

Aldeyra Therapeutics (ALDX - \$5.80)

3Q17: Preparing to Start Three Phase II or III Trials in 1H18 and Four Data Readouts in 2H18

This morning, ALDX reported 3Q17 financial results with a net loss of (\$5.0MM) vs. Laidlaw (\$5.7MM) and the Street (\$6.0MM) estimates. Net loss/share was (\$0.32) vs. (\$0.37) for Laidlaw and the Street. ALDX ended 3Q17 with cash of ~\$48MM, enough to support its operations into 2H18, in our opinion.

- **Reproxalap in allergic conjunctivitis EOP2 meeting expected in 4Q17.** The name of ADX-102 has changed to Reproxalap. ALDX plans to advance Reproxalap in allergic conjunctivitis into Phase III studies and has scheduled an EOP2 meeting in late 4Q17 with the FDA. The Phase III trial could start in 1Q18 with topline results possibly in 2H18. As a reminder, Reproxalap has a mechanism of action that is very different from that of anti-histamines, and Reproxalap appears to potentially provide a more lasting therapeutic effect but might take a longer time to show its efficacy.
- **Reproxalap in dry eye disease (DED) Phase IIb trial start in 1H18 with data expected in 2H18.** Management reiterated that the Reproxalap in DED Phase IIb vehicle-controlled trial will start in 1H18 with data readout in 2H18. The trial will evaluate 0.1% and 0.25% ADX-102 and a control for 12 weeks of treatment in 225 patients with moderate symptoms. The endpoints are standard dry eye disease signs and syndromes.
- **2H18 an important data readout period.** Management pointed out that the Reproxalap in noninfectious anterior uveitis (NAU) Phase III trial is on track and results could be available in 2H18. In addition, the first (dose finding) portion of the Reproxalap in Sjögren-Larsson Syndrome (SLS) Phase III results could start in 1H18 with interim results available in 2H18. Together, ALDX will start two Phase III and one Phase IIb trials in 1H18 and with four data readouts in 2H18 – making 2H18 an important period for ALDX share value appreciation.
- **More inroad into systemic aldehyde trappers.** ALDX announced the first systemically delivered aldehyde trapper (ADX-103) at their R&D day. We anticipate the company provides more details in 2018 as different routes of administrations could potentially serve different patient needs: parenterally delivered drugs could provide immediate relieve for acute conditions; while orally delivered drugs could be used more effectively in chronic conditions.
- **Action.** We are reiterating our Buy rating and our \$30 target price based on peer comparable probability adjusted DCF analyses. We view the ALDX shares remain under-exposed and under-valued.

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-17E	-0.37A	-0.35A	-0.32A	-0.33	-1.37	N.A.
FY-16A	-0.51	-0.41	-0.38	-0.37	-1.65	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.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

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

Trading Data:

Last Price (11/8/2017)	\$5.80
52-Week High (9/15/2017)	\$11.90
52-Week Low (5/9/2017)	\$3.80
Market Cap. (MM)	\$108
Shares Out. (MM)	11.352

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Table 1: Estimated and reported 3Q17 results

3Q17 Estimates and Reported Results			
(\$,000)	Laidlaw Estimate	Actual	Consensus
<u>Total revenue</u>	\$0.0	\$0.0	\$0.0
<u>Total op. profit (loss)</u>	(\$5,653)	(\$5,015)	(\$6,300)
R&D	\$4,157	\$3,539	
SG&A	\$1,497	\$1,476	
<u>EPS</u>	(\$0.37)	(\$0.32)	(\$0.37)
Net income (loss)	(\$5,653)	(\$4,986)	(\$6,000)

Source: Bloomberg, SEC filings and Laidlaw and Co.

Anticipated milestones in 2017 and beyond

Product	Indication	Event	Timing	Importance	
ADX-102 cream	Sjögren-Larsson Syndrome (SLS)	Start Phase III study	1H18	***	
		Potentially interim Phase III study results	2H18	****	
		Potentially Phase III study results	2019	****	
ADX-102 eyedrop	Noninfectious anterior uveitis	Potentially report Phase III study top-line results	4Q18	****	
		Potentially start 2nd Phase III trial	2019	***	
	Allergic conjunctivitis	Potentially EOP2 discussion with the FDA	4Q17	***	
		Potential to start Phase III trial	1H18	***	
		Potentially report Phase III trial outcome	2H18	****	
	Dry eye syndrome	Potentially start Phase IIb trial	1H18	***	
		Potentially report Phase IIb trial outcome	2H18	****	
	Oral ADX-102 or new trapper	Succinic Semi-aldehyde Dehydrogenase (SSADH)	Potentially to start safety Phase I study	1Q18	***
			Potentially to start Phase IIa study	2H18	***
Potentially to report Phase IIa study results			2019	****	
Sjögren-Larsson Syndrome (SLS) CNS disorders		Potentially to start Phase I study	2H18	***	
New aldehyde trapper		Provide more updates	2018	***	

**** / ***** 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, ADX-102 in the two indications under clinical trials; it remains too early to predict the safety and efficacy from the two ongoing and upcoming clinical studies. The clinical validation for these programs has not been established. The success of each study could illustrate ADX-102 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 clinical 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, ADX-102 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, ADX-102, 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 had ~\$29MM cash at the end of 3Q16, ALDX could need more financial resources going forward if it wants 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	2016	1Q17	2Q17	3Q17	4Q17E	2017E	2018E	2019E	2020E
Revenue											
Product revenue	0	0	0	-	-	-	-	0	0	0	2,944
Other revenue	0	0	0	-	-	-	-	0	0	0	0
Total revenue	0	0	0	-	-	-	-	0	0	0	2,944
Costs of goods				-	0	0	0	0	0	0	265
Gross sales				-	0	0	0	0	0	0	2,679
Research and development	3,708	7,574	13,176	3,369	3,849	3,539	3,752	14,509	23,069	25,146	27,157
General and administrative	3,563	4,415	5,520	1,727	1,482	1,476	1,520	6,205	6,515	6,841	7,183
Marketing and sales											16,500
Total Operating Expenses	7,271	11,989	18,696	5,096	5,331	5,015	5,272	20,714	29,584	31,986	50,840
Operating Incomes (losses)	(7,271)	(11,989)	(18,696)	(5,096)	(5,331)	(5,015)	(5,272)	(20,714)	(29,584)	(31,986)	(48,161)
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	0	0	0	-	-	-	-	0	0	0	0
Interest income	0	11	102	32	48	57	37	174	191	210	210
Other expenses		0	0	-	-	-	-	0	0	0	0
Interest expense	(244)	(113)	(106)	(27)	(26)	(28)	(27)	(108)	(108)	(108)	(108)
Total Other Income (Expense)	2,083	(102)	(3)	5	22	29	10	66	83	102	102
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(5,091)	(5,309)	(4,986)	(5,262)	(20,648)	(29,501)	(31,884)	(48,058)
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)	(18,699)	(5,091)	(5,309)	(4,986)	(5,262)	(20,648)	(29,501)	(31,884)	(48,058)
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(18,699)	(5,091)	(5,309)	(4,986)	(5,262)	(20,648)	(29,501)	(31,884)	(48,058)
Net Earnings (Losses) Per Share—Basic	(\$2.51)	(\$1.40)	(\$1.65)	(\$0.37)	(\$0.35)	(\$0.32)	(\$0.33)	(\$1.37)	(\$1.84)	(\$1.51)	(\$2.18)
Net Earnings (Losses) Per Share—Diluted	(\$3.09)	(\$1.40)	(\$1.65)	(\$0.37)	(\$0.35)	(\$0.32)	(\$0.33)	(\$1.37)	(\$1.84)	(\$1.51)	(\$2.18)
Shares outstanding—basic	3,818	8,634	11,352	13,797	15,136	15,581	15,731	15,062	16,062	21,062	22,062
Shares outstanding—diluted	3,851	8,634	11,352	13,797	15,136	15,581	15,731	15,062	16,062	21,062	22,062
Margin Analysis (% of Sales/Revenue)											
Costs of goods				NA	NA	NA	NA	NA	NA	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	922%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	244%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1636%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1632%
Financial Indicator Growth Analysis (YoY%)											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	140%	104%	74%	-4%	36%	5%	9%	10%	59%	9%	8%
SG&A	67%	24%	25%	19%	1%	6%	26%	12%	5%	5%	5%
Marketing and sales											
Operating Income (Losses)	98%	65%	56%	3%	24%	5%	13%	11%	43%	8%	51%
Pretax Income	-140%	133%	55%	2%	23%	4%	13%	10%	43%	8%	51%
Net Income	-963%	26%	55%	2%	23%	4%	13%	10%	43%	8%	51%
EPS	-172%	-44%	18%	-28%	-13%	-16%	-9%	-17%	34%	-18%	44%
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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates

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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.	65.31%	30.61%	2.04%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.08%	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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