

Source: Laidlaw &amp; Company

Created by: Blue-Compass.net

Laidlaw & Company Rating System*		% of Companies Under Coverage With This Rating	% of Companies for which Laidlaw & Company has performed services for in the last 12 months	
			Investment Banking	Brokerage
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	63.83%	31.91%	2.13%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	4.26%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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