

Aldeyra Therapeutics, Inc.

# Initiating Coverage with BUY and \$16.00 Price Target

**COVERAGE** INITIATION

**Rating: BUY** 

Ticker: ALDX

Price: \$7.34

Target: \$16.00

Advancing Novel Therapeutics for Trapping Free Aldehydes: Aldeyra Therapeutics is a small-cap biotech company that is advancing the development of its proprietary platform technology for trapping free aldehydes. Free aldehydes occur naturally in the body, generated through a variety of metabolic processes. High levels of free aldehydes, which are pro-inflammatory, have been implicated in autoimmune, inflammatory, neurological, cardiovascular and endocrinologic diseases. The Company plans to evaluate its lead compound NS2 in two clinical trials that it expects to file INDs for before the end of this month: a Phase 2/3 trial of NS2 administered as a topical dermatologic to treat patients with Sjögren-Larsson Syndrome (SLS), and a Phase 2 trial of NS2 administered as an eye drop to treat patients with acute anterior uveitis.

Initial Proof of Concept Should be Relatively Quick to Obtain: Sjögren-Larsson Syndrome is an orphan disease caused by mutation of a specific gene responsible for making an enzyme that is essential in the process that breaks down aldehydes. Given the unique nature of this patient population, and the fact that the upcoming clinical trial will be a small, single center, study of only 12 patients, with only an 8 week followup period, we believe it represents a quick and inexpensive way for the Company to demonstrate proof of concept for its aldehyde trapping compound. We expect the Company to report topline results from this study in Q2 2015.

Additional Information Will be Obtained from Acute Anterior Uveitis Study. Acute anterior uveitis is an inflammatory ocular disease that is characterized by rapid-onset pain, sensitivity to light, and potential loss of vision. Since the Company believes that its aldehyde trapping compounds can prevent or ameliorate inflammation, this clinical study, in addition to providing evidence of a potential solution for this indication, could also effectively serve as a gateway to other potential (larger) antiinflammatory applications. We expect topline results from this study could be available by the end of 2015.

Initiating Coverage with a BUY Rating: We believe that Aldeyra Therapeutics is an intriguing speculative small cap investment story. We believe that there would be substantial market demand for a novel therapy that is safe and effective in the indications that Aldeyra intends to pursue with its aldehyde trapping technology. Further, we believe that ALDX has the potential for significant upside from its current price, within the next 12 months, should its planned Phase 2/3 clinical studies achieve positive results. Our 12-month price target of \$16.00 is calculated using an NPV analysis.

#### **Company Description**

Aldeyra Therapeutics, Inc. was founded in 2004 and is based in Burlington, Massachusetts. The Company is focused on the development of drug candidates for capturing and removing free aldehydes to treat and prevent diseases, and slow the progression of chronic disease.

Healthcare

December 2, 2014

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#### Stock Data

Exchange:	NasdaqCM
52-week Range:	3.00 - 11.99
Shares Outstanding (million):	5.6
Market cap (\$million):	\$44
EV (\$million):	\$35
Debt (\$million):	\$1.5
Cash (\$million):	\$10.1
Avg. Daily Trading Vol. (\$million):	\$0.1
Float (million shares):	5.6
Short Interest (million shares):	0.01

#### Revenues (US\$ million)

	<u>2013A</u>	2014E	2015E	2016E
Q1 Mar	0.0A	0.0A	0.0E	0.0E
Q2 Jun	0.0A	0.0A	0.0E	0.0E
Q3 Sep	0.0A	0.0A	0.0E	0.0E
Q4 Dec	0.0A	<u>0.0E</u>	<u>0.0E</u>	<u>0.0E</u>
Total	0.0A	0.0E	0.0E	0.0E
EV/Revs	N/A	N/A	N/A	N/A

#### Earnings per Share (GAAP)

	2013A	2014E	2015E	2016E
Q1	3.68 A	0.64 A	(0.52)E	(0.25)E
Q2	(5.47)A	(1.43)A	(0.50)E	(0.70)E
Q3	2.76 A	(0.36)A	(0.29)E	(0.74)E
Q4	<u>2.44 A</u>	(0.40)E	(0.29)E	(0.60)E
Total	3.49 A	(2.47)E	(1.52)E	(2.29)E
P/E	N/A	N/A	N/A	N/A

#### EBITDA (US\$ million)

	<u>2013A</u>	2014E	2015E	<u>2016E</u>
Q1	(0.2)A	(0.9)A	(2.4)E	(1.6)E
Q2	(0.3)A	(0.9)A	(2.3)E	(5.3)E
Q3	(0.6)A	(1.5)A	(1.9)E	(5.7)E
Q4	<u>(0.8)A</u>	(1.7)E	(2.0)E	(5.7)E
Total	(1.9)A	(5.0)E	(8.7)E	(18.2)E

EBITDA is defined as earnings before interest, taxes, depreciation, and amortization.

#### **Important Disclosures**

Ascendiant Capital Markets LLC seeks to do business with companies covered by its research team. Consequently, 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 an investment decision.

For analyst certification and other important disclosures, refer to the Disclosure Section, located at the end of this report, beginning on page 14.



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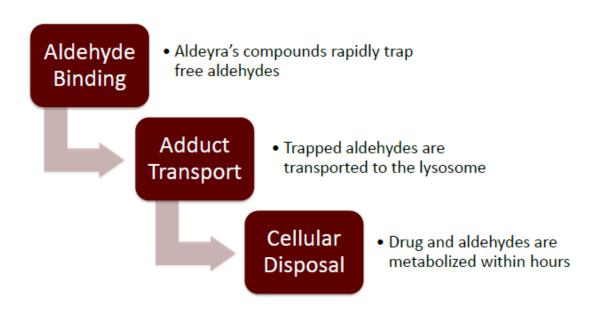
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#### **INVESTMENT THESIS**

We are initiating coverage of ALDX with a BUY rating and 12-month price target of \$16.00. We believe that Aldeyra Therapeutics is an intriguing speculative small cap investment story. The company is advancing the development of its proprietary chemical compounds that are designed specifically to trap free aldehydes. Aldehydes are naturally occurring chemical compounds that are formed as a result of a large number of metabolic processes. Aldehydes in turn have been shown to be pro-inflammatory. Hence, at high levels, aldehydes can be toxic and have been implicated as mediators of many immune-mediated and inflammatory diseases. Aldeyra's concept of trapping aldehydes represents a novel approach in treating inflammatory diseases. The Company's lead product candidate, NS2, is a small molecule designed specifically to trap and allow for the disposal of free aldehydes by the body. Although human clinical data for NS2 to date is very limited, the Company plans to evaluate NS2 in two clinical trials that are expected to commence enrollment within the next couple of months: a Phase 2/3 trial of NS2 administered as a topical dermatologic to treat patients with Sjögren-Larsson Syndrome (SLS), and a Phase 2 trial of NS2 administered as an eye drop to treat patients with acute anterior uveitis. We believe that the SLS study represents a quick and inexpensive way for the Company to demonstrate proof of concept for NS2. We expect the Company to report topline results from this study in Q2 2015. We further believe that the uveitis study could effectively serve as a gateway in demonstrating the potential of other (larger) anti-inflammatory applications for the Company's aldehyde trapping approach. We expect topline results from this study could be available by the end of 2015. Hence, we believe that ALDX has the potential for significant upside from its current price, within the next 12 months, should its planned Phase 2/3 clinical studies achieve positive results.

Exhibit 1: The Design Concept of Aldeyra's Aldehyde Trap



Source: Aldeyra Therapeutics Corporate Presentation



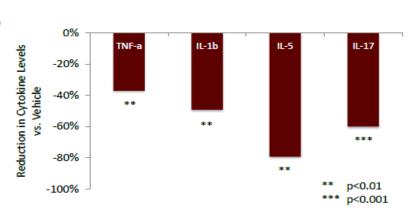
## A NOVEL THERAPEUTIC APPROACH BY TRAPPING ALDEHYDES

The company is advancing the development of a series of proprietary compounds that are designed specifically to trap and allow for the disposal of free aldehydes. An Aldehyde is a class of organic compounds, in which a carbon atom shares a double bond with an oxygen atom (the carbonyl group), a single bond with a hydrogen atom, and a single bond with another atom or group of atoms (designated as R in general chemical formulas). Aldehydes are naturally occurring chemical compounds that are formed as a result of a large number of metabolic processes. Aldehydes in turn have been shown to be able to enhance pro-inflammatory cytokines (such as TNF- $\alpha$  and IL-8) through activation of human macrophages. At high levels, aldehydes can be toxic and have been implicated as mediators of many immune-mediated and inflammatory diseases that include: autoimmune diseases (such as systemic lupus erythematosus), inflammatory diseases (such as uveitis), neurological diseases (such as multiple sclerosis), cardiovascular disease (such as atherosclerosis) and endocrinologic disease (such as diabetic nephropathy). Aldeyra's concept of trapping aldehydes represents a novel approach in treating such diseases.

The Company's lead product candidate is known as NS2. NS2 is a small molecule designed specifically to trap and allow for the disposal of free aldehydes. In *in vitro* and animal studies, NS2 has been shown to bind and trap free aldehydes, forming NS2-aldehyde adducts, which are then rapidly transported to cellular lysosomes, where the adduct is degraded within hours. Preclinical experiments have demonstrated that the administration of NS2 can reduce inflammation, promote healing, diminish the potential for scarring, and can protect a key lipid (fat) that is involved in lubricating the surface of the eye and preventing skin dryness. In one experiment (Exhibit 2), mice that were treated with a single injection of NS2, 30 minutes prior to being subjected to an injection of a proinflammatory (endotoxin) agent, demonstrated a statistically significant reduction in a variety of inflammatory cytokines (protein inflammatory mediators), including IL-5, Il-1 b , IL-17, and TNF- $\alpha$ , measured two hours after endotoxin exposure.

## Exhibit 2: NS2 Pre-Clinical Data - Trapping Aldehydes Reduces Pro-Inflammatory Cytokines

Mice treated with NS2 or vehicle 30 minutes prior to endotoxin exposure; cytokines measured two hours after endotoxin exposure



In an endotoxin model of cytokine generation in mice, NS2 administration significantly reduced levels of a broad array of pro-inflammatory cytokines.

Source: Aldeyra Therapeutics S1 Filing

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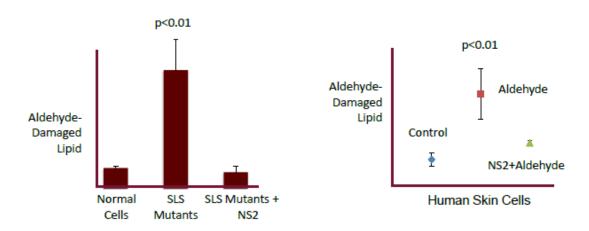
Data from use of NS2 in humans is scant at this point, limited to only a small study of 48 healthy volunteers, in which two different concentrations of NS2 formulated as eye drops were shown to be well tolerated.

The Company plans to evaluate its lead compound NS2 in two clinical trials that are expected to commence enrollment within the next couple of months: a Phase 2/3 trial of NS2 administered as a topical dermatologic to treat patients with Sjögren-Larsson Syndrome (SLS), and a Phase 2 trial of NS2 administered as an eye drop to treat patients with acute anterior uveitis.

## **OPPORTUNITY IN SJÖGREN-LARSSON SYNDROME**

Sjögren-Larsson Syndrome (SLS) is an orphan disease caused by mutation of a specific gene responsible for making an enzyme that is essential in the process that breaks down aldehydes. The ALDH3A2 gene provides instructions for making an enzyme called fatty aldehyde dehydrogenase (FALDH). This enzyme is part of a multistep process called fatty acid oxidation in which fats are broken down and converted into energy. Specifically, the FALDH enzyme breaks down fatty aldehyde molecules to fatty acids. An inability to break down fatty aldehyde molecules results in excess fat accumulation, which can interfere with the formation of membranes that act as protective barriers in the skin to control water loss. Without these protective barriers, the skin has difficulty maintaining its water balance, resulting in dry, scaly skin. The consequences of excess fat accumulation can also affect other areas of the body, such as in the brain, where it is believed that this disrupts the formation of myelin, which can lead to neurological problems. The primary symptom exhibited by SLS patients is severe skin thickening (ichthyosis). Other symptoms include retinal disease, and neurological disorders including mental retardation. The most common complaint of SLS patients is itchy skin. As a genetic disease, symptoms appear very early. Affected infants exhibit red skin (erythema) at birth, which later becomes dry, rough, and scaly. As the patients get older, the neurological disorders begin to manifest. SLS is a rare condition that is estimated to afflict approximately 1,000 patients in the U.S., and a similar number in Europe.

Exhibit 3: NS2 Prevents Aldehyde-Mediated Damage of a Lipid That is Critical to Moisture Barrier and Ocular Tear Integrity



Source: Aldeyra Therapeutics S1 Filing

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In another experiment (Exhibit 3), NS2 administered at low doses to a culture of human skin cells and in cells lacking the FALDH enzyme, was able to fully protect a lipid critical to the moisture barrier in skin, and ocular tear lubrication and moisturizing effectiveness.

Aldeyra plans to initiate a Phase 2/3 clinical trial that will evaluate a cream formulation of NS2 as a topical skin therapy for SLS patients. This will be a single center, placebo controlled, randomized, study that will enroll 12 patients. Patients in the study will be treated with drug or placebo for 2 weeks on a specific area on one of their legs, and then followed for 6 more weeks. The primary endpoint in this study is change in skin condition from baseline as measured using a visual ichthyosis skin score, which characterizes skin scales from small to large based on photographs of the skin that are evaluated by several physicians who are blinded to the treatment. The principal investigator of the study is Dr. William Rizzo, at the University of Nebraska, who is the leading expert of the disease in the U.S.

Given the unique nature of this SLS patient population, we believe that this study represents a quick and inexpensive way for the Company to demonstrate proof of concept for its aldehyde trapping compound. Since these patients lack the ability to produce effective FALDH, applying a therapeutic aldehyde trap like NS2 should be analogous to enzyme replacement therapy. Further, since the skin in these patients turns over in about a week, it should not take long for the theorized effect of preventing the loss of the skin moisture barrier to manifest as an improvement in skin texture in the drug treated cohort. Hence, given the small size (only 12 patients) of this single center study, with only an 8 week followup period, we expect the Company to be in a position to report topline results from this study in Q2 2015.

We believe that the market opportunity for SLS is attractive. Although the prevalence is small, at only 1,000 patients in the U.S., it is an orphan disease, with no current FDA approved therapy, which means that an effective therapy could be marketed at a very expensive price. We have modeled an effective topical NS2 formulation for SLS therapy at a price of \$200K per year, thus representing a potential market in the U.S. of \$200 million. Further, given that Dr. Rizzo at the University of Nebraska is the single expert of the disease in the U.S., we believe that this is a market opportunity that Aldeyra could capitalize on by itself, with minimal investment in sales and marketing.

## **OPPORTUNITY IN ACUTE UVEITIS**

Uveitis is a broad term that describes a condition involving inflammation of the uvea structure of the eye, which is characterized by rapid-onset pain, sensitivity to light, and loss of vision. Acute anterior uveitis is the most common form of uveitis. The anterior part of the uvea is the iris that surrounds the pupil and the adjacent ciliary body that synthesizes aqueous humor, the fluid that fills the front of the eye. The annual incidence of acute anterior uveitis in the U.S. is estimated to be about 25,000 patients, with approximately one-third of these patients experiencing one or more episodes per year. The primary therapy for acute uveitis is eye drops, which usually include a topical corticosteroid drop such as prednisolone acetate, and often a dilating drop such as cyclopentolate. The corticosteroid acts to treat the underlying inflammation, while the dilating drop reduces pain and helps to provide additional lubrication. The frequency of the drops depends primarily on the intensity of the inflammation. Patients with recurrent episodes are at risk of developing other severe eye complications. Prolonged used of corticosteroids is known to increase the risk of developing cataracts and glaucoma. Corticosteroids may also increase the incidence of infection and corneal ulceration.

Similar to diseases of the skin, Aldeyra believe that diseases of the eye may also be caused in part by free aldehyde toxicity. Specifically in uveitis, aldehydes may mediate, at least in part, inflammation, fibrotic changes, and lipid destruction that results in degradation of tear quality, which can lead to dryness and surface irritation of the eye. The Company has developed an eye drop formulation of its NS2 compound intended for use as a treatment of inflammatory eye diseases. The eye drop formulation has been evaluated in a Phase 1 clinical trial in which 45 healthy volunteers were treated with one of two different concentrations of the drug. The study results demonstrated the eye drop formulation to be well tolerated.

The Company now intends to file an IND before the end of this year to conduct a Phase 2 study of its NS2 compound as a treatment for acute anterior uveitis. This will be a multicenter, randomized, placebo controlled study that will enroll about 45 patients. The

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treatment time would be 8 weeks. The primary endpoint in the study is likely to be anterior chamber cell count, which is method to measure the degree of inflammation, and we would anticipate other endpoints that measure changes in pain, redness, and cloudiness will be part of the trial design as well.

We believe that the market opportunity for acute anterior uveitis is actually less attractive than SLS. Although the prevalence is larger at approximately 25,000 patients in the U.S., there are other alternative, low priced therapies, even if they have their drawbacks. That said, given the role that the Company believes that free aldehyde may play in mediating inflammation, we believe that positive results in the uveitis study could effectively serve as a gateway in demonstrating the potential of other (larger) anti-inflammatory applications for the Company's aldehyde trapping approach. As a larger study, we expect the uveitis study will take longer to conduct, but we do expect that topline results from this study could be available by the end of 2015.

## **OTHER OPPORTUNITIES**

Beyond the applications in SLS and acute uveitis, The Company is also considering other indications for its aldehyde trapping compounds. A second severe skin disease is discoid lupus erythematosus (DLE). DLE is a chronic dermatological disease that is characterized by sores with inflammation, typically occurring on the face, ears, and scalp, and at times on other body areas. These lesions develop as a red, inflamed patches with a scaling and crusty appearance, and can result in permanent scarring. Topical steroids are the mainstay of treatment of DLE, but can often offer only moderate to poor effectiveness in controlling or curing the disease without drug-related toxicity. Ocular rosacea is a second ocular condition. Ocular rosacea is related to a common inflammatory condition that causes redness, burning, stinging, eyelid swelling, and damage to the front of the eye. In cases of severe ocular rosacea, inflammation of the cornea may lead to a corneal ulcer with infection. Current therapies include temporary use of oral antibiotics or corticosteroids to reduce inflammation, and artificial tears to combat the dryness. The company has also conducted development work on different formulations of its aldehyde trapping compounds. This includes an oral formulation.

## **INVESTMENT RISKS**

Investors should be aware of several events or factors that could adversely impact the company's financial performance and valuation. These risks include:

#### The company has a history of losses and may never become and remain consistently profitable.

Aldeyra has experienced significant operating losses since its inception. As of September 30, 2014, the company had an accumulated deficit of \$44 million. The company has not yet commercialized any product, nor generated any revenues from the sale of such products. Further, the company is not expecting to generate any revenues from such product in the foreseeable future. The company is expected to continue to incur annual net operating losses over the next several years and will require further substantial resources as it expands its efforts to develop and commercialize its products. Net cash used in Aldeyra's operations was \$0.8 million in 2012 and \$1.7 million in 2013, and we expect it will be about \$4.9 million in 2014.

## The company may need to raise debt or equity funds in the future.

We believe that the company will need additional funds for its research and product development programs, regulatory processes, preclinical and clinical testing, and potential sales and marketing infrastructure, and potential licenses and acquisitions. Any additional equity financing may be dilutive to stockholders, and additional debt financing, if available, may involve restrictive covenants. However, external financing, depending on the prevailing financial environment, may be particularly difficult, and the source, timing and availability of any future fundraising will depend principally upon market conditions and, more specifically, on the company's progress in its research, preclinical and clinical development programs. Funding may not be available when needed at all or on acceptable terms.

## NS2 may never become a marketable product.

The Company's lead product candidate, NS2, will require additional clinical testing and regulatory review and/or approvals or clearances before marketing. As an early-stage clinical development company, there is a very limited amount of human clinical data

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about NS2 that can be used to assess its likelihood of success, as it has only been evaluated in healthy human volunteers, but not in any humans with the diseases for which the Company intends to seek approval for the treatment of. Further, the results of preclinical studies and early clinical trials are not always predictive of future results. Hence, NS2 may not prove to be a safe and effective treatment for the diseases for which it is being evaluated. Finally, there is always risk associated with FDA and other regulatory agencies' review of any new drug product.

#### The company faces significant competition.

The biotechnology and pharmaceutical industries are intensely competitive. The competitors include major multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Many of these competitors possess greater financial and other resources, larger research and development staffs and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Finally, the development of new treatment methods for this diseases, if successful, could render NS2 non-competitive or obsolete.

#### Key intellectual property could fail to protect products.

As of January 9, 2014, Aldeyra owned one U.S. patent, four U.S. non-provisional patent applications, and five provisional patent applications, as well as numerous foreign counterparts to these patents and patent applications. The U.S. issued patent is a composition of matter patent for NS2, which expires in 2028. Under the terms of an exclusive license agreement with CyDex Pharmaceuticals (Ligand Pharmaceuticals) for certain intellectual property, the Company is obligated to make milestone payments up to an aggregate of \$2.15 million upon reaching certain development and regulatory milestones in the development of the Company's product. Upon commercialization of the Company's product containing the licensed technology, the Company would also be obligated to pay royalties based on net sales subject to an annual cap. However, the biotechnology business is very litigious. Newly issued IP in this space has often been opposed, resulting in some issued patents being revoked. An unfavorable judgment or substantial legal fees can adversely affect financial performance.

#### 180-day lockup agreement associated with the IPO has recently expired.

The 180 day lock-up agreement associated with the IPO expired about a month ago. As a result, approximately 4 million additional shares of common stock are now eligible for sale in the public market. Sales of a substantial number of shares in the public market, or the perception that these sales might occur, could significantly reduce the market price of ALDX common stock. Of these shares, 3,655,746 shares are held by directors, executive officers and other affiliates and will be subject to volume limitations under Rule 144 under the Securities Act of 1933.

The above factors represent only some of the risks associated with investing in Aldeyra Therapeutics. For a complete list, investors should refer to the company's most recent S-1/A and 10-Q filings.

#### **MANAGEMENT**

#### President and Chief Executive Officer - Todd Brady M.D., Ph.D.

Dr. Brady has served as company President and Chief Executive Officer since January of 2012 and as a member of the board of directors since 2005. Dr. Brady has more than 18 years of pharmaceutical clinical and business development experience. Prior to joining Aldeyra as president and CEO in 2011, Dr. Brady was an entrepreneur-in-residence and principal at Domain Associates, where he led institutional financing in numerous biotechnology companies from 2004 to 2013. Prior to joining Domain, Dr. Brady was a cofounder and CEO of Phenome Sciences, a biotechnology firm he merged with Xanthus Pharmaceuticals (acquired by Antisoma), where he was later executive vice president of Strategic Development and Planning. Dr. Brady also worked as head of business development and medical director at Aderis Pharmaceuticals (acquired by Schwarz Pharma, now part of UCB). While at Xanthus and Aderis, Dr. Brady was a medical consultant on numerous pre-clinical programs and clinical programs in Phases I through IV, including Neupro®, a drug now marketed for Parkinson's Disease. Dr. Brady holds an M.D. from Duke University Medical School, a Ph.D. from Duke University Graduate School, and an A.B. from Dartmouth College

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#### Chief Operating Officer - Scott L. Young

Mr. Young has more than 25 years of pharmaceutical pre-clinical and clinical development experience. Prior to joining Aldeyra Therapeutics in December 2011 as chief operating officer (COO), he was the COO at Link Medicine, Inc., a biotechnology company developing novel pharmaceuticals to treat neurodegenerative diseases such as Alzheimer's disease and Parkinson's disease. While at Link Medicine, Mr. Young and colleagues successfully raised more than \$40 million in financing, advanced the lead program to clinical development, and subsequently out-licensed the technology to AstraZeneca. Mr. Young also served as COO for OXiGENE, Inc., a publicly traded NASDAQ oncology therapeutics development company, where, during the eight years of his tenure, he was instrumental in advancing a pharmaceutical candidate from laboratory testing into Phase III clinical trials and led the development of a compound in an orphan ophthalmology indication. Mr. Young has also held positions in clinical and regulatory affairs, GMP manufacturing operations and R&D and process development at Genzyme Corporation, RepliGen Corporation and Genetics Institute (now Pfizer). He holds a B.S. in biochemistry from the University of Massachusetts, Amherst.

## Chief Financial Officer - Mr. Stephen Tulipano

Mr. Tulipano has more than 27 years of accounting and financial experience, of which 12 years were focused on the pharmaceutical industry. Prior to joining Aldeyra as Chief Financial Officer in June 2014, Mr. Tulipano held positions at Three Tulips Inc., an accounting and management advisory services firm, where he provided full-time accounting services and financial management counsel. Prior to joining Three Tulips Inc., he served as Chief Financial Officer of Javelin Pharmaceuticals where he helped lead the company through its acquisition by Hospira in 2010. Mr. Tulipano also served as the Director of Corporate Accounting at Biogen Idec, and has held several accounting roles both within companies and accounting firms. Mr. Tulipano holds a B.S. in Business Administration and Accounting from Salem State College and an M.B.A. in Finance from Suffolk University. He is also a Certified Public Account.

Source for Management Biographies – Aldeyra's S-1/A filing and corporate website

## **FINANCIALS**

Aldeyra is a pre-revenue development stage company. In May 2014, the Company went public with the sale of 1.5 million shares at a price of \$8 per share. Prior to the IPO, in January 2014 the Company effected a 1-for-12 reverse stock split of its outstanding common stock. Further, holders of prior outstanding Series A and Series B Preferred Stock and Series A and Series B Preferred Stock Warrants elected to convert these shares into shares of common stock in connection with the IPO. The majority of the Company's outstanding shares are now held by three entities: VC funds Domain Associates (~35%) and Johnson & Johnson Development Corporation (~31%), and Fidelity Investments (~15%).

As a pre-revenue company, we expect Aldeyra to be in a net loss position for several more years. We would not expect the company to commercialize its first product until 2017 at the earliest. We project that the company will have approximately \$8 million in cash at the end of 2014. Our projected operating expense is expected to increase significantly in 2015 to approximately \$10.5 million once the company commences a Phase II/III trial of patients with SLS, and a Phase II trial of patients with acute anterior uveitis. Hence, we believe that the company will require additional capital in order to achieve its product development goals.

Aldeyra currently has a loan Credit Facility with Square 1 Bank with a notional limit of \$5 million, which at the end of September 2014, had a current outstanding principal balance of \$1.4 million. Under the terms of the agreement, the maturity date of the Credit Facility is November 2018.

For 2014, we are projecting a net loss of approximately (\$9) MM or GAAP EPS of (\$2.47).



For 2015, we are projecting a net loss of approximately (\$11) MM or GAAP EPS of (\$1.52). We project that operating expenses will increase significantly due to increased clinical trial activity. Our model assumes that the company will raise additional cash of approximately \$20 MM via an equity offering.

For 2016, we are projecting a net loss of approximately (\$20) MM or GAAP EPS of (\$2.29). We project that operating expenses will remain elevated due to clinical trial activity and preparation and submission of the NDA filing for SLS. Our model assumes that the company will raise additional cash of approximately \$20 MM via an equity offering.

## **VALUATION**

As a development stage company, accurate valuation is more complex and requires a number of forward assumptions, which at best are inexact. Since its IPO last May at \$8 per share, the stock price of ALDX has decreased approximately 8% to the current price. We have used an NPV analysis to establish our 12-month price target of \$16.00. Our analysis considers future estimated revenue out to 2025, consisting of revenue from direct commercial sales of its NS2 compound used to treat SLS, and royalties from its drugs used to treat acute uveitis, and other potential indications. Our model assumes that the company funds all of the clinical development costs for these products by itself, and then enters into a licensing agreement for marketing rights for the acute uveitis, ocular rosacea, and discoid lupus indications. We apply a further haircut adjustment to the future projected revenue streams from the SLS, acute uveitis, and other indications of 70%, 90%, and 99% respectively, to capture the remaining clinical and regulatory risk associated with these early stage product development programs. We use a WACC of 15% as our discount rate. Finally, we assume a fully diluted share count of 10 million.

## OTHER COMPANIES MENTIONED IN THE REPORT

Johnson & Johnson - (JNJ, 108.75, Not Rated) Ligand Pharmaceuticals - (LGND, \$53.85, Not Rated) Square 1 Financial – (SQBK, \$21.38, Not Rated)



# **FINANCIAL MODEL**

FY 2012			FY 2013					FY 2014E					FY 2015E					FY 2016		
YE	Q1	Q2	Q3	Q4	YE	Q1	Q2	Q3	Q4E	YE	Q1E	Q2E	Q3E	Q4E	YE	Q1E	Q2E	Q3E	Q4E	YE
_	_				_		_	_		_		_	_						_	_
		-	-								-				-					
0.5	0.0	0.0	0.7	0.4	4.5	0.4	0.7	4.0		0.7	4.0	4.0	4.0	4.0	7.0	4.0	4.0			40.4
***	**=	0.3	0.7	•	1.5	0.4	0.7	1.2	1.4	3.1	1.9	1.9	1.6	1.6		1.0	4.8	5.3	5.3	16.4
		•	•		•	•	•	•	•	•	•	•	•	•		•	•	•	•	
	•••									-										3.6
1.1	0.3	1.0	1.2	1.2	3.7	1.2	1.6	2.0	2.2	7.1	2.9	2.8	2.4	2.4	10.5	2.0	5.7	6.1	6.1	20.0
(1.1)	(0.3)	(1.0)	(1.2)	(1.2)	(3.7)	(1.2)	(1.6)	(2.0)	(2.2)	(7.1)	(2.9)	(2.8)	(2.4)	(2.4)	(10.5)	(2.0)	(5.7)	(6.1)	(6.1)	(20.0)
	(0.3)	(0.0)	0.9	0.1		1.8	0.6													
(22.0)	(3.4)	(0.5)	9.5	10.4	16.0	(0.1)	(0.1)	(0.0)	(0.0)	(0.3)										
(23.1)	(4.0)	(1.6)	9.3	9.3	13.1	0.4	(1.1)	(2.0)	(2.2)	(5.0)	(2.9)	(2.8)	(2.4)	(2.4)	(10.5)	(2.0)	(5.7)	(6.1)	(6.1)	(20.0)
- 1																				
0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		0.0%	0.0%	0.0%	0.0%	
(16.1)	(0.1)	(0.2)	(0.2)	(0.4)	(0.8)	(0.2)	(0.1)			(0.3)										
•	5.3	•	(8.2)	(8.1)	(11.1)	•	(4.1)			(4.1)										
(39.1)	1.2	(1.7)	0.9	0.8	1.1	0.2	(5.3)	(2.0)	(2.2)	(9.4)	(2.9)	(2.8)	(2.4)	(2.4)	(10.5)	(2.0)	(5.7)	(6.1)	(6.1)	(20.0)
(124.45)	3.68	(5.47)	2.76	2.44	3.49	0.64	(1.43)	(0.36)	(0.40)	(2.47)	(0.52)	(0.50)	(0.29)	(0.29)	(1.52)	(0.25)	(0.70)	(0.74)	(0.60)	(2.29)
(124.45)	3.68	(5.47)	0.90	2.44	(17.58)	0.47	(1.43)	(0.36)	(0.40)	(1.72)	(0.52)	(0.50)	(0.29)	(0.29)	(1.61)	(0.25)	(0.70)	(0.74)	(0.60)	(2.29)
0.3	0.3	0.3	0.3	0.3	0.3	0.3	3.7	5.6	5.6	3.8	5.6	5.6	8.2	8.2	6.9	8.2	8.2	8.2	10.2	8.7
0.3	0.3	0.3	1.0	0.3	0.5	0.4	3.8	5.6	5.6	3.9	5.6	5.6	8.3	8.3	7.0	8.3	8.3	8.3	10.3	8.8
(0.9)	(0.2)	(0.3)	(0.6)	(0.8)	(1.9)	(0.9)	(0.9)	(1.5)	(1.7)	(5.0)	(2.4)	(2.3)	(1.9)	(2.0)	(8.7)	(1.6)	(5.3)	(5.7)	(5.7)	(18.2)



Aldera Therapeutics Inc.	2012	2013	2014E	2015E	2016
Balance Sheet (in millions)	YE	YE	YE	YE	YE
ACCETC					
ASSETS					
Current Assets:	4			20	24
Cash and cash equivalents	1	3	8	20	21
Short-term investments	-	-	-	-	-
Accounts Receivable Inventories	-	-	-	-	-
Other current assets	1		- 0	- 0	- ^
Total current assets	2	3	9	0 20	0 22
Total current assets		3	9	20	22
Drop out a good on signmout not	-	-	-	-	-
Property and equipment-net	-	-	- 0	- 0	-
Other assets	-	0	0	0	0
Intangibles, net	-	-	-	-	-
Goodwill	-	-	-	-	-
Total Appara	-	-	-	-	-
Total Assets	2	- 4	9	20	22
LIABILITIES & STOCKHOLDERS' EQUITY	-			_	
Current Liabilities:	-	-	-	-	-
Accounts payable	0	0	0	0	0
Accrued liabilities	0	0	0	0	0
Capital lease obligation	0	0	-	-	-
Equipment loan	-	0	-	-	-
Total current liabilities	0	1	1	1	1
Long Term Liabilities:	-	-	-	-	-
Credit facility, net of current portion and debt disco	0	1	1	1	1
Other - non-current	27	4	-	-	-
Total Liabilities	27	6	2	2	2
	-	-	-	-	-
STOCKHOLDERS' EQUITY	-	-	-	-	-
	-	-	-	-	-
Preferred stock	29	38	-	-	-
Common stock	0	0	0	0	0
Additional paid-in capital	-	1	53	75	96
Accumulated deficit during development stage	(54)	(41)	(46)	(57)	(77)
	- 1	-	-	-	- 1
Total Stockholders' Equity	(25)	(2)	6	18	20
	-	-	-	-	-
Total Liabilities & Stockholders' Equity	2	4	9	20	22



Aldera Therapeutics Inc.	2012	2013	2014E	2015E
Cash Flow Statement (in millions)	YE	YE	YE	YE
OPERATING CASH FLOWS				
Net loss	-23	13	-5	-11
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	0	0	0	0
Amortization of debt discount – non-cash interest expense	0	0	0	0
Stock-based compensation expense for options and stock issued to employees	0	2	2	2
Non-cash gain on decrease in fair value of warrants	22	-17	-2	0
Changes in assets and liabilities:				
Accounts receivable	0	0	0	0
Inventories	0	0	0	0
Other current assets	0	0	0	0
Other assets	0	0	0	0
Accounts payable	0	0	0	0
Accrued interest on convertible notes payable-related parties				
Accrued expenses				
Net cash provided by (used in) operating activities	-1	-2	-5	-9
INVESTING CASH FLOWS				
Property and equipment purchases	0	0	0	0
Proceeds from disposal of property and equipment	0	0	0	0
Purchases of short-term investments	0	0	0	0
Proceeds from maturities and sales of short-term investments	0	0	0	0
Net cash provided by (used in) investing activities	0	0	0	0
FINANCING CASH FLOWS				
Proceeds from issuance of common stock	0	0	10	20
Net proceeds from issuance of convertible preferred stock	1	3	0	0
Proceeds from short-term borrowing	1	1	0	0
Principal payments on short-term barrowing	0	0	0	0
Cash paid for deferred offering costs	0	0	0	0
Proceeds from exercise of stock warrants	0	0	0	0
Proceeds from exercise of stock options	0	0	0	0
				_
Net cash provided by (used in) financing activities	2	4	10	20
				_
Net increase (decrease) in cash & cash equivalents	1	2	5	11
	-	_	J	
Cash & cash equivalents, beginning	0	1	3	8
Odon a odon oquivalonto, bogining				
Cash & cash equivalents, end	1	3	8	20



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#### Ascendiant Capital Markets, LLC Rating System

BUY: We expect the stock to provide a total return of 15% or more within a 12-month period.

**HOLD:** We expect the stock to provide a total return of negative 15% to positive 15% within a 12-month period.

**SELL:** We expect the stock to have a negative total return of more than 15% within a 12-month period.

Total return is defined as price appreciation plus dividend yield.

## Ascendiant Capital Markets, LLC Rating System

Prior to January 31, 2014, ASCM used the following rating system:

**Strong Buy:** We expect the stock to provide a total return of 30% or more within a 12-month period.

**Buy:** We expect the stock to provide a total return of between 10% and 30% within a 12-month period.

Neutral: We expect the stock to provide a total return of between minus 10% and plus 10% within a 12-month

period.

**Sell:** We expect the stock to provide a total return of minus 10% or worse within a 12-month period.

Speculative Buy: This rating is reserved for companies we believe have tremendous potential, but whose stocks are

illiquid or whose equity market capitalizations are very small, often in the definition of a nano cap (below \$50 million in market cap). In general, for stocks ranked in this category, we expect the stock to provide a total return of 50% or more within a 12-month period. However, because of the illiquid nature of the stock's trading and/or the nano cap nature of the investment, we caution that these

investments may not be suitable for all parties.

Total return is defined as price appreciation plus dividend yield.

### Ascendiant Capital Markets, LLC Distribution of Investment Ratings (as of October 6, 2014)

## **Investment Banking Services**

			Past 1	.2 months	
Rating	Count	Percent	Count	Percent	
Buy	52	75%	9	17%	
Hold	15	22%	0	0%	
Sell	2	3%	0	0%	
Total	69	100%	9	13%	

## **Other Important Disclosures**

Our analysts use various valuation methodologies including discounted cash flow, price/earnings (P/E), enterprise value/EBITDAS, and P/E to growth rate, among others. Risks to our price targets include failure to achieve financial results, product risk, regulatory risk, general market conditions, and the risk of a change in economic conditions.

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