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EQUITY RESEARCH
Company Report

May 15, 2017

# Aldeyra Therapeutics (ALDX - $3.95)

*Healthcare/Biotechnology*

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

## 1Q17: Ahead of the Planned Schedule Regarding Data Releases with the Next Readout in June

This morning, ALDX reported 1Q17 financial results with a net loss of ($5.1MM) vs. Laidlaw ($4.9MM) and the Street ($5.4MM) estimates. Net loss/share was ($0.37) vs. ($0.38) for Laidlaw and ($0.36) the Street. ALDX ended 1Q17 with cash of ~$31.2MM, enough to support its operations into 2H18, in our opinion.

- **ADX-102 in allergic conjunctivitis Phase IIb trial updates.** ALDX provided updates of its ongoing clinical programs with a few progressing ahead of previous guidance. One of them is the Phase IIb study of 0.1% and 0.5% topical ocular ADX-102 in allergic conjunctivitis. Management indicated that the top-line results could be reported in late 2Q17 (June). ALDX also indicated that the Phase IIb study could be qualified as a part of the pivotal studies if the outcome shows a $\geq$ 1 point change in ocular itching (patient reported using Ora Calibra conjunctival allergen challenge ocular itching scale) assessments for at least 2 of the 3 timepoints vs. the placebo. Secondary endpoints include ocular redness, tearing, and eyelid swelling.
- **ADX-102 in SLS Phase III trial updates.** Management provided more color on the ADX-102 in SLS Phase III study design. It consists of two parts: 1) the first part will randomize (n~10) SLS patients to receive ADX-102 or vehicle for 6-months therapy. The objective is to assess the surface areas needed to be treated in order to determine the statistical powering assumptions for the second part of the study. Vehicle treated patients from part one will be rolled over into Part two for randomization. 2) Part two will enroll an additional 20 SLS patients who will be randomized to receive either ADX-102 or vehicle treatment for the first 6 months followed by crossing over the treated patients to vehicle and vehicle patients to ADX-102 therapy for 6 more months. The primary endpoint is change in ichthyosis severity score (ISS) from baseline. The top-line results for the first part study could be available in 2H18, also ahead of our prior estimates. We estimate the final topline results could be available later in 2019. ADX-102 also recently received an orphan drug designation for the treatment of congenital ichthyosis based on the statistically significant Phase II clinical data of ISS improvement from baseline.
- **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 (5/12/2017) | $3.95 |
| 52–Week High (9/27/2016) | $8.19 |
| 52–Week Low (5/9/2017) | $3.80 |
| Market Cap. (MM) | $62 |
| Shares Out. (MM) | 11.352 |

**Earnings Estimates:** (per share)

| (Dec) | 1Q | 2Q | 3Q | 4Q | FY | P/E |
|---|---|---|---|---|---|---|
| **FY-17E** | -0.37A | -0.37 | -0.38 | -0.38 | -1.50 | N.A. |
| **FY-16A** | -0.51 | -0.41 | -0.38 | -0.37 | -1.65 | 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. |

*Source: Laidlaw & Company estimates*

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- **Other clinical program updates.** The ADX-102 (ocular) in noninfectious anterior uveitis (NAU) ongoing Phase III trial remains on track for a potential top-line result readout in 2H18. For this trial, patients are (n~100) randomized 1:1 to receive either 0.5% ADX-102 (ocular) or vehicle for four weeks and the primary endpoint is the clearing of inflammatory cells in the anterior chamber of the eye. The Phase III top-line results could be available in 2H18.

  ALDX indicated that the Phase IIa trial in dry eye syndrome will test three formulations of topical ocular ADX-102 over a treatment period of 28 days. Management characterized the results as "shotgun endpoints" as they encompass multiple metrics of dry eye symptoms, anti-inflammatory activities, impacts on tears and other aspects. The top-line results could be available in 3Q17. We anticipate the potential ocular formulation for dry eye could be different from other ocular indications in order to possibly better treat the patient and with greater flexibility with different pricing potential.

**Table 1: Estimated and reported 1Q17 results**

| 1Q17 Estimates and Reported Results | | | |
|---|---|---|---|
| **($,000)** | **Laidlaw Estimate** | **Actual** | **Consensus** |
| **Total revenue** | **$0.0** | **$0.0** | **$0.0** |
| **Total op. profit (loss)** | **($4,864)** | **($5,096)** | **($5,400)** |
| R&D | $3,622 | $3,369 | |
| SG&A | $1,242 | $1,727 | |
| **EPS** | **($0.38)** | **($0.37)** | **($0.36)** |
| Net income (loss) | ($4,864) | ($5,091) | ($5,400) |

*Source: Bloomberg, SEC filings and Laidlaw and Co.*


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## Anticipated milestones in 2017 and beyond

| Product | Indication | Event | Timing | Importance |
|---|---|---|---|---|
| ADX-102 cream | Sjögren-Larsson Syndrome (SLS) | Start Phase III study | **2H17** | *** |
| | | Potentially interim Phase III study results | **2H18** | **** |
| | | Potentially Phase III study results | **2019** | **** |
| ADX-102 eyedrop | Noninfectious anterior uveitis | Potentially report Phase III study top-line results | **4Q18** | **** |
| | | Potentially start 2nd Phase III trial | **2019** | *** |
| | Allergic conjunctivitis | Potentially report Phase IIb study top-line results | **June, 17** | **** |
| | | Potential to start next clinical trial | **2H17/2018** | *** |
| | Dry eye syndrome | Potentially report Phase II dose-optimizing trial results | **3Q17** | **** |
| Oral ADX-102 or new trapper | | Potentially to start safety Phase I study | **1Q18** | *** |
| | Succinic Semi-aldehyde Dehydrogenase (SSADH) | Potentially to start Phase IIa study | **2H18** | *** |
| | | Potentially to report Phase IIa study results | **2019** | **** |
| | Sjögren-Larsson Syndrome (SLS) CNS disorders | Potentially to start Phase I study | **2H18** | *** |
| New aldehyde trapper | | Provide more updates | **1H17** | *** |

***** / ***** 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 and upcoming clinical studies. The clinical validation for these programs has not been established. The success of 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 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, 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 had ~$29MM cash at the end of 3Q16, 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 | 1Q17 | 2Q17E | 3Q17E | 4Q17E | 2017E | 2018E | 2019E | 2020E |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **Revenue** | | | | | | | | | | | |
| 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 | 265 |
| Gross sales | | | | - | 0 | - | - | 0 | 0 | 0 | 2,679 |
| Research and development | 3,708 | 7,574 | 13,176 | 3,369 | 3,436 | 3,643 | 3,737 | 14,185 | 15,462 | 16,854 | 18,202 |
| General and administrative | 3,563 | 4,415 | 5,520 | 1,727 | 1,675 | 1,692 | 1,743 | 6,836 | 7,178 | 7,537 | 7,914 |
| Marketing and sales | | | | | | | | | 16,500 | 16,500 | 16,500 |
| **Total Operating Expenses** | 7,271 | 11,989 | 18,696 | 5,096 | 5,111 | 5,334 | 5,480 | 21,022 | 39,140 | 40,891 | 42,616 |
| **Operating Incomes (losses)** | (7,271) | (11,989) | (18,696) | (5,096) | (5,111) | (5,334) | (5,480) | (21,022) | (39,140) | (40,891) | (39,937) |
| 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 convertil | 0 | 0 | 0 | - | - | - | - | 0 | 0 | 0 | 0 |
| Interest income | 0 | 11 | 102 | 32 | 27 | 27 | 27 | 113 | 124 | 136 | 136 |
| Other expenses | | 0 | 0 | - | - | - | - | 0 | 0 | 0 | 0 |
| Interest expense | (244) | (113) | (106) | (27) | (27) | (27) | (27) | (108) | (108) | (108) | (108) |
| Total Other Income (Expense) | 2,083 | (102) | (3) | 5 | 0 | 0 | 0 | 5 | 16 | 28 | 28 |
| Net loss and comprehensive loss | (5,187) | (12,091) | (18,699) | (5,091) | (5,111) | (5,334) | (5,480) | (21,017) | (39,124) | (40,862) | (39,908) |
| 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) | (18,699) | (5,091) | (5,111) | (5,334) | (5,480) | (21,017) | (39,124) | (40,862) | (39,908) |
| Net Income (Loss) Applicable to Common Shareholders | (9,574) | (12,091) | (18,699) | (5,091) | (5,111) | (5,334) | (5,480) | (21,017) | (39,124) | (40,862) | (39,908) |
| Net Earnings (Losses) Per Share—Basic | ($2.51) | ($1.40) | ($1.65) | ($0.37) | ($0.37) | ($0.38) | ($0.38) | ($1.50) | ($2.60) | ($2.55) | ($2.34) |
| Net Earnings (Losses) Per Share—Diluted | ($3.09) | ($1.40) | ($1.65) | ($0.37) | ($0.37) | ($0.38) | ($0.38) | ($1.50) | ($2.60) | ($2.55) | ($2.34) |
| Shares outstanding—basic | 3,818 | 8,634 | 11,352 | 13,797 | 13,947 | 14,097 | 14,247 | 14,022 | 15,022 | 16,022 | 17,022 |
| Shares outstanding—diluted | 3,851 | 8,634 | 11,352 | 13,797 | 13,947 | 14,097 | 14,247 | 14,022 | 15,022 | 16,022 | 17,022 |
| **Margin Analysis (% of Sales/Revenue)** | | | | | | | | | | | |
| Costs of goods | | | | | | | | | | 9% | 9% |
| R&D | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | 618% |
| SG&A | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | 269% |
| Operating Income (loss) | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | -1356% |
| Net Income | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | -1355% |
| **Financial Indicator Growth Analysis (YoY%)** | | | | | | | | | | | |
| Total Revenue | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| R&D | 140% | 104% | 74% | -4% | 21% | 8% | 8% | 8% | 9% | 9% | 8% |
| SG&A | 67% | 24% | 25% | 19% | 15% | 21% | 45% | 24% | 5% | 5% | 5% |
| Marketing and sales | | | | | | | | | | | |
| Operating Income (Losses) | 98% | 65% | 56% | 3% | 19% | 12% | 18% | 12% | 86% | 4% | -2% |
| Pretax Income | -140% | 133% | 55% | 2% | 19% | 12% | 18% | 12% | 86% | 4% | -2% |
| Net Income | -963% | 26% | 55% | 2% | 19% | 12% | 18% | 12% | 86% | 4% | -2% |
| EPS | -172% | -44% | 18% | -28% | -10% | -1% | 4% | -9% | 74% | -2% | -8% |

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



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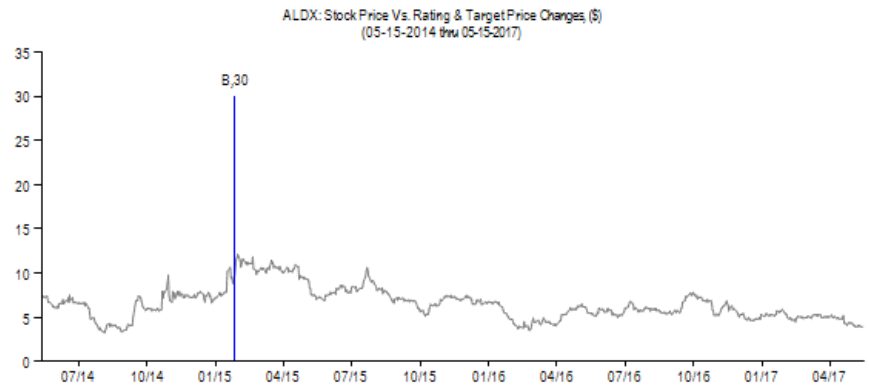
***Additional information available upon request.***

‡ 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**

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|---|---|---|---|---|
| | | | Investment Banking | Brokerage |
| **Strong Buy (SB)** | Expected to significantly outperform the sector over 12 months. | 2.27% | 0.00% | 0.00% |
| **Buy (B)** | Expected to outperform the sector average over 12 months. | 61.36% | 29.55% | 2.27% |
| **Hold (H)** | Expected returns to be in line with the sector average over 12 months. | 2.27% | 0.00% | 0.00% |
| **Sell (S)** | Returns expected to significantly underperform the sector average over 12 months. | 0.00% | 0.00% | 0.00% |

## ADDITIONAL COMPANIES MENTIONED

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