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EQUITY RESEARCH
Company Report

January 30, 2018

Aldeyra Therapeutics (ALDX - $5.80)

Healthcare/Biotechnology

Ocular Reproxalap in Dry Eye Disease Phase IIb Trial Started as Guided

This morning, ALDX reported the enrollment of the first patient for the ocular reproxalap (former ADX-102) in dry eye disease (DED) Phase IIb trial.

- **Details.** As a reminder, the ocular reproxalap in DED Phase IIb trial is a randomized, double masked, parallel-group and vehicle-controlled study that evaluates the safety and efficacy of two doses (0.25% and 0.1%) of reproxalap compared to vehicle. The study will enroll 300 patients (evenly divided among the three arms) with moderate symptoms and the treatment duration is 12 weeks. Although the primary endpoint is safety and tolerability, it is equally important for investors to examine the potential efficacy vs. vehicle of the drug based on multiple secondary endpoints. They include: Lissamine green staining, fluorescein staining (both based on Ora Calibra scale), tear film break-up time, ocular discomfort (based on the Ora Calibra Ocular Discomfort scale) and two for dry eye syndrome [based on the Ocular Surface and Disease Index (OSDI) questionnaire and Symptom Assessment in Dry Eye (SANDE) scale]. We anticipate the topline outcome readout by mid-2H17.
- **Implications.** We view today's news an important step demonstrating the company's execution for advancing the DED program forward. This is especially so as this would be a first critical clinical proof-of-concept study by comparing ocular reproxalap with vehicle to tease out the actual activities of signs and symptoms of the drug. Given Restasis and Xiidra are the only two approved treatments for chronic dry eye and each has their shortcomings, reproxalap, if successful, would be a $1+ billion opportunity. ALDX reported a promising Phase IIa trial outcome in 3Q17 without vehicle control. Given reproxalap also demonstrated rapid and accumulative response from the Phase IIa study, it is possible, in our opinion, that the drug potentially could also compete in the dry eye treatment space for more accurate and episodic events. In addition to multiple clinical data readout-driven catalysts in 2H18 for ALDX (more details in the ensuing section), we also anticipate the company later this year to provide more details of different systemically administrated aldehyde trappers. We believe the parenterally delivered drugs could provide immediate relieve for acute conditions; while orally delivered drugs could be more effective in chronic conditions.
- **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 (11/8/2017)	$5.80
52–Week High (9/15/2017)	$11.90
52–Week Low (5/9/2017)	$3.80
Market Cap. (MM)	$108
Shares Out. (MM)	11.352

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.37A	-0.35A	-0.32A	-0.33	-1.37	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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- **2018 will likely be a value inflection year for ALDX given the critical and frequent clinical data readouts in 2H18.** We view 2018 as potentially a value inflection year for ALDX shares given the multiple late stage clinical data readouts, especially in 2H18. ALDX already completed an EOP2 meeting with the FDA late last year and is scheduled to start a Reproxalap in allergic conjunctivitis Phase III trial in 1Q18 with topline results possibly in 2H18 (possibly in 4Q18). In addition, our discussions with management suggested that the Reproxalap in noninfectious anterior uveitis (NAU) Phase III trial is on track and results could also be available in 2H18. Along with the DED Phase IIb trial outcome readout, 2H18 could be loaded with critical clinical trial data releases.

  In addition, the first (dose finding) portion of the topical Reproxalap in Sjögren-Larsson Syndrome (SLS) Phase III results could start in 1H18 with interim results available in late 2H18 or early 2019.

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Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
ADX-102 cream	Sjögren-Larsson Syndrome (SLS)	Start Phase III study	**1H18**	***
		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	**4Q17**	***
		Potential to start Phase III trial	**1H18**	***
		Potentially report Phase III trial outcome	**2H18**	****
	Dry eye syndrome	Potentially report Phase IIb trial outcome	**2H18**	****
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	**2018**	***

***** / ***** 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, 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	2Q17	3Q17	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	0	0	265
Gross sales				-	0	0	0	0	0	0	2,679
Research and development	3,708	7,574	13,176	3,369	3,849	3,539	3,752	14,509	23,069	25,146	27,157
General and administrative	3,563	4,415	5,520	1,727	1,482	1,476	1,520	6,205	6,515	6,841	7,183
Marketing and sales											16,500
Total Operating Expenses	7,271	11,989	18,696	5,096	5,331	5,015	5,272	20,714	29,584	31,986	50,840
Operating Incomes (losses)	(7,271)	(11,989)	(18,696)	(5,096)	(5,331)	(5,015)	(5,272)	(20,714)	(29,584)	(31,986)	(48,161)
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	48	57	37	174	191	210	210
Other expenses		0	0	-	-	-	-	0	0	0	0
Interest expense	(244)	(113)	(106)	(27)	(26)	(28)	(27)	(108)	(108)	(108)	(108)
Total Other Income (Expense)	2,083	(102)	(3)	5	22	29	10	66	83	102	102
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(5,091)	(5,309)	(4,986)	(5,262)	(20,648)	(29,501)	(31,884)	(48,058)
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)	(5,309)	(4,986)	(5,262)	(20,648)	(29,501)	(31,884)	(48,058)
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(18,699)	(5,091)	(5,309)	(4,986)	(5,262)	(20,648)	(29,501)	(31,884)	(48,058)
Net Earnings (Losses) Per Share—Basic	($2.51)	($1.40)	($1.65)	($0.37)	($0.35)	($0.32)	($0.33)	($1.37)	($1.84)	($1.51)	($2.18)
Net Earnings (Losses) Per Share—Diluted	($3.09)	($1.40)	($1.65)	($0.37)	($0.35)	($0.32)	($0.33)	($1.37)	($1.84)	($1.51)	($2.18)
Shares outstanding—basic	3,818	8,634	11,352	13,797	15,136	15,581	15,731	15,062	16,062	21,062	22,062
Shares outstanding—diluted	3,851	8,634	11,352	13,797	15,136	15,581	15,731	15,062	16,062	21,062	22,062
Margin Analysis (% of Sales/Revenue)											
Costs of goods										9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	922%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	244%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1636%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1632%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	140%	104%	74%	-4%	36%	5%	9%	10%	59%	9%	8%
SG&A	67%	24%	25%	19%	1%	6%	26%	12%	5%	5%	5%
Marketing and sales											
Operating Income (Losses)	98%	65%	56%	3%	24%	5%	13%	11%	43%	8%	51%
Pretax Income	-140%	133%	55%	2%	23%	4%	13%	10%	43%	8%	51%
Net Income	-963%	26%	55%	2%	23%	4%	13%	10%	43%	8%	51%
EPS	-172%	-44%	18%	-28%	-13%	-16%	-9%	-17%	34%	-18%	44%

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

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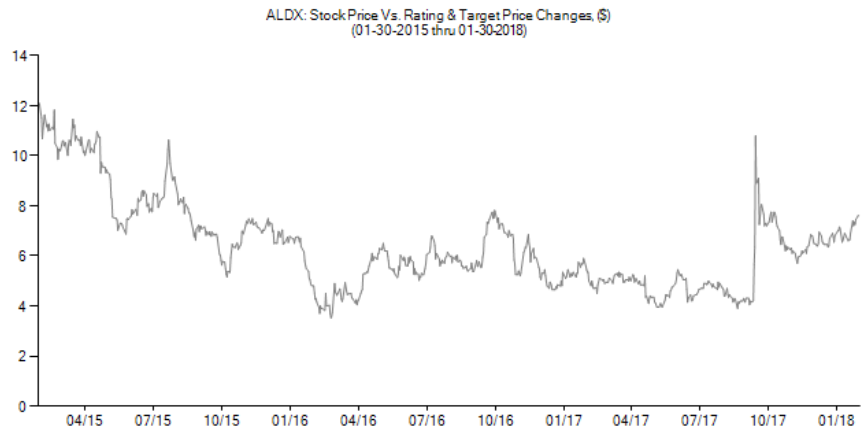
Additional information available upon request.

‡ Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

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.

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%	29.41%	1.96%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	1.96%	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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