

## Aldeyra Therapeutics (ALDX - \$9.49)

### ADX-1612 in Pleural Malignant Mesothelioma Phase I/II Trial Showed Encouraging Results

This morning, ALDX reported robust results from an investigator-sponsored ADX-1612/platinum combination in pleural malignant mesothelioma Phase I/II (MESO-2) trial. The data will be presented orally at the International Association for the Study of Lung Cancer (ASLC) 19<sup>th</sup> World Conference on Lung Cancer today.

- Details.** The study evaluates the combination of ADX-1612 (ganetespib) and the standard pemetrexed and platinum (cisplatin or carboplatin) therapy in pleural malignant mesothelioma. The results showed a 61% (14/23) ORR and 96% (22/23) of patients experienced stable disease or clinical response. As a reference, historical ORR of standard of care was 20 to 40% with a five-year survival rate <20%. The response rate in patients with epithelial histology was 76%. Tumor burden reduction of >50% was observed in seven patients, with one patient being progression-free for 37 months. In addition, total loss of heterozygosity (LOH) was correlated with increased tumor burden (n=7, correlation=0.7, p=0.078). ADX-1612 was well-tolerated, with DLT found in three patients, all of them at the highest dose (200 mg/m<sup>2</sup>). As a reminder, MESO-2 trial is an investigator-sponsored, single site, dose escalation study designed to assess ADX-1612 in combination with standard pemetrexed and platinum therapy. A total of 27 patients (median age 66) have been enrolled with 23 evaluable. Three doses (100, 150, or 200mg/m<sup>2</sup>) of ADX-1612 have been tested. Patients will receive ADX-1612 treatment on days 1 and 15 every 21 days as one treatment cycle. Management will meet with regulatory authorities to discuss these results before progressing to the next step.
- Implications.** ADX-1612 (ganetespib) is a selective heat shock protein 90 (Hsp90) inhibitor that ALDX licensed from Synta Pharmaceuticals for treating various immune-mediate diseases. Although some study results were already available in early September from the released abstract, the outcome reported today remains very encouraging especially compared to the historical standard of care results. These results are consistent with the hypothesis that Hsp90 inhibitor could potentially potentiate the treatment effect of a platinum-based regimen. Given the small patient size (estimated 3,000 incidences each year) of mesothelioma, it is foreseeable that ALDX might advance this program forward after discussions with the FDA. Overall, all eyes are currently still on the readout of reproxalap in DED Phase IIb study, which should occur in the very near future.
- Action.** We are reiterating our Buy rating and our \$30 target price based on peer comparable probability adjusted DCF analyses.

#### Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
<b>FY-18E</b>	-0.43A	-0.46A	-0.50	-0.47	-1.86	N.A.
<b>FY-17A</b>	-0.37	-0.35	-0.32	-0.36	-1.40	N.A.
<b>FY-16A</b>	-0.51	-0.41	-0.38	-0.37	-1.65	N.A.
<b>FY-15A</b>	-0.32	-0.27	-0.35	-0.45	-1.40	N.A.

Source: Laidlaw & Company estimates

Healthcare/Biotechnology

Ticker:	<b>ALDX</b>
Rating:	<b>Buy</b>
Price Target:	<b>\$30.00</b>

#### Trading Data:

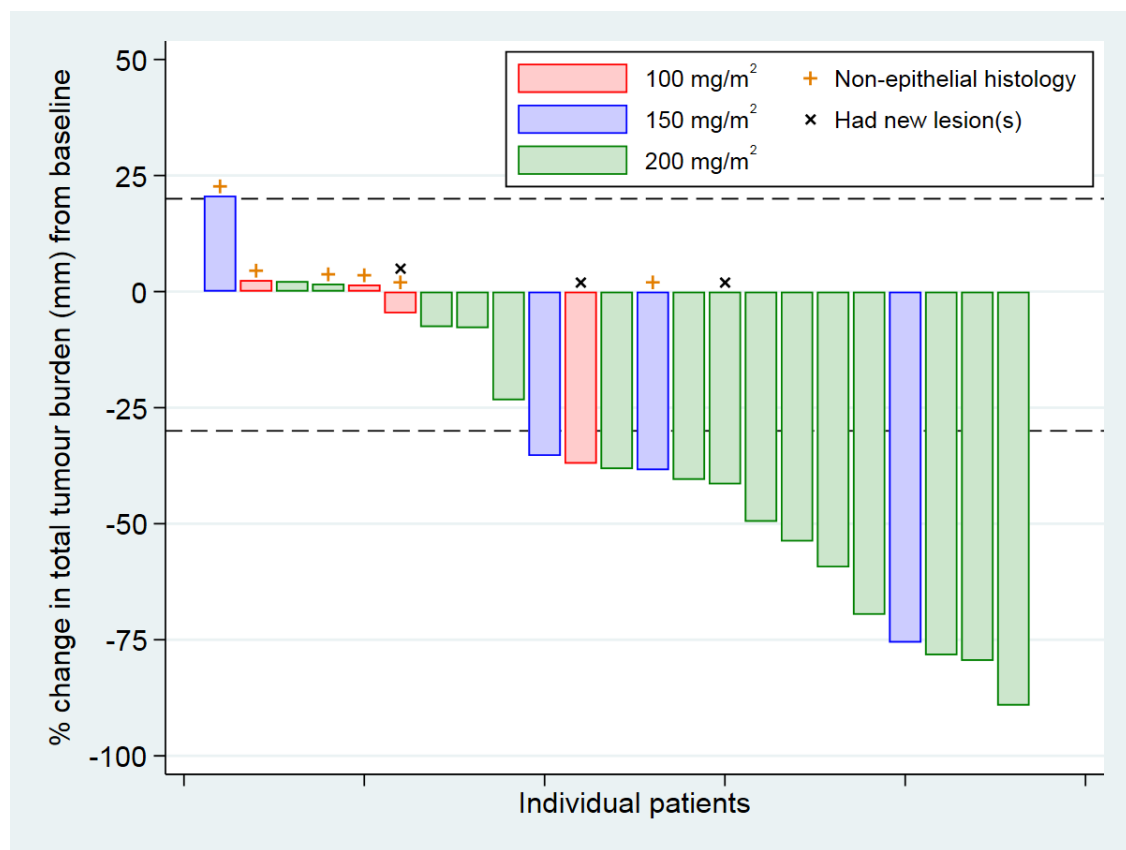
Last Price (9/25/2018)	\$9.49
52-Week High (9/24/2018)	\$10.64
52-Week Low (11/9/2017)	\$5.55
Market Cap. (MM)	\$199
Shares Out. (MM)	21.02

#### Yale Jen, Ph.D.

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

FOR ANALYST CERTIFICATION AND DISCLOSURES, PLEASE SEE DISCLOSURES SECTION AT THE END OF THIS REPORT. This report has been prepared by Laidlaw & Co (UK), Ltd. Investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. All prices are those current at the end of the previous trading session unless otherwise indicated. Prices and consensus estimates are sourced from a reliable market source

**Figure 1: Best tumour response (% change in tumour burden from baseline)**



Source: Fennell, D.A. et. al., Abstract #11921, 2018 ASLC 19<sup>th</sup> World Conference on Lung Cancer

## Anticipated milestones in 2018 and beyond

Product	Indication	Event	Timing	Importance
Reproxalap cream	Sjögren-Larsson Syndrome (SLS)	Potentially interim Phase III study results	1H19	****
		Potentially Phase III study results	2019/2020	****
Reproxalap eyedrop	Noninfectious anterior uveitis	Potentially report Phase III study top-line results	2019	****
	Allergic conjunctivitis	Potentially report Phase III trial outcome	4Q18/1Q19	****
		Potential meeting with the FDA for second Phase III trial design and expectation	2019	***
		Potentially start 2nd Phase III trial	2019	***
		Potential NDA filing	Late 2019/2020	***
Dry eye syndrome	Potentially report Phase IIb trial outcome	Sep./Oct. 2018	****	
ADX-103	Retina disease	Potentially start Phase I/IIa study	2019	***
ADX-629		Potentially start safety Phase I study	2019	***
	NASH	Potentially start Phase IIa study	2019	***
	IBD	Potentially start Phase IIa study	2019	***
ADX-1612	Mesothelioma	Meeting with the FDA	4Q18	***
	Ovarian cancer	Start investigator sponsored Phase II study	2H18	***
	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

## 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 ~\$42MM cash at the end of 2Q18, 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

<b>Aldeyra Therapeutics – Income Statement</b>											
<b>(\$'000)</b>	<b>2014</b>	<b>2015</b>	<b>2016</b>	<b>2017</b>	<b>1Q18</b>	<b>2Q18</b>	<b>3Q18E</b>	<b>4Q18E</b>	<b>2018E</b>	<b>2019E</b>	<b>2020E</b>
<b>Revenue</b>											
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	265
Gross sales				0	-	0	0	-	0	0	2,679
Research and development	3,708	7,574	13,176	16,303	6,600	6,793	7,472	7,846	28,711	31,295	33,799
General and administrative	3,563	4,415	5,520	6,186	1,891	2,373	2,444	2,518	9,226	9,688	10,172
Marketing and sales											6,500
<b>Total Operating Expenses</b>	<b>7,271</b>	<b>11,989</b>	<b>18,696</b>	<b>22,488</b>	<b>8,491</b>	<b>9,166</b>	<b>9,917</b>	<b>10,363</b>	<b>37,937</b>	<b>40,983</b>	<b>50,471</b>
<b>Operating Incomes (losses)</b>	<b>(7,271)</b>	<b>(11,989)</b>	<b>(18,696)</b>	<b>(22,488)</b>	<b>(8,491)</b>	<b>(9,166)</b>	<b>(9,917)</b>	<b>(10,363)</b>	<b>(37,937)</b>	<b>(40,983)</b>	<b>(47,791)</b>
Interest income	0	11	102	261	122	142	55	56	375	413	413
Other expenses		0	0	0	-	-	-	-	0	0	0
Interest expense	(244)	(113)	(106)	(113)	(28)	(26)	(27)	(27)	(108)	(108)	(108)
Total Other Income (Expense)	2,083	(102)	(3)	148	94	116	28	29	267	304	304
Net loss and comprehensive loss	(5,187)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(9,889)	(10,334)	(37,670)	(40,678)	(47,487)
Accretion of preferred stock	(333)	0	0	0	-	-	-	-	0	0	0
Allocation of undistributed earnings to preferred stock	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
<b>Net Income (Loss)</b>	<b>(9,574)</b>	<b>(12,091)</b>	<b>(18,699)</b>	<b>(22,341)</b>	<b>(8,397)</b>	<b>(9,050)</b>	<b>(9,889)</b>	<b>(10,334)</b>	<b>(37,670)</b>	<b>(40,678)</b>	<b>(47,487)</b>
Net Income (Loss) Applicable to Common Shareholders	(9,574)	(12,091)	(18,699)	(22,341)	(8,397)	(9,050)	(9,889)	(10,334)	(37,670)	(40,678)	(47,487)
Net Earnings (Losses) Per Share—Basic	(\$2.51)	(\$1.40)	(\$1.65)	(\$1.40)	(\$0.43)	(\$0.46)	(\$0.50)	(\$0.47)	(\$1.86)	(\$1.61)	(\$1.81)
Net Earnings (Losses) Per Share—Diluted	(\$3.09)	(\$1.40)	(\$1.65)	(\$1.40)	(\$0.43)	(\$0.46)	(\$0.50)	(\$0.47)	(\$1.86)	(\$1.61)	(\$1.81)
Shares outstanding—basic	3,818	8,634	11,352	15,922	19,367	19,761	19,961	21,961	20,263	25,263	26,263
Shares outstanding—diluted	3,851	8,634	11,352	15,922	19,367	19,761	19,961	21,961	20,263	25,263	26,263
<b>Margin Analysis (% of Sales/Revenue)</b>											
Costs of goods										9%	9%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	1148%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	345%
Operating Income (loss)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1623%
Net Income	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	-1613%
<b>Financial Indicator Growth Analysis (YoY%)</b>											
Total Revenue	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
R&D	140%	104%	74%	24%	96%	76%	111%	41%	76%	9%	8%
SG&A	67%	24%	25%	12%	10%	60%	66%	68%	49%	5%	5%
Marketing and sales											
Operating Income (Losses)	98%	65%	56%	20%	67%	72%	98%	47%	69%	8%	17%
Pretax Income	-140%	133%	55%	19%	65%	70%	98%	49%	69%	8%	17%
Net Income	-963%	26%	55%	19%	65%	70%	98%	49%	69%	8%	17%
EPS	-172%	-44%	18%	-15%	18%	31%	55%	30%	32%	-13%	12%
Yale Jen, Ph.D. 212-953-4978											

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

## DISCLOSURES:

### ANALYST CERTIFICATION

The analyst responsible for the content of this report hereby certifies that the views expressed regarding the company or companies and their securities accurately represent his personal views and that no direct or indirect compensation is to be received by the analyst for any specific recommendation or views contained in this report. Neither the author of this report nor any member of his immediate family or household maintains a position in the securities mentioned in this report.

### EQUITY DISCLOSURES

For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell most closely correspond to Buy, Hold and Sell, respectively, the meanings are not the same because our ratings are determined on a relative basis against the analyst sector universe of stocks. An analyst's coverage sector is comprised of companies that are engaged in similar business or share similar operating characteristics as the subject company. The analysis sector universe is a sub-sector to the analyst's coverage sector, and is compiled to assist the analyst in determining relative valuations of subject companies. The composition of an analyst's sector universe is subject to change over time as various factors, including changing market conditions occur. Accordingly, the rating assigned to a particular stock represents solely the analyst's view of how that stock will perform over the next 12-months relative to the analyst's sector universe.

#### Additional information available upon request.

‡ Laidlaw & Company has received compensation from the subject company for investment banking services in the past 12 months and expects to receive or intends to seek compensation for investment banking services from the company in the next three months.

### RATINGS INFORMATION

#### Rating and Price Target Change History



#### 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
<b>Strong Buy (SB)</b>	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
<b>Buy (B)</b>	Expected to outperform the sector average over 12 months.	62.50%	21.43%	3.57%
<b>Hold (H)</b>	Expected returns to be in line with the sector average over 12 months.	3.57%	1.79%	0.00%
<b>Sell (S)</b>	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

### ADDITIONAL COMPANIES MENTIONED

Synta Pharmaceuticals (SYNTA – Not Rated)

### ADDITIONAL DISCLOSURES

As of the date of this report, neither the author of this report nor any member of his immediate family or household maintains an ownership position in the securities of the company (ies) mentioned in this report.

This report does not provide individually tailored investment advice and has been prepared without regard to the individual financial circumstances and objectives of persons who receive it. Laidlaw & Co (UK), Ltd. recommends that investors independently evaluate particular investments and strategies, and encourages investors to seek the advice of a financial adviser. The appropriateness of a particular investment or strategy will depend on an investor's individual circumstances and objectives. The securities, instruments, or strategies discussed in this report may not be suitable for all investors, and certain investors may not be eligible to purchase or participate in some or all of them. This report is not an offer to buy or sell or the solicitation of an offer to buy or sell any security/instrument or to participate in any particular trading strategy.

Associated persons of Laidlaw & Co (UK), Ltd not involved in the preparation of this report may have investments in securities/instruments or derivatives of securities/instruments of companies mentioned herein and may trade them in ways different from those discussed in this report. While Laidlaw & Co (UK), Ltd., prohibits analysts from receiving any compensation. Bonus or incentive based on specific recommendations for, or view of, a particular company, investors should be aware that any or all of the foregoing, among other things, may give rise to real or potential conflicts of interest.

With the exception of information regarding Laidlaw & Co (UK), Ltd. this report is based on public information. Laidlaw & Co (UK), Ltd makes every effort to use reliable, comprehensive information, but we make no representation that it is accurate or complete and it should not be relied upon as such. Any opinions expressed are subject to change and Laidlaw & Co (UK), Ltd disclaims any obligation to advise you of changes in opinions or information or any discontinuation of coverage of a subject company. Facts and views presented in this report have not been reviewed by, and may not reflect information known to, professionals in other Laidlaw & Co (UK), Ltd business areas. Laidlaw & Co (UK), Ltd associated persons conduct site visits from time to time but are prohibited from accepting payment or reimbursement by the company of travel expenses for such visits. The value of and income from your investments may vary because of changes in interest rates, foreign exchange rates, default rates, prepayment rates, securities/instruments prices, market indexes, operational or financial conditions of companies or other factors. There may be time limitations on the exercise of options or other rights in securities/instruments transactions. Past performance is not necessarily a guide to future performance. Estimates of future performance are based on assumptions that may not be realized. If provided, and unless otherwise stated, the closing price on the cover page is that of the primary exchange for the subject company's securities/instruments.

Any trademarks and service marks contained in this report are the property of their respective owners. Third-party data providers make no warranties or representations of any kind relating to the accuracy, completeness, or timeliness of the data they provide and shall not have liability for any damages of any kind relating to such data. This report or any portion thereof may not be reprinted, sold or redistributed without the written consent of Laidlaw & Co (UK), Ltd. This report is disseminated and available primarily electronically, and, in some cases, in printed form.

The information and opinions in this report were prepared by Laidlaw & Co (UK), Ltd. For important disclosures, please see Laidlaw & Co (UK), Ltd.'s disclosure website at [www.Laidlawltd.com](http://www.Laidlawltd.com), or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

© 2018 Laidlaw & Co. (UK), Ltd.

**NOTES:**