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EQUITY RESEARCH
Company Report

May 9, 2016

Aldeyra Therapeutics (ALDX - $ 5.71)

Healthcare/Biotechnology

1Q16: Positive POC Top-line Results of NS2 in Noninfectious Anterior Uveitis Phase II Trial

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

This morning, ALDX reported 1Q16 financial results with a net loss of ($5.0MM), vs. Laidlaw ($4.6MM) and the Street ($4.9MM) estimates. Net loss per share was ($0.51) vs. ($0.47) and ($0.50) for Laidlaw and the Street, respectively. ALDX ended 1Q16 with cash of $23MM, enough to support its operations deep into 2017, in our opinion.

- **Encouraging results on NS2 in noninfectious anterior uveitis (NAU) Phase II trial.** Along with 1Q16 financial results, ALDX reported positive NS2 in NAU (n=45) Phase II results. The study demonstrated that NS2 is non-inferior to that of topical ocular corticosteroids (Pred Forte) under several measurements. The trial also includes a study arm with NS2 in combination of sub-standard care level of corticosteroid. Together, the results indicated that grade 0 (cell count of zero or one) ACC (anterior chamber cell counts) were at ~30% (at week 2) and low to mid-40% (at week 8), respectively for all three groups. In addition, ~50% of patients have experienced one or greater ACC grade improvements. NS2 is well tolerated and overall safe with two patients who discontinued the study due to eye stinging/burning. Our discussion with management suggested that this AE could be managed and mitigated via formulation; and the KOL also suggested this is not a serious concern. Coupled with the recently reported positive results for the NS2 in allergic conjunctivitis (AC) Phase IIa study, we believe NS2 has exhibited POC as a viable potential ocular anti-inflammatory drug, in our opinion. Given corticosteroid's negative impact on increased ocular pressure and potential to cause cataracts, a fast-acting anti-inflammatory agent, like NS2, could be a welcome replacement. ALDX is planning to conduct separate pre-IND meetings later in 2016 for each indication with the FDA to discuss the clinical path forward. We anticipate ALDX could start two Phase II/III dose optimizing studies for AC and NAU, respectively, in 4Q16 with top-line results potentially available in late 2017 or 2018. ALDX currently is planning to target NS2 for all, instead of only the NAU patients who have the propensity to develop modest to severe impact by corticosteroids.
- **Action.** We are reiterating our Buy rating and our $30 target price based on peer comparable probability adjusted DCF analyses. Clinical NS2 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 (05/09/2016)	$ 5.71
52–Week High (7/23/2015)	$ 10.90
52–Week Low (2/9/2016)	$ 3.39
Market Cap. (MM)	$ 55
Shares Out. (MM)	10

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.51A	-0.53	-0.54	-0.55	-2.13	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.
FY-13A	-13.03	-5.47	2.76	18.47	3.49	N.A.

Source: Laidlaw & Company estimates

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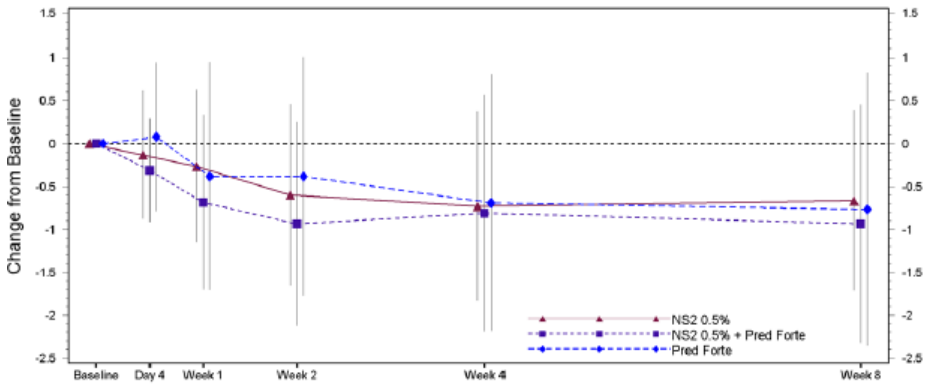
- **NS2 demonstrated non-inferiority in efficacy vs. topical ocular corticosteroids (Pred Forte).** The Phase II study demonstrated that clinical outcomes of NS2 vs. corticosteroids are similar in three measurements: anterior chamber cell counts (ACC) of grade 0 (cell count of zero or one) in week two and week eight; and ACC improvement of at least one grade (Figure 1). In addition, for patients inadequately treated, rescue medication rates were similar between NS2 and corticosteroids, with rescue medication required in 20%, 38% and 25% for NS2, corticosteroids and combination therapy treated patients.

Figure 1: Clinical efficacy of NS2 is non-distingishable to that of corticosteroid

	NS2 (n=15)	Pred Forte (n=13)	NS2 + Pred Forte (n=16)
Week 2 Cell Grade 0	5 (33%)	4 (31%)	5 (31%)
Week 8 Cell Grade 0	6 (40%)	6 (46%)	7 (44%)
≥ 1 Cell Grade Reduction	8 (53%)	6 (46%)	8 (50%)
Rescue Medication Required	3 (20%)	5 (38%)	4 (25%)

Source: Company presentation

Figure 2: ACC changs over time from baseline based on mITT



Source: Company presentation

Table 1: Estimated and reported 1Q16 results

1Q16 Estimates and Reported Results			
($,000)	Laidlaw Estimate	Actual	Consensus
Total revenue	**$0.0**	**$0.0**	**$0.0**
Total op. profit (loss)	**($4,544)**	**($4,967)**	**($5,000)**
R&D	$3,268	$3,511	
SG&A	$1,276	$1,456	
EPS	**($0.47)**	**($0.51)**	**($0.50)**
Net income (loss)	($4,572)	($4,967)	($4,900)

Source: Bloomberg, SEC filings and Laidlaw and Co.

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Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
NS2 cream	Sjögren-Larsson Syndrome (SLS)	Potentially report Phase II study top-line results	**3Q16**	****
NS2 eyedrop	Noninfectious anterior uveitis	Potentially conduct pre-IND meeting with the FDA	**2H16**	***
		Potentially start Phase II/III dose-optimizing trial	**4Q16**	***
		Potentially report Phase II/III study top-line results	**2017**	****
	Allergic conjunctivitis	Potentially conduct pre-IND meeting with the FDA	**2H16**	***
		Potentially start Phase II/III dose-optimizing trial	**4Q16**	***
		Potentially report Phase II/III study top-line results	**2017**	****
Systemic delvered (IV) NS2	Succinic Semi-aldehyde Dehydrogenase (SSADH) Deficiency, CNS disorders of SLS and /or autoimmune disorders	Potentially report pre-clinical data	**2016**	***
		Potentially to start Phase I studies	**2H16**	****
		Potentially to start Phase II studies	**2017**	***

***** / ***** 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, NS2 in the two indications under clinical trials; it remains too early to predict the safety and efficacy from the two ongoing Phase II studies. The clinical validation for these programs has not been established. The success of the each study could illustrate NS2 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 Phase II 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, NS2 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, NS2, 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 currently has ~$17MM (pro forma) cash after recent financing, ALDX could need more financial resources going forward if they want 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	1Q16	2Q16E	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue											
Product revenue	0	0	-	-	-	-	0	1,492	12,162	49,287	123,139
Other revenue	0	0	-	-	-	-	0	0	0	0	0
Total revenue	0	0	-	-	-	-	0	1,492	12,162	49,287	123,139
Costs of goods								134	1,095	4,436	11,083
Gross sales								1,358	11,067	44,851	112,057
Research and development	3,708	7,574	3,511	3,757	3,870	3,947	15,086	17,047	18,582	20,254	21,874
General and administrative	3,563	4,415	1,456	1,470	1,485	1,529	5,940	6,771	7,110	7,465	7,839
Marketing and sales								15,000	16,500	25,575	26,854
Total Operating Expenses	7,271	11,989	4,967	5,227	5,355	5,477	21,026	38,819	42,192	53,294	56,567
Operating Incomes (losses)	(7,271)	(11,989)	(4,967)	(5,227)	(5,355)	(5,477)	(21,026)	(37,461)	(31,125)	(8,443)	55,490
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 convert	0	0	-	-	-	-	0	0	0	0	0
Interest income	0	11	25	24	23	22	94	103	113	125	125
Other expenses		0	-	-	-	-	0	0	0	0	0
Interest expense	(244)	(113)	(25)	(25)	(25)	(25)	(100)	(100)	(100)	(100)	(100)
Total Other Income (Expense)	2,083	(102)	(0)	(1)	(2)	(3)	(6)	3	13	25	25
Net loss and comprehensive loss	(5,187)	(12,091)	(4,967)	(5,228)	(5,357)	(5,480)	(21,032)	(37,458)	(31,111)	(8,418)	55,515
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	(20,540)
Net Income (Loss)	(9,574)	(12,091)	(4,967)	(5,228)	(5,357)	(5,480)	(21,032)	(37,458)	(31,111)	(8,418)	34,974
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(4,967)	(5,228)	(5,357)	(5,480)	(21,032)	(37,458)	(31,111)	(8,418)	34,974
Net Earnings (Losses) Per Share—Basic	($2.51)	($1.40)	($0.51)	($0.53)	($0.54)	($0.55)	($2.13)	($3.16)	($2.42)	($0.61)	$2.35
Net Earnings (Losses) Per Share—Diluted	($3.09)	($1.40)	($0.51)	($0.53)	($0.54)	($0.55)	($2.13)	($3.16)	($2.42)	($0.61)	$2.35
Shares outstanding—basic	3,818	8,634	9,713	9,813	9,913	10,013	9,863	11,863	12,863	13,863	14,863
Shares outstanding—diluted	3,851	8,634	9,713	9,813	9,913	10,013	9,863	11,863	12,863	13,863	14,863
Margin Analysis (% of Sales/Revenue)											
Costs of goods								9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	1142%	153%	41%	18%
SG&A	NA	NA	NA	NA	NA	NA	NA	454%	58%	15%	6%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	-2511%	-256%	-17%	45%
Net Income	NA	NA	NA	NA	NA	NA	NA	-2510%	-256%	-17%	28%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	715%	305%	150%
R&D	140%	104%	209%	201%	86%	27%	99%	13%	9%	9%	8%
SG&A	67%	24%	50%	54%	18%	25%	35%	14%	5%	5%	5%
Marketing and sales									10%	55%	5%
Operating Income (Losses)	98%	65%	136%	137%	60%	26%	75%	78%	-17%	-73%	-757%
Pretax Income	-140%	133%	132%	134%	59%	25%	74%	78%	-17%	-73%	-759%
Net Income	-963%	26%	132%	134%	59%	25%	74%	78%	-17%	-73%	-515%
EPS	-172%	-44%	60%	100%	56%	22%	52%	48%	-23%	-75%	-487%

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

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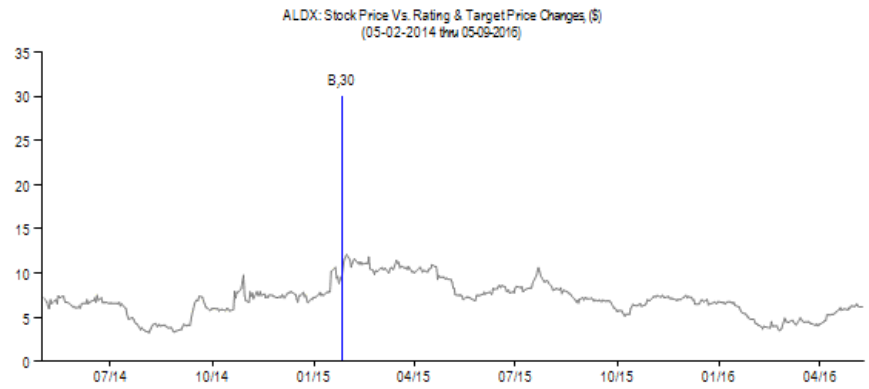
RATINGS INFORMATION

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.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	66.67%	27.78%	2.78%
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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