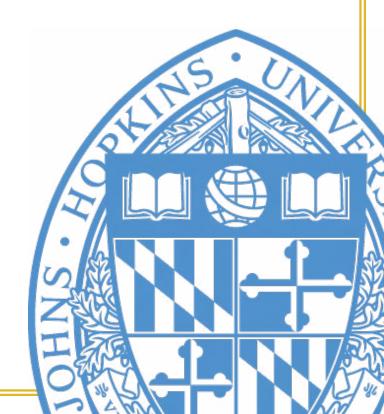
Studies in Applied Finance

INVESTMENT THESIS FOR ALDEYRA THERAPEUTICS, INC. (NASDAQ: ALDX)

William Hua

Johns Hopkins Institute for Applied Economics, Global Health, and the Study of Business Enterprise



Investment Thesis for Aldeyra Therapeutics, Inc. (NASDAQ: ALDX)

By William Hua

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About the Series

The Studies in Applied Finance series is under the general direction of Professor Steve H. Hanke, Co-Director of the Johns Hopkins Institute for Applied Economics, Global Health, and the Study of Business Enterprise (hanke@jhu.edu) and Dr. Hesam Motlagh (hesamnmotlagh@gmail.com), a Fellow at the Johns Hopkins Institute for Applied Economics, Global Health, and Study of Business Enterprise.

This working paper is one in a series on applied financial economics, which focuses on company valuations. The authors are mainly students at the Johns Hopkins University in Baltimore who have conducted their work at the Institute as undergraduate researchers.

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<u>Summary</u>

This working paper is an in-depth analysis Aldeyra Therapeutics, Inc. Our analysis examines the factors that impact ALDX's underlying business. This economic analysis is then combined with our unique net present value (NPV) model to determine ALDX's financial position. The NPV model will be presented along-side Monte-Carlo simulations to reveal the distribution of probable free cash flows and the likelihood of future earnings. We also studied the proxy report to examine the compensation practices of ALDX and determine whether they are well-aligned with shareholder interests. Our objective is for readers to understand ALDX's business plan and financial standing to construct a sound investment decision.

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JEL codes: C63, G11



Rating: Buy with High Risk

Company Name	Aldeyra Therapeutics
Date	5/15/2016
Fiscal year ends (current period)	12/31/2015
Current price	\$5.53
52 week high	\$10.63
52 week low	\$3.52
Market Cap	\$53.7 Million
Enterprise Value	\$27.4 Million
Total Debt	\$1.3 Million
Cash	\$27.6 Million
Net Debt/Enterprise Value	N/A
Diluted Shares Outstanding	9.7 Million
Current EPS	-\$1.58
2017 EPS	-\$2.17*
2016 EPS	-\$1.77*
2015 EPS	-\$1.40
2014 EPS	-\$2.51

^{*}Consensus Estimates as of the time of this writing

Contents

Executive Summary	4
Catalysts and Risks	4
Company Description and Historical Performance	4
Company Description	4
Historical Performance	5
Model of the Company	6
General Overview	6
Balance Sheet and Income Statement Trends	6
Model of the FDA Drug Approval Process	7
Modeling Drug Revenue	9
Projecting Expenses	10
Results and Discussion of the Model	11
Proxy Report	13
Executive Compensation	13
Equity Incentive Plan	14
Compensation Committee Members	14
Conclusion	14
Additional Bloomherg Screenshots	15

Executive Summary

Aldeyra Therapeutics, Inc. (NASDAQ: ALDX) is a pre-profit biotechnology company headquartered in Massachusetts. Using a uniquely developed discounted net present value (NPV) model and Monte-Carlo simulations, we have determined the probable NPV to be \$30.96 with a ~25% chance, and a ~75% chance of the stock price falling significantly from its current stock price of \$5.53. There are many complications involved with modeling the NPV of Aldeyra Therapeutics, which we will discuss throughout this report. However, given the risk/reward asymmetry and management's compensation alignment with shareholders, we rate ALDX as a **buy with high risk.**

Catalysts and Risks

- As with any biotechnology company in the clinical trials phase, there is significant risk associated with ALDX. It is possible that all of the drugs being researched by ALDX will never hit the market.
- Allergic conjunctivitis, the disease that ALDX's most developed drug aims to treat, affects 20-40% of the population worldwide. Thus, this drug has a high demand and even conservative values of market penetration (<1%) will yield significant revenue.
- There are many competing drugs to treat the same disease in the biotechnology industry.

Company Description and Historical Performance

Company Description

Aldeyra Therapeutics Inc., founded in 2004, is focused on developing treatments for diseases related to endogenous aldehydes¹. The initial public offering of ALDX was in 2014, and it is part of the NASDAQ Composite Index. ALDX has minimal representation in ETFs, since it has only been on the stock market for two years and is a very small company by market capitalization².

ALDX only has one business segment, which is the development and eventual sales of drugs. It is also reasonable to assume that ALDX will sell drugs only in the United States for the next 10 years, as overseas expansion for biotechnology companies is typically a complicated and lengthy process requiring other approval processes.

http://www.sec.gov/Archives/edgar/data/1105705/000119312515146682/d887693ddef14a.htm (Accessed 3/23/16)

¹ALDX 2015 Proxy report,

² https://www.etfchannel.com/symbol/aldx/ (Accessed 5/13/16)

As a pre-profit biotechnology company, it is not surprising that Aldeyra Therapeutics has not made any significant acquisitions or mergers. However, they entered into a License and Supply Agreement with Ligand Pharmaceuticals in 2010, which grants "exclusive license in the field of aldehyde traps in ocular disease to a certain excipient-related composition of matter." This agreement also stipulates that if a drug is commercialized utilizing the license in this agreement, ALDX is obligated to pay a "low single digit percentage of net sales" as a royalty ³. Unfortunately, there are no further specifications on the details of this royalty.

Historical Performance



Bloomberg Screenshot 1- Historical Stock Performance

Bloomberg Screenshot 1 shows that the share price of ALDX has fluctuated from \$4-\$12 since the IPO while the volume of trades has steadily risen. Since the 52 week high of \$10.63 in June 2015, share price dropped back down to its current value of \$5.53. There is also a weak but observable correlation with the S&P 500 Index (purple) and the NASDAQ Composite Index (green).

³ ALDX 2015 10-K, http://www.sec.gov/Archives/edgar/data/1341235/000119312516523952/d105518d10k.htm (Accessed 5/13/16)

Model of the Company

General Overview

We developed a unique discounted net present value (NPV) model for biotechnology valuations. The steps that we took to set up this model are specific to ALDX and are described below. Aldeyra Therapeutics has many drugs in its pipeline that are in development (Figure 1). We will assume that the market only gives ALDX credit for the most developed drug, which is the allergic conjunctivitis eye drop treatment that is in Phase 2. This is a reasonable assumption for biotechnology companies with drugs in the pre-approval phases, due to the low probabilities of drug success. Our model of revenue and drug development will focus only on the allergic conjunctivitis drug. Allergic conjunctivitis (also known as pink eye) is an allergic eye inflammation that is common in the U.S.

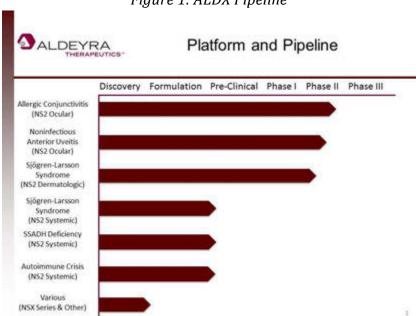


Figure 1: ALDX Pipeline

Balance Sheet and Income Statement Trends

The only balance sheet and income statements available are for the 2013-2015 years. We observe from the balance sheet that the cash and cash equivalents rose from \$3 million in 2013 to \$14 million in 2015. This is enough cash to pay off all of their total liabilities in 2015, which is \$3 million. ALDX also has \$13 million in marketable securities. In the income statement, we see that research and development (R&D) expenses grew 140% in 2014 and 100% in 2015 to its current yearly cost of \$7.5 million. General and administrative expenses also grew significantly at 67% and 24%, respectively in 2014 and 2015 to its current \$4.4 million. There has also been a large increase in the number of shares outstanding, which is currently 8.6 million. This shows

that ALDX grew significantly in the past couple years and has managed its money well since its IPO.

Model of the FDA Drug Approval Process

After the drug is created, there are four main phases of the FDA approval process: phases 1-3 and the approval phase. The probabilities of success at each of these phases are as follows:

Table 1-Expected Probabilities of success at various FDA approval stages:

Phase 1	15%
Phase 2	25%
Phase 3	60%
Approval Phase	90%

Source: Keegan, Karl, Biotechnology Valuation: An Introductory Guide (England: John Wiley & Sons, 2008), 40.

Since the allergic conjunctivitis drug is in phase 2, the expected probability of success is 25%. However, this probability varies for different drugs. We will use a beta distribution to model this probability, as this distribution has a domain of (0, 1) and we can vary the parameters (α, β) to change the shape of the distribution. The probability density function (pdf) of the distribution is given below. The beta function is used as a normalization of the probability to ensure the integral of the pdf is 1.

$$p(x) = \begin{cases} \frac{x^{\alpha - 1}(1 - x)^{\beta - 1}}{B(\alpha, \beta)} & \text{for } 0 < x < 1, \\ 0, & \text{for } x \text{ otherwise} \end{cases}$$

$$B(\alpha,\beta)$$
 is the beta function defined as: $B(\alpha,\beta) = \int_0^1 t^{\alpha-1} (1-t)^{\beta-1} dt$

Solving for the expected value (mean) and variance of this distribution gives us:

$$E(X) = \mu = \frac{\alpha}{\alpha + \beta}$$

$$Var(X) = \sigma^2 = \frac{\alpha\beta}{(\alpha + \beta)^2(\alpha + \beta + 1)}$$

The expected probability of success is 25%, which means that the mean of our distribution is 0.25. If we also assign a desired variance to our distribution, then we can recursively solve for α and β . Our goal is to pick a distribution that roughly resembles a normal distribution. A reasonable variance to choose is 10%, or 0.1. Using the previous equations and setting μ =0.25 and σ ²=0.1, we can derive the following values for α , β :

$$\alpha = \left(\frac{1-\mu}{\sigma^2} - \frac{1}{\mu}\right)\mu^2 = 4.4375$$

$$\beta = \alpha \left(\frac{1}{\mu} - 1\right) = 13.3125$$

These parameters yield the following pdf (generated in MATLAB):

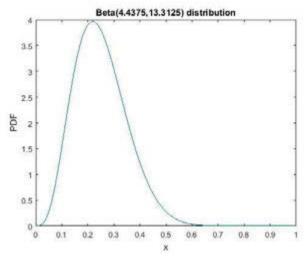


Figure 2: Probability distribution used to model drug success.

Figure 2 graphs the pdf that will be used to model the probability of drug success. The next step would be to use a Bernoulli(p) random variable with p=probability of drug success generated with the beta distribution. This means that this Bernoulli random variable will equal 1 with probability p and 0 with probability (1-p). However, we cannot use this method in Excel due to the limitations of Crystal *Ball* (used for Monte-Carlo simulations). Since we cannot assign a cell as a parameter for *Crystal Ball*, we must also generate a uniform (0,1) random variable to create a binary (0,1) cell in Excel representing 1=drug success and 0=drug failure. This random variable is compared to the probability of success random variable and if it is greater, then our binary cell takes the value 1 (and 0 if the uniform random variable is smaller than the probability of success). This is equivalent to using a Bernoulli random variable. This binary cell will be used in our Monte-Carlo simulations to determine whether the drug is generating revenue on the market.

Another important factor to consider is the timeline of the FDA approval process. We assume that if the drug succeeds, it will follow the timeline:

Table 2. Timetime for TETT approval process					
Year	FDA Stage				
2016	Phase 2				
2017	Phase 2 results				
2018	Initiate Phase 3				
2019	Phase 3 results				
2020	New drug application (NDA)				
2021	Launch				

Table 2: Timeline for FDA approval process

Modeling Drug Revenue

We will model the revenue of an approved drug for the next 10 years (until 2026). The first step is to model the market for this drug, or the number of people that have allergic conjunctivitis and seek professional medical advice. To model this population, we must first model the entire the U.S. population. We observe from historical population growth rates in the past 10 years that there is an average growth rate of 0.79% and a standard deviation of 0.15%. We use these parameters on a normal distribution in our Monte-Carlo simulations for U.S. population. There are many varying opinions on the percentage of the U.S. population with allergic conjunctivitis but most sources state it affects approximately 20-40% of the U.S. population⁴. Even though this may seem like a massive number of people, not all of these people seek medical attention. According to a journal article by Azari and Barney⁴, "only about 10% of individuals with allergic conjunctivitis seek medical attention and this entity is often underdiagnosed." The likely explanation for this is that 90% of allergic conjunctivitis cases are a result of seasonal allergies⁴. Thus, people are more likely to use over-the-counter allergy medication. Nevertheless, we have determined our market to be modeled by an average of 30% of the U.S. population having allergic conjunctivitis and an average of 10% of these people seeking medical help. Both of these values are also modeled using a normal distribution for the MC simulations.

The next step is to model the price of our drug and the market penetration. From the 2015 10-K, the most competitive products for treating allergic conjunctivitis are topical antihistamines. Two common drugs on the market in this category are Alcaftadine⁵ and Pataday⁶. Both of these drugs are eye drops, and thus are similar to the drug that ALDX is producing.

Given that the price for Alcaftadine and Pataday is \$60/mL, we can assume a similar price for our drug. Assuming our drug will be sold in 5mL eye drop bottles and that a standard eyedropper dispenses 0.05mL per drop, there are 100 drops in each bottle that costs \$300. The instructions for both of these similar eye drops are to use once a day in each affected eye, thus each bottle lasts about 1.5 months. Since a large majority of allergic conjunctivitis cases are caused by seasonal allergies, it is reasonable to assume that on average, our drug is being used for 6 months per year. This means that on average, the drug will be sold for \$300/bottle at the rate of 4

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4049531/#R15

https://www.blueshieldca.com/bsca/pharmacy/drugdatabaseformulary/drug information monograph.sp?type=p ackaged&drugld1=00023429003&drugld2=155189&drugName=Lastacaft&dispensableId=&nametype=

http://www.goodrx.com/pataday

⁴ Amir A. Azari, Neal P. Barney, "Conjunctivitis- A Systematic Review of Diagnosis and Treatment", *The Journal of the American Medical Association* 310, no. 10 (2013): 1721-1729. Accessed May 12, 2016.

⁵ Alcaftadin- Ophthalmic. Accessed May 13, 2016

⁶ Pataday. Accessed May 13, 2016

bottles/year for each person that uses it. We assume a conservative market penetration of 0.7% the first year, and 0.3% growth for each subsequent year. All of the values here are modeled using a normal distribution.

Projecting Expenses

To project expenses for the next 10 years, we need to look at each expense individually. The growth in research and development (R&D) and general and administrative costs (no sales) is difficult to predict for the future because the only historical data we have is for the past 3 years. We also have to project the selling costs (part of SG&A) and cost of goods sold, both as a percentage of revenue. Note that both of these expenses are nonzero only if the drug hits the market. We can first examine these margins (Table 3) for Alcon Inc., the producer of Pataday.

8	(
Accounting Terms	% Revenue in 2010
Operating Income	34%
Cost of goods sold	23%
Sales, General and Administrative costs	29%
(SG&A)	
Research and Development (R&D)	10%

Table 3: Alcon Inc. Margins on revenue. Source: Alcon Inc. 2011 (most recent) 10-K

For the cost of goods sold, we can assume a comparable 25% margin on revenue. We will also assume 25% of revenue for the selling costs (contribution of SG&A) and an initial 20% growth in general and administrative costs, which will slowly decrease to 10% growth. The sum of these two values gives SG&A, and these assumptions yield a reasonable margin on revenue in 2026 of our projected costs (Table 4). R&D expenses growth rate is projected to be 40% in the first year and will slowly decrease to 5% growth. The projected margins on revenue in 2026 of our model can be seen below:

9 1 1	<u>g</u>
Accounting Terms	% Revenue
Operating Income	35%
Cost of goods sold	25%
Sales, General and Administrative costs	30%
(SG&A)	
Research and Development (R&D)	10%

Table 4: Margins on projected revenue in 2026 for ALDX model.

The tax rate on our operating income cannot be compared to Alcon because it is a Swedish company. It will be estimated using Table 4.24 in Biotechnology Valuation⁷, which provides the

⁷ Keegan, Karl, *Biotechnology Valuation* (England: John Wiley & Sons, 2008), 98.

averages for many biotechnology companies' tax rates. This number is around 25%, so we will assume this for our model. The royalties to Ligand Pharmaceuticals as a percentage of revenue will also be deducted from our operating income. Since there is no specified number in the ALDX 10-K and proxy report, and it is described as a "low single digit number", we will assume this to be 5%. Note that similarly to projecting revenue, all of these expenses are assumed to be normally distributed in the Monte-Carlo simulation.

Net Present Value (NPV) Model

To determine net income, we subtract total expenses from total revenue. Net present value for each year (except the last) is then calculated using the following formula:

$$NPV = \frac{Net \ income}{(1 + Discount \ Factor)^{k'}}$$

where k represents the number of years after 2015 (i.e. the discounting period).

The NPV for the last year (2026) will account for all of the future NPV as a terminal value. The discount factor is assumed to be 10%, and the residual growth rate is assumed to be 1.5%. This is calculated in the following manner:

NPV in 2026 =
$$\frac{(Net Income)}{(Discount Factor - Residual Growth Rate)(1 + Discount Factor)^9}$$

Results and Discussion of the Model

Our discounted NPV model yielded a NPV/share of \$30.96 if the drug is commercialized, which is significantly higher than the current stock price of \$5.53. However, there is a high chance that the drug is not approved (~75%) so the current price falls in the 75th percentile of the simulation (Figure 3).

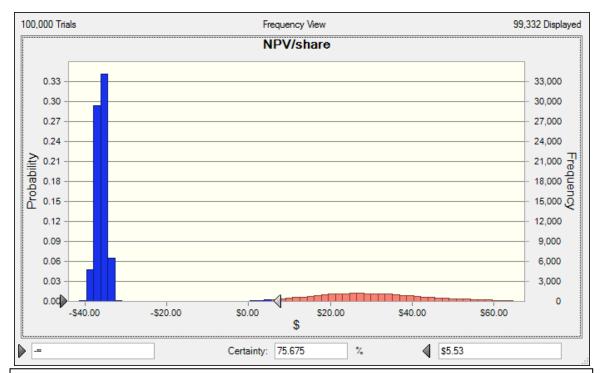


Figure 3- Results of the MC simulation for ALDX. The current stock price falls in the 75th percentile. The red region represents the upside probability while the blue region represents downside probability.

From this MC simulation, we conclude that if the drug is commercialized, we should expect roughly 460% return on our initial \$5.53/share investment. All of the assumptions in our model were reasonable (some even conservative) when compared to other similar biotechnology companies. One of the most conservative assumptions in our model is the market penetration (0.7% in 1st year, growing at 0.3%/yr.). It isn't unreasonable to assume that this number could be a mid-single digit percentage within the first few years, which would have a large multiplicative effect on our shareholder returns.

Under the assumption that rejection of the allergic conjunctivitis drug will lead to the subsequent rejection of the other drugs in the ALDX pipeline or the eventual failure of ALDX as a biotechnology company, we will expect the stock to plummet with a 75% chance. However, in the other 25% of scenarios, we will expect significant returns on our investment.

Proxy Report

Executive Compensation

Current Executive Officers:

Name	Age	Position(s)
Todd C. Brady, M.D., Ph.D.	44	Chief Executive Officer and Director
Stephen J. Tulipano	57	Chief Financial Officer
Scott L. Young	54	Chief Operating Officer
David J. Clark, M.D., M.R.C.P., A.F.P.M.	51	Chief Medical Officer

Executive compensation at Aldeyra Therapeutics has three components: base salary, option awards, and non-equity incentives. Base salary is determined every year by the compensation committee and accounts for roughly 40% of the total compensation. The executive compensation from 2014-2015 has been summarized below in Table 5.

Table 5: Summary compensation table for 2014-2015:

Name and Principal Position	Year	Salary (\$)(1)	Stock Awards (\$)(2)	Option Awards (\$)(2)	Non-Equity Incentive Pla Compensatio (\$)		All Other Compensation (\$)	Total (\$)
Todd C. Brady, M.D., Ph. D.	2015	\$400,000	\$	\$528,034	144,000	(3)	4,564	\$1,076,598
President and Chief Executive Officer	2014	377,500	_	454,871	234,000		9,013	1,075,384
Stephen J. Tulipano Chief Financial Officer(4)	2015 2014	274,270 135,000	_	146,676 246,994	94,050 44,898	(3)	_	514,996 426,892
Scott L. Young Chief Operating Officer	2015 2014	315,000 322,679	_ _	58,670 —	88,200 132,300	(3)		461,870 454,979

The compensation packages for each executive officer are determined annually by the compensation committee based on "his or her performance and relevant criteria". However, this criterion is not defined in the proxy report, something that should raise concern in shareholders.

Companies that are attractive to investors are transparent with compensation practices and ensure executive compensation is consistent with shareholders' interests. Sensible compensation practices are especially important for a pre-profit biotechnology company, since it does not generate any revenue from sales and relies on financing from investors.

Equity Incentive Plan

ALDX conceived an equity incentive plan in 2013 that schedules increases in the common stock available. The number of shares reserved for issuance under the plan is increase yearly by a number equal to the smallest of:

- •1,000,000 shares
- •7.00% of the shares of common stock outstanding on December 31 of the prior year
- •the number of shares determined by our board of directors.

Compensation Committee Members

Gary Phillips, M.D (Chair) Ben R. Bronstein, M.D. Neal S. Walker, D.O.

The following is quoted from the 2015 proxy report as a comment on the practices of the compensation committee and the absence of conflicts of interests:

None of the members of our compensation committee is or has in the past served as an officer or employee of our company. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Conclusion

From our discounted NPV model and Monte-Carlo simulations, we conclude that the ALDX stock has significant potential upside with high risk. Specifically, given the risk/reward asymmetry, we believe that ALDX provides a viable investment opportunity. As with any biotechnology stock, it is ideal to buy this stock as a part of a larger portfolio to mitigate some the risk involved. The significant potential upside even with conservative assumptions outweighs the vagueness in executive compensation demonstrated in the proxy report. Therefore, we rate ALDX as a **buy with high risk**.

Additional Bloomberg Screenshots

Screenshot 2: Company Overview



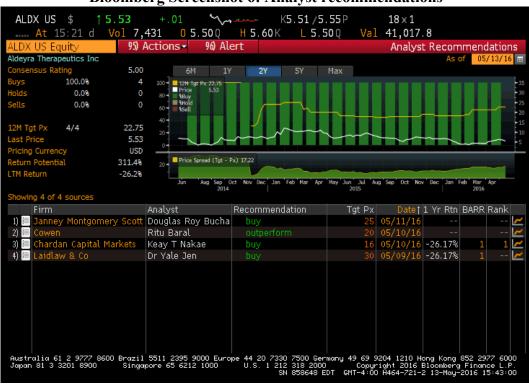
Screenshot 3: Current Shares Outstanding





Screenshots 4 and 5: Current Holders

45% of ALDX is owned by venture capitals, which is not surprising given the tendency of venture capitals to invest in biotechnology and information technology companies. The executives of ALDX are also some of the top shareowners.



Bloomberg Screenshot 6: Analyst recommendations

Although there are only 4 analyst recommendations, they all recommend a buy.

Bloomberg Screenshot 7: Executive transactions



Over the past year, management has bought a significant amount of shares, suggesting confidence in their own research and development.