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EQUITY RESEARCH
Company Report

July 24, 2018

Aldeyra Therapeutics (ALDX - $8.65)

Healthcare/Biotechnology

Topical Dermal Reproxalap in Sjögren-Larsson Syndrome Phase III Trial Started

This morning, ALDX announced the enrollment of the first patient for its topical dermal Reproxalap in Sjögren-Larsson Syndrome (SLS) Phase III trial.

- **Details.** As a reminder, the Reproxalap in SLS Phase III trial is a randomized, double-blind, multi-center, parallel-group study which can be divided into two parts. The first part will assess six months of treatment in select areas of ichthyosis over increasing proportions of body surface area to explore the safety profile given the drug has not been administrated to the full body. The second part is expected to assess six months of treatment in all areas of ichthyosis. Data generated from the first part of the trial will be used to confirm statistical power for the second part of the trial. The primary endpoint for the second part of the trial will be improvement in ichthyosis in drug-treated patients over six months of therapy. Given SLS is an ultra-rare orphan disease, we anticipate a successful completion of the second part of the study would be eligible for approval.
- **Implications.** We believe the commencement of the topical dermal Reproxalap in SLS Phase III trial would be an important milestone advancing this program forward with the possibility of bringing this drug to market in the early 2020's. Topical dermal Reproxalap addresses the direct etiological cause of the disorder of having excess reactive aldehyde caused by impairments (mutations) of fatty acid aldehyde dehydrogenase. We believe the earlier robust clinical results bode well for the potential success of the ongoing Phase III study. As a reminder, the Phase II trial was a randomized, parallel-group, double-blind, vehicle-controlled study showed clinically relevant activity in diminishing the severity of ichthyosis in SLS patients. Specifically, 83% (5/6) of Reproxalap treated vs. 20% (1/5) vehicle-treated patients achieved composite ISS of $\leqslant 5$ at week 8 (p=0.04). 83% (5/6) of Reproxalap treated vs. 17% (1/6) vehicle-treated patients achieved $\geqslant 2$ point reduction from baseline in composite ISS at week 8 (p=0.02). From central reader digital photography assessment, ISS reduction was observed between Reproxalap vs. vehicle (~-2.5 vs. -1 with p<0.05). Further, Reproxalap treated patients showed greater mean ichthyosis severity reductions after eight weeks vs. four weeks therapy, suggesting the drug might have disease modifying activity. Reproxalap was administered once-daily (QD) on a 4x10 inch area of skin mainly on the leg.
- **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.

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

Trading Data:

Last Price (07/24/2018)	$8.65
52–Week High (9/15/2017)	$ 11.90
52–Week Low (8/21/2017)	$ 3.90
Market Cap. (MM)	$ 168
Shares Out. (MM)	21

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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Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
Reproxalap cream	Sjögren-Larsson Syndrome (SLS)	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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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 ($)

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.

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			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.	67.27%	25.45%	3.64%
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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