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EQUITY RESEARCH
Company Report

October 11, 2017

Aldeyra Therapeutics (ALDX - $7.75)

Healthcare/Biotechnology

R&D Day Highlighted ADX-102 Could Treat Multiple Ocular Disorders with Shared Etiology

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

Yesterday, ALDX hosted a R&D Day discussing its drug developments and potentially shared etiology of different ocular disorders. Key highlights include:

- **Additional clinical data from two prior Phase II trials.** ALDX reported additional data from the allergic conjunctivitis (AC) and dry eye disease (DED) Phase II trials. For AC, ADX-102 decreased ocular itch score (defined as one-point improvement within-patient), based on the total AUC, from 10 to 60 minutes vs. vehicle (p=0.02). Further, ADX-102 could achieve a clinical response faster vs. vehicle (p=0.0006). For DED, the study showed functional improvements (ocular staining scores and tear osmolarity) correlated with statistically significant reduction of malondialdehyde. ALDX is scheduled to start an ADX-102 in AC Phase III trial in 1H18 with topline readout in 2H18. The study design is nearly identical to that of the Phase IIb trial with seasonal patients only, given they have exhibited better responses. ALDX is also scheduled to start an ADX-102 in DED Phase IIb trial in 1H18 with topline readout in 2H18. The trial will evaluate 0.1% and 0.25% ADX-102 and a control for 12 weeks of treatment in 225 patients with moderate symptoms. The endpoints are standard dry eye disease signs and syndromes.
- **AC and DED might share similar etiology and this could bode well for ADX-102.** Dr. John D. Sheppard from Eastern Virginia Medical School highlighted that DE is an inflammatory condition – an etiology that also causes AC. He indicated that 50% of AC patients also have concomitant DED. It is estimated that ~30 MM Americans have both eye disorders. Given the anti-inflammatory nature of ADX-102, it makes great sense why ADX-102 can demonstrate therapeutic activity for the two very distinct indications because of their shared etiology. This also possibly places ADX-102 in a unique position with significant market potential. In the U.S. eye drop market, a total of ~22MM scripts are for dry eye disease, corticosteroids and antihistamine/mast cell stabilizers. For AC therapy, antihistamine appears to have an immediate anti-inching effect (peak at 5 min.); while ADX-102 could have a delayed but more lasting effect (≥60 min). As such, the two drugs could be complementary. For DED drug approval, the FDA requires two pivotal studies to demonstrate statistically significant differences in sign and in symptom. The safety packages require 300-500 subjects with 100 under chronic exposures. Causes of dry eye include aqueous-deficient, lipid-deficient, mucin-deficient, neural loop-associated and environmentally induced/exacerbated.
- **Action.** We are reiterating our Buy rating and our $30 target price based on peer comparable probability adjusted DCF analyses.

Trading Data:

Last Price (10/10/2017)	$7.75
52–Week High (9/15/2017)	$11.90
52–Week Low (5/9/2017)	$3.80
Market Cap. (MM)	$143
Shares Out. (MM)	11.352

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.37A	-0.35A	-0.37	-0.39	-1.48	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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- **The first systemic aldehyde trapper, ADX-103, enters the stage.** ADX-103 has a similar mechanism of action as ADX-102 by forming covalent bonding with free aldehyde but with a different chemical structure. ALDX pointed out that ADX-103 could potentially be used for several ocular indications, such as endotoxin-induced uveitis and diabetic macular edema (intravitreal), and macular degeneration (systemic). Equally interesting, in our opinion, is that a systemically available aldehyde trapper could potentially treat many more inflammation related or excess free aldehyde caused disorders. As such, it could have a much greater commercial outlook. We anticipate more updates by ALDX in 2018.

Figure 1: ADX-102 in AC Phase III (left) and DED Phase IIb (right) trial design

Groups	Topical Ocular ADX-102 0.1%, ADX-102 0.5%, or Vehicle
Randomization	Double-Masked, Vehicle-Controlled 1:1:1
Enrollment	150 Patients with History of Allergic Conjunctivitis
Model	Single Dose Seasonal Allergen Challenge
Endpoint	Patient-Reported Itching Score (0 to 4)

Groups	0.1% ADX-102, 0.25% ADX-102, and Control
Randomization	1:1:1 Double-Masked
Treatment Time	12 Weeks
Enrollment	225 Patients with Dry Eye Disease
Endpoints	Standard Dry Eye Disease Signs and Symptoms

Source: Company report

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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	**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	**2H17**	***
		Potential to start Phase III trial	**1H18**	***
		Potentially report Phase III trial outcome	**2H18**	****
	Dry eye syndrome	Potentially start Phase IIb trial	**1H18**	***
		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	**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 ~$26MM cash at the end of 2Q17, 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	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	0	265
Gross sales				-	0	0	-	0	0	0	2,679
Research and development	3,708	7,574	13,176	3,369	3,849	4,157	4,406	15,781	17,201	18,749	20,249
General and administrative	3,563	4,415	5,520	1,727	1,482	1,497	1,542	6,247	6,559	6,887	7,231
Marketing and sales									16,500	16,500	16,500
Total Operating Expenses	7,271	11,989	18,696	5,096	5,331	5,653	5,948	22,028	40,260	42,136	43,981
Operating Incomes (losses)	(7,271)	(11,989)	(18,696)	(5,096)	(5,331)	(5,653)	(5,948)	(22,028)	(40,260)	(42,136)	(41,301)
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	27	27	134	147	162	162
Other expenses		0	0	-	-	-	-	0	0	0	0
Interest expense	(244)	(113)	(106)	(27)	(26)	(27)	(27)	(107)	(107)	(107)	(107)
Total Other Income (Expense)	2,083	(102)	(3)	5	22	0	0	27	40	55	55
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(5,091)	(5,309)	(5,653)	(5,948)	(22,001)	(40,220)	(42,082)	(41,247)
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)	(5,653)	(5,948)	(22,001)	(40,220)	(42,082)	(41,247)
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(18,699)	(5,091)	(5,309)	(5,653)	(5,948)	(22,001)	(40,220)	(42,082)	(41,247)
Net Earnings (Losses) Per Share—Basic	($2.51)	($1.40)	($1.65)	($0.37)	($0.35)	($0.37)	($0.39)	($1.48)	($2.53)	($2.49)	($2.30)
Net Earnings (Losses) Per Share—Diluted	($3.09)	($1.40)	($1.65)	($0.37)	($0.35)	($0.37)	($0.39)	($1.48)	($2.53)	($2.49)	($2.30)
Shares outstanding—basic	3,818	8,634	11,352	13,797	15,136	15,286	15,436	14,914	15,914	16,914	17,914
Shares outstanding—diluted	3,851	8,634	11,352	13,797	15,136	15,286	15,436	14,914	15,914	16,914	17,914
Margin Analysis (% of Sales/Revenue)											
Costs of goods										9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	688%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	246%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1403%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1401%
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%	23%	28%	20%	9%	9%	8%
SG&A	67%	24%	25%	19%	1%	7%	28%	13%	5%	5%	5%
Marketing and sales											
Operating Income (Losses)	98%	65%	56%	3%	24%	18%	28%	18%	83%	5%	-2%
Pretax Income	-140%	133%	55%	2%	23%	18%	28%	18%	83%	5%	-2%
Net Income	-963%	26%	55%	2%	23%	18%	28%	18%	83%	5%	-2%
EPS	-172%	-44%	18%	-28%	-13%	-3%	4%	-10%	71%	-2%	-7%

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

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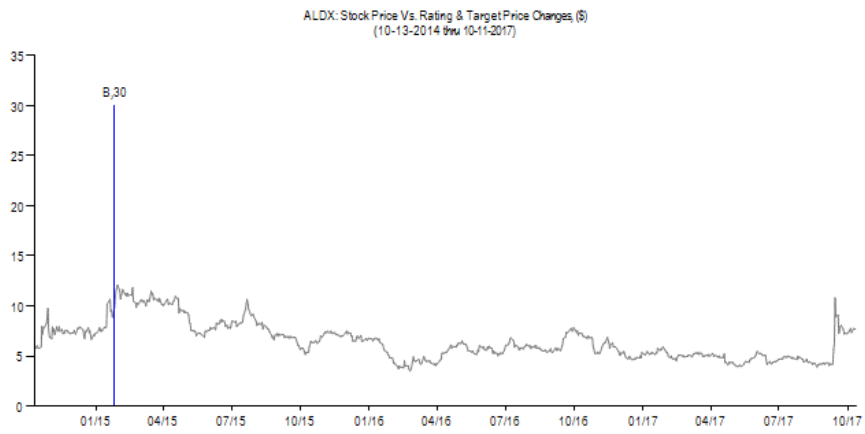

3 Year Rating Change History

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.	64.58%	31.25%	2.08%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.17%	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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