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EQUITY RESEARCH
Company Report

August 9, 2016

# Aldeyra Therapeutics (ALDX - $ 6.65)

*Healthcare/Biotechnology*

## Robust NS2 in Sjögren-Larsson Syndrome Phase II Results

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

This morning, ALDX reported positive NS2 in Sjögren-Larsson Syndrome (SLS) Phase II results as the drug significantly reduced multiple symptoms vs. placebo with acceptable safety profile.

- **Details.** This morning ALDX reported positive NS2 in SLS (n=12) Phase II results, which met endpoint of Ichthyosis Severity Score (ISS). Specifically, 83% (5/6) of NS2 treated vs. 20% (1/5) vehicle-treated patients achieved composite ISS of $\leqslant$ 5 at week 8 (p=0.04). 83% (5/6) of NS2 treated vs. 17% (1/6) vehicle-treated patient achieved $\geqslant$2 point reduction from baseline in composite ISS at week 8 (p=0.02). From central reader digital photography assessment, ISS reduction observed between NS2 vs. vehicle (~-2.5 vs. -1 with p<0.05). The reduction was also observed in several individual symptoms, such as erythema, lichenification, excoriation and global score. All NS2-treated patients (n=6) exhibited greater ISS reduction after 8 weeks of therapy comparing after 4 weeks of therapy, potentially suggesting a disease modifying effect. Analysis of biomarker changes (mainly various types of lipid) is correlated with treatment effects. The study is a randomized, parallel-group, double-blind, vehicle-controlled, multi-center Phase II trial that evaluated topical 1.0% NS2 in SLS patients in 8-week treatment. NS2 is administered once-daily (QD) on a 4x10 inch area of skin mainly on the leg.
- **Implications.** We are very encouraged by the positive results of topical NS2 in SLS treatment and the outcome has well validated the therapeutic utility of aldehyde trapping in treating both inflammation and disorders directly due to metabolic defect of aldehyde removal. ALDX is scheduled to conduct meetings with the U.S. and some EU regulatory agencies later to determine the next steps. ALDX also reiterated its plan to start systemic NS2 clinical studies in 2017 for treating SSADH and to provide more details regarding the overall developments of various clinical programs over the 2Q16 earnings call scheduled tomorrow morning. We continue to view the potential success of aldehyde trapping in ultra-orphan indications, like SLS and SSADH as being a potential major value driver for ALDX shareholders; while treatment for inflammation-related indications would be an ultimate jackpot.
- **Action.** We are reiterating our Buy rating and our $30 target price based on peer comparable probability adjusted DCF analyses. Clinical NS2 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 (08/09/2016) | $ 6.65 |
| 52–Week High (8/10/2015) | $ 9.22 |
| 52–Week Low (2/9/2016) | $ 3.39 |
| Market Cap. (MM) | $ 83 |
| Shares Out. (MM) | 12 |

**Earnings Estimates:** (per share)

| (Dec) | 1Q | 2Q | 3Q | 4Q | FY | P/E |
|---|---|---|---|---|---|---|
| **FY-16E** | -0.51A | -0.53 | -0.54 | -0.55 | -2.13 | 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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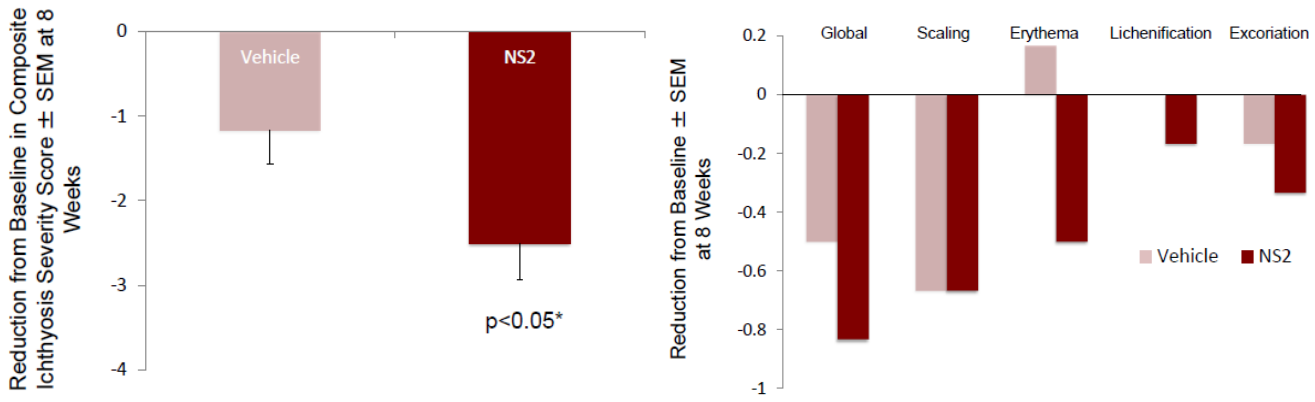
**Figure 1: NS2 demonstrated clinical activity in treating SLS**

| Digital Photography Central Review | NS2 | Vehicle | Unadjusted Chi Square p value# |
|---|---|---|---|
| Subjects with composite Ichthyosis Severity Score of ≤ 5 at Week 8 (average rating of "almost clear") | 5/6 (83%) | 1/5 (20%)* | 0.04 |
| Subjects with ≥2 point reduction from baseline in composite Ichthyosis Severity Score at Week 8 | 5/6 (83%) | 1/6 (17%) | 0.02 |

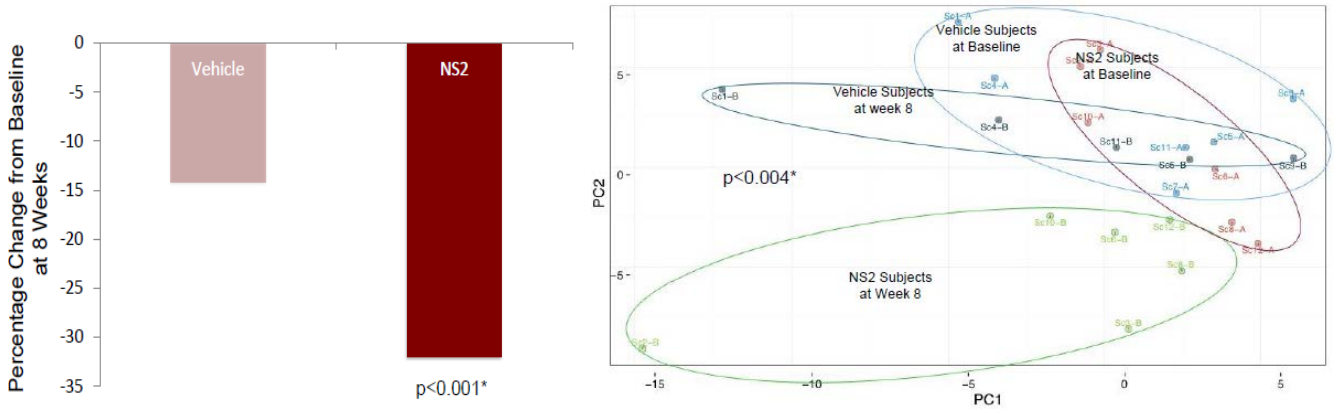
*Source: Company presentation*

**Figure 2: NS2 reduced Ichthyosis Severity Score and individual symptoms by central reader digital photography assessment**




*Source: Company presentation*

**Figure 3: NS2 increased skin cholesterol reduction (left) and improved biomarker profile (right)**




*Source: Company presentation*


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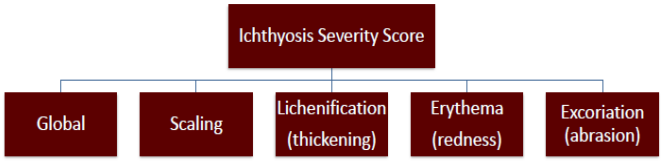
**Figure 4: Ichthyosis Severity Score (left) and patient baseline characteristics (right)**




Each measure rated separately as follows:

| Score | Definition |
|---|---|
| 0 | Clear |
| 1 | Almost Clear |
| 2 | Mild |
| 3 | Moderate |
| 4 | Severe |

Composite Ichthyosis Severity Score is the sum of all components (range 0-20)

| | NS2 (n=6) | Vehicle (n=6) |
|---|---|---|
| Age (years) ± SD | 14 ± 5 | 17 ± 5 |
| Gender (Male, Female) | 3, 3 | 3, 3 |
| Race (White, Black, Latino) | 3,2,1 | 5,1,0 |
| Body Surface Area ($m^2$) ± SD | 1.54 ± 0.5 | 1.95 ± 0.9 |
| Baseline Exam Ichthyosis Global Assessment ± SD | 3.0 ± 0 | 3.2 ± 0.4 |

*Source: Company presentation*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## Anticipated milestones in 2016 and beyond

| Product | Indication | Event | Timing | Importance |
|---|---|---|---|---|
| NS2 cream | Sjögren-Larsson Syndrome (SLS) | Discussions with regulatory agencies | **2H16** | *** |
| NS2 eyedrop | Noninfectious anterior uveitis | Potentially conduct pre-IND meeting with the FDA | **2H16** | *** |
| | | Potentially start Phase II/III dose-optimizing trial | **4Q16** | *** |
| | | Potentially report Phase II/III study top-line results | **2017** | **** |
| | Allergic conjunctivitis | Potentially conduct pre-IND meeting with the FDA | **2H16** | *** |
| | | Potentially start Phase II/III dose-optimizing trial | **4Q16** | *** |
| | | Potentially report Phase II/III study top-line results | **2017** | **** |
| Systemic delvered (IV) NS2 | Succinic Semi-aldehyde Dehydrogenase (SSADH) Deficiency, CNS disorders of SLS and /or autoimmune disorders | Potentially report pre-clinical data | **2016** | *** |
| | | Potentially to start Phase I studies | **2H16** | **** |
| | | Potentially to start Phase II 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, NS2 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 NS2 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, NS2 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, NS2, 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 ~$17MM (pro forma) cash after recent financing, 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 | 2Q16E | 3Q16E | 4Q16E | 2016E | 2017E | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Revenue** | | | | | | | | | | | |
| Product revenue | 0 | 0 | - | - | - | - | 0 | 1,492 | 12,162 | 49,287 | 123,139 |
| Other revenue | 0 | 0 | - | - | - | - | 0 | 0 | 0 | 0 | 0 |
| Total revenue | 0 | 0 | - | - | - | - | 0 | 1,492 | 12,162 | 49,287 | 123,139 |
| Costs of goods | | | | | | | | 134 | 1,095 | 4,436 | 11,083 |
| Gross sales | | | | | | | | 1,358 | 11,067 | 44,851 | 112,057 |
| Research and development | 3,708 | 7,574 | 3,511 | 3,757 | 3,870 | 3,947 | 15,086 | 17,047 | 18,582 | 20,254 | 21,874 |
| General and administrative | 3,563 | 4,415 | 1,456 | 1,470 | 1,485 | 1,529 | 5,940 | 6,771 | 7,110 | 7,465 | 7,839 |
| Marketing and sales | | | | | | | | 15,000 | 16,500 | 25,575 | 26,854 |
| **Total Operating Expenses** | 7,271 | 11,989 | 4,967 | 5,227 | 5,355 | 5,477 | 21,026 | 38,819 | 42,192 | 53,294 | 56,567 |
| **Operating Incomes (losses)** | (7,271) | (11,989) | (4,967) | (5,227) | (5,355) | (5,477) | (21,026) | (37,461) | (31,125) | (8,443) | 55,490 |
| 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 | 24 | 23 | 22 | 94 | 103 | 113 | 125 | 125 |
| Other expenses | | 0 | - | - | - | - | 0 | 0 | 0 | 0 | 0 |
| Interest expense | (244) | (113) | (25) | (25) | (25) | (25) | (100) | (100) | (100) | (100) | (100) |
| Total Other Income (Expense) | 2,083 | (102) | (0) | (1) | (2) | (3) | (6) | 3 | 13 | 25 | 25 |
| Net loss and comprehensive loss | (5,187) | (12,091) | (4,967) | (5,228) | (5,357) | (5,480) | (21,032) | (37,458) | (31,111) | (8,418) | 55,515 |
| 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 | (20,540) |
| **Net Income (Loss)** | (9,574) | (12,091) | (4,967) | (5,228) | (5,357) | (5,480) | (21,032) | (37,458) | (31,111) | (8,418) | 34,974 |
| Net Income (Loss) Applicable to Common Shareholders | (9,574) | (12,091) | (4,967) | (5,228) | (5,357) | (5,480) | (21,032) | (37,458) | (31,111) | (8,418) | 34,974 |
| Net Earnings (Losses) Per Share—Basic | ($2.51) | ($1.40) | ($0.51) | ($0.53) | ($0.54) | ($0.55) | ($2.13) | ($3.16) | ($2.42) | ($0.61) | $2.35 |
| Net Earnings (Losses) Per Share—Diluted | ($3.09) | ($1.40) | ($0.51) | ($0.53) | ($0.54) | ($0.55) | ($2.13) | ($3.16) | ($2.42) | ($0.61) | $2.35 |
| Shares outstanding—basic | 3,818 | 8,634 | 9,713 | 9,813 | 9,913 | 10,013 | 9,863 | 11,863 | 12,863 | 13,863 | 14,863 |
| Shares outstanding—diluted | 3,851 | 8,634 | 9,713 | 9,813 | 9,913 | 10,013 | 9,863 | 11,863 | 12,863 | 13,863 | 14,863 |
| **Margin Analysis (% of Sales/Revenue)** | | | | | | | | | | | |
| Costs of goods | | | | | | | | 9% | 9% | 9% | 9% |
| R&D | NA | NA | NA | NA | NA | NA | NA | 1142% | 153% | 41% | 18% |
| SG&A | NA | NA | NA | NA | NA | NA | NA | 454% | 58% | 15% | 6% |
| Operating Income (loss) | NA | NA | NA | NA | NA | NA | NA | -2511% | -256% | -17% | 45% |
| Net Income | NA | NA | NA | NA | NA | NA | NA | -2510% | -256% | -17% | 28% |
| **Financial Indicator Growth Analysis (YoY%)** | | | | | | | | | | | |
| Total Revenue | NA | NA | NA | NA | NA | NA | NA | NA | 715% | 305% | 150% |
| R&D | 140% | 104% | 209% | 201% | 86% | 27% | 99% | 13% | 9% | 9% | 8% |
| SG&A | 67% | 24% | 50% | 54% | 18% | 25% | 35% | 14% | 5% | 5% | 5% |
| Marketing and sales | | | | | | | | | 10% | 55% | 5% |
| Operating Income (Losses) | 98% | 65% | 136% | 137% | 60% | 26% | 75% | 78% | -17% | -73% | -757% |
| Pretax Income | -140% | 133% | 132% | 134% | 59% | 25% | 74% | 78% | -17% | -73% | -759% |
| Net Income | -963% | 26% | 132% | 134% | 59% | 25% | 74% | 78% | -17% | -73% | -515% |
| EPS | -172% | -44% | 60% | 100% | 56% | 22% | 52% | 48% | -23% | -75% | -487% |

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



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***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 ($) |
|---|---|---|
| 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. | 62.16% | 27.03% | 2.70% |
| **Hold (H)** | Expected returns to be in line with the sector average over 12 months. | 2.70% | 0.00% | 0.00% |
| **Sell (S)** | Returns expected to significantly underperform the sector average over 12 months. | 2.70% | 0.00% | 0.00% |

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