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EQUITY RESEARCH
Company Report

June 14, 2017

Aldeyra Therapeutics (ALDX - $5.10)

Healthcare/Biotechnology

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

New Opportunity Potentially Opened Up for ADX-102 in Allergic Conjunctivitis Due to Its Long-Lasting Effects

This morning, ALDX announced the top-line results of ADX-102 in allergic conjunctivitis (AC) Phase IIb trial. The study did not meet the primary endpoint of a one-point itching score reduction vs. control, but the drug demonstrated later-phase anti-inflammatory activities. ALDX plans to advance this program into a Phase III trial after discussions with the FDA in 2H17.

- **Details.** The results showed a superior reduction of ocular itching from ADX-102 (0.5%) vs. vehicle at 10, 20, 30 and 60 minutes post-challenge (p=0.02, 0.04, 0.03, and <0.03, respectively). The drug performed better in patients challenged by seasonal allergens with itch score improvements of 23%, 37%, 55%, and 65% at 10, 20, 30, and 60 minutes post-challenge. Conventionally, allergic conjunctivitis clinical studies (mainly testing antihistamines and corticosteroids) will seek a one-point or greater difference in itch score (0 to 4-point scale) at 5 minutes post-challenge, or a 38% or greater improvement relative to that of the vehicle values observed in the trial. The ADX-102 data suggest that the 38% one-point equivalent threshold was met or exceeded 20 minutes post-challenge and later. Although ADX-102 might not provide acute relief, ALDX believes the drug could potentially treat AC patients who experience a sub-optimal response from current antihistamine therapies given its slower onset but longer lasting effect. ALDX is scheduled to conduct an EOP2 meeting with the FDA (we estimate later in 2H17) and potentially start a Phase III trial thereafter, possibly in seasonal AC cases. Management also guided that two Phase III trials might be needed and the overall design of the Phase III trial might not deviate too much from the completed Phase IIa trial.
- **Implications**. We view the outcome of the news is mixed since the ADX-102 in AC development now needs to gain additional buy-in by the FDA for potentially adjusting the trial design and endpoint compared to studies with conventional agents. However, the unique Phase IIb trial outcome could potentially open up a new treatment paradigm for ADX-102 to potentially relieve a later phase inflammation burden that current treatments cannot address. It also appears that no other agents are currently competing in this arena.
- **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.

Trading Data:

Last Price (6/13/2017)	$5.10
52–Week High (9/27/2016)	$8.19
52–Week Low (5/9/2017)	$3.80
Market Cap. (MM)	$69
Shares Out. (MM)	11.352

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.37A	-0.37	-0.38	-0.38	-1.50	N.A.
FY-16A	-0.51	-0.41	-0.38	-0.37	-1.65	N.A.
FY-15A	-0.32	-0.27	-0.35	-0.45	-1.40	N.A.
FY-14A	-0.04	-1.43	-0.36	-0.39	-2.51	N.A.

Source: Laidlaw & Company estimates

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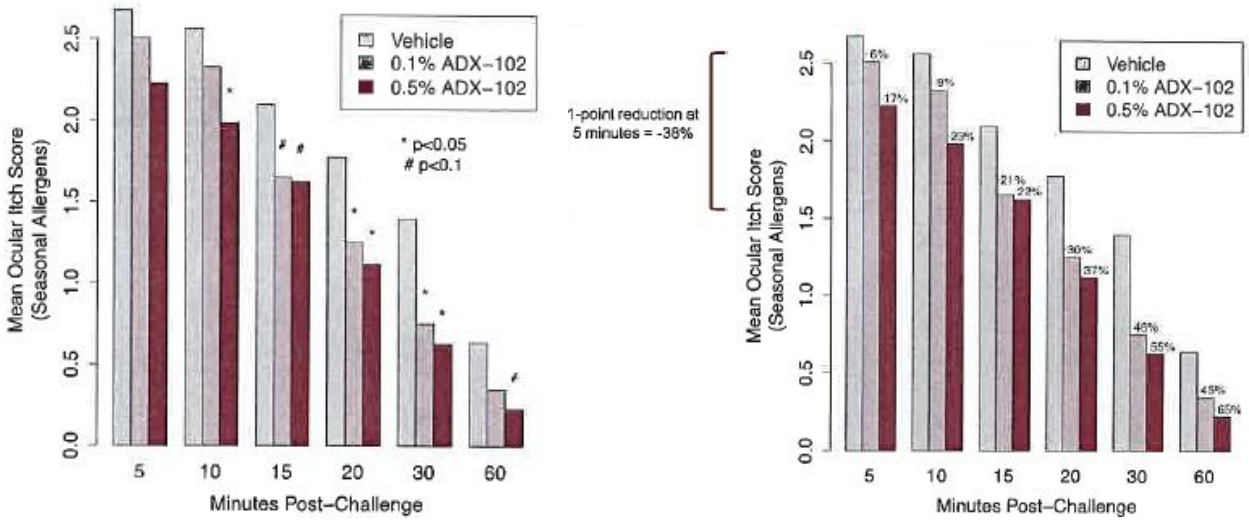
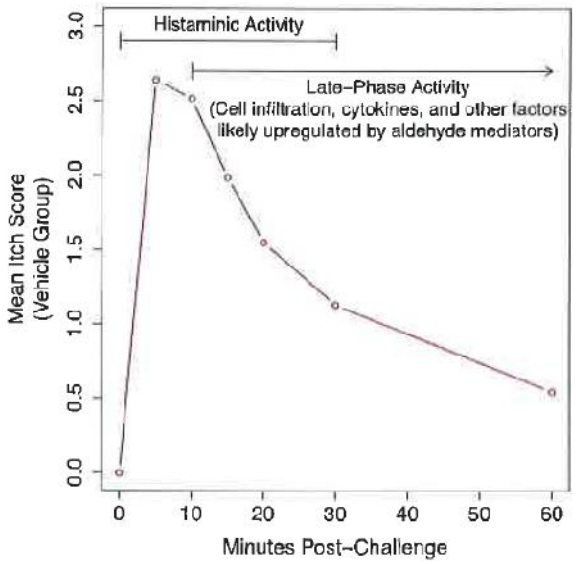
- **ADX-102 in AC treatment demonstrated a slower onset but durable responses.** Specifically, 0.5% ADX-102 demonstrated a slower onset but longer lasting itching reduction (Figure 1). Further, Figure 2 illustrates the potential treatment benefits of histamine and non-histamine agents.

Figure 1: Itch score vs. time post-challenge by seasonal allergens (itch score-left, %-right)



Source: Company report

Figure 2: Potential treatment benefits of histamine and non-histamine agents



Source: Company report

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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 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	**2H17/1H18**	***
	Dry eye syndrome	Potentially report Phase II dose-optimizing trial results	**3Q17**	****
Oral ADX-102 or new trapper		Potentially to start safety Phase I study	**1Q18**	***
	Succinic Semi-aldehyde Dehydrogenase (SSADH)	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

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Major Risks

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 ~$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,

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shareholders wanting to increase or reduce their positions in a volatile stock market may face constraints.

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Figure 1: Income Statement

Aldeyra Therapeutics – Income Statement

($'000)	2014	2015	2016	1Q17	2Q17E	3Q17E	4Q17E	2017E	2018E	2019E	2020E
Revenue											
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	3,369	3,436	3,643	3,737	14,185	15,462	16,854	18,202
General and administrative	3,563	4,415	5,520	1,727	1,675	1,692	1,743	6,836	7,178	7,537	7,914
Marketing and sales									16,500	16,500	16,500
Total Operating Expenses	7,271	11,989	18,696	5,096	5,111	5,334	5,480	21,022	39,140	40,891	42,616
Operating Incomes (losses)	(7,271)	(11,989)	(18,696)	(5,096)	(5,111)	(5,334)	(5,480)	(21,022)	(39,140)	(40,891)	(39,937)
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	32	27	27	27	113	124	136	136
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)	5	0	0	0	5	16	28	28
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(5,091)	(5,111)	(5,334)	(5,480)	(21,017)	(39,124)	(40,862)	(39,908)
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
Net Income (Loss)	(9,574)	(12,091)	(18,699)	(5,091)	(5,111)	(5,334)	(5,480)	(21,017)	(39,124)	(40,862)	(39,908)
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(18,699)	(5,091)	(5,111)	(5,334)	(5,480)	(21,017)	(39,124)	(40,862)	(39,908)
Net Earnings (Losses) Per Share—Basic	($2.51)	($1.40)	($1.65)	($0.37)	($0.37)	($0.38)	($0.38)	($1.50)	($2.60)	($2.55)	($2.34)
Net Earnings (Losses) Per Share—Diluted	($3.09)	($1.40)	($1.65)	($0.37)	($0.37)	($0.38)	($0.38)	($1.50)	($2.60)	($2.55)	($2.34)
Shares outstanding—basic	3,818	8,634	11,352	13,797	13,947	14,097	14,247	14,022	15,022	16,022	17,022
Shares outstanding—diluted	3,851	8,634	11,352	13,797	13,947	14,097	14,247	14,022	15,022	16,022	17,022
Margin Analysis (% of Sales/Revenue)											
Costs of goods										9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	618%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	269%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1356%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1355%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	140%	104%	74%	-4%	21%	8%	8%	8%	9%	9%	8%
SG&A	67%	24%	25%	19%	15%	21%	45%	24%	5%	5%	5%
Marketing and sales											
Operating Income (Losses)	98%	65%	56%	3%	19%	12%	18%	12%	86%	4%	-2%
Pretax Income	-140%	133%	55%	2%	19%	12%	18%	12%	86%	4%	-2%
Net Income	-963%	26%	55%	2%	19%	12%	18%	12%	86%	4%	-2%
EPS	-172%	-44%	18%	-28%	-10%	-1%	4%	-9%	74%	-2%	-8%

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

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Additional information available upon request.

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RATINGS INFORMATION

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
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	64.44%	31.11%	2.22%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.22%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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