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EQUITY RESEARCH
Company Report

July 19, 2017

Aldeyra Therapeutics (ALDX - $4.85)

Healthcare/Biotechnology

ADX-102 in Dry Eye Disease Phase IIa Study Last Patient Dosed

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

Yesterday, ALDX announced the completion of dosing of the last patient in the ADX-102 in dry eye disease (DED) Phase IIa study. The trial includes three different doses/formulations of ADX-102.

- **Details.** The Phase IIa study will evaluate 0.5% and 0.1% ADX-102 ophthalmic solutions, and 0.5% ADX-102 ophthalmic lipid solution. It is a double-blind, 45-patient randomized Phase IIa trial with a treatment duration of 28 days. Eligible patients are those with a reported history of DED for at least 6 months. In addition to safety, the primary aim of the study is to determine the optimal formulation of ADX-102, based on secondary efficacy measures, to advance into a likely vehicle-controlled Phase IIb study. Secondary outcomes include ocular discomfort measured by the Ora Calibra ocular discomfort scale, symptom assessment in dry eye (SANDE) scale, ocular surface and disease index (OSDI) questionnaire, tear film break-up time (TFBUT), and others. Top-line results could be available in late 3Q17. Since the placebo effect is known to be significant in DED clinical studies, it would be important to tease out the treatment effects from the placebo impact moving forward. Our discussion with management also indicated that the ongoing ocular ADX-102 in noninfectious anterior uveitis Phase III study is progressing well and topline results could be available in 4Q18. In addition, ALDX is in preparation for the EOP2 meeting with the FDA to discuss the advancement of ocular ADX-102 in allergic conjunctivitis into pivotal studies. We estimate the meeting could take place in late 3Q17/early 4Q17, followed by initiation of Phase III trial possibly in 1H18. Further, we estimate that the ADX-102 cream in Sjögren-Larsson Syndrome (SLS) Phase III trial could start in late 2017 after the company completes certain preclinical preparations.
- **Implications**. We view the news as an important step in the advancement of ADX-102 in DED development. ADX-102 could have the benefit of being a fast-acting anti-inflammatory agent, which could differentiate it from other marketed medications, such as Restasis or Xiidra. Given that large marketing and sales efforts are needed for promoting DED medication, we believe ALDX could potentially partner out this drug in the future if clinical studies are successful.
- **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 (7/18/2017)	$4.85
52–Week High (9/27/2016)	$8.19
52–Week Low (5/9/2017)	$3.80
Market Cap. (MM)	$72
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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Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance
ADX-102 cream	Sjögren-Larsson Syndrome (SLS)	Start Phase III study	**4Q17**	***
		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	**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	**2H17**	***

***** / ***** 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	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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3 Year Rating Change History

Date	Rating	Closing Price ($)
01/26/2...	Buy (B)	9.86

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
01/26/2...	30.00	9.86

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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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.	62.22%	31.11%	2.22%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.44%	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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