

## Aldeyra Therapeutics (ALDX - \$4.40)

### ADX-102 in Noninfectious Anterior Uveitis Phase III Trial Commenced with First Patient Enrolled

ALDX reported this morning that the ADX-102 in noninfectious anterior uveitis (NAU) Phase III trial has started (in line with our estimate) and enrolled the first patient. As such, we anticipate that top-line results could be available in 4Q18.

- Details.** As a reminder, this Phase III trial is the first vehicle controlled study in this indication. Patients (~n=100) will be randomized 1:1 to receive ADX-102 (0.5%) or vehicle 8x/day for 4 weeks. The primary endpoint of this Phase III trial, consistent with that of the earlier positive Phase II trial, is resolution of inflammation assessed through the clearing of inflammatory cells in the anterior chamber of the eye. Non-responders will be rescued by topical steroids. Additionally, cell counts will be measured at various timepoints throughout the treatment duration. We anticipate the top-line results could be available in 4Q18 or early 2019.
- Implications.** We view today's news as a positive for demonstrating ALDX management's timely execution of its pipeline development as the starting of their first Phase III trial. We believe that the future data readout of the ADX-102 in NAU Phase III trial would be an inflection point for ALDX shares given it could be the first completion of a Phase III trial of the aldehyde trapper. Should the outcome be positive, it could be a major milestone for clinically validating the anti-inflammatory potential of the aldehyde trapper as a potentially safer and better alternative to steroid. A second Phase III trial of ADX-102 in NAU would most likely be needed prior to NDA filing. A positive Phase III readout would also substantially de-risk the 2<sup>nd</sup> Phase III study and enhance the prospect for a potential approval. ALDX is ready to start a second Phase III trial in Sjorgren-Larsson syndrome (SLS) in 2H17 and dry eye syndrome Phase II study later this quarter. We project that several impactful data readouts could occur in 2017 through 2019. Additionally, ALDX is developing an orally available aldehyde trapper with the potential for treating conditions that require systemic drug delivery, and we anticipate it could enter first clinical trial in 2018.
- Action.** We are reiterating our Buy rating and our \$30 target price based on peer comparable probability adjusted DCF analyses. Clinical ADX-102 development in orphan and inflammatory indications are all under study. We view the ALDX shares remain under-exposed and under-valued.

*Healthcare/Biotechnology*

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

#### Trading Data:

Last Price (4/26/2017)	\$4.40
52-Week High (9/27/2016)	\$8.19
52-Week Low (4/24/2017)	\$3.98
Market Cap. (MM)	\$67
Shares Out. (MM)	11.352

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-17E</b>	-0.38	-0.38	-0.39	-0.40	-1.55	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.

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Source: Laidlaw & Company estimates

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## Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
ADX-102 cream	Sjögren-Larsson Syndrome (SLS)	Start Phase III study	2H17	***
		Potentially Phase III study results	2019	****
ADX-102 eyedrop	Noninfectious anterior uveitis	Potentially start Phase III trial	2Q17	***
		Potentially report Phase III study top-line results	4Q18	****
		Potentially start 2nd Phase III trial	2019	***
	Allergic conjunctivitis	Potentially start Phase IIb dose-optimizing trial	2Q17	***
		Potentially report Phase IIb study top-line results	2H17	****
	Dry eye syndrome	Potentially start Phase II dose-optimizing trial	2Q17	***
Potentially report Phase II dose-optimizing trial results		2H17	****	
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	1H17	***

\*\*\*\* / \*\*\*\*\* 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 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 ~\$29MM cash at the end of 3Q16, 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					2017E	2018E	2019E	2020E
				1Q17E	2Q17E	3Q17E	4Q17E				
<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	265
Gross sales				0	-	-	-	0	0	0	2,679
Research and development	3,708	7,574	13,176	3,622	3,695	3,917	4,018	15,252	16,625	18,121	19,571
General and administrative	3,563	4,415	5,520	1,242	1,205	1,217	1,253	4,917	5,162	5,421	5,692
Marketing and sales									16,500	16,500	16,500
<b>Total Operating Expenses</b>	<b>7,271</b>	<b>11,989</b>	<b>18,696</b>	<b>4,864</b>	<b>4,900</b>	<b>5,133</b>	<b>5,272</b>	<b>20,169</b>	<b>38,288</b>	<b>40,042</b>	<b>41,763</b>
<b>Operating Incomes (losses)</b>	<b>(7,271)</b>	<b>(11,989)</b>	<b>(18,696)</b>	<b>(4,864)</b>	<b>(4,900)</b>	<b>(5,133)</b>	<b>(5,272)</b>	<b>(20,169)</b>	<b>(38,288)</b>	<b>(40,042)</b>	<b>(39,083)</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 rig	0	0	0	-	-	-	-	0	0	0	0
Value provided in excess of issuance price of Series B converti	0	0	0	-	-	-	-	0	0	0	0
Interest income	0	11	102	27	27	27	27	108	119	131	131
Other expenses		0	0	-	-	-	-	0	0	0	0
Interest expense	(244)	(113)	(106)	(27)	(27)	(27)	(27)	(108)	(108)	(108)	(108)
Total Other Income (Expense)	2,083	(102)	(3)	0	0	0	0	0	11	23	23
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(4,864)	(4,900)	(5,133)	(5,272)	(20,169)	(38,277)	(40,019)	(39,061)
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>(18,699)</b>	<b>(4,864)</b>	<b>(4,900)</b>	<b>(5,133)</b>	<b>(5,272)</b>	<b>(20,169)</b>	<b>(38,277)</b>	<b>(40,019)</b>	<b>(39,061)</b>
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(18,699)	(4,864)	(4,900)	(5,133)	(5,272)	(20,169)	(38,277)	(40,019)	(39,061)
Net Earnings (Losses) Per Share—Basic	(\$2.51)	(\$1.40)	(\$1.65)	(\$0.38)	(\$0.38)	(\$0.39)	(\$0.40)	(\$1.55)	(\$2.74)	(\$2.67)	(\$2.45)
Net Earnings (Losses) Per Share—Diluted	(\$3.09)	(\$1.40)	(\$1.65)	(\$0.38)	(\$0.38)	(\$0.39)	(\$0.40)	(\$1.55)	(\$2.74)	(\$2.67)	(\$2.45)
Shares outstanding—basic	3,818	8,634	11,352	12,749	12,899	13,049	13,199	12,974	13,974	14,974	15,974
Shares outstanding—diluted	3,851	8,634	11,352	12,749	12,899	13,049	13,199	12,974	13,974	14,974	15,974
<b>Margin Analysis (% of Sales/Revenue)</b>											
Costs of goods										9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	665%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	193%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1327%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1327%
<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%	3%	30%	16%	16%	16%	9%	9%	8%
SG&A	67%	24%	25%	-15%	-18%	-13%	4%	-11%	5%	5%	5%
Marketing and sales											
Operating Income (Losses)	98%	65%	56%	-2%	14%	7%	13%	8%	90%	5%	-2%
Pretax Income	-140%	133%	55%	-2%	14%	7%	13%	8%	90%	5%	-2%
Net Income	-963%	26%	55%	-2%	14%	7%	13%	8%	90%	5%	-2%
EPS	-172%	-44%	18%	-25%	-6%	3%	8%	-6%	76%	-2%	-9%

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Source: Bloomberg LP; Company reports; Laidlaw &amp; Company estimates

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#### Rating and Price Target Change History



#### 3 Year Rating Change History

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 & 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.	2.27%	2.27%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	61.36%	29.55%	2.27%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	0.00%	0.00%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	2.27%	0.00%	0.00%

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