AEGIS CAPITAL CORP

Biopharmaceuticals
Raghuram Selvaraju, Ph.D.
(646) 502-2464
rselvaraju@aegiscap.com

Yi Chen, Ph.D.
(646) 502-2463
ychen@aegiscap.com

Company Update

March 5, 2013

Galectin Therapeutics, Inc.

Rating: Buy

Galectin Receives Approval To Begin Phase 1 Trial

Key Metrics

GALT - NASDAQ	$3.32
Pricing Date	Mar 5 2013
Price Target	$7.00
52-Week Range	$6.00 - $1.60
Shares Outstanding (mm)	16.0
Market Capitalization ($mm)	$53.1
3-Mo Average Daily Volume	57,643
Institutional Ownership	0%
Debt/Total Capital	NM
ROE	NM
Book Value/Share	$0.15
Price/Book	22.1x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPS ($) FY: December

	2011A	Prior 2012E	Curr. 2012E	Prior 2013E	Curr. 2013E
1Q-Mar	(0.04)	--	(0.17)A	--	(0.18)E
2Q-Jun	(0.06)	--	(0.19)A	--	(0.17)E
3Q-Sep	(0.03)	--	(0.19)A	--	(0.17)E
4Q-Dec	(0.31)	--	(0.19)E	--	(0.17)E
FY	(0.23)	--	(0.76)E	--	(0.69)E
P/E	NM		NM		NM

Company Description:

Galectin Therapeutics, Inc., an emerging biotechnology firm (http://www.galectintherapeutics.com/), is headquartered in Newton, MA. The firm focuses on developing therapies for cancer and fibrotic diseases.

Investment Highlights:

- **Phase 1 Testing To Begin Shortly.** This morning, Galectin announced that the FDA has approved its Investigational New Drug (IND) application for permission to begin first-in-man testing of its lead drug candidate GR-MD-02. A Phase 1 study of the drug is now slated to start patient dosing by May 2013 and is expected to yield data later in the year. Patients with non-alcoholic steatohepatitis (NASH) who exhibit advanced fibrotic disease are slated to be enrolled at up to seven centers in the U.S. The firm's Phase 2 study in NASH, a highly unmet medical need with no currently-approved effective therapy, could begin before the end of 2013 and yield data in early 2015, potentially paving the way for a transformative partnership or potentially an acquisition of the company. We aim to draw investors' attention to Galectin's current valuation, which represents an attractive entry point, in our view. In anticipation of additional value-driving catalysts from both the GR-MD-02 program in liver fibrosis and the ongoing GM-CT-01 program in cancer, we reiterate our Buy rating and price target of $7.00 per share, which we currently anticipate being attained within the next 12 months. In our view, the firm is an undiscovered gem that possesses a technology platform founded upon cutting-edge science and validated targets.
- **Attractive Comparable Metrics.** In recent months, the progress of a firm that has certain attributes in common with Galectin Therapeutics has demonstrated the appetite of investors for drug development opportunities in hepatology. The firm in question, Intercept Pharmaceuticals, went public in October 2012 at a valuation of $235mm and already has an enterprise value of roughly $650mm. Galectin, meanwhile, trades at an enterprise value of about $40mm. Intercept has yet to begin Phase 3 testing of its lead drug candidate, obeticholic acid (OCA or INT-747) in NASH. We also believe that OCA is unlikely to reverse fibrosis and that its safety profile may prove inferior to that of Galectin's GR-MD-02. Given the high unmet need in liver fibrosis, we believe peak global sales for a drug that can reverse fibrosis could be $1.7 billion in 2020. In our opinion, there is very strong preclinical proof that Galectin's drugs can reverse liver fibrosis.
- **Strong Data From Second Lead Drug.** From Phase 1 and 2 studies with the firm's lead drug candidate GM-CT-01, there is solid safety and encouraging signs of efficacy in colorectal cancer. Additional efficacy data could come on an ongoing basis from a study currently running in Germany that is assessing the impact of GM-CT-01 in skin cancer.

The Disclosure section may be found on pages 7 - 8 of this report.

Investment Risks

Financial outlook and history of unprofitable operations. Galectin Therapeutics has incurred operating losses since inception and, in our view, may not achieve sustainable profitability for several years. We estimate that the firm may raise additional funds within the next 12 – 18 months to support testing of its pipeline candidates in the U.S. Because of these factors, Galectin Therapeutics shares may constitute above-average risk and volatility, in our opinion.

FDA unpredictability. Drug development is a multi-year process that requires human clinical trials prior to market entry. The agency may require substantial pivotal clinical trial data from Galectin Therapeutics prior to granting approval for its pipeline candidates, necessitating lengthy development times for the firm's lead drug candidates. Also, review times at the FDA may prove longer than originally expected. If clinical data and/or other supporting evidence are not accepted by the FDA, marketing authorization for Galectin's lead candidates could be delayed or might not occur at all, preventing the firm from realizing the commercial potential of its pipeline.

Potential dependency on partners to provide enhanced market penetration. Galectin Therapeutics currently lacks any direct sales and marketing organization or commercial infrastructure. The firm does not, at this point, have any plans to forward integrate and could elect to either be acquired or partner its lead candidates with an established pharmaceutical firm once clinical proof-of-concept is achieved. We think that a lack of partnering or acquisition interest could prevent the firm from commercializing its product candidates, should they achieve regulatory approval.

Competitive landscape. Galectin is likely to compete with other companies within the drug development industry, many of which have more capital, more extensive research and development capabilities and greater human resources. Some of these competitors with documented interest in both the fibrosis and oncology arenas include Amgen Inc. Biogen Idec, Bristol-Myers Squibb, Dendreon Corporation, GlaxoSmithKline and Pfizer.

Intellectual property risk. The company relies on patents and trade secrets to protect its products from competition. A court might not uphold Galectin's intellectual property rights, or it could find that Galectin infringed upon another party's property rights. In addition, generics firms could potentially launch generic versions of GM-CT-01, GR-MD-02, or other candidates prior to the expiration of patent protection on these products.

Reimbursement risk. Following the institution of broad-based healthcare reform policy, reimbursement agencies have grown more wary of systematically reimbursing for drugs that are either unnecessary or provide marginal benefit at excessive cost. If Medicare spending growth continues to outpace GDP growth, and governmental ability to fund healthcare becomes impaired, changes could be made to reimbursement policy that would negatively affect Galectin Therapeutics, despite what we believe to be the compelling value proposition inherent in both GR-MD-02 and GM-CT-01.

Additional risks. As of September 30th, 2012, Galectin Therapeutics had roughly $11 million in cash and equivalents. Other sources of cash could include: licensing fees from partnerships, warrant and option exercises or issuance of more shares. If GM-CT-01 and GR-MD-02 fail in proof-of-concept studies, Galectin may not be able to raise cash at all.

Industry risks. Emerging biotechnology and pharmaceuticals stocks are inherently volatile and increasingly subject to development and regulatory risk. Meeting or missing commercialization milestones may result in a significant change in the perception of the company and the stock price. We do not anticipate volatility subsiding in the near term.

For additional risk considerations, please refer to the company's SEC filings.

GR-MD-02 Market Model

We have modeled sales of Galectin Therapeutics' proprietary drug candidate GR-MD-02 in the U.S. and European markets, assuming approval and launch for treatment of non-alcoholic steatohepatitis (NASH). Although we believe that the drug could have important applicability in alcoholic cirrhosis of the liver as well as fibrosis of other organs, including end-stage renal disease (ESRD), we do not currently project sales of the agent in these indications as a clinical development pathway has yet to be proposed in these areas. Nevertheless, we note that these other indications represent potential upside.

Herewith we present our market assumptions for GR-MD-02 going forward (Table 5, overleaf). We project launch in mid-2017 in the U.S. and mid-2018 ex-U.S. The drug could achieve significant market penetration for the treatment of NASH, in our view, since we believe that it is unlikely to have substantial competition at the time of launch. Our market model assumptions include the pricing of the drug at $85,000 per patient annually in the U.S. and $60,000 per patient annually in Europe. We factor in 3% price increases each year to account for inflation, and assume generic competition in the U.S. beyond 2030, as the year of patent expiry could easily be later than this time frame. In Europe, we assume a similar time window for commercialization.

We note that GR-MD-02 could continue to benefit from two significant demographic trends – the emergence of chronic hepatitis C infection as a major cause of chronic liver disease, and the rise in obesity in the developed world. As the numbers on direct-acting antivirals aimed at reducing hepatitis C viral load increases, the likelihood of long-term non-alcoholism-related liver injury rises as well. Galectin is entering proof-of-concept clinical development with GR-MD-02, so it is still an early-stage initiative. However, we note that the firm's proposed timeline for development of the drug is likely to permit the release of top-line data from a Phase 2 dose-escalation trial in NASH sufferers – an initial value inflection point – in late 2013 and data from a Phase 2 study – the main value inflection point, in our view – in late 2014 or early 2015. We project launch in the U.S. in 2017 and in Europe in 2018.

We are encouraged by the fact that Intercept Pharmaceuticals, another firm working in the liver fibrosis arena, has a partnership deal in place with Dainippon Sumitomo Pharma for the development and commercialization of INT-747 (obeticholic acid, or OCA) in Japan and China. The indications specifically named in the agreement, inked in early 2011, are PBC and NASH. It is important, in our view, for investors to note the terms of this deal. Dainippon Sumitomo paid Intercept $15 million in upfront fees, and Intercept is eligible to receive up to $300 million in additional pre- and post-commercial milestone payments. Tiered double-digit royalties are also payable to Intercept, and Dainippon Sumitomo has the option to in-license other territories as well, such as Korea and Taiwan. Since this deal was quite lucrative, from our perspective, despite only covering Japan and China, we believe that U.S. and European rights for indications such as NASH ought to be quite valuable and could enable a firm like Galectin Therapeutics to extract favorable terms from a future partner if its proof-of-concept Phase 2 data with GR-MD-02 prove positive. We also note the substantial valuation discrepancy between Galectin and Intercept – currently, Intercept trades at an enterprise value of roughly $650 million, while Galectin's enterprise value is approximately $40 million. Intercept has not yet begun Phase 3 development of OCA in NASH. Accordingly, we consider the valuation discrepancy between the two firms unwarranted.

Accordingly, we consider Galectin's current valuation attractive as well as largely risk-mitigated, since Galectin is both targeting a much larger patient population with GR-MD-02 as well as developing another pipeline agent that already has shown favorable clinical data, GM-CT-01, in a completely different indication.

Table 1: GR-MD-02 Estimated Global Sales – Non-Alcoholic Steatohepatitis (NASH) Market Size Model

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030
US Population																			
Cirrhosis population	450,000	453,825	457,683	461,573	465,496	469,453	473,443	477,468	481,526	485,619	489,747	493,910	498,108	502,342	506,612	510,918	515,261	519,640	524,057
Non-alcoholic steatohepatitis sufferers	67,500	70,875	74,419	78,140	82,047	86,149	90,456	94,979	99,728	104,715	109,950	115,448	121,220	127,281	133,645	140,328	147,344	154,711	162,447
GR-MD-02 Penetration	0%	0%	0%	0%	0%	3%	7%	9%	11%	15%	18%	21%	23%	25%	23%	21%	18%	17%	16%
Patients on GR-MD-02				0	0	2,584	6,332	8,548	10,970	15,707	19,791	24,244	27,881	31,820	30,738	29,469	26,522	26,301	25,991
Cost per patient ($)						85,000	87,550	90,177	92,882	95,668	98,538	101,494	104,539	107,675	110,906	114,233	117,660	121,190	124,825
US GR-MD-02 sales ($ MM)				0	0	220	554	771	1,019	1,503	1,950	2,461	2,915	3,426	3,409	3,366	3,121	3,187	3,244
European Population																			
Cirrhosis population	600,000	615,000	630,375	658,742	691,679	726,263	762,576	800,705	840,740	882,777	926,916	973,262	1,021,925	1,073,021	1,126,672	1,183,006	1,242,156	1,304,264	1,369,477
Non-alcoholic steatohepatitis sufferers	84,000	86,100	88,253	92,224	96,835	101,677	106,761	112,099	117,704	123,589	129,768	136,257	143,069	150,223	157,734	165,621	173,902	182,597	191,727
GR-MD-02 Penetration	0%	0%	0%	0%	0%	0%	4%	7%	9%	12%	14%	16%	18%	17%	16%	15%	12%	10%	9%
Patients on GR-MD-02				0	0	0	4,270	7,847	10,593	14,831	18,168	21,801	25,753	25,538	25,237	24,843	20,868	18,260	17,255
Cost per patient ($)							60,000	61,800	63,654	65,564	67,531	69,556	71,643	73,792	76,006	78,286	80,635	83,054	85,546
European GR-MD-02 sales ($ MM)				0	0	0	256	485	674	972	1,227	1,516	1,845	1,885	1,918	1,945	1,683	1,517	1,476
Global GR-MD-02 sales ($ MM)				**0**	**0**	**220**	**811**	**1,256**	**1,693**	**2,475**	**3,177**	**3,977**	**4,760**	**5,311**	**5,327**	**5,311**	**4,803**	**4,704**	**4,721**
Galectin Therapeutics Net Income ($ MM)				**0**	**0**	**26**	**113**	**188**	**254**	**371**	**477**	**597**	**714**	**797**	**799**	**797**	**720**	**706**	**708**

Source: Company Reports and Aegis Capital Corp. estimates

Intellectual Property Portfolio

Galectin Therapeutics owns the rights to several issued patents and a wide array of pending patent applications. The table below lists the issued patent portfolio for the company, including the patent estate that provides the firm freedom to operate within the galectin modulation arena. Since the firm – under its original name, Pro-Pharmaceuticals – was originally focusing on oncology applications for its platform, the issued patent estate principally covers various galectin inhibitors from composition-of-matter and method-of-use perspectives in the cancer domain. In particular, the patent estate covers a particular carbohydrate-based polysaccharide, galactomannan, which was shown to illustrate the principle of binding to galectins and inactivating them.

The claims in the issued patent estate cover both the structures of the various carbohydrate-based drug candidates, including galactomannan, as well as the combination of these drug candidates with various known chemotherapy agents. Furthermore, the scope of the patent claims allows Galectin Therapeutics to pursue the development of its carbohydrate-based drug platform in a wide range of cancer indications, irrespective of tissue or cell type.

Table 2: Galectin Therapeutics Issued Intellectual Property

Patent Number	Title	Issue Date	Expiry Date	Country	Description
6,642,205	Methods and Compositions for Reducing Side Effects in Chemotherapy Treatments	11/4/2003	9/24/2001	United States	Reduction of chemotherapy toxicity via co-administration with a galectin inhibitor
6,645,946	Delivery of a Therapeutic Agent in a Formulation for Reduced Toxicity	11/11/2003	3/27/2021	United States	Reducing toxicity of chemotherapy via combined therapy with a galectin blocker (covers GM-CT-01)
6,914,055	Delivery of a Therapeutic Agent in a Formulation for Reduced Toxicity	7/5/2005	8/27/2023	United States	Reducing toxicity of chemotherapy via combined therapy with a galectin blocker (covers GM-CT-01)
6,982,255	Delivery of a Therapeutic Agent in a Formulation for Reduced Toxicity	1/3/2006	8/27/2023	United States	Reducing toxicity of chemotherapy via combined therapy with a galectin blocker (covers GM-CT-01)
7,012,068	Co-administration of a Polysaccharide with a Chemotherapeutic Agent for the Treatment of Cancer	3/14/2006	3/27/2022	United States	Reducing toxicity of chemotherapy via combined therapy with a galectin blocker (covers GM-CT-01)
7,893,252	Selectively Depolymerized Galacto-mannan Polysaccharide	2/22/2011	2/25/2028	United States	Compositions and methods covering combinations of polysaccharide admixtures with chemotherapy drugs
8,236,780	Galactose-Pronged Polysaccharides in a Formulation for Anti-Fibrotic Therapies	11/26/2012	5/16/2027	United States	Covers formulation of galectin-blocking compounds aimed at treatment of fibrotic disorders, including liver fibrosis
272022B2	Co-administration of Polysaccharide with a Chemotherapeutic Agent for the Treatment of Cancer	NA	NA	Australia	Reducing toxicity of chemotherapy via combined therapy with a galectin blocker (covers GM-CT-01)
2002 731786	Co-administration of Polysaccharide with a Chemotherapeutic Agent for the Treatment of Cancer	NA	2022	European Union	Reducing toxicity of chemotherapy via combined therapy with a galectin blocker (covers GM-CT-01)
2002 4744782	Co-administration of Polysaccharide with a Chemotherapeutic Agent for the Treatment of Cancer	NA	2022	European Union	Reducing toxicity of chemotherapy via combined therapy with a galectin blocker (covers GM-CT-01)

Source: Company reports

The firm recently received a notice of allowance from the U.S. Patent and Trademark Office for a divisional patent of U.S. Patent Number 8,236,780, entitled "Galactose-prolonged polysaccharides in a formulation for antifibrotic therapies". The patent covers key methods of derivation and use for the company's galactomannan-based carbohydrate galectin inhibitor compounds, for use in patients with chronic liver disease associated with development of fibrosis, established liver fibrosis or end-stage scarring (cirrhosis).

In our view, this recent patent issuance has significant strategic importance because the claims in this patent broaden Galectin's intellectual property to include two distinct classes of galectin inhibitors for the treatment of liver fibrosis. The intellectual property protection for the firm's galactomannan (GM)-based compounds augments an existing IP portfolio that already contains coverage for galacto-rhamnogalacturonan (GR)-based compounds, thus enabling a pipeline of candidates with drugs from each class that can be evaluated for the treatment of fibrosis. It also means that Galectin could potentially use its anti-cancer lead compound, GM-CT-01, for use in fibrosis as well.

Table 3: Galectin Therapeutics (GALT) – Historical Income Statements, Financial Projections

FY end December 31
$ in thousands, except per share data

				2012E					2013E				
	2009A	2010A	2011A	1QA	2QA	3QA	4QE	2012E	1QE	2QE	3QE	4QE	2013E
Revenue													
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Service revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Research and other	-	-	-	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Expenses													
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
Research & development	1,110	1,066	3,552	901	1,215	1,409	1,500	5,025	1,600	1,700	1,800	1,900	7,000
General and administrative	4,983	3,817	6,857	1,052	1,453	1,487	1,500	5,492	1,500	1,500	1,500	1,500	6,000
Total expenses	6,093	4,883	10,409	1,953	2,668	2,896	3,000	10,517	3,100	3,200	3,300	3,400	13,000
Gain (loss) from operations	(6,093)	(4,883)	(10,409)	(1,953)	(2,668)	(2,896)	(3,000)	(10,517)	(3,100)	(3,200)	(3,300)	(3,400)	(13,000)
Other income/expense													
Interest income/expense	3	6	18	3	8	7	2	20	8	6	4	3	21
Change in fair value of convertible debt instrument	-	-	-	-	-	-	-	-					
Change in fair value of warrant liabilities	(1,374)	(1,241)	(524)	-	-	-	-	-	-	-	-	-	-
Other income	2	489	-	-	-	200	-	200	-	-	-	-	-
Total investment income and other	(1,369)	(746)	(506)	3	8	207	2	220	8	6	4	3	21
Loss before provision for income taxes	(7,462)	(5,629)	(10,915)	(1,950)	(2,660)	(2,689)	(2,998)	(10,297)	(3,092)	(3,194)	(3,296)	(3,397)	(12,979)
Series A 12% Convertible Preferred Stock Dividend	(209)	(192)	(232)	(58)	(167)	(138)	(138)	(501)	(138)	(138)	(138)	(138)	(552)
Series B 12% Convertible Preferred Stock Dividend	(341)	(710)	(1,336)	(139)	(100)	(100)	(100)	(439)	(100)	(100)	(100)	(100)	(400)
Series B-1 Redeemable Convertible Preferred Stock Accretion	(1,407)	(2,178)	(230)	(57)	(57)	(58)	(58)	(230)	(58)	(58)	(58)	(58)	(232)
Net loss/income	(9,419)	(8,709)	(12,713)	(2,204)	(2,984)	(2,985)	(3,294)	(11,467)	(3,388)	(3,490)	(3,592)	(3,693)	(14,163)
Net loss per share (basic)	(0.20)	(0.15)	(0.23)	(0.17)	(0.19)	(0.19)	(0.21)	(0.76)	(0.18)	(0.17)	(0.17)	(0.17)	(0.69)
Net loss per share (diluted)	(0.20)	(0.15)	(0.23)	(0.17)	(0.19)	(0.19)	(0.21)	(0.76)	(0.18)	(0.17)	(0.17)	(0.17)	(0.69)
Weighted average number of shares outstanding (basic)	48,274	56,301	55,644	13,010	15,710	15,822	15,966	15,127	18,491	21,041	21,091	21,141	20,441
Weighted average number of shares outstanding (diluted)	48,274	56,301	55,644	13,010	15,710	15,822	15,966	15,127	18,491	21,041	21,091	21,141	20,441

Source: Company Reports and Aegis Capital Corp. estimates

Required Disclosures

Price Target

Our 12-month price target for GALT is $7.00 per share.

Valuation Methodology

We utilize a discounted cash flow analysis supporting a risk-adjusted Net Present Value framework to derive the price target. Intrinsic value for the company's product candidates is calculated based upon the size of the market, projected peak penetration rate, competitive landscape, probability of approval based on publicly available clinical data, length of patent term protection and other factors. Intrinsic values are then added to derive the price target.

Risk Factors

Issues that could prevent the achievement of our price objective include, but are not limited to, clinical, regulatory, competitive, reimbursement and financial risks. Drugs in clinical development may not advance due to inadequate safety, efficacy, or tolerability. Regulatory agencies may decline to approve regulatory submissions in a timely manner, or may not approve a drug candidate at all. The firm may require substantial funding to advance the clinical progress of its candidates, which could be dilutive to current shareholders. We expect competition for the company's drugs from several public and private companies developing pharmaceuticals. Sales of the firm's drugs could depend upon reimbursement from private, as well as public, reimbursement agencies.

For important disclosures go to www.aegiscap.com.

Research analyst compensation is dependent, in part, upon investment banking revenues received by Aegis Capital Corp.

Aegis Capital Corp. intends to seek or expects to receive compensation for investment banking services from the subject company within the next three months.

Aegis Capital Corp. has performed investment banking services for and received fees from Galectin Therapeutics, Inc. within the past 12 months.

Rating	Percent	Investment Banking Services/Past 12 Mos. Percent
BUY [BUY]	80.65	28.00
HOLD [HOLD]	19.35	16.67
SELL [SELL]	0.00	0.00

Meaning of Ratings

A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.
B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.
C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

Other Disclosures

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Aegis Capital Corp.
(212) 813-1010
810 Seventh Avenue, 18th Floor
New York, New York 10019