March 17, 2015

# **Aldeyra Therapeutics (ALDX - \$ 11.24)**

NS2 in SLS Phase II Study Started and the Non-infectious Anterior Uveitis Phase II Study to Come Likely in 2Q15

This morning, ALDX announced the commencement of the NS2 in Sjogren-Larsson Syndrome (SLS) Phase II study, and also indicated that the FDA has accepted the amended protocol for the NS2 in noninfectious anterior uveitis Phase II trial.

- **Details.** This morning, ALDX announced that the NS2 in Sjogren-Larsson Syndrome (SLS) Phase II study has started to enroll patients. In addition, the FDA has accepted the amended study protocol of the NS2 in noninfectious anterior uveitis Phase II trial. The company expects institutional review board (IRB) approvals from various clinical study sites near term. As a reminder, the adjustments of the noninfectious anterior uveitis Phase II trial include 1) the study enrollment criteria will exclude a small subset of the most severe uveitis patients; and 2) 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 view the commencement of the NS2 in SLS clinical study demonstrates the proper execution by the ALDX management team. We anticipate top-line results could be available in 3Q15. With the FDA acceptance of minor adjustments to the study protocol, we also believe the NS2 in noninfectious anterior uveitis Phase II study should begin in 2Q15, with top-line preliminary data available by year-end 2015. Near term, we believe several pre-clinical data releases could be very informative in demonstrating the potential of NS2. These presentations include 1) NS2 cream in SLS, to be reported between March 28-31, 2015, and 2) NS2 eyedrop in acute anterior uveitis, to be reported between May 3-7, 2015 at the Association for Research in Vision and Ophthalmology (ARVO) 2015 Annual Meeting.
- 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 underexposed and the shares as under-valued, in our opinion.

Earnings Estimates: (per share)

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.	2 2	( <b>Dec</b> ) 10	1Q 2Q	3Q	4Q	FY	P/E
	7 -0	-0.3	-0.37 -0.36	-0.37	-0.37	-1.54	N.A.
<b>FV-13A</b> -13 03 -5 47 2 76 18 47 3 49 N A	ŀΑ -1.	-14E -0.04	-0.04A -1.43A -	-0.36A	-0.37	-2.47	N.A
11-13A -13.03 -3.47 2.70 10.47 3.49 10.11.	03 -5	<b>-13A</b> -13.	-13.03 -5.47	2.76	18.47	3.49	N.A.
<b>FY-12A</b> NA NA NA -124.44 N.A	\ N	-12A NA	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 (03/17/2015)	\$ 11.24
52-Week High (1/28/2015)	\$ 13.50
52-Week Low (8/4/2014)	\$ 3.00
Market Cap. (MM)	\$ 63
Shares Out. (MM)	6

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# Anticipated milestones in 2015 and beyond

Product	Indication	Event	Timing	Importance
NS2 cream S	Sjögren-Larsson Syndrome	Potentially report Phase II study top-line results	3Q15	****
		Potentially report pre-clinical results	March 28-31, 2015	***
NS2 eyedrop		Potentially enroll first patient for Phase II study	2Q15	***
	Acute anterior uveitis	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	****

<sup>\*\*\*\* / \*\*\*\*\*</sup> 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

(\$'000)	2012	2013	1Q14	2Q14	3Q14	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
evenue Product recove	0	0			0411		0			02.02		0	0	1 400	10.160	40.007	100 10
Product revenue Other revenue	0	0	-	-	-		0	-	-	-	-	0	0	1,492 0	12,162 0	49,287 0	123,13 0
Total revenue	0	0	-	-	-		0	-		_	_	0	0	1,492	12,162	49,287	123,13
Costs of goods														134	1,095	4,436	11,083
Gross sales														1,358	11,067	44,851	112,05
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	15,00
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	46,46
perating 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 rig	(126)	16,175	-	-	-	-	0	-	-	-	-	0	0	0	0	0	0
Value provided in excess of issuance price of Series B converti	(21,485)	0					0	-	-	-	-	0	0	0	0	0	0
Interest income Other expenses	0 1	0	-	-	-	-	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	65,42
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 Tax	(15,662)	0	-	(4,054)	-	-	(4,054) 0	-	-	-	-	0	0	0	0	0	0
let 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)	(308) 524	(24,208 41,220
let 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	13,41
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	13,41
Margin Analysis (% of Sales/Revenue)		1									Į.						
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 NA	NA NA	NA NA	NA NA	NA NA	NA NA	NA NA	-1964% -1976%	-184% -185%	2% 1%	53% 33%
Net Income	NA	NA	INA	NA	NA	NA	NA	INA	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										400:					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 Net Income	NA NA	-157% -103%	-110% -100%	-28% 210%	-122% -329%	-123% -136%	-137% -956%	-749% 19601%	130% -51%	38% 38%	38% 38%	134% 21%	22% 22%	111% 111%	-24% -24%	-104% -102%	7766°
INCL HICOHIC	IVA	-10370	-10070	21070	-32570	-13070	-90070	1900170	-0170	30 /0	3070	Z 1 70	ZZ 70	11170	-2470	-10270	1100

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

March 17, 2015

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3 Year Rating Change History								
Date	Rating	Closing Price (\$)						
01/26/2015	Ruy (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 & C	ompany Rating System*	% of Companies Under Coverage	% of Companies for which Laidlaw & Company has performed services for in the last 12 months				
		With This Rating	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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