

Aldeyra Therapeutics (ALDX - \$ 10.20)

NS2 Clinical Developments on SLS and Non-infectious Anterior Uveitis Remain On-track

This morning, ALDX provided an update on the clinical developments of NS2 indicating that the overall progress remains on track. The NS2 in Sjogren-Larsson Syndrome (SLS) Phase II study is at the final institutional review board (IRB) approval stage. Another study, NS2 in noninfectious anterior uveitis Phase II, is undergoing minor protocol changes with patient enrollment expected possibly in 2Q15.

- Details.** This morning, ALDX announced that the NS2 clinical developments in the two indications remained on-track. The NS2 in Sjogren-Larsson Syndrome (SLS) Phase II study is at the final institutional review board (IRB) approval stage, and patient recruitment slated to begin in 1Q15. The NS2 in noninfectious anterior uveitis Phase II study is undergoing minor protocol changes. Specifically, the study enrollment criteria will exclude a small subset of the most severe uveitis patients. In addition, the dosing frequency of the Phase II study will match that employed in the prior Phase I safety study. The company reiterated that the trial is expected to begin enrollment in 1H15, with preliminary data available by year-end 2015.
- Implications.** We believe the slight adjustments to the NS2 clinical study should not delay the development timeline projected earlier. We also believe the clinical development of NS2 in SLS is tracking the timeline the company indicated previously. The minor adjustments for the NS2 in noninfectious anterior uveitis Phase II study is likely a reflection of FDA conservatism. Conducting the Phase II study at the same dosing regimen as the prior Phase I trial could provide a more comprehensive and in-depth check of the therapeutic effect, as the safety data at the exact doses are already available. It also might be more prudent to initially test a new drug's efficacy in a less severely affected patient population before exploring its potential in patients with significantly more severe disease.
- Action.** We are reiterating our Buy rating and our \$30 target price based on peer comparable probability adjusted DCF analyses. This reflects our view that NS2 could take a shorter time to market than the two leading orphan indications currently under study. We view the ALDX story as under-exposed and the shares as under-valued, in our opinion.

Healthcare/Biotechnology

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

Trading Data:

Last Price (02/27/2015)	\$ 10.20
52-Week High (1/28/2015)	\$ 13.50
52-Week Low (8/4/2014)	\$ 3.00
Market Cap. (MM)	\$ 57
Shares Out. (MM)	6

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.37	-0.36	-0.37	-0.37	-1.54	N.A.
FY-14E	-0.04A	-1.43A	-0.36A	-0.37	-2.47	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.

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Source: Laidlaw & Company estimates

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Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
NS2 cream	Sjögren-Larsson Syndrome	Potentially enroll first patient for Phase II study	1Q15	***
		Potentially report Phase II study top-line results	3Q15	****
		Potentially report pre-clinical results	March 28-31, 2015	***
NS2 eyedrop	Acute anterior uveitis	Potentially enroll first patient for Phase II study	2Q15	***
		Presentation of pre-clinical anti-inflammation data at the 2015 American Academy of Allergy Asthma & Immunology Annual Meeting	Feb. 24, 2015	***
		Presentation of pre-clinical data at the Association for Research in Vision and Ophthalmology (ARVO) 2015 Annual Meeting	May 3-7, 2015	***
		Potentially report Phase II study top-line results	4Q15	****

**** / ***** 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

Aldeyra Therapeutics – Income Statement																	
(\$'000)	2012	2013	1Q14	2Q14	3Q14	4Q14E	2014E	1Q15E	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	444	664	1,196	1,327	3,631	1,778	1,956	2,132	2,218	8,085	10,348	11,694	12,746	13,893	15,005
General and administrative	645	2,135	801	983	772	780	3,336	788	796	804	812	3,200	3,488	3,976	4,175	4,383	4,602
Marketing and sales														15,000	16,500	25,575	26,854
Total Operating Expenses	1,114	3,676	1,245	1,646	1,968	2,107	6,967	2,566	2,752	2,936	3,030	11,284	13,836	30,669	33,421	43,852	46,461
Operating Incomes (Losses)	(1,114)	(3,676)	(1,245)	(1,646)	(1,968)	(2,107)	(6,967)	(2,566)	(2,752)	(2,936)	(3,030)	(11,284)	(13,836)	(29,312)	(22,354)	1,000	65,596
Change in fair value of preferred stock warrant liabilities	(9)	721	1,760	568	-	-	2,328	-	180	200	110	490	500	500	500	500	500
Change in fair value of convertible preferred stock rights and rights	(126)	16,175	-	-	-	-	0	-	-	-	-	0	0	0	0	0	0
Value provided in excess of issuance price of Series B convertible	(21,485)						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
Interest expense	(342)	(159)	(113)	(56)	(41)	(42)	(253)	(42)	(42)	(42)	(42)	(168)	(168)	(168)	(168)	(168)	(168)
Total Other Income (Expense)	(21,951)	16,737	1,647	511	(41)	(42)	2,075	(42)	138	158	68	(168)	(168)	(168)	(168)	(168)	(168)
Net loss and comprehensive loss	(23,075)	13,060	402	(1,135)	(2,009)	(2,149)	(4,892)	(2,608)	(2,614)	(2,778)	(2,962)	(11,452)	(14,004)	(29,480)	(22,522)	832	65,428
Accretion of preferred stock	(389)	(823)	(192)	(142)	-	-	(333)	-	-	-	-	0	0	0	0	0	0
Allocation of undistributed earnings to preferred stockholders		(11,128)	(223)	-	-	-	(223)	-	-	-	-	0	0	0	0	0	0
Deemed dividend	(15,662)	0	-	(4,054)	-	-	(4,054)	-	-	-	-	0	0	0	0	0	0
Tax	0	0	-	-	-	-	0	-	-	-	-	0	0	0	0	(308)	(24,208)
Net Income (Loss)	(39,126)	1,110	(13)	(5,330)	(2,009)	(2,149)	(9,502)	(2,608)	(2,614)	(2,778)	(2,962)	(11,452)	(14,004)	(29,480)	(22,522)	524	41,220
Net Income (Loss) Applicable to Common Shareholders	(39,126)	1,110	(13)	(5,330)	(2,009)	(2,149)	(9,502)	(2,608)	(2,614)	(2,778)	(2,962)	(11,452)	(14,004)	(29,480)	(22,522)	524	41,220
Net Earnings (Losses) Per Share—Basic	(\$124.44)	\$3.49	(\$0.04)	(\$1.43)	(\$0.36)	(\$0.37)	(\$2.47)	(\$0.37)	(\$0.36)	(\$0.37)	(\$0.37)	(\$1.54)	(\$1.49)	(\$2.83)	(\$1.97)	\$0.04	\$3.07
Net Earnings (Losses) Per Share—Diluted	(\$124.44)	(\$17.58)	(\$4.00)	(\$1.56)	(\$0.36)	(\$0.37)	(\$2.45)	(\$0.37)	(\$0.36)	(\$0.37)	(\$0.37)	(\$1.54)	(\$1.49)	(\$2.83)	(\$1.97)	\$0.04	\$3.07
Shares outstanding—basic	314	318	327	3,738	5,565	5,765	3,849	7,065	7,165	7,465	7,965	7,415	9,415	10,415	11,415	12,415	13,415
Shares outstanding—diluted	314	857	444	3,769	5,565	5,765	3,886	7,065	7,165	7,465	7,965	7,415	9,415	10,415	11,415	12,415	13,415
Margin Analysis (% of Sales/Revenue)																	
Costs of goods													9%	9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	784%	105%	28%	12%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	266%	34%	9%	4%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1964%	-184%	2%	53%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1976%	-185%	1%	33%
Financial Indicator Growth Analysis (YoY%)																	
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	715%	305%	150%
R&D	NA	229%	196%	104%	80%	232%	136%	300%	195%	78%	67%	123%	28%	13%	9%	9%	8%
SG&A	NA	231%	467%	49%	54%	-6%	56%	-2%	-19%	4%	4%	-4%	9%	14%	5%	5%	5%
Marketing and sales															10%	55%	5%
Operating Income (Losses)	NA	230%	327%	67%	69%	71%	90%	106%	67%	49%	44%	62%	23%	112%	-24%	-104%	6461%
Pretax Income	NA	-157%	-110%	-28%	-122%	-123%	-137%	-749%	130%	38%	38%	134%	22%	111%	-24%	-104%	7766%
Net Income	NA	-103%	-100%	210%	-329%	-136%	-956%	19601%	-51%	38%	38%	21%	22%	111%	-24%	-102%	7766%
EPS	NA	-103%	-100%	-74%	-113%	-102%	-171%	813%	-74%	3%	0%	-37%	-4%	90%	-30%	-102%	7179%

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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

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.	81.82%	36.36%	9.09%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.55%	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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