

Aldeyra Therapeutics (ALDX - \$ 7.62)

Management Update Provided Renewed Confidence

After recent meeting with ALDX management, we walked away with renewed confidence that the company's developments are on-track, and with multiple expansion opportunities given the pathological impact of excess toxic aldehyde.

- Updates on hereditary orphan aldehyde metabolic disease development.** Management indicated that the NS2 in Sjögren-Larsson syndrome (SLS) Phase II study is on track with top-line results expected in late 2015 (we estimated 4Q15). With no treatment available for SLS and depending on the robustness of the Phase II results, ALDX could have the option either to seek conditional approval or to conduct another pivotal trial prior to requesting approval. On the succinic semialdehyde dehydrogenase (SSADH) deficiency (Figure 1) front, by trapping toxic aldehyde in a pre-clinical study, ALDX recently demonstrated NS2's effectiveness in a SSADH knock-out (KO) mouse model (Figure 2). We anticipate ALDX will conduct additional pre-clinical POC studies before starting clinical development. There are several features that potentially could facilitate clinical development of NS2 in SSADH deficiency: 1) KO mouse model results provided initial positive evidence of NS2 treatment; 2) gamma-hydroxybutyric acid (GHB) could be used as a bio-marker for identifying new patients and assessing efficacy; 3) a well-defined patient registry and active patient advocacy group (www.ssadh.net) in the U.S.; 4) given epilepsy, usually with generalized seizures is common in SSADH deficiency patients, the change of such symptoms could potentially be used for measuring treatment efficacy; and 5) since SSADH deficiency also has an inflammation component, NS2 (or other aldehyde trappers) could potentially provide more therapeutic benefits.
- Research on other product development in place.** Given 1) systemically delivered aldehyde trapping agents could address more indications (such as SSADH deficiency); and 2) additional aldehyde trappers with different chemical structure could increase drug development options, we believe ALDX is actively pursuing development in these two directions supported by recently enriched balance sheet.
- Action.** We are reiterating our Buy rating and our \$30 target price based on peer comparable probability adjusted DCF analyses. Given current ALDX enterprise value is of ~<\$40MM while two Phase II programs are underway with potential additional opportunities; we view the ALDX story as under-exposed and the shares as under-valued, in our opinion.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.32A	-0.28	-0.36	-0.40	-1.38	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.
FY-12A	NA	NA	NA	NA	-124.44	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:

Last Price (06/10/2015)	\$ 7.62
52-Week High (1/28/2015)	\$ 13.50
52-Week Low (8/4/2014)	\$ 3.00
Market Cap. (MM)	\$ 73
Shares Out. (MM)	10

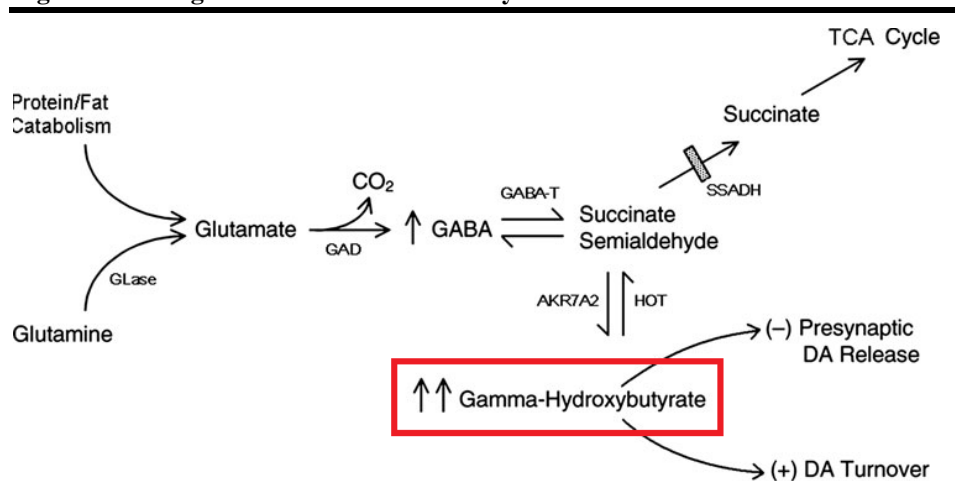
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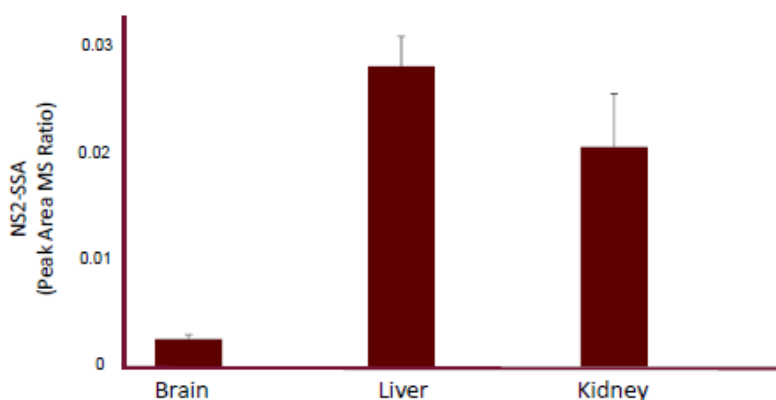
- Inflammatory indications.** ALDX is developing NS2 in noninfectious anterior uveitis (NAU) with a Phase II study underway and results expected in 4Q15. The NS2 in NAU trial is a POC study for exploring aldehyde trapping agent's anti-inflammatory potential. It is easier to identify inflammatory symptom changes from ophthalmological indications comparing to other inflammatory disorders. Should NS2 exhibited anti-inflammatory activities be clinically demonstrated, coupled with the recently reported capability for the drug to regulate a broad spectrum of pro-inflammatory cytokines; we believe NS2 has the potential to treat many inflammatory disorders. It potentially could be used as a treatment for a broad spectrum of indications, similar to that of steroids but possibly much safer.

Figure 1: Pathogenesis of SSADH deficiency



Source: Kim, K-J., et al., (2011) *Antioxidants & Redox signaling*, 15: 691-718

Figure 2: NS2 demonstrated to trap aldehyde in SSADH knock-out mouse model



Source: Company presentation.

Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
NS2 cream	Sjögren-Larsson Syndrome	Potentially report Phase II study top-line results	4Q15	****
NS2 eyedrop	Noninfectious anterior uveitis	Potentially report Phase II study top-line results	4Q15	****
NS2	Potential other indications	Presentation of pre-clinical data at at the Multinational Association of Supportive Care in Cancer 2015 Annual Meeting	June 1015	***
Next gen NS2		Other delivered format, including systemic	2015 / 2016	***
		Potentially to start clinical studies in other indications	2015 / 2016	****

**** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative

Source: Laidlaw & Company and company presentation

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.

Figure 1: Income Statement

Aldevyra Therapeutics – Income Statement													
(\$'000)	2012	2013	2014E	1Q15	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Revenue													
Product revenue	0	0	0	-	-	-	-	0	0	1,492	12,162	49,287	123,139
Other revenue	0	0	0	-	-	-	-	0	0	0	0	0	0
Total revenue	0	0	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	469	1,542	3,708	1,136	1,739	2,573	3,088	8,537	10,927	12,347	13,458	14,670	15,843
General and administrative	645	2,135	3,563	972	992	1,011	1,052	4,027	4,389	5,004	5,254	5,517	5,792
Marketing and sales										15,000	16,500	25,575	26,854
Total Operating Expenses	1,114	3,676	7,271	2,109	2,730	3,585	4,140	12,563	15,316	32,351	35,212	45,761	48,490
Operating Incomes (losses)	(1,114)	(3,676)	(7,271)	(2,109)	(2,730)	(3,585)	(4,140)	(12,563)	(15,316)	(30,993)	(24,145)	(910)	63,567
Change in fair value of preferred stock warrant liabilities	(9)	721	2,328	-	-	-	-	0	500	500	500	500	500
Change in fair value of convertible preferred stock rights and rig	(126)	16,175	0	-	-	-	-	0	0	0	0	0	0
Value provided in excess of issuance price of Series B convert	(21,485)	0	0	-	-	-	-	0	0	0	0	0	0
Interest income	0	0	0	-	-	-	-	0	0	0	0	0	0
Other expenses	1	0	0	0	0	-	-	0	0	0	0	0	0
Interest expense	(342)	(159)	(244)	(28)	(28)	(28)	(28)	(112)	(112)	(112)	(112)	(112)	(112)
Total Other Income (Expense)	(21,951)	16,737	2,083	(28)	(28)	(28)	(28)	(112)	(112)	(112)	(112)	(112)	(112)
Net loss and comprehensive loss	(23,075)	13,060	(5,187)	(2,137)	(2,758)	(3,613)	(4,168)	(12,675)	(15,428)	(31,105)	(24,258)	(1,022)	63,455
Accretion of preferred stock	(389)	(823)	(333)	-	-	-	-	0	0	0	0	0	0
Allocation of undistributed earnings to preferred stockholders		(11,128)	0	-	-	-	-	0	0	0	0	0	0
Deemed dividend	(15,662)	0	(4,054)	-	-	-	-	0	0	0	0	0	0
Tax	0	0	0	-	-	-	-	0	0	0	0	0	(23,478)
Net Income (Loss)	(39,126)	1,110	(9,574)	(2,137)	(2,758)	(3,613)	(4,168)	(12,675)	(15,428)	(31,105)	(24,258)	(1,022)	39,977
Net Income (Loss) Applicable to Common Shareholders	(39,126)	1,110	(9,574)	(2,137)	(2,758)	(3,613)	(4,168)	(12,675)	(15,428)	(31,105)	(24,258)	(1,022)	39,977
Net Earnings (Losses) Per Share—Basic	(\$124.44)	\$3.49	(\$2.51)	(\$0.32)	(\$0.28)	(\$0.36)	(\$0.40)	(\$1.38)	(\$1.38)	(\$2.55)	(\$1.84)	(\$0.07)	\$2.63
Net Earnings (Losses) Per Share—Diluted	(\$124.44)	(\$17.58)	(\$3.09)	(\$0.32)	(\$0.28)	(\$0.36)	(\$0.40)	(\$1.38)	(\$1.38)	(\$2.55)	(\$1.84)	(\$0.07)	\$2.63
Shares outstanding—basic	314	318	3,818	6,668	9,768	10,068	10,368	9,218	11,218	12,218	13,218	14,218	15,218
Shares outstanding—diluted	314	857	3,851	6,668	9,768	10,068	10,368	9,218	11,218	12,218	13,218	14,218	15,218
Margin Analysis (% of Sales/Revenue)													
Costs of goods									9%	9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	827%	111%	30%	13%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	335%	43%	11%	5%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	-2077%	-199%	-2%	52%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	-2085%	-199%	-2%	32%
Financial Indicator Growth Analysis (YoY%)													
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	715%	305%	150%
R&D	NA	229%	140%	156%	162%	115%	120%	130%	28%	13%	9%	9%	8%
SG&A	NA	231%	67%	21%	1%	31%	4%	13%	9%	14%	5%	5%	5%
Marketing and sales											10%	55%	5%
Operating Income (Losses)	NA	230%	98%	69%	66%	82%	72%	73%	22%	102%	-22%	-96%	-7086%
Pretax Income	NA	-157%	-140%	-632%	143%	80%	70%	144%	22%	102%	-22%	-96%	-6309%
Net Income	NA	-103%	-963%	16037%	-48%	80%	88%	32%	22%	102%	-22%	-96%	-4011%
EPS	NA	-103%	-172%	692%	-80%	-1%	2%	-45%	0%	85%	-28%	-96%	-3754%
Yale Jen, Ph.D. 212-953-4978													

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

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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.	75.00%	32.14%	7.14%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	3.57%	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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