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EQUITY RESEARCH
Company Report

March 8, 2019

Aldeyra Therapeutics (ALDX - $7.64)

Healthcare/Biotechnology

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

Recent Management Updates Pointed Out Multiple Phase III Trial Readouts in 2019 and 2020

After our recent meetings with ALDX management and investors, we walked away with renewed confidence that the company is heading into several potential inflection points over the next four to five quarters. Key takeaways include:

- **Reproxalap in AC Phase III study readout on-track in late 1Q19.** Management reiterated that the reproxalap in allergic conjunctivitis (AC) Phase III study readout is on-track in late 1Q19. Given the robust prior Phase IIb study readout (p=0.004 in ocular itch AUC of 0.5% reproxalap vs. vehicle) and the similar trial design of the Phase III study, we are very optimistic about a positive readout for this study. Under this scenario, ALDX will conduct a type C meeting with the FDA before finalizing the 2nd Phase III study design. Further, we do not anticipate any readthrough (positive or negative) from the AC data to clinical study readouts of other indications, given the substantial differences in the nature of the disorders, the treatment design, and study endpoints.
- **We are bullish on the outlook of reproxalap in DED Phase III study outcomes.** A major investor focus is the dried eye disease (DED) Phase III study. The adaptive two-stage randomized, and placebo-controlled Phase III study will start in 1H19. The clinical risks of a successful Phase III part one study is mitigated, in our view, given the robust readout of the prior Phase IIb trial (p=0.0048 and 0.0007); the prospectively stratified study design regarding the chosen sign (fluorescein nasal region staining) and symptom (ocular dryness score); which ensures a balanced randomization. If the multiple timepoint sign and symptom readout recapitulate the positive results of the Phase IIb study, we believe the abundant clinical data could further enhance the probability for approval. Treatment duration is 12 weeks. For the QID to BID tapper study, the transition starts in week 4. We estimate the data readout could be in late 2019 or more likely in 1H20 – potentially one of more significant inflection points for ALDX shares. If the outcome is robust, business development activities will likely heat up, since reproxalap in DED development would be further de-risked based on the repeated confirmation of drug's treatment efficacy. Given reproxalap's substantially differentiated product attributes vs. other marketed DED therapies (i.e. fast drug onset), we believe the commercial outlook could be significant despite the likely launch of Restasis generics, possibly in 2019.
- **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.

Trading Data:

Last Price (3/6/2019)	$7.64
52–Week High (9/26/2018)	$16.70
52–Week Low (7/30/2018)	$6.75
Market Cap. (MM)	$201.9
Shares Out. (MM)	15.92

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-19E	-0.43	-0.44	-0.46	-0.48	-1.81	N.A.
FY-18E	-0.43A	-0.46A	-0.52A	-0.41	-1.81	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.

Source: Laidlaw & Company estimates

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- **A truly catalyst-rich period to come with multiple clinical data readouts.** We believe the next six quarters would be a truly catalyst-rich period for ALDX shares. From the clinical data reporting perspective, reproxalap in allergic conjunctivitis (AC) 1st Phase III (ALLEVIATE) study outcome is immanent in late 1Q19; reproxalap in noninfectious anterior uveitis (NAU) Phase III (SOLACE) study readout in 3Q19; topical reproxalap in Sjögren-Larsson Syndrome (SLS) first part of the Phase III study readout in mid- to late 2H19. Should ALDX start the reproxalap in DED adaptive Phase III study in 1H19, the data readout of the first part of the Phase III study could occur in late 2019 or more likely in 1H20. Further, should the company start the ADX-2191 in proliferative vitreoretinopathy (PVR) adaptive Phase III study in 2H19, the readout of the first part of the Phase III study could be available in 2020.
- **Strategic optionality enhanced.** Although ALDX could potentially launch reproxalap in DED and AC by themselves, this asset, in our opinion, would be a very attractive target for being partnered or acquired by a large pharma or biotech company given the substantial market potential and positively differentiating attributes of reproxalap. By acquiring several mid- to late clinical stage assets during the last 12 months, ALDX, in our opinion, has enhanced their optionality of future business and corporate development. For instance, besides a simple acquisition of the entire company by a pharma prospect, ALDX now has a deep enough pipeline that the company could potentially just carve out the late clinical stage reproxalap ocular asset for potential partnering, and retain their significant pipeline for further development, potentially gaining upside since the current valuation is not accounting for this portion of assets.

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Anticipated milestones in 2019 and beyond

Product	Indication	Event	Timing	Importance
Reproxalap cream	Sjögren-Larsson Syndrome (SLS)	Potentially interim Phase III (RESET) study results	**2H19**	****
		Potentially Phase III (RESET) study results	**2020**	****
Reproxalap eyedrop	Noninfectious anterior uveitis	Potentially report Phase III (SOLACE) study topline results	**3Q19**	****
	Allergic conjunctivitis	Potentially report Phase III (ALLEVIATE) trial outcome	**Late-1Q19**	****
		Potential Type C meeting with the FDA	**Mid-19**	***
		Potentially start 2nd Phase III trial	**2H19**	***
		Potential readouts of the second Phase III trial	**2020/2021**	***
	Dry eye syndrome	Potentially start Phase III trial	**1H19**	***
		Potentially start 2nd Phase III trial	**Late 2H19/2020**	***
ADX-103	Retina disease	Potentially start Phase I/IIa study	**2020**	***
ADX-2191	Proliferative vitreoretinopathy	Potentially start Phase III study	**2H19**	***
		Potential readout of first part of the Phase III study	**2020**	****
ADX-629		Potentially start safety Phase I study	**2H19**	***
	NASH	Potentially start Phase IIa study	**2H19**	***
	IBD	Potentially start Phase IIa study	**2H19/2020**	***
ADX-1612	Mesothelioma	Potentially start Phase II study	**2019**	***
	Lymphoproliferative immune disease	Start Phase II study	**2019**	***

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company and company presentation

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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, Reproxalap 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 Reproxalap 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, Reproxalap 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, Reproxalap, 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 ~$100MM cash (pro forma) currently, 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.

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Figure 1: Income Statement

Aldeyra Therapeutics – Income Statement

($'000)	2014	2015	2016	2017	1Q18	2Q18	3Q18	4Q18E	2018E	2019E	2020E	2021E
Revenue												
Product revenue	0	0	0	0	-	-	-	-	0	0	2,944	18,288
Other revenue	0	0	0	0	-	-	-	-	0	0	0	0
Total revenue	0	0	0	0	-	-	-	-	0	0	2,944	18,288
Costs of goods				0	-	-	-	0	0	0	265	1,646
Gross sales				0	-	-	-	0	0	0	2,679	16,642
Research and development	3,708	7,574	13,176	16,303	6,600	6,793	7,881	8,275	29,549	37,449	40,445	43,276
General and administrative	3,563	4,415	5,520	6,186	1,891	2,373	3,066	3,158	10,488	13,608	14,288	15,003
Marketing and sales											6,500	9,100
Total Operating Expenses	7,271	11,989	18,696	22,488	8,491	9,166	10,947	11,433	40,037	51,057	61,233	67,379
Operating Incomes (losses)	(7,271)	(11,989)	(18,696)	(22,488)	(8,491)	(9,166)	(10,947)	(11,433)	(40,037)	(51,057)	(58,554)	(50,737)
Interest income	0	11	102	261	122	142	163	256	683	913	913	913
Other expenses		0	0	0	-	-	-	-	0	0	0	0
Interest expense	(244)	(113)	(106)	(113)	(28)	(26)	(29)	(27)	(110)	(104)	(104)	(104)
Total Other Income (Expense)	2,083	(102)	(3)	148	94	116	134	229	573	809	809	809
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(10,813)	(11,204)	(39,464)	(50,248)	(57,745)	(49,928)
Accretion of preferred stock	(333)	0	0	0	-	-	-	-	0	0	0	0
Allocation of undistributed earnings to preferred s	0	0	0	0	-	-	-	-	0	0	0	0
Deemed dividend	(4,054)	0	0	0	-	-	-	-	0	0	0	0
Tax	0	0	0	0	-	-	-	-	0	0	0	0
Net Income (Loss)	(9,574)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(10,813)	(11,204)	(39,464)	(50,248)	(57,745)	(49,928)
Net Income (Loss) Applicable to Common Shareholo	(9,574)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(10,813)	(11,204)	(39,464)	(50,248)	(57,745)	(49,928)
Net Earnings (Losses) Per Share—Basic	($2.51)	($1.40)	($1.65)	($1.40)	($0.43)	($0.46)	($0.52)	($0.41)	($1.81)	($1.81)	($2.01)	($1.68)
Net Earnings (Losses) Per Share—Diluted	($3.09)	($1.40)	($1.65)	($1.40)	($0.43)	($0.46)	($0.52)	($0.41)	($1.81)	($1.81)	($2.01)	($1.68)
Shares outstanding—basic	3,818	8,634	11,352	15,922	19,367	19,761	20,970	27,007	21,776	27,757	28,757	29,757
Shares outstanding—diluted	3,851	8,634	11,352	15,922	19,367	19,761	20,970	27,007	21,776	27,757	28,757	29,757
Margin Analysis (% of Sales/Revenue)												
Costs of goods										9%	9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1374%	237%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	485%	82%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1989%	-277%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1961%	-273%
Financial Indicator Growth Analysis (YoY%)												
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	521%
R&D	140%	104%	74%	24%	96%	76%	123%	49%	81%	27%	8%	7%
SG&A	67%	24%	25%	12%	10%	60%	108%	110%	70%	30%	5%	5%
Marketing and sales												40%
Operating Income (Losses)	98%	65%	56%	20%	67%	72%	118%	62%	78%	28%	15%	-13%
Pretax Income	-140%	133%	55%	19%	65%	70%	117%	61%	77%	27%	15%	-14%
Net Income	-963%	26%	55%	19%	65%	70%	117%	61%	77%	27%	15%	-14%
EPS	-172%	-44%	18%	-15%	18%	31%	61%	14%	29%	0%	11%	-16%

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

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RATINGS INFORMATION

3 Year Rating Change History

Date	Rating	Closing Price ($)

3 Year Price Change History

Date	Target Price ($)	Closing Price ($)

Source: Laidlaw & Company Created by: Blue-Compass.net
Note stock rated Buy with $30 price target on 01/26/2015.

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.	64.52%	25.81%	3.23%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.84%	1.61%	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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