

Aldeyra Therapeutics (ALDX - \$8.65)

Healthcare/Biotechnology

4Q17: Next Data Readout - Reproxalap in Dry Eye Phase IIb Trial

ALDX recently reported 4Q17 financial results with a net loss of (\$6.9MM) vs. Laidlaw (\$5.3MM) and the Street (\$5.7MM) estimates. Net loss/share was (\$0.36) vs. (\$0.33) and (\$0.32) for Laidlaw and the Street. ALDX ended 4Q17 with cash of ~\$43MM, enough to support its operations into 2H19, in our opinion.

- Reproxalap in dry eye development garners great investor interest.** Several questions during the conference call focused on the Reproxalap in dry eye development. The Phase IIb study is the first vehicle-controlled trial with topline results expected in 2H18. The trial's objective is to identify a few signs and symptoms among the many that have been tested as potential endpoints for the future pivotal Phase III studies. The study size (n=100) is substantially smaller than that of a typical study (~700+). As such, potentially positive trends, instead of statistically significant readouts are expected. The regulatory filing requirement in dry eye is to meet an endpoint comprised of one sign and one symptom. Possible statistically significant readouts, if achieved, would be a major upside in our opinion. Further, if the Phase IIb study demonstrates the potential fast-acting aspect of Reproxalap as prior Phase IIa outcome suggested, it could be a highly valuable attribute to be explored in the Phase III trial. It would also suggest that Reproxalap could be a better chronic dry eye therapy. If the Phase IIb outcome is robust enough to advance into a Phase III trials, ALDX could contemplate various financing options (partnering or offering) for the trials. Ultimately partnering this asset with a large company is likely since very large size sales rep forces are needed for successful commercialization.
- Other reproxalap development updates.** ALDX indicated patient recruitment of the noninfectious anterior uveitis (NAU) Phase III trial is slower than expected, and as such, topline results are expected in 2019. The commencement of reproxalap in allergic conjunctivitis Phase III trial is expected in 2Q18 with topline readout in 2H18 or early 2019. The first portion (n=9) of the reproxalap in Sjögren-Larsson Syndrome (SLS) Phase III study will also start in 2Q18 with topline expected in 2019. It is characterized as a body surface area dose escalation study. The initial treatment covers 20% and subsequently escalate to 90% of body surface area. The powering assumption of the final Phase III study will be based on the outcome from the first portion of the study.
- 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.

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

Trading Data:

Last Price (3/29/2018)	\$8.65
52-Week High (9/15/2017)	\$11.90
52-Week Low (5/9/2017)	\$3.80
Market Cap. (MM)	\$147
Shares Out. (MM)	15.92

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-18E	-0.38	-0.41	-0.44	-0.42	-1.65	N.A.
FY-17A	-0.37	-0.35	-0.32	-0.36	-1.40	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.

Yale Jen, Ph.D.

Managing Director/Senior
Biotechnology Analyst
(212) 953-4978
yjen@laidlawltd.com

Source: Laidlaw & Company estimates

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- **Additional pipeline updates.** ALDX also provided additional updates on other pipeline developments. The company expects to advance ADX 629 (an oral aldehyde trap indicated for autoimmune diseases) into clinical studies with Phase I clinical trial expected to start in 2019. In addition, ALDX in-licensed ADX-1612 (Ganetespi), a HSP90 inhibitor for potentially treating various immune-mediated diseases – of which the excess replications of immune cells are implicated. Ganetespi was developed by Synta Pharmaceuticals before it failed a Phase III (GALAXY-2) study in non-small cell lung cancer. Several anti-cancer drugs have been developed and approved for anti-inflammatory indications. We anticipate ALDX will provide more visibility for the Ganetespi development going forward as the safety/efficacy requirements of an anti-cancer drug are not necessarily identical to that of an anti-inflammatory agent.

Table 1: Estimated and reported 4Q17 results

4Q17 Estimates and Reported Results			
(\$,000)	Laidlaw Estimate	Actual	Consensus
Total revenue	\$0.0	\$0.0	\$0.0
Total op. profit (loss)	(\$5,272)	(\$7,047)	(\$6,000)
R&D	\$3,752	\$5,545	
SG&A	\$1,520	\$1,501	
EPS	(\$0.33)	(\$0.36)	(\$0.32)
Net income (loss)	(\$5,262)	(\$6,955)	(\$5,700)

Source: Bloomberg, SEC filings and Laidlaw and Co.

Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
Reproxalap cream	Sjögren-Larsson Syndrome (SLS)	Start Phase III study	2Q18	***
		Potentially interim Phase III study results	1H19	****
		Potentially Phase III study results	2019/2020	****
Reproxalap eyedrop	Noninfectious anterior uveitis	Potentially start Phase III study	2Q18	***
		Potentially report Phase III study top-line results	2019	****
		Potentially start 2nd Phase III trial	2019	***
	Allergic conjunctivitis	Potentially report Phase III trial outcome	2019	****
	Dry eye syndrome	Potentially report Phase IIB trial outcome	2H18	****
Oral reproxalap or new trapper	Succinic Semi-aldehyde Dehydrogenase (SSADH)	Potentially to start safety Phase I study	2019	***
		Potentially to start Phase IIa study	2019	***
		Potentially to report Phase IIa study results	2020	****
	Sjögren-Larsson Syndrome (SLS) CNS disorders	Potentially to start Phase I study	2019	***
New aldehyde trapper		Provide more updates	2018/2019	***

**** / ***** 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	4Q17	2017	1Q18E	2Q18E	3Q18E	4Q18E	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	265
Gross sales				-	-	-	-	0	0	-	-	-	0	0	2,679
Research and development	3,708	7,574	13,176	3,369	3,849	3,539	5,545	16,303	5,878	6,466	7,112	7,468	26,924	29,347	31,695
General and administrative	3,563	4,415	5,520	1,727	1,482	1,476	1,501	6,186	1,546	1,593	1,640	1,690	6,469	6,793	7,132
Marketing and sales															16,500
Total Operating Expenses	7,271	11,989	18,696	5,096	5,331	5,015	7,047	22,488	7,424	8,058	8,753	9,158	33,393	36,140	55,327
Operating Incomes (losses)	(7,271)	(11,989)	(18,696)	(5,096)	(5,331)	(5,015)	(7,047)	(22,488)	(7,424)	(8,058)	(8,753)	(9,158)	(33,393)	(36,140)	(52,648)
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	125	261	50	54	55	56	215	237	237
Other expenses	0	0	0	-	-	-	-	0	-	-	-	-	0	0	0
Interest expense	(244)	(113)	(106)	(27)	(26)	(28)	(33)	(113)	(27)	(27)	(27)	(27)	(108)	(108)	(108)
Total Other Income (Expense)	2,083	(102)	(3)	5	22	29	92	148	23	27	28	29	107	129	129
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(5,091)	(5,309)	(4,986)	(6,955)	(22,341)	(7,401)	(8,031)	(8,725)	(9,129)	(33,286)	(36,011)	(52,520)
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)	(6,955)	(22,341)	(7,401)	(8,031)	(8,725)	(9,129)	(33,286)	(36,011)	(52,520)
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(18,699)	(5,091)	(5,309)	(4,986)	(6,955)	(22,341)	(7,401)	(8,031)	(8,725)	(9,129)	(33,286)	(36,011)	(52,520)
Net Earnings (Losses) Per Share—Basic	(\$2.51)	(\$1.40)	(\$1.65)	(\$0.37)	(\$0.35)	(\$0.32)	(\$0.36)	(\$1.40)	(\$0.38)	(\$0.41)	(\$0.44)	(\$0.42)	(\$1.65)	(\$1.43)	(\$2.01)
Net Earnings (Losses) Per Share—Diluted	(\$3.09)	(\$1.40)	(\$1.65)	(\$0.37)	(\$0.35)	(\$0.32)	(\$0.36)	(\$1.40)	(\$0.38)	(\$0.41)	(\$0.44)	(\$0.42)	(\$1.65)	(\$1.43)	(\$2.01)
Shares outstanding—basic	3,818	8,634	11,352	13,797	15,136	15,581	19,172	15,922	19,372	19,572	19,772	21,772	20,122	25,122	26,122
Shares outstanding—diluted	3,851	8,634	11,352	13,797	15,136	15,581	19,172	15,922	19,372	19,572	19,772	21,772	20,122	25,122	26,122
Margin Analysis (% of Sales/Revenue)															
Costs of goods	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1077%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	242%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1788%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1784%
Financial Indicator Growth Analysis (YoY%)															
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	140%	104%	74%	-4%	36%	5%	61%	24%	74%	68%	101%	35%	65%	9%	8%
SG&A	67%	24%	25%	19%	1%	6%	25%	12%	-10%	7%	11%	13%	5%	5%	5%
Marketing and sales															
Operating Income (Losses)	98%	65%	56%	3%	24%	5%	51%	20%	46%	51%	75%	30%	48%	8%	46%
Pretax Income	-140%	133%	55%	2%	23%	4%	49%	19%	45%	51%	75%	31%	49%	8%	46%
Net Income	-963%	26%	55%	2%	23%	4%	49%	19%	45%	51%	75%	31%	49%	8%	46%
EPS	-172%	-44%	18%	-28%	-13%	-16%	-2%	-15%	4%	17%	38%	16%	18%	-13%	40%

Yale Jen, Ph.D. 212-953-4978

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

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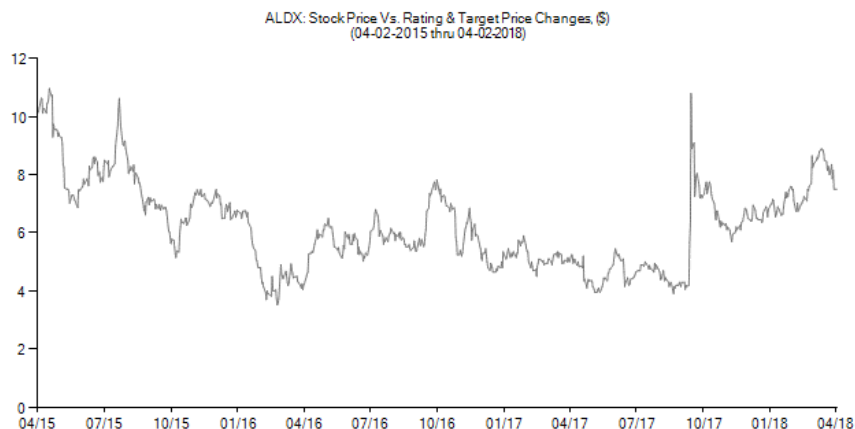
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3 Year Rating Change History

Date	Rating	Closing Price (\$)
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3 Year Price Change History

Date	Target Price (\$)	Closing Price, (\$)
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Source: Laidlaw & Company Created by: Blue-Compass.net
Note stock rated Buy with \$30 price target on 01/26/2015.

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