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EQUITY RESEARCH
Company Report

July 13, 2018

Aldeyra Therapeutics (ALDX - $8.65)

Healthcare/Biotechnology

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

On the Road with Management Strengthened Our Investment Thesis on Reproxalap Potential and Pipeline Diversification

We recently hosted several meetings with investors and ALDX management for a company update. We walked away with strengthened confidence that Reproxalap could be a significant ocular product, and the enhanced value of their diversified pipeline based on different MOA. Key takeaways include:

- **Reproxalap in DED Phase IIb readout is a main discussion focus.** After ALDX just completed dosing the last patient of the Reproxalap in DED Phase IIb study, we anticipate the topline results could be available in September this year. This is Reproxalap's first vehicle-controlled study to potentially show the drug's effect over placebo. Given the patient size (100/dose cohort for a total of three cohorts) of the study is relatively small, it is unlikely, and also was not intended, to demonstrate statistically significant readout of the endpoints in signs and symptoms (five each with a total of ten). As such, in our opinion, an outcome where Reproxalap demonstrates positive trends over vehicle in one or more signs and symptoms would be considered a success. This could provide the basis for study designs, like patient size and selection of signs and symptoms, for the pivotal Phase III studies. A home run scenario would be that one or more signs and symptoms show statistically significant or near significant results; while the worst scenario would be no meaningful positive trend being observed in either signs or symptoms. It would also be interesting to compare each study arm and the combined treatments (0.1% and 0.25% if the AE profile is similar) vs. vehicle.
- **Reproxalap is a much larger franchise product beyond DED.** Further, the first Phase III study data reporting for Reproxalap in allergic conjunctivitis (AD) is scheduled in 4Q18/1Q19. Given the similar study design and the robust outcome of the previous Phase II study, we are optimistic for a positive outcome. If so, the second Phase III study could start in 2019. AD patient size is larger than that of DED with ~40% of them suffering from both indications. Since AD therapy (antihistamine via its anti-cholinergic activities) could increase eye dryness, while DED medication (like Restasis) could increase itch; Reproxalap, in theory, is best positioned for treating these two indications, particularly to those suffering from both disorders. Further, Reproxalap in non-infectious anterior uveitis (NAU) Phase III study is ongoing with topline readout possibly in late 2019.
- **Action.** We are reiterating our Buy rating and our $30 target price based on peer comparable probability adjusted DCF analyses. We view the ALDX shares remain under-exposed and under-valued.

Trading Data:

Last Price (7/12/2018)	$8.65
52–Week High (9/15/2017)	$11.90
52–Week Low (8/21/2017)	$3.90
Market Cap. (MM)	$169
Shares Out. (MM)	15.92

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	-0.43A	-0.47	-0.50	-0.48	-1.89	N.A.
FY-17A	-0.37	-0.35	-0.32	-0.36	-1.40	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.

Source: Laidlaw & Company estimates

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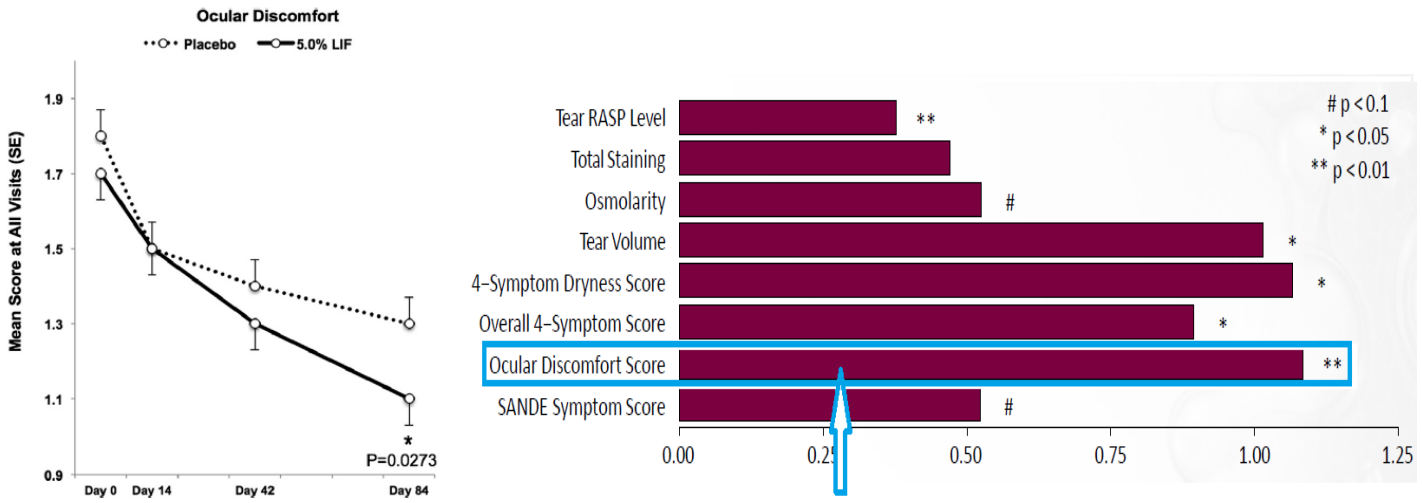
- **Newly added Hsp90 inhibitors expand pipeline diversity.** The main objective for the expanded Hsp90 inhibitor pipeline products are for treating inflammatory diseases. Supported by the anti-inflammatory effects observed on vasculitis from a prior leukemia Phase I study and preclinical lupus model, ALDX plans to conduct an ADX-1612 in post-transplant lymphoproliferative disorder (PTLD) Phase IIa trial in 2019. In addition, ADX-1615, an oral pro-drug of ADX-1612, is under preclinical development. Two cancer treatment developments: ADX-1612/pemextred/platinum in mesothelioma study topline readout in 2H18; and a start of ADX-1612/carboplatin/niraparib in ovarian cancer trial (in 2H18); are likely to be a free call option to investors since these developments are not being priced-in by investors.
- **A potential peek at the ocular discomfort zone score (ODS) effect of a control vehicle.** The main objective of the Reproxalap in DED Phase IIb study is to determine the drug's activities over the vehicle control. One possible way to potentially gauge the vehicle effect alone is to examine clinical performance a similar vehicle (water-based) in another DED trial. We fully recognize the caveat of such a comparison but believe this might provide some approximation for examining this issue. From the OPUS-1 study, which is one of the three Phase III studies for Xiidra (lifitegrast) approval, Xiidra and placebo both showed ~0.4 point of reduction in ocular discomfort zone score (ODS) at day 45 (see left panel of Figure 1). Reproxalap in DED Phase IIa study showed >1-point improvement from baseline in ODS over 28 days treatment (see highlighted portion of the right panel of Figure 1). Assuming a linear relationship exists between time and ODS changes, the readout at the 28-day could be ~0.27 for the vehicle – a number that is significantly smaller than 1+ improvements demonstrated from the Reproxalap in DED Phase IIa study (see arrow). Should this scenario play out during the Phase IIb trial, Reproxalap could score well in this symptom (ODS) measurment vs. vehicle. We do not expect to extrapolate similar performance to other sign and symptom criteria unless we would have similar historical clinical data as reference points.

Figure 1: ODS of lifitegrast vs. placebo from OPUS-1 trial (left) and 0.1% Reproxalap in DED Phase IIa readout



Source: Sheppard, J.D., et al., 2014, Ophthalmology. 121:475-83; and Corporate presentation

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Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
Reproxalap cream	Sjögren-Larsson Syndrome (SLS)	Potentially start first part of the Phase III study	**3Q18**	***
		Potentially interim Phase III study results	**1H19**	****
		Potentially Phase III study results	**2019/2020**	****
Reproxalap eyedrop	Noninfectious anterior uveitis	Potentially report Phase III study top-line results	**2019**	****
	Allergic conjunctivitis	Potentially report Phase III trial outcome	**4Q18/1Q19**	****
		Potential meeting with the FDA for second Phase III trial design and expectation	**2019**	***
		Potentially start 2nd Phase III trial	**2019**	***
		Potential NDA filing	**Late 2019/2020**	***
	Dry eye syndrome	Potentially report Phase IIb trial outcome	**3Q18**	****
ADX-103	Retina disease	Potentially start Phase I/IIa study	**2019**	***
ADX-629		Potentially start safety Phase I study	**2019**	***
	NASH	Potentially start Phase IIa study	**2019**	***
	IBD	Potentially start Phase IIa study	**2019**	***
ADX-1612	Mesothelioma	Investigator sponsored trial data readout	**2H18**	***
	Ovarian cancer	Start investigator sponsored Phase II study	**2H18**	***
	Lymphoproliferative immune disease	Start Phase II study	**2019**	***

***** / ***** 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, Reproxalap 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 Reproxalap 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, Reproxalap 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, Reproxalap, 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 ~$39MM cash at the end of 1Q18, 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.

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Figure 1: Income Statement

Aldeyra Therapeutics – Income Statement

($'000)	2014	2015	2016	2017	1Q18	2Q18E	3Q18E	4Q18E	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	16,303	6,600	7,260	7,986	8,385	30,232	32,953	35,589
General and administrative	3,563	4,415	5,520	6,186	1,891	1,948	2,006	2,067	7,913	8,308	8,724
Marketing and sales											16,500
Total Operating Expenses	7,271	11,989	18,696	22,488	8,491	9,208	9,993	10,452	38,144	41,261	60,812
Operating Incomes (losses)	(7,271)	(11,989)	(18,696)	(22,488)	(8,491)	(9,208)	(9,993)	(10,452)	(38,144)	(41,261)	(58,133)
Interest income	0	11	102	261	122	54	55	56	287	316	316
Other expenses		0	0	0	-	-	-	-	0	0	0
Interest expense	(244)	(113)	(106)	(113)	(28)	(27)	(27)	(27)	(109)	(109)	(109)
Total Other Income (Expense)	2,083	(102)	(3)	148	94	27	28	29	178	207	207
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(22,341)	(8,397)	(9,181)	(9,965)	(10,423)	(37,966)	(41,054)	(57,926)
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)	(22,341)	(8,397)	(9,181)	(9,965)	(10,423)	(37,966)	(41,054)	(57,926)
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(18,699)	(22,341)	(8,397)	(9,181)	(9,965)	(10,423)	(37,966)	(41,054)	(57,926)
Net Earnings (Losses) Per Share—Basic	($2.51)	($1.40)	($1.65)	($1.40)	($0.43)	($0.47)	($0.50)	($0.48)	($1.89)	($1.63)	($2.22)
Net Earnings (Losses) Per Share—Diluted	($3.09)	($1.40)	($1.65)	($1.40)	($0.43)	($0.47)	($0.50)	($0.48)	($1.89)	($1.63)	($2.22)
Shares outstanding—basic	3,818	8,634	11,352	15,922	19,367	19,567	19,767	21,767	20,117	25,117	26,117
Shares outstanding—diluted	3,851	8,634	11,352	15,922	19,367	19,567	19,767	21,767	20,117	25,117	26,117
Margin Analysis (% of Sales/Revenue)											
Costs of goods										9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1209%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	296%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1974%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1967%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	140%	104%	74%	24%	96%	89%	126%	51%	85%	9%	8%
SG&A	67%	24%	25%	12%	10%	31%	36%	38%	28%	5%	5%
Marketing and sales											
Operating Income (Losses)	98%	65%	56%	20%	67%	73%	99%	48%	70%	8%	41%
Pretax Income	-140%	133%	55%	19%	65%	73%	100%	50%	70%	8%	41%
Net Income	-963%	26%	55%	19%	65%	73%	100%	50%	70%	8%	41%
EPS	-172%	-44%	18%	-15%	18%	34%	58%	32%	35%	-13%	36%

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

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Rating and Price Target Change History

3 Year Rating Change History

Date	Rating	Closing Price ($)

3 Year Price Change History

Date	Target Price ($)	Closing Price. ($)

Source: Laidlaw & Company Created by: Blue-Compass.net
Note stock rated Buy with $30 price target on 01/26/2015.

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.	66.67%	25.93%	3.70%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	0.00%	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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