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EQUITY RESEARCH
Company Report

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Aldeyra Therapeutics (ALDX - $ 5.05)

Healthcare/Biotechnology

Positive NS2 in Allergic Conjunctivitis Phase IIa Trial Results Would Be a Major Clinical Validation for Aldehyde Trapping

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

This morning, ALDX reported positive NS2 in allergic conjunctivitis (AC) Phase IIa trial results with two study endpoints that both achieved statistical significance.

- **Details.** This morning, ALDX announced positive NS2 in AC Phase IIa trial results. The drug achieved statistically significant reductions in ocular itching and ocular tearing (both $p<0.05$) based on conjunctival allergen provocation test (CAPT) model. It is also very encouraging, in our opinion, that this positive outcome is built on a backdrop that the placebo response is twice higher as expected. The peak reductions of CAPT scores (on a 0 to 4 point scale) from baseline exceeded one point (of both itching and tearing), which are of the same magnitude seen in existing AC therapies. An AUC analysis also indicated that NS2 exhibited >25% reduction vs. placebo. NS2's safety profile is acceptable and two patients dropped out of the trial due to stinging. We do not consider such transient stinging a major issue given transient burning/stinging rates of multiple current AC-treating ophthalmic NSAIDS are between 7% and 40%. ALDX will provide more clinical result details, including cytokine expression profile, in the future and will make a future development path decision on ophthalmological indications after the report of the noninfectious anterior uveitis Phase II results, likely in 2Q16.
- **Implications.** We view today's news as a major positive for ALDX shareholders given 1) it is the first clinical proof-of-concept (POC) study to demonstrate NS2's anti-inflammatory activities. As such, this would likely mitigate a major risk of whether an aldehyde trapping agent could have sufficient anti-inflammatory activities for potentially treating inflammation driven indications; 2) based on this assumption, market potential of NS2 could be increased substantially especially if an effective systemically delivered drug also becomes available; and 3) despite NS2's exhibited similar efficacy based on current study, its novel mechanism of action and its potentially more benign safety profile, in our opinion, could potentially afford the drug to be used in combination or as a potential safer replacement for various ophthalmological indications.
- **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 (02/29/2016)	$ 5.05
52–Week High (4/20/2015)	$ 11.79
52–Week Low (2/9/2016)	$ 3.39
Market Cap. (MM)	$ 49
Shares Out. (MM)	10

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.35	-0.36	-0.36	-0.37	-1.44	N.A.
FY-15E	-0.32A	-0.27A	-0.35A	-0.38	-1.33	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 in allergic conjunctivitis Phase IIa trial design.** It is a randomized, parallel, single center, double masked, vehicle controlled study (n=100). The study's objective is to determine the activity and safety of NS2 in patients with at least a two-year history of grass, tree or ragweed-pollen induced seasonal allergic conjunctivitis. Patients were randomized 1:1 to receive multiple doses of NS2 ophthalmic drops (0.5%) or placebo (4x/day). Allergen challenges are conducted on day one, 14, 15 and 16. The clinical endpoints are patient assessment (on a 0 to 4point scale) of ocular itching and tearing, include examining ocular itching, redness, and tearing based on conjunctival allergen provocation test (CAPT) model of allergic conjunctivitis. Other assessments include lid swelling, redness of the eye and cytokine expression.

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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	**2Q/3Q16**	****
NS2 eyedrop	Noninfectious anterior uveitis	Potentially report Phase II study top-line results	**2Q16**	****
	Allergic conjunctivitis	Potentially provide future development direction	**2Q/3Q16**	****
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)	2014E	1Q15	2Q15	3Q15	4Q15E	2015E	1Q16E	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	1,136	1,249	2,076	2,492	6,954	2,284	2,444	2,542	2,720	9,989	11,288	12,304	13,411	14,484
General and administrative	3,563	972	955	1,261	1,312	4,500	1,312	1,338	1,351	1,405	5,406	6,163	6,471	6,795	7,134
Marketing and sales												15,000	16,500	25,575	26,854
Total Operating Expenses	7,271	2,109	2,204	3,338	3,803	11,453	3,596	3,782	3,893	4,125	15,395	32,451	35,275	45,781	48,472
Operating Incomes (losses)	(7,271)	(2,109)	(2,204)	(3,338)	(3,803)	(11,453)	(3,596)	(3,782)	(3,893)	(4,125)	(15,395)	(31,093)	(24,208)	(929)	63,585
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	-	-	-	-	0	-	-	-	-	0	0	0	0	0
Other expenses		-	-	-	-	0	-	-	-	-	0	0	0	0	0
Interest expense	(244)	(28)	(28)	(28)	(28)	(113)	(28)	(28)	(28)	(28)	(113)	(113)	(113)	(113)	(113)
Total Other Income (Expense)	2,083	(28)	(28)	(28)	(28)	(113)	(28)	(28)	(28)	(28)	(113)	(113)	(113)	(113)	(113)
Net loss and comprehensive loss	(5,187)	(2,137)	(2,232)	(3,366)	(3,832)	(11,566)	(3,624)	(3,810)	(3,921)	(4,153)	(15,508)	(31,206)	(24,321)	(1,042)	63,472
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	(23,485)
Net Income (Loss)	(9,574)	(2,137)	(2,232)	(3,366)	(3,832)	(11,566)	(3,624)	(3,810)	(3,921)	(4,153)	(15,508)	(31,206)	(24,321)	(1,042)	39,987
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(2,137)	(2,232)	(3,366)	(3,832)	(11,566)	(3,624)	(3,810)	(3,921)	(4,153)	(15,508)	(31,206)	(24,321)	(1,042)	39,987
Net Earnings (Losses) Per Share—Basic	($2.51)	($0.32)	($0.27)	($0.35)	($0.38)	($1.33)	($0.35)	($0.36)	($0.36)	($0.37)	($1.44)	($2.65)	($1.91)	($0.08)	$2.71
Net Earnings (Losses) Per Share—Diluted	($3.09)	($0.32)	($0.27)	($0.35)	($0.38)	($1.33)	($0.35)	($0.36)	($0.36)	($0.37)	($1.44)	($2.65)	($1.91)	($0.08)	$2.71
Shares outstanding—basic	3,818	6,668	8,398	9,713	10,013	8,698	10,313	10,613	10,913	11,213	10,763	11,763	12,763	13,763	14,763
Shares outstanding—diluted	3,851	6,668	8,398	9,713	10,013	8,698	10,313	10,613	10,913	11,213	10,763	11,763	12,763	13,763	14,763
Margin Analysis (% of Sales/Revenue)															
Costs of goods												9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	756%	101%	27%	12%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	413%	53%	14%	6%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-2084%	-199%	-2%	52%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-2091%	-200%	-2%	32%
Financial Indicator Growth Analysis (YoY%)															
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	715%	305%	150%
R&D	140%	156%	88%	74%	78%	88%	101%	96%	22%	9%	44%	13%	9%	9%	8%
SG&A	67%	21%	-3%	63%	30%	26%	35%	40%	7%	7%	20%	14%	5%	5%	5%
Marketing and sales													10%	55%	5%
Operating Income (Losses)	98%	69%	34%	70%	58%	58%	71%	72%	17%	8%	34%	102%	-22%	-96%	-6942%
Pretax Income	-140%	-632%	97%	68%	57%	123%	70%	71%	16%	8%	34%	101%	-22%	-96%	-6190%
Net Income	-963%	16037%	-58%	68%	72%	21%	70%	71%	16%	8%	34%	101%	-22%	-96%	-3937%
EPS	-172%	692%	-81%	-4%	-3%	-47%	10%	35%	4%	-3%	8%	84%	-28%	-96%	-3677%

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

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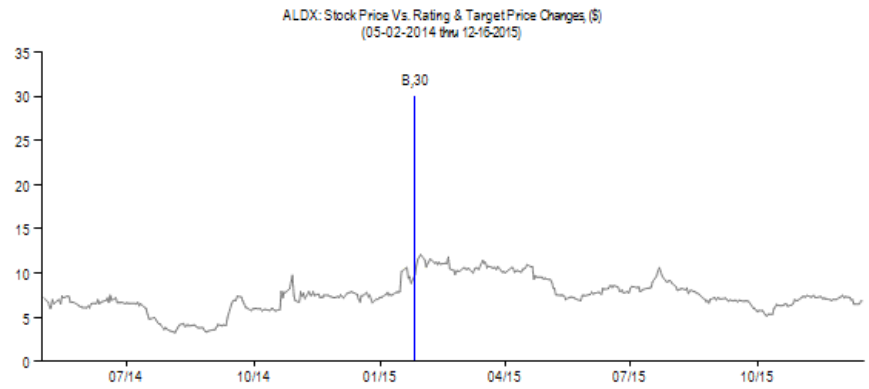
Rating and Price Target Change History



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**

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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.	64.71%	26.47%	2.94%
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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