LAIDLAW & COMPANY
Est. 1842
London
New York
San Francisco
Boston

EQUITY RESEARCH
Company Report

August 8, 2017

# Aldeyra Therapeutics (ALDX - $4.70)

*Healthcare/Biotechnology*

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

## 2Q17: All Eyes on Dry Eye Phase II Data Readout in September and EOP2 Meeting Feedback in 2H17

This morning, ALDX reported 2Q17 financial results with a net loss of ($5.3MM) vs. Laidlaw ($5.1MM) and the Street ($5.6MM) estimates. Net loss/share was ($0.35) vs. ($0.37) for Laidlaw and ($0.39) the Street. ALDX ended 2Q17 with cash of ~$25.6MM, enough to support its operations into 2H18, in our opinion.

- **ADX-102 in allergic conjunctivitis EOP2 meeting expected in 2H17.** ALDX plans to advance ADX-102 in allergic conjunctivitis into Phase III studies after they have reviewed promising results, especially longer lasting treatment effects, from the Phase IIb trial. ALDX is scheduling an EOP2 meeting (possibly in late 2017) with the FDA before advancing it into the Phase III trials (possibly in 1Q18). ADX-102's mechanism of action is very different from that of anti-histamines, and ADX-102 appears to potentially provide a more lasting therapeutic effect but might take a longer time to show its efficacy. Given that, ALDX would like to have discussions with the FDA during an EOP2 meeting to discuss the potential for approving clinical endpoints that more appropriately reflect the therapeutic benefit of ADX-102. In our opinion, such potential approvable endpoint adjustments are analogous to the circumstance in earlier days of cancer treatment for targeted or immunological therapies, while the approval endpoints were more appropriate for chemotherapy.
- **ADX-102 in dry eye disease (DED) Phase IIa trial data expected in September.** Management reiterated that the ADX-102 in DED Phase IIa trial readout is expected in September this year. The primary purpose is to establish the safety and tolerability of the drug, and to determine the optimal formulation for potentially moving forward. Given the short treatment duration (one month) and relatively small patient size, the study might not provide an efficacy signal with statistical significance. In addition, we anticipate future studies will include placebo to further tease out the therapeutic effect and benefit of ADX-102.
- **2H18 an important data readout period.** Management pointed out that the ADX-102 in noninfectious anterior uveitis (NAU) Phase III trial is on track and results could be available in 2H18. In addition, the first (dose finding) portion of the ADX-102 in Sjögren-Larsson Syndrome (SLS) Phase III results could also be available in 2H18. Together, this potentially makes 2H18 an important period for ALDX share value appreciation.
- **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 (8/7/2017) | $4.70 |
| 52–Week High (9/27/2016) | $8.19 |
| 52–Week Low (5/9/2017) | $3.80 |
| Market Cap. (MM) | $71 |
| Shares Out. (MM) | 11.352 |

**Earnings Estimates:** (per share)

| (Dec) | 1Q | 2Q | 3Q | 4Q | FY | P/E |
|---|---|---|---|---|---|---|
| **FY-17E** | -0.37A | -0.35A | -0.37 | -0.39 | -1.48 | 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*

**Yale Jen, Ph.D.**
Managing Director/Senior
Biotechnology Analystt
(212) 953-4978
yjen@laidlawltd.com

- **More updates on ADX-102 in SLS Phase III trial design.** The ADX-102 in SLS Phase III trial will be divided into two portions due to the slight adjustment of the formulation vs. the prior trial. The first part (n=8-9) will be a randomized and controlled assessment of safety and efficacy of different doses of ADX-102 over six months. All patients who've participated in the first part will be crossed-over to the second portion of the study. The second part of the study could potentially include 20 patients for evaluating change from baseline in drug-treated patients. Data from the first part of the trial will be used to confirm statistical power for the second part. The results from the first part of the Phase III SLS trial are expected in 2H18.
- **R&D day is scheduled for 4Q17.** Management announced during the call that ALDX will host a R&D day in 4Q17. Some of the topics to be discussed include the potential approvable endpoint adjustment for the allergic conjunctivitis Phase III studies, and the commercial potential of unmet need for treating allergic conjunctivitis.

**Table 1: Estimated and reported 2Q17 results**

| 2Q17 Estimates and Reported Results | | | |
|---|---|---|---|
| **($,000)** | **Laidlaw Estimate** | **Actual** | **Consensus** |
| **Total revenue** | **$0.0** | **$0.0** | **$0.0** |
| **Total op. profit (loss)** | **($5,111)** | **($5,331)** | **($5,700)** |
| R&D | $3,436 | $3,849 | |
| SG&A | $1,675 | $1,482 | |
| **EPS** | **($0.37)** | **($0.35)** | **($0.39)** |
| Net income (loss) | ($5,111) | ($5,309) | ($5,600) |

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


Yale Jen, Ph.D.
yjen@laidlawltd.com

## Anticipated milestones in 2017 and beyond

| Product | Indication | Event | Timing | Importance |
|---|---|---|---|---|
| ADX-102 cream | Sjögren-Larsson Syndrome (SLS) | Start Phase III study | **4Q17** | *** |
| | | 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 EOP2 discussion with the FDA | **2H17** | *** |
| | | Potential to start next clinical trial | **1H18** | *** |
| | 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 | **2H17** | *** |
| | | R&D day | **4Q17** | *** |

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

*Source: Laidlaw & Company and company presentation*


Yale Jen, Ph.D.
yjen@laidlawltd.com

## 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.


Yale Jen, Ph.D.
yjen@laidlawltd.com

**Figure 1: Income Statement**

## Aldeyra Therapeutics – Income Statement

| ($'000) | 2014 | 2015 | 2016 | 1Q17 | 2Q17 | 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 | 0 | 265 |
| Gross sales | | | | - | 0 | 0 | - | 0 | 0 | 0 | 2,679 |
| Research and development | 3,708 | 7,574 | 13,176 | 3,369 | 3,849 | 4,157 | 4,406 | 15,781 | 17,201 | 18,749 | 20,249 |
| General and administrative | 3,563 | 4,415 | 5,520 | 1,727 | 1,482 | 1,497 | 1,542 | 6,247 | 6,559 | 6,887 | 7,231 |
| Marketing and sales | | | | | | | | | 16,500 | 16,500 | 16,500 |
| **Total Operating Expenses** | 7,271 | 11,989 | 18,696 | 5,096 | 5,331 | 5,653 | 5,948 | 22,028 | 40,260 | 42,136 | 43,981 |
| **Operating Incomes (losses)** | (7,271) | (11,989) | (18,696) | (5,096) | (5,331) | (5,653) | (5,948) | (22,028) | (40,260) | (42,136) | (41,301) |
| 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 converti | 0 | 0 | 0 | - | - | - | - | 0 | 0 | 0 | 0 |
| Interest income | 0 | 11 | 102 | 32 | 48 | 27 | 27 | 134 | 147 | 162 | 162 |
| Other expenses | | 0 | 0 | - | - | - | - | 0 | 0 | 0 | 0 |
| Interest expense | (244) | (113) | (106) | (27) | (26) | (27) | (27) | (107) | (107) | (107) | (107) |
| Total Other Income (Expense) | 2,083 | (102) | (3) | 5 | 22 | 0 | 0 | 27 | 40 | 55 | 55 |
| Net loss and comprehensive loss | (5,187) | (12,091) | (18,699) | (5,091) | (5,309) | (5,653) | (5,948) | (22,001) | (40,220) | (42,082) | (41,247) |
| 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) | (5,309) | (5,653) | (5,948) | (22,001) | (40,220) | (42,082) | (41,247) |
| Net Income (Loss) Applicable to Common Shareholders | (9,574) | (12,091) | (18,699) | (5,091) | (5,309) | (5,653) | (5,948) | (22,001) | (40,220) | (42,082) | (41,247) |
| Net Earnings (Losses) Per Share—Basic | ($2.51) | ($1.40) | ($1.65) | ($0.37) | ($0.35) | ($0.37) | ($0.39) | ($1.48) | ($2.53) | ($2.49) | ($2.30) |
| Net Earnings (Losses) Per Share—Diluted | ($3.09) | ($1.40) | ($1.65) | ($0.37) | ($0.35) | ($0.37) | ($0.39) | ($1.48) | ($2.53) | ($2.49) | ($2.30) |
| Shares outstanding—basic | 3,818 | 8,634 | 11,352 | 13,797 | 15,136 | 15,286 | 15,436 | 14,914 | 15,914 | 16,914 | 17,914 |
| Shares outstanding—diluted | 3,851 | 8,634 | 11,352 | 13,797 | 15,136 | 15,286 | 15,436 | 14,914 | 15,914 | 16,914 | 17,914 |
| **Margin Analysis (% of Sales/Revenue)** | | | | | | | | | | | |
| Costs of goods | | | | | | | | | | 9% | 9% |
| R&D | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | 688% |
| SG&A | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | 246% |
| Operating Income (loss) | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | -1403% |
| Net Income | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | -1401% |
| **Financial Indicator Growth Analysis (YoY%)** | | | | | | | | | | | |
| Total Revenue | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA | NA |
| R&D | 140% | 104% | 74% | -4% | 36% | 23% | 28% | 20% | 9% | 9% | 8% |
| SG&A | 67% | 24% | 25% | 19% | 1% | 7% | 28% | 13% | 5% | 5% | 5% |
| Marketing and sales | | | | | | | | | | | |
| Operating Income (Losses) | 98% | 65% | 56% | 3% | 24% | 18% | 28% | 18% | 83% | 5% | -2% |
| Pretax Income | -140% | 133% | 55% | 2% | 23% | 18% | 28% | 18% | 83% | 5% | -2% |
| Net Income | -963% | 26% | 55% | 2% | 23% | 18% | 28% | 18% | 83% | 5% | -2% |
| EPS | -172% | -44% | 18% | -28% | -13% | -3% | 4% | -10% | 71% | -2% | -7% |

Yale Jen, Ph.D. 212-953-4978

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



Yale Jen, Ph.D.
yjen@laidlawltd.com

# 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

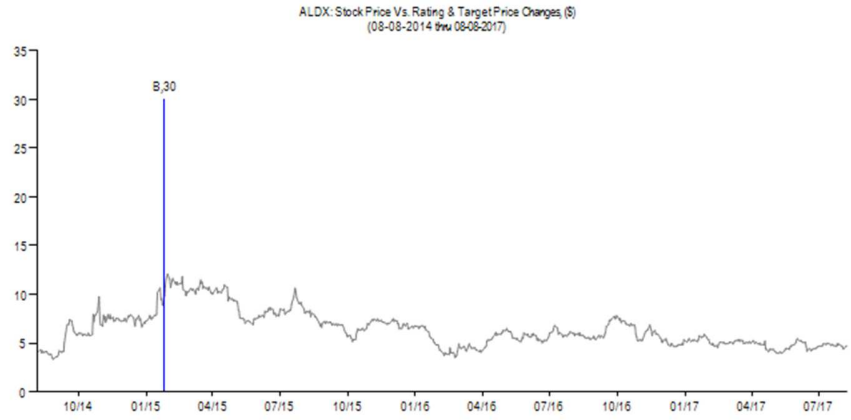
For the purpose of ratings distributions, regulatory rules require the firm to assign ratings to one of three rating categories (i.e. Strong Buy/Buy-Overweight, Hold, or Underweight/Sell) regardless of a firm's own rating categories. Although the firm's ratings of Buy/Overweight, Hold, or Underweight/Sell 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 ($) |
|---|---|---|
| 01/26/2... | Buy (B ) | 9.86 |

*3 Year Price Change History*

| Date | Target Price ($) | Closing Price, ($) |
|---|---|---|
| 01/26/2... | 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. | 63.04% | 30.43% | 2.17% |
| **Hold (H)** | Expected returns to be in line with the sector average over 12 months. | 4.35% | 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

## 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, or contact your investment representative or Laidlaw & Co (UK), Ltd at 546 Fifth Ave, 5th Floor, New York, NY 10036 USA.

***NOTES:***