

Aldeyra Therapeutics (ALDX - \$ 6.01)

2Q16: Six Clinical Programs to Start in Late 2016 and 2017 Including First Systemic NS2 in Rare Diseases

This morning, ALDX reported 2Q16 financial results with a net loss of (\$4.3MM), vs. Laidlaw (\$5.2MM) and the Street (\$4.8MM) estimates. Net loss per share was (\$0.41) vs. (\$0.53) and (\$0.44) for Laidlaw and the Street, respectively. ALDX ended 2Q16 with cash of ~\$32MM, enough to support its operations deep into 2H18, in our opinion.

- Six clinical programs are scheduled to start starting late 2016.** On the heels of the release of a robust topical NS2 in SLS Phase II study results yesterday, ALDX announced this morning its clinical plan for advancing various forms of NS2 in several indications during the conference call. Specifically, ALDX plans to commence six clinical studies in late 2016 and 2017, including 1) Phase II/III trial for NS2 eye drop in noninfectious anterior uveitis; 2) Phase II/III trial for NS2 eye drop in allergic conjunctivitis; 3) Phase II trial for NS2 eye drop in an undisclosed ocular inflammatory indication; 4) Phase I safety study in healthy volunteers for systemic (IV) NS2; 5) Phase IIa study in succinic semi-aldehyde dehydrogenase (SSADH) for systemic NS2; and 6) Phase IIa study in SLS for systemic NS2. ALDX indicated that its cash position could support all studies. Management indicated that the allergic conjunctivitis study could start in late 2016 with top-line results potentially available in late 2017. The noninfectious anterior uveitis study could also start during a similar timeframe with top-line results potentially available in late 2017 or 2018 depending on the study patient size and pace of recruitment. ALDX will discuss with the FDA potentially finalizing the study design of all ophthalmological indications and SLS before providing more details. Overall, we are encouraged by ALDX's approach to advance NS2 in the two formats that potentially might tackle a broad spectrum of symptoms in selected ocular and rare indications.
- Additional details.** The allergic conjunctivitis study will be a dose ranging trial as more information might be needed before pivotal trials. The noninfectious anterior uveitis study is not a dose ranging trial since an optimal dose has been identified and potentially be part of pivotal studies.
- 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.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-16E	-0.51A	-0.41A	-0.41	-0.44	-1.76	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

Healthcare/Biotechnology

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

Trading Data:

Last Price (08/10/2016)	\$ 6.01
52-Week High (8/10/2015)	\$ 9.22
52-Week Low (2/9/2016)	\$ 3.39
Market Cap. (MM)	\$ 75
Shares Out. (MM)	12

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Table 1: Estimated and reported 2Q16 results

2Q16 Estimates and Reported Results			
(\$,000)	Laidlaw Estimate	Actual	Consensus
Total revenue	\$0.0	\$0.0	\$0.0
Total op. profit (loss)	(\$5,227)	(\$4,297)	(\$4,700)
R&D	\$3,757	\$2,835	
SG&A	\$1,470	\$1,462	
EPS	(\$0.53)	(\$0.41)	(\$0.44)
Net income (loss)	(\$5,228)	(\$4,303)	(\$4,800)

Source: Bloomberg, SEC filings and Laidlaw and Co.

Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance	
NS2 cream	Sjögren-Larsson Syndrome (SLS)	Discussions with regulatory agencies	2H16	***	
NS2 eyedrop	Noninfectious anterior uveitis	Potential meeting with the FDA	2H16	***	
		Potentially start Phase II/III trial	4Q16	***	
		Potentially report Phase II/III study top-line results	2017/2018	****	
	Allergic conjunctivitis	Potential meeting with the FDA	2H16	***	
		Potentially start Phase II/III dose-optimizing trial	4Q16	***	
		Potentially report Phase II/III study top-line results	2017	****	
	Non-disclosed ocular inflammatory indication	Potentially start Phase II dose-optimizing trial	2017	***	
	Systemic delivered (IV) NS2		Potentially to start safety Phase I study	2017	***
		Succinic Semi-aldehyde Dehydrogenase (SSADH) Deficiency, CNS disorders of SLS and /or autoimmune disorders	Potentially to start Phase IIa studies	2017	***
Sjögren-Larsson Syndrome (SLS)		Potentially to start Phase IIa study	2017	***	

**** / ***** 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)	2014	2015	1Q16	2Q16	3Q16E	4Q16E	2016E	2017E	2018E	2019E	2020E
Revenue											
Product revenue	0	0	-	-	-	-	0	0	1,492	12,162	49,287
Other revenue	0	0	-	-	-	-	0	0	0	0	0
Total revenue	0	0	-	-	-	-	0	0	1,492	12,162	49,287
Costs of goods								0	134	1,095	4,436
Gross sales								0	1,358	11,067	44,851
Research and development	3,708	7,574	3,511	2,835	2,920	3,270	12,535	14,165	15,440	16,830	18,176
General and administrative	3,563	4,415	1,456	1,462	1,477	1,521	5,916	6,744	7,081	7,435	7,807
Marketing and sales									16,500	25,575	26,854
Total Operating Expenses	7,271	11,989	4,967	4,297	4,396	4,791	18,451	20,909	39,021	49,840	52,837
Operating Incomes (losses)	(7,271)	(11,989)	(4,967)	(4,297)	(4,396)	(4,791)	(18,451)	(20,909)	(37,663)	(38,773)	(7,985)
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 rights	0	0	-	-	-	-	0	0	0	0	0
Value provided in excess of issuance price of Series B convertible preferred stock	0	0	-	-	-	-	0	0	0	0	0
Interest income	0	11	25	22	23	22	92	101	111	122	122
Other expenses		0	-	-	-	-	0	0	0	0	0
Interest expense	(244)	(113)	(25)	(28)	(28)	(28)	(108)	(108)	(108)	(108)	(108)
Total Other Income (Expense)	2,083	(102)	(0)	(6)	(5)	(6)	(17)	(8)	2	14	14
Net loss and comprehensive loss	(5,187)	(12,091)	(4,967)	(4,303)	(4,401)	(4,797)	(18,468)	(20,917)	(37,661)	(38,759)	(7,972)
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	0
Net Income (Loss)	(9,574)	(12,091)	(4,967)	(4,303)	(4,401)	(4,797)	(18,468)	(20,917)	(37,661)	(38,759)	(7,972)
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(4,967)	(4,303)	(4,401)	(4,797)	(18,468)	(20,917)	(37,661)	(38,759)	(7,972)
Net Earnings (Losses) Per Share—Basic	(\$2.51)	(\$1.40)	(\$0.51)	(\$0.41)	(\$0.41)	(\$0.44)	(\$1.76)	(\$1.68)	(\$2.80)	(\$2.68)	(\$0.52)
Net Earnings (Losses) Per Share—Diluted	(\$3.09)	(\$1.40)	(\$0.51)	(\$0.41)	(\$0.41)	(\$0.44)	(\$1.76)	(\$1.68)	(\$2.80)	(\$2.68)	(\$0.52)
Shares outstanding—basic	3,818	8,634	9,713	10,622	10,722	10,822	10,470	12,470	13,470	14,470	15,470
Shares outstanding—diluted	3,851	8,634	9,713	10,622	10,722	10,822	10,470	12,470	13,470	14,470	15,470
Margin Analysis (% of Sales/Revenue)											
Costs of goods								9%	9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	1035%	138%	37%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	475%	61%	16%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	-2524%	-319%	-16%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	-2524%	-319%	-16%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	715%	305%
R&D	140%	104%	209%	127%	41%	5%	65%	13%	9%	9%	8%
SG&A	67%	24%	50%	53%	17%	24%	34%	14%	5%	5%	5%
Marketing and sales									10%	55%	5%
Operating Income (Losses)	98%	65%	136%	95%	32%	10%	54%	13%	80%	3%	-79%
Pretax Income	-140%	133%	132%	93%	31%	10%	53%	13%	80%	3%	-79%
Net Income	-963%	26%	132%	93%	31%	10%	53%	13%	80%	3%	-79%
EPS	-172%	-44%	60%	52%	18%	-1%	26%	-5%	67%	-4%	-81%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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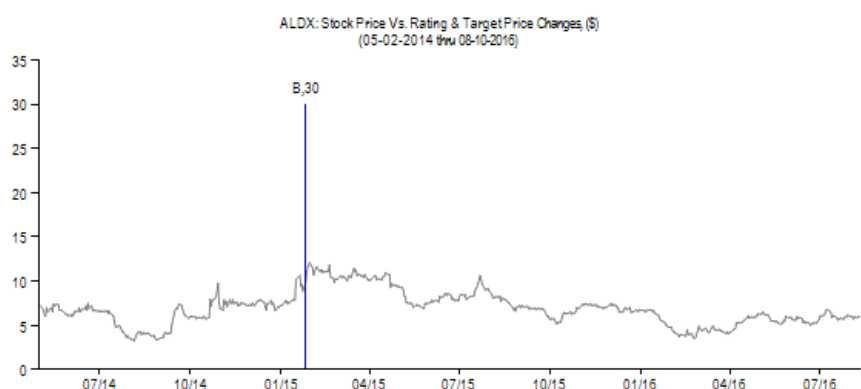
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3 Year Rating Change History

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

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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%
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Hold (H)	Expected returns to be in line with the sector average over 12 months.	2.70%	0.00%	0.00%
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