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EQUITY RESEARCH
Company Report

January 25, 2017

Aldeyra Therapeutics (ALDX - $5.70)

Healthcare/Biotechnology

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

Commencement of Two Phase III Trials and Potential Data Readouts from Two Phase II Trials Makes for an Event-Rich 2017

This morning, ALDX announced the schedule for starting two ADX-102 Phase III trials of noninfectious anterior uveitis (NAU) in 2Q17 and Sjögren-Larsson syndrome (SLS) in 2H17. As such, ALDX could potentially report the top-line results of NAU and SLS studies in late 2018 and in 2019, respectively.

- **Details.** ALDX indicated that the ADX-102 (ocular) in NAU Phase III study is on track to start in 2Q17. It is the first vehicle controlled study in this indication (~n=100) with patients to be randomized 1:1 to ADX-102 (0.5%) or vehicle. Patients will be dosed 8x/day for 4 weeks and the primary endpoint is the clearing of inflammatory cells in the anterior chamber of the eye. This is the same endpoint as the prior Phase II study. All non-responders will be rescued by topical steroids. In addition, cell count measures will be carried out at various timepoints throughout the treatment duration. ALDX guided that the Phase III study top-line results could be available in late 2018. After the EOP2 meeting with the FDA, ALDX plans to start ADX-102 (1% dermatologic topical) in SLS Phase III study in 2H17. The trial intends to enroll ~30 patients in the U.S. and EU. The treatment duration is at least 4 months. The change in ichthyosis severity score from baseline is the primary endpoint, and top-line results are expected in 2019. Further, two Phase II trials will be started in 2017: 1) ADX-102 in allergic conjunctivitis Phase IIb dose optimizing trial in 1H17 with top-line expected in 2H17, and 2) dry eye syndrome dose optimizing Phase II trial will also start in 1H17 for testing two different active drugs, ADX-102 and ADX-103, with data potentially available in 2H17. Additionally, an oral aldehyde trapper Phase I trial will start in 1H18 with Phase II trials in SLS and SSADH to follow potentially in 2H18.
- **Implications.** The timing for the commencement of the two Phase III trials is overall in-line with our expectations. However, given 1) the current share valuation, 2) two pivotal trials will be underway and data readouts expected from two other Phase II trials in 2017, and 3) rather robust prior Phase II study results of three different trials, we believe ALDX shares are under-valued given the potential of the aldehyde trapping modality.
- **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 (1/24/2017)	$5.70
52–Week High (9/27/2016)	$8.19
52–Week Low (2/9/2016)	$3.39
Market Cap. (MM)	$74
Shares Out. (MM)	8.634

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.38	-0.37	-0.38	-0.39	-1.52	N.A.
FY-16E	-0.51A	-0.41A	-0.38A	-0.40	-1.68	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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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	**1H17**	***
		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	**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**	****
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	1Q16	2Q16	3Q16	4Q16E	2016E	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	265
Gross sales								0	0	0	2,679
Research and development	3,708	7,574	3,511	2,835	3,380	3,616	13,342	13,856	15,103	16,462	17,779
General and administrative	3,563	4,415	1,456	1,462	1,397	1,439	5,753	5,866	6,159	6,467	6,791
Marketing and sales									16,500	16,500	16,500
Total Operating Expenses	7,271	11,989	4,967	4,297	4,776	5,055	19,095	19,722	37,763	39,430	41,070
Operating Incomes (losses)	(7,271)	(11,989)	(4,967)	(4,297)	(4,776)	(5,055)	(19,095)	(19,722)	(37,763)	(39,430)	(38,391)
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	25	22	28	28	102	108	119	131	131
Other expenses		0	-	-	-	-	0	0	0	0	0
Interest expense	(244)	(113)	(25)	(28)	(27)	(27)	(106)	(108)	(108)	(108)	(108)
Total Other Income (Expense)	2,083	(102)	(0)	(6)	1	1	(4)	0	11	23	23
Net loss and comprehensive loss	(5,187)	(12,091)	(4,967)	(4,303)	(4,775)	(5,054)	(19,099)	(19,722)	(37,752)	(39,407)	(38,368)
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)	(4,967)	(4,303)	(4,775)	(5,054)	(19,099)	(19,722)	(37,752)	(39,407)	(38,368)
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(4,967)	(4,303)	(4,775)	(5,054)	(19,099)	(19,722)	(37,752)	(39,407)	(38,368)
Net Earnings (Losses) Per Share—Basic	($2.51)	($1.40)	($0.51)	($0.41)	($0.38)	($0.40)	($1.68)	($1.52)	($2.71)	($2.64)	($2.41)
Net Earnings (Losses) Per Share—Diluted	($3.09)	($1.40)	($0.51)	($0.41)	($0.38)	($0.40)	($1.68)	($1.52)	($2.71)	($2.64)	($2.41)
Shares outstanding—basic	3,818	8,634	9,713	10,622	12,475	12,575	11,346	12,950	13,950	14,950	15,950
Shares outstanding—diluted	3,851	8,634	9,713	10,622	12,475	12,575	11,346	12,950	13,950	14,950	15,950
Margin Analysis (% of Sales/Revenue)											
Costs of goods										9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	604%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	231%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1304%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1303%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	140%	104%	209%	127%	63%	16%	76%	4%	9%	9%	8%
SG&A	67%	24%	50%	53%	11%	17%	30%	2%	5%	5%	5%
Marketing and sales											
Operating Income (Losses)	98%	65%	136%	95%	43%	17%	59%	3%	91%	4%	-3%
Pretax Income	-140%	133%	132%	93%	42%	16%	58%	3%	91%	4%	-3%
Net Income	-963%	26%	132%	93%	42%	16%	58%	3%	91%	4%	-3%
EPS	-172%	-44%	60%	52%	10%	-10%	20%	-10%	78%	-3%	-9%

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

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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.	2.44%	2.44%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	58.54%	26.83%	2.44%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.88%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	4.88%	0.00%	0.00%

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