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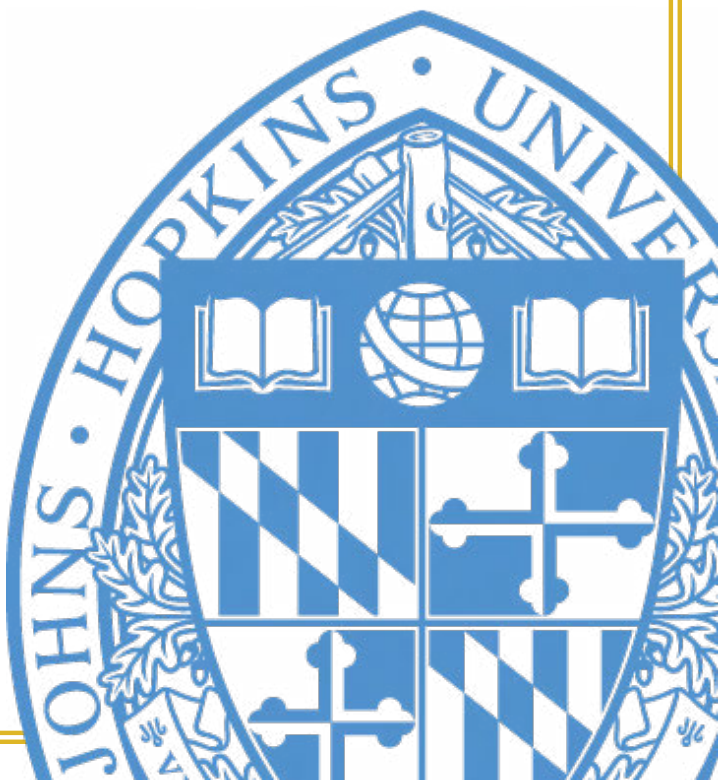
Studies in Applied Finance

INVESTMENT THESIS FOR GALECTIN THERAPEUTICS, INC. (NASDAQ: GALT)

Tu Nguyen



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

Investment Thesis for Galectin Therapeutics, Inc. (NASDAQ: GALT)

By Tu Nguyen

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About the Series

The Studies in Applied Finance series is under the general direction of Prof. Steve H. Hanke, Co-Director of the Johns Hopkins Institute for Applied Economics, Global Health, and 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.

About the Author

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Summary

This working paper is an in-depth analysis of Galectin Therapeutics, Inc. Our analysis examines the economic factors that impact GALT's underlying business and how GALT has adapted to these ever-changing factors. This economic analysis is then combined with our proprietary Net present value (NPV) model to determine GALT'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. In addition to these quantitative factors, we also examine the compensation plans of GALT's executives to assess alignment with shareholders. At the conclusion of this analysis, it is our intention for readers to understand GALT's business plan and the company's financial standing to arrive at a sound investment decision.

Acknowledgements

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Keywords: Financial Modeling, Galectin Therapeutics, Inc., Discounted Cash Flow, Net Present Value, Monte-Carlo Simulation, Investment Thesis, Management Compensation.

JEL codes: C63, G11

Rating: Buy, with High Risk

Company Name:	Galectin Therapeutics, Inc.
Date:	5/13/2016
Fiscal year ends:	3/15/2016
Current price:	$1.44
52 week high:	$4.11
52 week low:	$1.08
Market Cap:	$42.1 Million
Enterprise Value:	$29.9 Million
Total Debt:	N/A
Cash:	$21.3 Million
Net Debt/Enterprise Value:	N/A
Dividend Yield:	N/A
Diluted Shares Outstanding:	25.9 Million
Current P/E:	N/A
2017 EPS:	-$0.69*
2016 EPS:	-$0.69*
2015 EPS:	-$0.88
2014 EPS:	-$0.78
2013 EPS:	-$1.30
2012 EPS:	-$0.72

*Consensus estimates as of the time of this writing.

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Executive Summary

Galectin Therapeutics, Inc. (NASDAQ: GALT) is a clinical-stage biopharmaceutical company headquartered in Atlanta, GA. The company focuses on drug discovery and development; its main goal is to develop new therapies for fibrotic disease and cancer. Based on historical averages, recent statements from the management team, and our own estimations, our uniquely developed discounted net present value (NPV) model, together with Monte Carlo simulations, give a probable net present value of $2.89 per share, which is 100% higher than the current price of $1.44. However, the current price is sitting at the 75th percentile of the price distribution obtained from Monte Carlo simulations, meaning it has a 75 percent chance of falling and a 25 percent chance of rising. As a result, we rate GALT as a BUY, but with **high risk**.

Catalysts and Risks

- If at least one drug hits the market, the potential is huge; in particular, because there are no current therapies for treatment of liver fibrosis, if approved, GR-MD-02 will be the only go-to drug in the market.
- Since GALT is a pre-profit biotechnology company, it has not been able to generate any revenue, and hence has incurred net losses in each year of operation since 2000.
- The current, "burn rate," of the company, calculated by summing the research and development (R&D) and the selling, general, and administrative (SG&A) expenses, is relatively high compared to the amount of cash the company has. As a result, it is estimated that there is only sufficient cash to fund operations through the first quarter of 2017.
- There is a high chance that none of drugs in the company's pipeline will hit the market.
- The company might be unable to commercialize its products even if they receive regulatory approvals.

Company Description and Historical Performance

Company Description

Galectin Therapeutics, Inc. (NASDAQ: GALT) is a clinical stage biopharmaceutical company focused on drug discovery and development. The company's drug candidates aim at targeting galectin proteins, which are key mediators of pathologic functions. It has been shown that there is a large number of galectin proteins implicated in many important diseases, such as inflammatory diseases, scarring of organs, and numerous cancers. GALT's strategy is to focus on serious diseases for which there are limited treatment options available.

Galectin Therapeutics, Inc. was incorporated in Massachusetts in July 2000 as Pro-Pharmaceuticals, Inc. On April 25, 2001, the company completed a stock exchange agreement with DTR-Med Pharma Corp. ("DTR"), whereby DTR purchased all of the company's outstanding common shares. On June 7, 2001, there was a merger between the two companies; the new company was renamed "Galectin Therapeutics Inc." In October 2012, GALT moved its headquarters to Atlanta, GA. The company went public in the same year, listed under the NASDAQ stock exchange symbol GALT. GALT has minimal exposure to ETFs, being included in only 2 ETFs, IWC and ITOT[1].

Product Pipeline

GALT is pursuing therapies for indications where galectin proteins have a demonstrated role in the pathogenesis of a particular disease. The company is currently engaging in several drug development programs. Ongoing programs, along with their respective stage of development, are listed in the following figure:

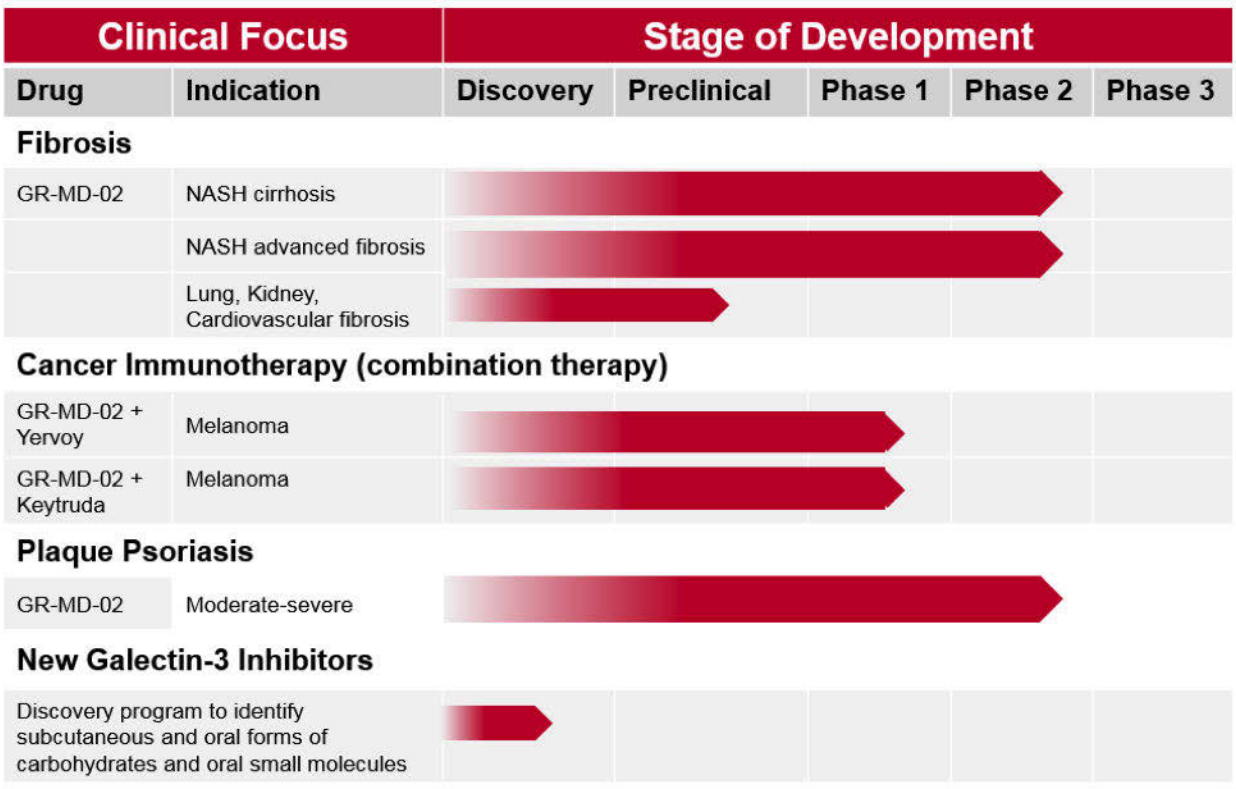

Figure 1: GALT Pipeline. Retrieved from the company's website.

[1] https://www.etfchannel.com/symbol/galt/

GR-MD-02, a new chemical entity in development, has shown some positive results in preclinical and early clinical studies in treatment of fibrosis and in cancer therapy. After chemical processing, GR-MD-02 – a proprietary, patented compound derived from natural and plant-based starting materials – has the ability to bind and inhibit galectin-3 proteins. The other new chemical entity, GM-CT-01, is also a proprietary and patented compound that is currently in the pipeline.

Besides conducting in-house research at SBH laboratories in Massachusetts, the company also contracts with independent laboratories and other facilities to conduct research, assist in designing clinical trial protocols, and monitor clinical trials. GALT, however, holds all the patents and trademarks to its products, allowing the company to maintain its competitiveness in the market.

Historical Performance

In the past five years, GALT's stock has been in the range of $1.08 - $16.86. The stock reached its peak in early 2014. It plummeted more than 55% on July 29, 2014, from $14.54 to $6.41, due to an unfavorable report from an early-stage trial of GR-MD-02 for treatment of a fatty liver disease. This reflects the inherent risk in pre-profit biotechnology companies[2]. The stock then went on a downward trend, possibly due to a securities fraud class action lawsuit that accused Galectin and some of its officers and directors for purposely hiring a penny-stock promotions firm to conduct an illegal stock promotion campaign on behalf of Galectin[3]. Finally, as can be seen from Figure 2, GALT's stock price does not show any correlation with either the NASDAQ (CMMP) Index or the Standard & Poor's (S&P) Index.

Due to some positive results from recent trials, we believe that there are some catalysts that signal potential future earnings growth for GALT. As a result, the stock may be poised to appreciate in value significantly. Our hypothesis is supported by financial analysts: 3 out of 3 analysts covering GALT rate it a buy, with an average target price of $7.00 (see Figure 3, below).

[2] https://www.thestreet.com/story/12825050/1/why-galectin-therapeutics-galt-stock-is-plummeting-today.html
[3] http://www.classactionsnews.com/investments/galectin-therapeutics-galt-securities-fraud-class-action-lawsuit

Figure 2: 5-year price chart of GALT's stock, the CCMP Index, and the S&P Index. Source: Bloomberg terminal (function <GP>).

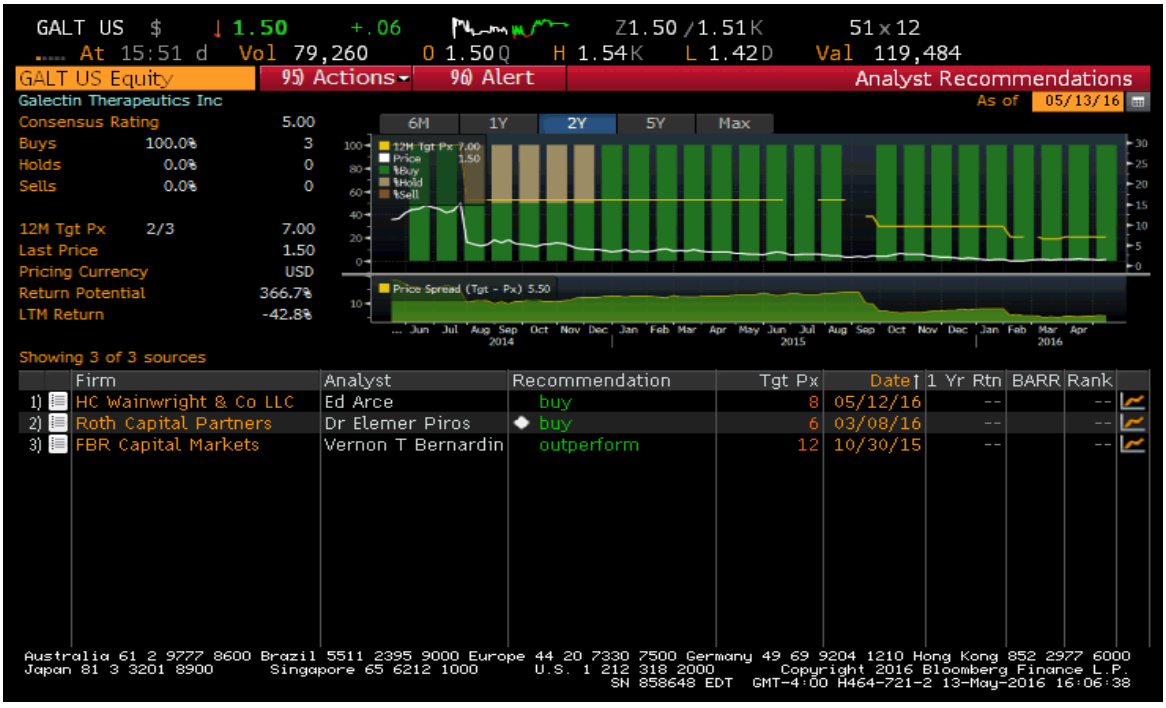

Figure 3: Analyst Recommendations for GALT. Source: Bloomberg Terminal (function <ANR>)

Model of the Company

General Overview

Since GALT is a pre-profit biotechnology company, we developed a proprietary discounted net present value (NPV) model to estimate its stock price. As shown in Figure 1, GALT has many drugs in its pipeline, and they are in various stages of development. However, because of the low probability of drug success (only 1 out of 5,000-10,000 molecules studied in the discovery stage makes it to the market as an approved drug[4]), we only used GALT's most developed drug, GR-MD-02, for treatment of non-alcoholic steatohepatitis (NASH) with cirrhosis, to project the company's future earnings. This conservative approach has one drug in the pipeline projected to move forward and the company's projected expenses assume none of the other drugs get approved, thus understating potential earnings and overstating expenses.

Balance Sheet and Income Statement Trends

In the balance sheet, a line-item that stands out is the tremendous increase of about $20 million in cash and cash equivalents from 2013 to 2014. This is due to the company issuing new shares during the time the stock price was at its peak (Figure 4). Other than that, all other line items, especially the company's liabilities, in the balance sheet stay relatively constant over the past 5 years, signaling good management. In addition, the company has no long-term debt, a good sign for investors.

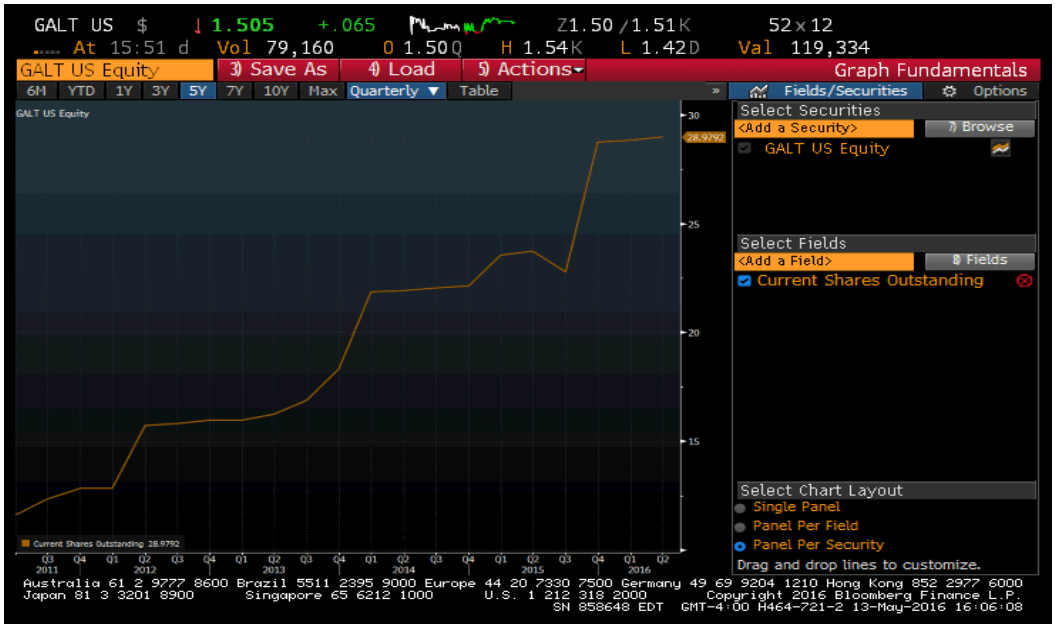

Figure 4: GALT's current shares outstanding from 2011 to 2016. Source: Bloomberg Terminal (function <GP>)

[4] Keegan, K. D. (2008). *Biotechnology valuation: An introductory guide*. Chichester, England: John Wiley & Sons. P. 40

As a pre-profit biotechnology company, the company is not generating any significant revenues, which is reflected in the income statement. We expect this to continue for a few more years until any drug in the pipeline hits the market. In addition, we can see a clear increasing trend in the amount of capital spent on research and development reflecting the capital intensive drug approval process. From 2010 to the first quarter of 2016, the operating expenses have grown consistently from about $1 million to more than $17 million. For a biotechnology company, this is reasonable because the further a drug advances to the next stage of development, the more capital it is going to require to fund additional research. Since it costs the most to conduct Phase 2 and Phase 3 trials, usually $10-$15 million and $30-$65 million respectively[5], we expect this trend to continue in the near future.

One important point to notice is that at the current burn rate, which is calculated by summing the R&D and SG&A expenses, the cash and cash equivalents available will not be sufficient to cover the company's operations after the first quarter of 2017. As a result, this presents the inherent risk that the company will issue additional shares to the market to raise capital or seek other sources of capital.

Model of FDA Drug Approval Process

The discovery and development process for new drugs to pass the regulatory authorities into the marketplace can be divided into five main stages: drug discovery; preclinical development; early clinical phase incorporating phase 1 and 2 studies; phase 3 trials; and phase 4 trials (or post-marketing surveillance studies). Since most of GALT's drugs have passed the preclinical development stage, we only focus on the four phases that come after it. The phase success rate for each phase, defined as the probability that a drug will obtain marketing approval from its current phase, is outlined in Table 1.

Table 1-The phase success rate at various phases

Phase 1	15%
Phase 2	25%
Phase 3	60%
Phase 4	90%

Source: Keegan, K. D. (2008). Biotechnology valuation: An introductory guide. Chichester, England: John Wiley & Sons. P. 40

As previously mentioned, we only projected potential revenues from GALT's most advanced drug, GR-MD-02, which is a lead candidate for treatment of fibrotic liver disease associated with NASH, particularly for patients with cirrhosis. Since the drug is in phase 2, its expected

[5] Keegan, K. D. (2008). *Biotechnology valuation: An introductory guide*. Chichester, England: John Wiley & Sons. P. 55

probability of success is 25%. Because the phase success rate obtained in Table 1 is just the average value over many different drugs, instead of using a point estimate for the probability that GR-MD-02 is going to be a success, we used a probability distribution, with the mean of the distribution at 25%. Since our probability distribution ranges from 0 to 1(or 0% to 100%), a beta distribution is the most appropriate model to use. The probability density function of a beta distribution is given below.

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

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

Solving for the mean and variance, we obtain:

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

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

With the expected probability of success at 25% and the variance at 10%, we can solve for α and 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 values of α and β yield the following probability density function:

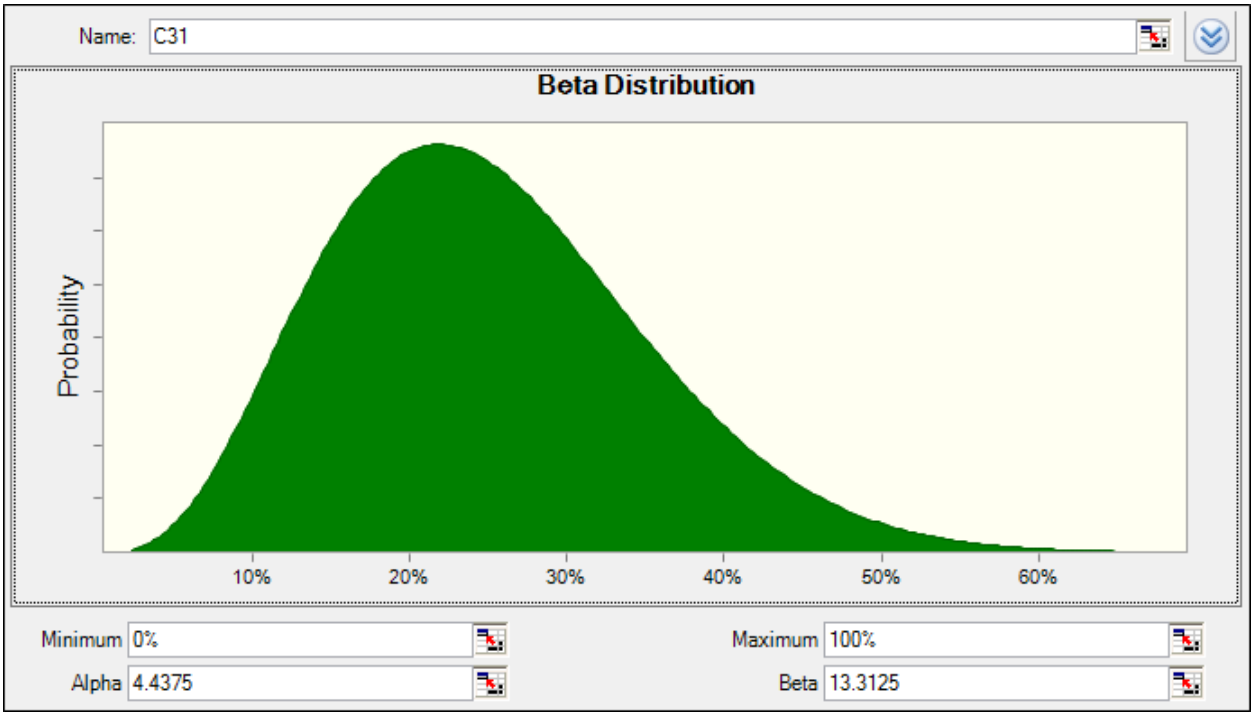

Figure 5: The distribution of probability of success for GR-MD-02

We then create a uniform distribution from 0 to 1 and a binary cell that only takes a value of their 0 or 1. Finally, we compare this random variable to the probability of success variable: If it is greater, the binary cell takes the value 1 (meaning the drug is going to be a success); on the other hand, if it is smaller, the binary cell takes the value 0 (meaning the drug will not be approved). We will then multiply the projected revenue with this binary cell to calculate the expected revenue for every scenario. A snapshot of the model in Excel is given in Table 2.

Table 2: FDA Drug Approval Process Model

		alpha	beta
Probability of drug success	25%	4.4375	13.3125
Uniform (0,1) R.V. generation:	0		
Is Uniform R.V. generated greater than probability of success? (1=Yes, 0=No). Multiply this by profits	1		

Lastly, we must also consider is the timeline of the FDA approval process. Assuming success, the drug will fit into the following timeline:

Table 3: Timeline for FDA approval process

Year	Stage
2016	Phase 2
2017	Phase 2 results
2018	Initiate Phase 3
2019	Phase 3 results
2020	New drug application (NDA)
2021	Launch

Revenue Projection

Having determined the probability of success for the drug, we will then project revenues for the next 10 years. The steps that must be taken to model revenue growth are outlined below:

1. ***Model the U.S. population***
   First, we assume that GALT only operates in the United States. This is a reasonable assumption because it is still a young company. As a result, the potential market for GALT's drugs is U.S. residents. To model the population, we calculate the population growth in the past 10 years, which gives an average of 0.79% and a standard deviation of 0.15%. We then use these parameters to assign a normal distribution to future population growth rate.
2. ***Model the proportion of U.S. population with NASH***
   According to the National Institute of Diabetes and Digestive and Kidney Diseases, 2 to 5 percent of Americans are affected by NASH. In addition, this number is increasing because of the higher obesity rate[6]. As a result, the percentage of U.S. population with NASH is assumed to have a uniform distribution from 2 to 5 percent in the first year, with an increment of 0.5% for every year after that.
3. ***Model the proportion of U.S. population with NASH who might develop cirrhosis***
   It is estimated that 8 to 26 percent of people with NASH might develop cirrhosis[7]. As a result, a uniform distribution from 8 to 26 percent is used for every projected year in the model.
4. ***Model the drug price***
   According to GALT's 2015 10-K, there are 1-2 million Americans who have cirrhosis, and about 50,000 of those die every year. Unfortunately, the only treatment available is to perform liver transplantation at a cost of approximately $350,000 per transplant. Hence, if GR-MD-02 hits the market, it would not be unreasonable to assume the price of such drug to be in the range of $1,000 - $1,500, as Gilead Sciences' hepatitis C drug was

[6] http://www.niddk.nih.gov/health-information/health-topics/liver-disease/nonalcoholic-steatohepatitis/Pages/facts.aspx
[7] http://www.uptodate.com/contents/nonalcoholic-fatty-liver-disease-nafld-including-nonalcoholic-steatohepatitis-nash-beyond-the-basics

priced at $1,125 per pill[8]. We even believe that the price assumed is somewhat conservative compared to the cost of performing liver transplantation. In addition, we assume a market penetration of 5% for the first year with a 1% growth for every year afterwards. Since as of now there are no competing drugs in the market, this is a realistic assumption. All of these values are modeled using a normal distribution.

Expense Projection

As mentioned earlier, the later stages of the FDA approval process cost much more than earlier stages. As a result, in 2016 and 2017, when the drug is in phase 2, we project R&D expense growth rate at 30%. In 2018 and 2019, when the drug is in phase 3, this number grows to 50%. For every year afterwards, the R&D expense growth rate is assumed to drop down to 5% to account for post marketing surveillance trials.

On the other hand, general and administrative expense growth rate is assumed to be constant at 1.6%, its historical value. In addition, after the drug hits the market, we introduce a new sales and marketing expense, which is projected to consume 25% of revenue. Finally, for every year the company makes a profit, the tax rate as a percentage of EBITDA is assumed to be 30%. Similar to the revenue projection, all of these expenses are assumed to be normally distributed in our Monte Carlo simulation.

Net Present Value (NPV) Model

For every projected year, subtracting total expenses from expected revenue gives us expected net income. We then discount this back to the current year using the following formula:

$$NPV = \frac{Net\ income}{(1 + Discount\ Rate)^{k}},$$
$$where\ k\ represents\ the\ number\ of\ years\ passed\ since\ 2016$$

For the final year, 2026, its NPV also accounts for all the future NPVs as a terminal value. Using a discount rate of 10% and a residual growth rate of 1.5%, the NPV in the final year is calculated using the following formula:

$$NPV\ in\ 2026 = \frac{(Net\ Income)}{(Discount\ Rate - Residual\ Growth\ Rate)(1 + Discount\ Rate)^{10}}$$

[8] http://www.uptodate.com/contents/nonalcoholic-fatty-liver-disease-nafld-including-nonalcoholic-steatohepatitis-nash-beyond-the-basics

Model Results

Assuming the drug turns out to be a success, our NPV model gives a NPV/share of $2.89, which is 100% higher than the current price. However, as with any drugs in development, there is a very high chance that GR-MD-02 is not going to be approved. As can be seen in the price distribution, at the current price of $1.44, there is 75% chance that the stock price will fall below that and only 25% chance that the stock price will be a home run. However, if the drug hits the market, potential return is huge. Since we took a conservative approach in our model, as explained in above sections, this means we should expect an even higher return.

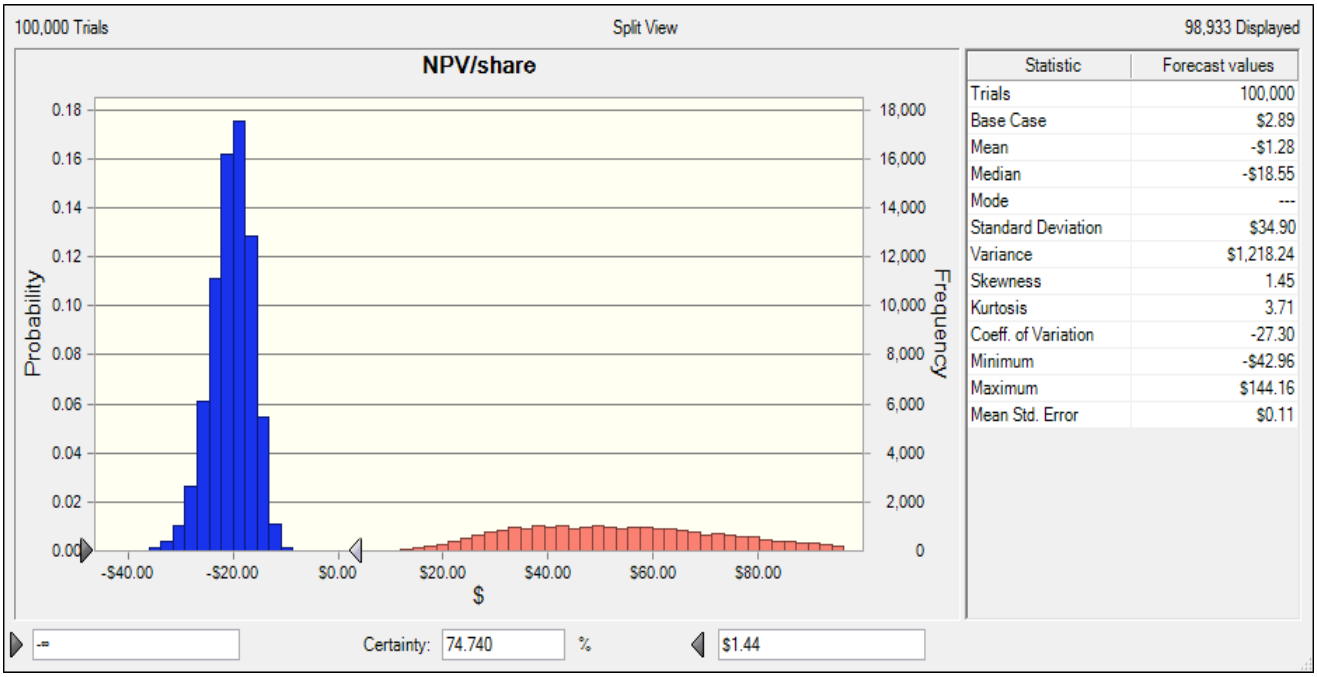

Figure 6: Distribution of GALT stock. The current stock price falls in the 75th percentile. The red region represents the upside probability while the blue region represents downside probability.

Proxy Findings

Management Compensation

Since management is able to allocate capital at its own discretion, we performed a compensation analysis to determine if management is incentivized to generate returns for shareholders.

According to GALT's 2014 proxy statement, executive compensation comprises of 3 main components:

1. Base salary

2. Annual Performance bonuses
3. Long-term compensation in the form of equity-based awards

Base Salary

Base salary is the only fixed component in the executive compensation program. Named Executive Officers (NEO)'s base salaries are reviewed annually, taking into account marketplace rates, individual responsibilities, performance, and experience. In 2014, only 2 out of 4 NEOs got a base salary raise.

Table 4: Base salaries for NEOs in 2013 and 2014

Name	2013 Base Salary	2014 Base Salary
Peter G. Traber, M.D.	$ 375,000	$ 485,000
James C. Czirr	$ 240,000	$ 240,000
Harold H. Shlevin, Ph.D.	$ 200,000	$ 230,000
Jack W. Callicutt	$ 175,000	$ 175,000

Annual Performance Bonuses

The annual cash bonus is targeted to be up to 20% to 40% of the NEO's base salary. 50% of each NEO's annual performance bonus is based on the company's performance objectives for the year and the other 50% is based on individual performance objectives. According to the company's DEF 14A form, the overall performance objectives for the company in 2014 are:

(1) Establish human proof of concept for GR-MD-02 treatment of non-alcoholic steatohepatitis with advanced fibrosis.

(2) Establish human proof of concept for use of galectin inhibitors in combination with immunotherapy for cancer.

(3) Establish sustainable program for GR-MD-02 manufacturing and controls.

(4) Establish appropriate quality assurance and quality control oversight and strengthen regulatory support.

(5) Strengthen and expand pipeline and indications for galectin blocking drugs.

(6) Strengthen business practices, financial resources, investor communication and strategic partnerships.

The actual amounts of annual performance bonuses awarded to the NEOs in 2014 are included in Table 5.

Table 5: Annual performance bonuses in 2014

Name	Annual Performance Bonus Amount	Awarded Amount As % of Base Salary
Peter G. Traber, M.D.	$ 213,400	57%
James C. Czirr	$ 84,000	35%
Harold H. Shlevin, Ph.D.	$ 77,625	33.75%
Jack W. Callicutt	$ 38,500	22%

Long-term Incentive Compensation

The amount of options granted to each NEO is based upon company performance, individual performance, and rank in the company. The exercise price of these options is set at the closing price of the stock as of the grant date.

Total compensation for all the NEOs is included in Table 6.

Table 6: Executive compensation for the period 2012-2014

Name and Principal Position	Year	Salary ($)	Bonus ($) (2)	Option Awards ($) (1)	All Other Compensation ($)	Total ($)
Peter G. Traber, M.D.	2014	485,000	213,400	1,512,150	41,502(5)	2,252,052
Chief Executive Officer &	2013	375,000	194,688	—	43,002(6)	612,690
President	2012	314,946	25,000	713,332	36,021(7)	1,089,299
James C. Czirr	2014	240,000	84,000	688,367	75,882(8)	1,088,249
Executive Chairman and Director	2013	240,000	120,025	—	77,189(9)	437,214
	2012	212,503	—	—	79,689(10)	292,192
Harold H. Shlevin, Ph.D.,	2014	230,000	77,625	428,819	35,304(11)	771,748
Chief Operating Officer (3)	2013	200,000	59,975	—	32,454(12)	292,429
	2012	50,000	25,000	473,381	8,908(13)	557,289
Jack W. Callicutt,	2014	175,000	38,500	293,402	38,812(14)	545,714
Chief Financial Officer (4)	2013	87,500	39,803	709,542	17,074(15)	853,919
	2012	—	—	—	—	—

Even though the parameters that go into the calculation of long-term incentive compensation are not clearly aligned with shareholders' interests, the fact that many of the objectives aim at growing the company and that the option awards take a large proportion of each NEO's compensation is a good sign to investors.

Dividend and Share History

GALT has not declared any dividends since the day it was founded. This is not a surprise given the fact that it has not been able to generate any revenues. In addition, as can be seen in Figure 4, the company's outstanding shares have been on an upward trend for the last few years because the company prefers equity financing to long-term debt to raise capital. We expect this trend to continue in the foreseeable future as the company is running out of cash to fund its operations.

Holders and Insider Trading

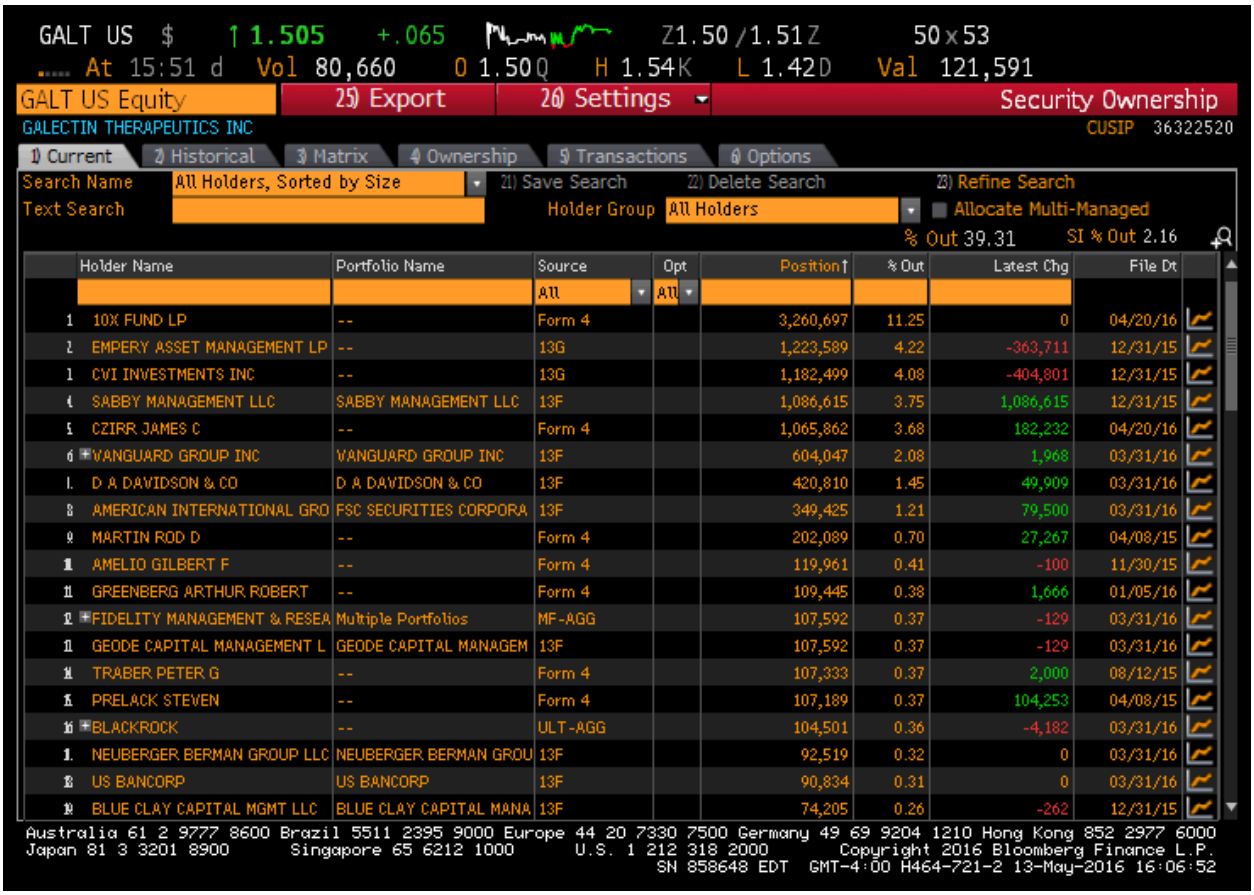

Figure 7: GALT's Institutional and Insider Shareholders

Figure 7 (above) is a list of GALT's shareholders in order of positions in the company. At the top of the list is 10x Fund LP, owned by Rod D. Martin, a director, and James Czirr, executive chairman and a director. It is reassuring to see many GALT insiders, marked by the "Form 4" source title, in this ownership table. It shows that many of these executive officers have their, "skin in the game," and they are incentivized to maximize shareholders' return.

A snapshot of insider transactions is provided in Figure 8. The dominance of green pentagonal shapes, which represents purchases of shares, suggests that the officers believe in the future of the company.

Figure 8: GALT's Insider Transactions.

Conclusion

With recent positive results from Phase 2 trials, GR-MD-02, the lead candidate for treatment of fibrotic liver disease associated with NASH, is getting closer to being approved. Our discounted NPV and Monte Carlo simulation shows us that if the drug hits the market, GALT will have a huge upside potential. This, though, comes with a high risk: GALT's stock is projected to go upward in only 25% of the scenarios. However, with a good management team, whose interests also align with shareholders', we believe GALT is positioned to become a winner given the risk/reward asymmetry. Thus, we rate GALT as a BUY, with high risk.