

## Aldeyra Therapeutics (ALDX - \$ 6.45)

### 3Q16: Four Clinical Programs to Start in 2017; While Oral Aldehyde Trappers Could Be Available in Late 2017

This morning, ALDX reported 3Q16 financial results with a net loss of (\$4.8MM), vs. Laidlaw (\$4.4MM) and the Street (\$5.1MM) estimates. Net loss per share was (\$0.38) vs. (\$0.41) for Laidlaw and the Street. ALDX ended 3Q16 with cash of ~\$29MM, enough to support its operations deep into 1H18, in our opinion.

- Four clinical programs are scheduled to start in 2017.** ALDX indicated that ADX-102 in noninfectious anterior uveitis Phase III study will start in 1H17 as the first vehicle-control pivotal study in this indication. We estimate top-line results could be in 2H18. Also in 1H17, two more ocular clinical trials will begin: ADX-102 in allergic conjunctivitis (Phase IIb), and ADX-102 or a new aldehyde trap in dry eye syndrome (Phase IIa). ALDX indicated that a new aldehyde trap could be potentially more suited specifically for a particular indication, i.e. more lipophilic for dry eye. We anticipate ALDX will make a decision on which specific aldehyde trapper for the relevant indication in 1H17. Further, we believe multiple aldehyde trappers could improve the commercial outlook of the platform, especially regarding the efficacy/safety of a specific indication, business development potential, and pricing flexibility. We estimate top-line results of the allergic conjunctivitis study could be available in 2H17. Management pointed out potential benefits of aldehyde trappers in treating dry eye are its unique mechanism of action compared to other drugs and potential advantages in improving the surface lubrication of the eye since aldehyde could degrade lipids. Further, a Phase III study that evaluates ADX-102 (topical) in SLS could start in 2H17 after ALDX has received feedbacks from the FDA and EMEA, possibly in 1Q17.
- Oral aldehyde trap is being developed.** ALDX announced that they are developing orally administrated aldehyde trappers for indications that require the drug to be delivered systemically. We view this as a substantial technical improvement since we were only aware of an IV trap before. Oral drug has significant value over IV drug as a long term chronic therapy. ALDX guided to start a clinical study in SSADH in late 2017 or 1Q18, depending on which aldehyde trap is to be selected for the trial.
- Action.** We are reiterating our Buy rating and our \$30 target price based on peer comparable probability adjusted DCF analyses. Clinical NS2 development in orphan and inflammatory indications are all under study. We view the ALDX shares remain under-exposed and under-valued.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-16E</b>	-0.51A	-0.41A	-0.38A	-0.40	-1.68	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.
<b>FY-13A</b>	-13.03	-5.47	2.76	18.47	3.49	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker: **ALDX**  
Rating: **Buy**  
Price Target: **\$ 30.00**

#### Trading Data:

Last Price (11/14/2016)	\$ 6.45
52-Week High (9/27/2016)	\$ 8.19
52-Week Low (2/9/2016)	\$ 3.39
Market Cap. (MM)	\$ 80
Shares Out. (MM)	12

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**Table 1: Estimated and reported 3Q16 results**

<b>3Q16 Estimates and Reported Results</b>			
<b>(\$,000)</b>	<b>Laidlaw Estimate</b>	<b>Actual</b>	<b>Consensus</b>
<b>Total revenue</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>
<b>Total op. profit (loss)</b>	<b>(\$4,396)</b>	<b>(\$4,776)</b>	<b>(\$5,600)</b>
R&D	\$2,920	\$3,380	
SG&A	\$1,477	\$1,397	
<b>EPS</b>	<b>(\$0.41)</b>	<b>(\$0.38)</b>	<b>(\$0.41)</b>
Net income (loss)	(\$4,401)	(\$4,775)	(\$5,100)

Source: Bloomberg, SEC filings and Laidlaw and Co.

## Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
ADX-102 cream	Sjögren-Larsson Syndrome (SLS)	Receive feedbacks from regulatory agencies	1H17	***
		Start Phase III study	2H17	***
ADX-102 eyedrop	Noninfectious anterior uveitis	Potentially start Phase III trial	1H17	***
		Potentially report Phase III study top-line results	2H18	****
	Allergic conjunctivitis	Potentially start Phase IIb dose-optimizing trial	1H17	***
		Potentially report Phase IIb study top-line results	2H17	****
	Dry eye syndrome	Potentially start Phase II dose-optimizing trial	1H17	***
		Potentially report Phase II dose-optimizing trial results	2H17	****
Systemic delivered (IV) ADX-102		Potentially to start safety Phase I study	YE17/1Q18	***
	Succinic Semi-aldehyde Dehydrogenase (SSADH)	Potentially to start Phase IIa study	1Q18	***
		Potentially to report Phase IIa study results	2H18	****
	Sjögren-Larsson Syndrome (SLS) CNS disorders	Potentially to start Phase III study	2H17	***
New aldehyde trapper		Provide more updates	2017	***

\*\*\*\* / \*\*\*\*\* 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, NS2 in the two indications under clinical trials; it remains too early to predict the safety and efficacy from the two ongoing Phase II studies. The clinical validation for these programs has not been established. The success of the each study could illustrate NS2 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 Phase II 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, NS2 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, NS2, 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 currently has ~\$17MM (pro forma) cash after recent financing, ALDX could need more financial resources going forward if they want 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

<b>Aldeyra Therapeutics – Income Statement</b>											
(\$'000)	2014	2015	1Q16	2Q16	3Q16	4Q16E	2016E	2017E	2018E	2019E	2020E
<b>Revenue</b>											
Product revenue	0	0	-	-	-	-	0	0	1,492	12,162	33,312
Other revenue	0	0	-	-	-	-	0	0	0	0	0
Total revenue	0	0	-	-	-	-	0	0	1,492	12,162	33,312
Costs of goods								0	134	1,095	2,998
Gross sales								0	1,358	11,067	30,314
Research and development	3,708	7,574	3,511	2,835	3,380	3,616	13,342	15,076	16,433	17,912	19,345
General and administrative	3,563	4,415	1,456	1,462	1,397	1,439	5,753	6,559	6,887	7,231	7,592
Marketing and sales									16,500	25,575	26,854
<b>Total Operating Expenses</b>	<b>7,271</b>	<b>11,989</b>	<b>4,967</b>	<b>4,297</b>	<b>4,776</b>	<b>5,055</b>	<b>19,095</b>	<b>21,635</b>	<b>39,820</b>	<b>50,718</b>	<b>53,791</b>
<b>Operating Incomes (Losses)</b>	<b>(7,271)</b>	<b>(11,989)</b>	<b>(4,967)</b>	<b>(4,297)</b>	<b>(4,776)</b>	<b>(5,055)</b>	<b>(19,095)</b>	<b>(21,635)</b>	<b>(38,462)</b>	<b>(39,651)</b>	<b>(23,478)</b>
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 preferred stock	0	0	-	-	-	-	0	0	0	0	0
Interest income	0	11	25	22	28	28	102	113	124	136	136
Other expenses		0	-	-	-	-	0	0	0	0	0
Interest expense	(244)	(113)	(25)	(28)	(27)	(27)	(106)	(106)	(106)	(106)	(106)
Total Other Income (Expense)	2,083	(102)	(0)	(6)	1	1	(4)	7	18	30	30
Net loss and comprehensive loss	(5,187)	(12,091)	(4,967)	(4,303)	(4,775)	(5,054)	(19,099)	(21,629)	(38,444)	(39,621)	(23,447)
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>	<b>(9,574)</b>	<b>(12,091)</b>	<b>(4,967)</b>	<b>(4,303)</b>	<b>(4,775)</b>	<b>(5,054)</b>	<b>(19,099)</b>	<b>(21,629)</b>	<b>(38,444)</b>	<b>(39,621)</b>	<b>(23,447)</b>
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(4,967)	(4,303)	(4,775)	(5,054)	(19,099)	(21,629)	(38,444)	(39,621)	(23,447)
Net Earnings (Losses) Per Share—Basic	(\$2.51)	(\$1.40)	(\$0.51)	(\$0.41)	(\$0.38)	(\$0.40)	(\$1.68)	(\$1.62)	(\$2.68)	(\$2.58)	(\$1.43)
Net Earnings (Losses) Per Share—Diluted	(\$3.09)	(\$1.40)	(\$0.51)	(\$0.41)	(\$0.38)	(\$0.40)	(\$1.68)	(\$1.62)	(\$2.68)	(\$2.58)	(\$1.43)
Shares outstanding—basic	3,818	8,634	9,713	10,622	12,475	12,575	11,346	13,346	14,346	15,346	16,346
Shares outstanding—diluted	3,851	8,634	9,713	10,622	12,475	12,575	11,346	13,346	14,346	15,346	16,346
<b>Margin Analysis (% of Sales/Revenue)</b>											
Costs of goods								9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	1101%	147%	58%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	462%	59%	23%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	-2578%	-326%	-70%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	-2576%	-326%	-70%
<b>Financial Indicator Growth Analysis (YoY%)</b>											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	715%	174%
R&D	140%	104%	209%	127%	63%	16%	76%	13%	9%	9%	8%
SG&A	67%	24%	50%	53%	11%	17%	30%	14%	5%	5%	5%
Marketing and sales									10%	55%	5%
Operating Income (Losses)	98%	65%	136%	95%	43%	17%	59%	13%	78%	3%	-41%
Pretax Income	-140%	133%	132%	93%	42%	16%	58%	13%	78%	3%	-41%
Net Income	-963%	26%	132%	93%	42%	16%	58%	13%	78%	3%	-41%
EPS	-172%	-44%	60%	52%	10%	-10%	20%	-4%	65%	-4%	-44%
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Source: Bloomberg LP; Company reports; Laidlaw &amp; Company estimates

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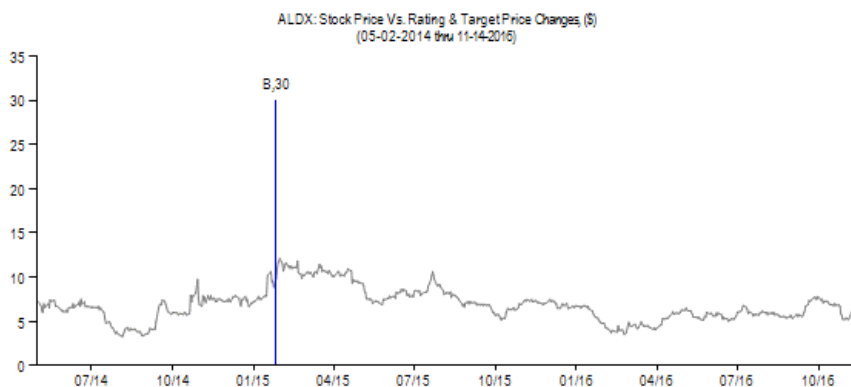
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Date	Rating	Closing Price (\$)
01/26/2015	Buy (B)	9.86

**3 Year Price Change History**

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

Source: Laidlaw &amp; Company

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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.	2.56%	2.56%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	58.97%	28.21%	2.56%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	5.13%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	2.56%	0.00%	0.00%

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