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EQUITY RESEARCH
Company Report

March 1, 2019

Aldeyra Therapeutics (ALDX - $15.30)

Healthcare/Biotechnology

R&D Day Recap: Trial Design of Two Phase III Studies Revealed and Indications Covering Both Sides of the Eye

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

ALDX hosted a R&D Day highlighting the ocular pipeline. Key takeaways include:

- **More details on PVR and ADX-2191 development plan.** Dr. Dean Eliott from Harvard Medical School provided an overview of proliferative vitreoretinopathy (PVR) and earlier clinical data of ADX-2191 treating PVR. Initially driven by inflammation after retinal detachment surgery, patients with PVR will develop scarring in their eye with the possibility of permanent vision loss. The propensity of developing PVR after retinal detachment surgery is ~10% and ≥50% for regular patients and patients with prior open globe injury, respectively. An earlier clinical study of ADX-2191 (intravitreal methotrexate) showed very promising results (Figure 1) with 0% (regular retinal detachment surgery) and 20% (post open globe injury) retinal detachment by the revised protocol. ALDX plans to start an ADX-2191 in PVR prevention Phase III randomized, controlled and two-part study in 2H19. We estimate initial data readout in 2020. Patients expect to receive 13 injections followed by two months follow-up. Primary endpoint is retinal re-detachment due to PVR requiring re-operation within six months. Management indicated the study will prospectively stratify open globe injury and non-open globe injury patient cohorts given the different PVR occurrence rate.
- **Reproxalap in DED Phase III study design revealed.** After meeting with the FDA this January, ALDX reported the study design of the reproxalap in DED Phase III trial. It is an adaptive two-stage, randomized and placebo-controlled study to be started in 1H19. The 1st part evaluates QID and QID to BID of 0.25% reproxalap for 12 weeks treatment. The dosing regimen of the confirmatory 2n part of study will be determined by the outcome from the 1st part of the study. The co-primary endpoint is ocular dryness score (0-100mm VAS with baseline score of ≥3) and fluorescein nasal region staining (baseline score ≥2). Both co-primary endpoints will be assessed using Mixed Model Repeated Measures (MMRM) from week 2 to week 12. The early readout could be valuable in differentiating reproxalap from other marketed DED therapies given reproxalap's quick onset nature. Results of the two selected endpoints have shown superior reproxalap treatment effect (p=0.0048 or 0.0007) from the Phase IIb study. Eligible patient (moderate to severe DED) for Phase III study is the same as that of Phase IIb study. Management indicated eligible patients would have material levels of both the symptoms and sign.
- **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 (2/28/2019)	$15.30
52–Week High (9/26/2018)	$16.701
52–Week Low (7/30/2018)	$6.756
Market Cap. (MM)	$212.9
Shares Out. (MM)	15.922

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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- **Additional updates.** The readout of reproxalap in allergic conjunctivitis (AC) 1st Phase III (ALLEVIATE) study is immanent in early 2019 (1Q19). Further, the readout of reproxalap in noninfectious anterior uveitis (NAU) Phase III (SOLACE) study would be available in 2H19. By advancing reproxalap in DED and AC in parallel, ALDX suggested that they could support concurrent NDA filings of both conditions.

Figure 1: Initial clinical readout of intravitreal methotrexate in PVR

Percent of patients with at least one re-detachment due to any cause	Grade C PVR		Open globe injury		All patients		
HV001							
Initial protocol	38%	(3/8)	50%	(1/2)	40%	(4/10)	
Revised protocol	0%	(0/8)	13%	(1/8)	6%	(1/16)	(Protocol to be used in pivotal trial)
Combined	19%	(3/16)	20%	(2/10)	19%	(5/26)	
Standard of care[1,2]	54%		47%		51%		

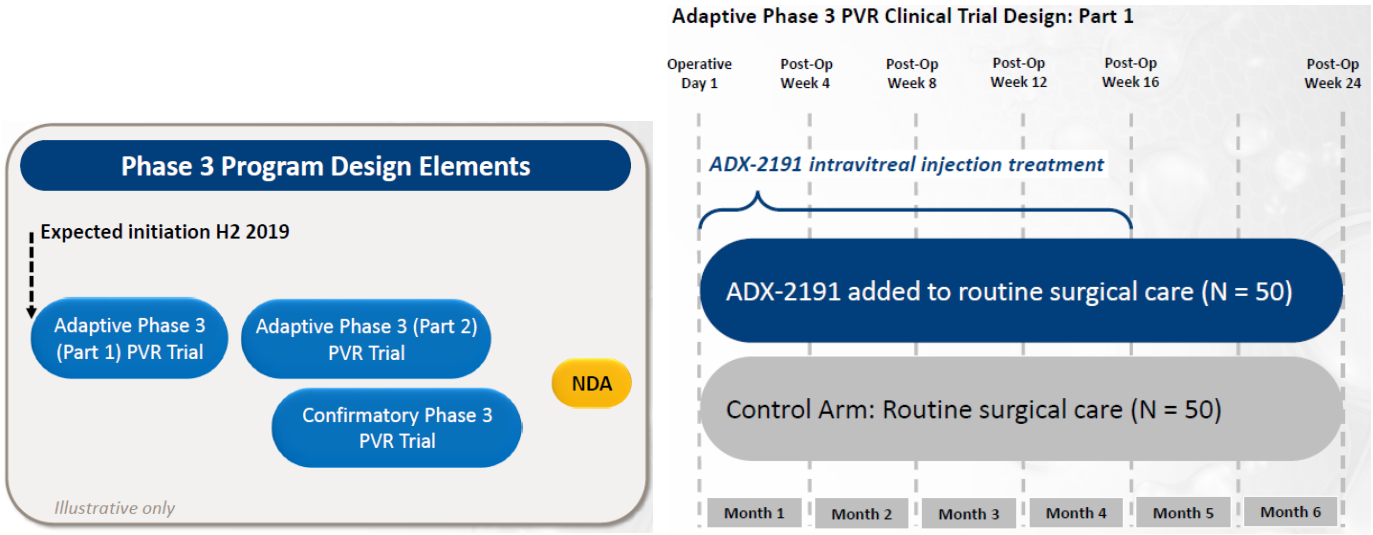
Source: Company presentation

Figure 2: ADX-2191 in PVR Phase III study design-1

	Control Arm (100 Subjects)	Intervention Arm (100 subjects)	
Operative Day 0	Routine Surgical Care: Pars Plana Vitrectomy	Routine Surgical Care: Pars Plana Vitrectomy	Experimental Care: Injection #1: Intraoperatively Methotrexate 400mcg/0.1ml
Post-Op Day 1	Routine Post-Op Visit: VA, IOP, Photo, & OCT	Routine Post-Op Visit: VA, IOP, Photo, & OCT	
Post-Op week 1	Routine Post-Op Visit: VA, IOP, Photo, & OCT	Routine Post-Op Visit: VA, IOP, Photo, & OCT	Injection #2: Methotrexate 400mcg/0.1ml
Post-Op week 2			Injection #3: Methotrexate 400mcg/0.1ml
Post-Op week 3			Injection #4: Methotrexate 400mcg/0.1ml
Post-Op week 4	Routine Post-Op Visit: VA, IOP, Photo, & OCT	Routine Post-Op Visit: VA, IOP, Photo, & OCT	Injection #5: Methotrexate 400mcg/0.1ml
Post-Op week 5			Injection #6: Methotrexate 400mcg/0.1ml
Post-Op week 6			Injection #7: Methotrexate 400mcg/0.1ml
Post-Op week 7			Injection #8: Methotrexate 400mcg/0.1ml
Post-Op week 8	Routine Post-Op Visit: VA, IOP, Photo, & OCT	Routine Post-Op Visit: VA, IOP, Photo, & OCT	Injection #9: Methotrexate 400mcg/0.1ml
Post-Op week 10			Injection #10: Methotrexate 400mcg/0.1ml
Post-Op week 12	Routine Post-Op Visit: VA, IOP, Photo, & OCT	Routine Post-Op Visit: VA, IOP, Photo, & OCT	Injection #11: Methotrexate 400mcg/0.1ml
Post-Op week 14			Injection #12: Methotrexate 400mcg/0.1ml
Post-Op week 16	Routine Post-Op Visit: VA, IOP, dilated exam	Routine Post-Op Visit: VA, IOP, dilated exam	Injection #13: Methotrexate 400mcg/0.1ml
Post-Op Month 6	Routine Post-Op Visit: VA, IOP, dilated exam	Routine Post-Op Visit: VA, IOP, dilated exam	

Source: Company presentation

Figure 3: ADX-2191 in PVR Phase III study design-2



Source: Company presentation

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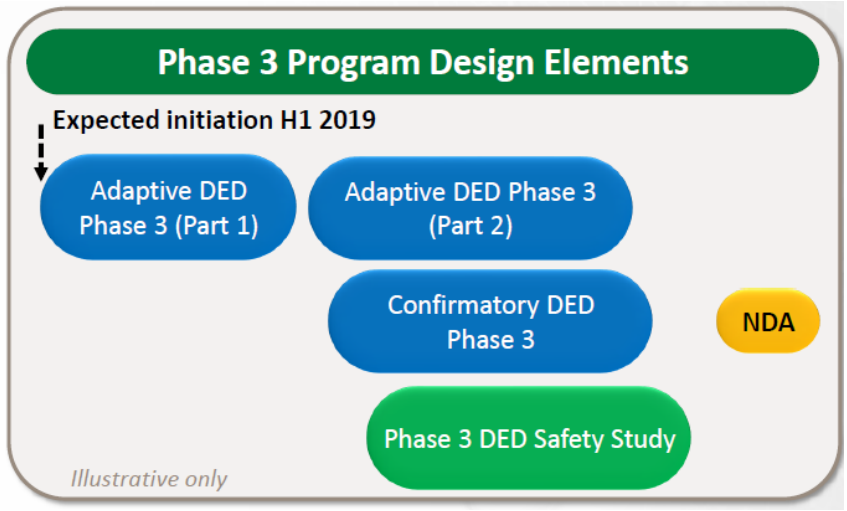
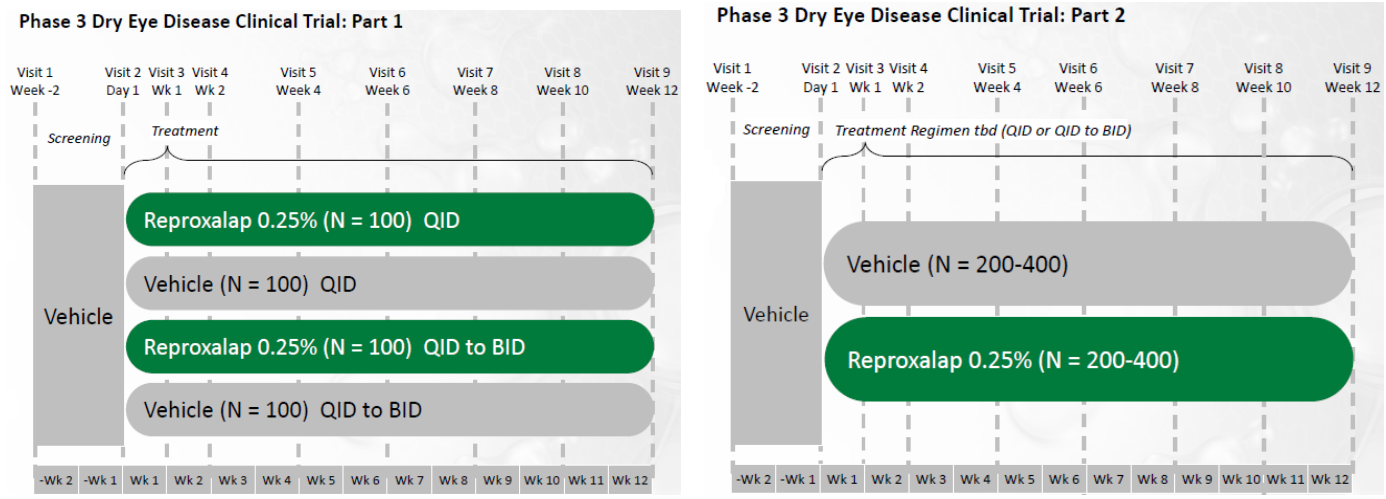
Figure 4: Overall reproxalap in DED Phase III study design



Source: Company presentation

Figure 5: Reproxalap in DED Phase III study design-2



Source: Company presentation

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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	**2H19**	****
	Allergic conjunctivitis	Potentially report Phase III (ALLEVIATE) trial outcome	**Mid-1H19**	****
		Potential readouts for exploratory design to be incorporated into the second Phase III trial	**Mid-19**	***
		Potentially start 2nd Phase III trial	**2H19**	***
		Potential readouts of the second Phase III trial	**2020**	***
	Dry eye syndrome	Potentially start Phase III trial	**1H19**	***
		Potentially start 2nd Phase III trial	**2H19/2020**	***
ADX-103	Retina disease	Potentially start Phase I/IIa study	**2020**	***
ADX-2191	Proliferative vitreoretinopathy	Potentially start Phase III study	**2H19**	***
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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Additional information available upon request.

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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.

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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%
Buy (B)	Expected to outperform the sector average over 12 months.	63.93%	24.59%	3.28%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.92%	1.64%	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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