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EQUITY RESEARCH
Company Report

September 27, 2016

Aldeyra Therapeutics (ALDX - $ 7.70)

Healthcare/Biotechnology

R&D Day Recap with Two Phase III Trials Underway in 2017

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

ALDX hosted an R&D day yesterday with emphasis on advancements of its current and expanded ophthalmological and rare orphan disease pipeline. As such, the company will have two Phase III programs underway starting in 2017.

- **Three ophthalmological programs to start in 2017.** After reporting positive results of the three ADX-102 (formerly NS2) Phase II trials and pipeline development update at the 2Q16 call, the R&D day provided substantially greater details on future product development. For noninfectious anterior uveitis, ALDX is scheduled to start a vehicle-controlled Phase III trial (n=45/arm or 90 in total) in 2017 with top-line results expected in 2H18. The overall study design will be very similar to that of the prior successful Phase II trial but without a corticosteroid combination arm. All non-responders will be rescued by topical steroids. If outcome is very robust, the Phase III trial could be the only pivotal trial needed for approval. Anterior chamber cell counts (ACC) grade improvements are likely be the primary endpoint. For allergic conjunctivitis, a Phase IIb trial could start in 1H17 with top-line results expected in 2H17. It is dose-ranging (two doses and modified vehicle) trial (n=50/arm or 150 in total). Reductions of CAPT scores (of both itching and tearing) from baseline could be the primary endpoint. ALDX is scheduled to start a new ADX-102 in dry eye syndrome Phase IIa trial (n~30/arm) in 1H17 with top-line results in 2H17. It will be a new formulation given the drug need to provide anti-inflammatory and lubricative benefits.
- **SLS in Phase III and systemically delivered trapper start in 2017**. ALDX plans to start an ADX-102 (cream/dermatologic) in Sjorgen-Larsson Syndrome (SLS) Phase III study (N=20-30) in 1H17 mainly to alleviate ichthyosis. Pending on final FDA/EMA feedback, reduction in ichthyosis severity score (ISS) from baseline could be the major study endpoint. ADX-102 systemic led oral formulation has been selected, ALDX plans to file an IND in 2H17 to study systemic ADX-102 with objective for treating inborn errors of aldehyde metabolism, such as neurological impairment of SLS and SSADD. A biomarker-based Phase IIa trials are scheduled to start in 1H18 with n=5-10 per trial. Top-line results of SSADD study expected in 2Q18.
- **Action.** We are reiterating our Buy rating and our $30 target price based on peer comparable probability adjusted DCF analyses. Clinical ADX-102 development in orphan and inflammatory indications are all under study. We view the ALDX shares remain under-exposed and under-valued.

Trading Data:

Last Price (09/26/2016)	$ 7.70
52–Week High (9/26/2016)	$ 8.17
52–Week Low (2/9/2016)	$ 3.39
Market Cap. (MM)	$ 96
Shares Out. (MM)	12

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

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- **Corticosteroid might be a panacea for treating multiple ocular inflammatory indications but it is at a cost of developing cataract, glaucoma due to increase intraocular pressure (IOP).** Dr. John Sheppard of Eastern Virginia Medical School indicated that although topical ocular corticosteroids have exhibited broad anti-inflammatory effects, IOP elevation (moderate and severe) occurs in ~40% of corticosteroid users. Prolonged use of corticosteroid could result in glaucoma with damage to optic nerve, defects in visual acuity and fields of vision. It is therefore, a bad trade-off between efficacy and multiple ocular related damages, such as punctate keratopathy and opportunistic infections. As such, a much safer alternative therapy is needed. Dr. Sheppard indicated that he might initially prescribe ADX-102 in his practice (if the drug performed as the Phase II study results have suggested) to patients who have a chronic inflammatory condition; peri-operative patient, such as for glaucoma; and recommend to general ophthalmologists who are afraid of prescribing corticosteroids to patient who only suffer from mild uveitis.
- **SLS could be under-diagnosed.** Dr. William Rizzo from Nebraska Medical Center is the lead investigator of ADX-102 in SLS Phase II trial and a top expert in treating SLS in the U.S. He indicated that SLS patients experience ichthyosis shortly after birth and neurological problems later at age one or two. He believes SLS is under-diagnosed mainly due to: 1) there being no approved treatment, 2) that many patients who only have been diagnosed at a much older age (he cited patients identified in age 16 and even in their thirties); and 3) the lack of awareness of SLS and proper communication between dermatologists (treating dermatological conditions) and neurologists (treating neurological symptoms) who are treating the same patient without connecting the dots, many SLS cases have not been properly identified.

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Anticipated milestones in 2016 and beyond

Product	Indication	Event	Timing	Importance
ADX-102 cream	Sjögren-Larsson Syndrome (SLS)	Discussions with regulatory agencies	**2H16**	***
		Start Phase III study	**1H17**	***
ADX-102 eyedrop	Noninfectious anterior uveitis	Potentially start Phase III trial	**2017**	***
		Potentially report Phase III study top-line results	**2H18**	****
	Allergic conjunctivitis	Potentially start Phase IIb dose-optimizing trial	**1H17**	***
		Potentially report Phase IIb study top-line results	**2H17**	****
	Dry eye syndrome	Potentially start Phase II dose-optimizing trial	**1H17**	***
		Potentially report Phase II dose-optimizing trial results	**2H17**	****
Systemic delvered (IV) ADX-102		Potentially to start safety Phase I study	**2017**	***
	Succinic Semi-aldehyde Dehydrogenase (SSADH)	Potentially to start Phase IIa study	**1Q18**	***
		Potentially to report Phase IIa study results	**2Q18**	****
	Sjögren-Larsson Syndrome (SLS) CNS disorders	Potentially to start Phase IIa study	**1Q18**	***
New aldehyde trapper		Start preclinical studies	**2017**	***

***** / ***** 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, ADX-102 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 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 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, 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 currently has ~$32MM cash as of end of 2Q16, 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.

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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 rig	0	0	-	-	-	-	0	0	0	0	0
Value provided in excess of issuance price of Series B convert	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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Additional information available upon request.

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Rating and Price Target Change History

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 **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.	60.53%	28.95%	2.63%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	5.26%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	2.63%	0.00%	0.00%

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