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**Company Update / Estimates Change** 

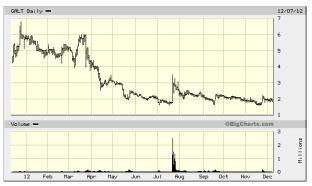
#### December 10, 2012

#### **Key Metrics**

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GALT - NASDAQ	\$1.88
Pricing Date	Dec 7 2012
Price Target	\$7.00
52-Week Range	\$6.78 - \$1.61
Shares Outstanding (mm)	15.7
Market Capitalization (\$mm)	\$29.5
3-Mo Average Daily Volume	39,979
Institutional Ownership	0%
Debt/Total Capital	NM
ROE	NM
Book Value/Share	\$0.15
Price/Book	12.5x
Dividend Yield	NM
LTM EBITDA Margin	NM

#### EPS (\$) FY: December

		Prior	Curr.	Prior	Curr.
	2011A	2012E	2012E	2013E	2013E
1Q-Mar	(0.04)		(0.17)A	(0.17)E	(0.18)E
2Q-Jun	(0.06)	(0.16)E	(0.19)A	(0.16)E	(0.17)E
3Q-Sep	(0.03)	(0.18)E	(0.19)A	(0.16)E	(0.17)E
4Q-Dec	(0.31)		(0.19)E	(0.16)E	(0.17)E
FY	(0.23)	(0.71)E	(0.76)E	(0.65)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.

# Galectin Therapeutics, Inc. Rating: Buy

**Galectin Therapeutics: Still Undervalued** 

# **Investment Highlights:**

- Valuation Presents Opportunity. We aim to draw investors' attention to Galectin Therapeutics' current valuation, which represents an attractive entry point, in our view. The firm is slated to file an Investigational New Drug (IND) application with the FDA for permission to begin first-in-man testing of its lead drug candidate GR-MD-02 by the end of January 2013. A Phase 1 study of the drug could begin before the end of 1Q 2013 and is expected to yield data later in the year. The firm's Phase 2 study in nonalcoholic steatohepatitis (NASH), a highly unmet medical need with no currently-approved effective therapy, could begin before the end of 2013 and yield data in early- to mid-2014, potentially paving the way for a transformative partnership or potentially an acquisition of the company. In anticipation of these value-creating events, we reiterate our Buy rating and an 18-month price target of \$7.00 per share. 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 is approaching an enterprise value of \$300mm. Galectin, meanwhile, trades at an enterprise value of <\$20mm. 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.

# **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 30<sup>th</sup>, 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.

# **Valuation**

Comparables Analysis: Given that Galectin Therapeutics is currently unprofitable and considering our belief that sustainable profitability is a few years away, we use a discounted cash flow-based approach to value the shares. Based on a comparables analysis, it appears the stock is worth roughly \$7.00 per share, utilizing our estimate of a \$210 million risk-adjusted net present value (rNPV) for the firm's products. This assumes that the shares trade in-line with the comp group's present average enterprise value of roughly \$230 million and that the firm has 36 million shares outstanding (fully-diluted) and \$39 million in cash at end-2013 (including proceeds from warrant exercises).

**Table 1: Comparable Company Analysis** (Millions, Except Per-Share Data)

					Closing	Shares	Market	Cash	Debt	Enterprise
Development	Therapeutic Area	Company	Ticker	Rating	12/10/2012	(MM)	(\$MM)	(\$MM)	(\$MM)	value (\$MM
Phase 2	Infectious Diseases	Achillion Pharmaceuticals	ACHN	Not Rated	\$7.48	80	595	81	1	515
Pre-registration	Inflammation / Metabolic Disorders / Diagnostics	Ampio Pharmaceuticals	AMPE	Buy	\$3.70	37	137	20	0	117
Preclinical	Stem Cells	BioTime, Inc.	BTX	Not Rated	\$3.28	49	161	8	0	153
Phase 1 / 2	CNS Disorders	Neuralstem, Inc.	CUR	Buy	\$1.16	68	79	10	0	69
Phase 1 / 2	Orphan Disorders	Synageva BioPharma	GEVA	Not Rated	\$48.83	24	1187	233	0	954
Phase 3	Liver / Kidney Disease	Intercept Pharmaceuticals	ICPT	Not Rated	\$28.45	17	470	36	0	434
Phase 1 / 2	Biosimilars	Medgenics	MDGN	Not Rated	\$8.74	12	106	9	0	97
Preclinical	CNS Disorders	InVivo Therapeutics	NVIV.OB	Buy	\$1.68	66	111	16	0	95
Preclinical	Stem Cells	Organovo	ONVO.OB	Not Rated	\$2.13	47	100	8	0	92
Phase 2	Monoclonal Antibodies	Sorrento Therapeutics	SRNE.OB	Not Rated	\$0.22	300	66	6	Ö	60
Preclinical	Oncology	VeraStem	VSTM	Not Rated	\$6.74	21	143	47	Ö	96
Phase 2 / 3	Hematology / Oncology	YM BioSciences	YMI	Not Rated	\$1.62	158	255	128	0	127
		Average					284			235
								Discre	pancy	
Current valuation	Fibrosis / Oncology	Galectin Therapeutics	GALT	Buy	\$1.88	16	30	11	0	19
				Derived 18	-month compa	rable value				
Farget valuation (18-month)	Fibrosis / Oncology	Galectin Therapeutics	GALT	Buy	\$7.00	36	275	39	0	Projected 235

Source: First Call and Aegis Capital Corp. estimates

**Free Cash Flow:** We estimate that Galectin Therapeutics will be free cash flow negative for the foreseeable future. We define free cash flow as operating cash flow minus capital expenditures and dividend payments. We utilize a discounted cash flow analysis supporting a risk-adjusted Net Present Value (rNPV) framework to derive our 18-month \$7.00 price target. This approach is described further in the next section of the report. Our detailed analysis is split into three components — our discounted cash flow model comprising the rNPV of GR-MD-02 and GM-CT-01, along with our assessments of the market sizes for GR-MD-02 and GM-CT-01 and the associated sales models for these drug candidates; the residual value of the company's drug development technology platforms; and the near-term financial outlook for the company. Our historical income statement and financial projections are presented at the back of this report.

## Risk-Adjusted Net Present Value Analysis

The table below depicts our rNPV breakdown of the sum-of-the-parts discounted cash flow valuation approach used for Galectin Therapeutics. We ascribe a \$90 million rNPV to GR-MD-02, the firm's principal value driver, along with an \$80 million rNPV value to GM-CT-01, the company's most broadly-tested clinical candidate. We also provide a \$40 million residual value for the company's technology platform, yielding a total enterprise value of \$210 million – in-line with the comparables-based analysis above.

Table 2: Risk-Adjusted NPV-Based Sum-of-the-Parts Analysis

Galectin Therapeutics								
	Product	Launch Year	Patent Expiry	Peak Sales	Royalty Rate	Probability	NPV	Amount
				Estimate		To Launch		Per Share
Preclinical								
Liver Fibrosis	GR-MD-02	2017	2028	\$5.3B	12-22%	25%	\$90MM	\$2.52
Cancer	GM-CT-01	2015	2028	\$3.4B	10-18%	25%	\$80MM	\$2.24
Total							\$170MM	\$4.75
Technology Platform	Galectin Inhibition	NA		NA	NA	NA	\$40MM	\$1.12
Cash at end-2013							\$39MM	\$1.12
Firm Value							\$250MM	\$7.00

Source: Company reports; Aegis Capital Corp. estimates

## **Obeticholic Acid Assessment**

We believe that it is appropriate at this juncture to provide investors with some background on a competitor to Galectin Therapeutics in the liver fibrosis field. Unlike the former privately-held firm Solana Therapeutics, now part of La Jolla Pharmaceuticals, this other competitor is not focusing on galectin inhibition at all. The company in question is called Intercept Pharmaceuticals, which originally went public in October 2012 in a relatively successful IPO. The firm sold five million shares at \$15 apiece and raised gross proceeds of \$75 million in an offering that was originally sized at \$60 million. Intercept was valued at \$235 million immediately post-closing; the company currently has a market capitalization approaching \$400 million less than two months after the public listing became effective.

Intercept has derived a number of bile acid derivatives for clinical development in a variety of liver diseases. Bile acids and derivatives have been studied for many years, but the relatively recent discovery that they serve as agonists for the steroid hormone receptor FXR has stimulated renewed interest in this mechanism. Intercept covers a broad range of potential indications, as shown in the company's pipeline chart below. The initial indication that the firm is pursuing is primary biliary cirrhosis, or PBC, where bile acids such as chenodexoycholic acid and others have shown some benefit<sup>1</sup>.

Preclinical Phase I Phase II Phase III Rights OCA (FXR Agonist) PBC (Orphan Indication) Portal Hypertension WW- excluding certain Asian countries licensed to DSP NASH Bile Acid Diarrhea INT-777 (TGR5 Agonist) WW Type 2 Diabetes INT-767 (Dual FXR/TGR5 Agonist) ww

Figure 1: Intercept Pharmaceuticals Product Candidate Pipeline

Source: Intercept Pharmaceuticals, Inc.

Obeticholic acid (OCA, or INT-747) is Intercept's lead candidate. The primary data on the effectiveness of OCA in NASH appears to relate principally to effects on metabolic syndrome and liver fat<sup>2</sup>. However, the key issue from a competitive standpoint, in our view, is its level of efficacy in fibrosis and whether or not it can reverse already-established fibrosis. The only reasonable data on this is a 2005 abstract, from which the data have not been published. This abstract suggests that OCA can reverse fibrosis, but the amount of fibrosis was less than that seen in Galectin's unpublished studies.

What is telling, however, is that Intercept does not appear to be focused on fibrosis in clinical development. NASH activity is the primary endpoint in the firm's studies. One of the reasons for this may simply be that NASH activity is the endpoint that all other NASH trials have utilized. Another may be that the anti-fibrosis effect is not very robust, which we consider to be more likely.

<sup>2</sup> Adorini *et al.*, Drug Discovery Today 17: 988-997 (2012)

<sup>&</sup>lt;sup>1</sup> Poupon. Clinics and Research in Hepatology and Gastroenterology 36 S3-S12 (2012)

With regard to PBC, others have shown reduction in alkaline phosphatase with ursodeoxycholic acid and it is still not clear that these agents really have clinical benefit. Similar data has been shown with OCA, a more potent agonist of FXR (see below). In a Phase 2 clinical trial conducted by Intercept, OCA showed improvement in some serum indicators of PBC and patients are now being enrolled in a Phase 3 trial.

p < 0.0001 p < 0.0001 p < 0.0001Mean % Change in AP -10 -20 25 -30 Placebo 10 mg 25 mg 50 mg n=38 n=47 n=39 n=37

Figure 2: Obeticholic Acid Primary Biliary Cirrhosis Clinical Data

Source: Intercept Pharmaceuticals, Inc.

The alkaline phosphatase data does not guarantee improvement in fibrosis, which is the real problem in PBC. We also note that, at both the intermediate and high doses of the drug, there was a very high incidence of pruritus (itching), as shown below.

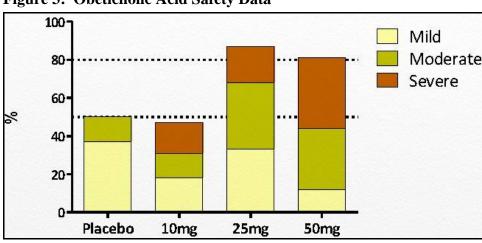


Figure 3: Obeticholic Acid Safety Data

Source: Intercept Pharmaceuticals, Inc.

Due to the pruritus issue, Intercept is starting with a dose of 5mg in its pivotal study of OCA, which is below the lowest dosage assessed in the Phase 2 trial. Pruritus is a major side effect, in our view. In fact, it is the most problematic symptom in PBC. The itching seems to be directly related to agonism of the FXR receptor so it is a pharmacological effect. At therapeutic doses, virtually all subjects get itching, although it is manageable in most people. We believe that this will be a problem for long-term therapy, especially in asymptomatic NASH. With the caveat that GR-MD-02 has not yet entered human testing, there are no detectable side effects at therapeutic doses. Despite the fact that OCA is in pivotal development, we expect it to take a lengthy period of time before the drug's efficacy profile is definitively established. Primary readout from the Phase 3 trial is January 2014, with final outcome data expected in 2018.

In terms of non-alcoholic fatty liver disease (NAFLD), which is directly comparable to NASH, Intercept has been testing OCA in a Phase 2 trial that was implemented through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), a division of the NIH. This was a 72-week, 280-patient placebo-controlled trial. We believe that top-line efficacy data could become available soon. This study assessed OCA at a 25mg dose, with the primary endpoint being hepatic histological improvement in disease. However, this is being assessed as "no worsening in fibrosis" along with a decrease in disease activity as measured by the NAFLD Activity Score (NAS), which is defined as a reduction of at least two points on this scale. Accordingly, therefore, we believe that even if this data is positive, it may not necessarily show that OCA can reverse or even directly impact fibrosis in NAFLD or NASH.

The major difference between the Galectin Therapeutics program and the lead program at Intercept is that Galectin is directly targeting fibrosis. The firm has a parenteral formulation that is not suitable for very long-term treatment, but it appears to be powerful for reversing fibrosis. Therefore, we expect Galectin to attempt to treat NASH with advanced fibrosis with the object of reversing it. The data shown below were generated in an animal model of fibrotic liver disease, using Galectin's lead candidate GR-MD-02. The evidence for inhibition of fibrosis appears to be quite robust, with activity across a range of doses.

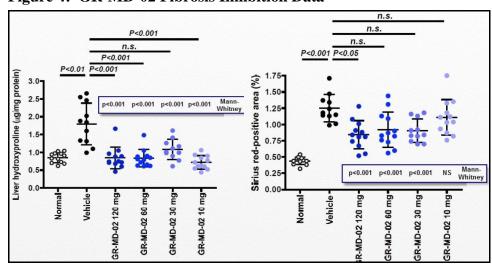


Figure 4: GR-MD-02 Fibrosis Inhibition Data

Source: Galectin Therapeutics, Inc.

An unnamed expert on non-alcoholic steatohepatitis also indicated to us that "FXR agonists, such as obeticholic acid, work primary on SREBP1 and decrease FFA production in the liver. There is unlikely to be a significant amount of activity against inflammation or fibrosis development/regression."

Another bile acid therapeutic has also been tested in NASH. Colesevelam (brand name Cholestagel) is an intestinal bile salt binding which was supposed to increase bile acids. Clinical trial results released this year showed that it increased fat in the liver of NASH patients and had no other effects. Accordingly, therefore, we believe there is a preponderance of evidence demonstrating that OCA, while potentially an effective therapy in the NASH setting, may not be able to elicit all of the therapeutic effects that might be achievable with Galectin's lead drug candidate GR-MD-02 and with the galectin-blocking approach overall. Thus, we continue to have significant confidence in Galectin Therapeutics' strategy for the treatment of NASH and would recommend that investors consider establishing positions in Galectin stock as GR-MD-02 moves towards the achievement of proof-of-concept clinical results in the NASH indication.

At this year's annual meeting of the American Association for the Study of Liver Diseases (AASLD), held in Boston, MA in November 2012, Galectin presented data showing that the robustly anti-fibrotic effects of its lead drug candidate GR-MD-02 could be linked to impact on galectin expression by macrophages in liver tissue (see below).

Figure 5: GR-MD-02 Macrophage Galectin Inhibition Data

Source: Galectin Therapeutics, Inc.

In our view, the mechanistic evidence demonstrating a link between the inhibition of galectin expression – specifically Galectin-3 – in macrophages and the suppression of fibrosis appears to be quite compelling. If Galectin Therapeutics can replicate this in human studies, we believe that GR-MD-02 could become a highly differentiated drug for the treatment of NASH and that its main distinguishing factor would likely be its ability to reverse already-established fibrosis. In this regard, we consider GR-MD-02 to have the potential to show superiority to bile acid derivatives in treatment of liver fibrosis. Should an agent like OCA be available on the market at the time that GR-MD-02 is still undergoing clinical development, we do not believe that it would significantly restrict the market opportunity for Galectin Therapeutics. In any case, it is our view that the main area of applicability for OCA is more likely to be PBC rather than NASH.

## **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 1 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, which we have discussed in detail earlier in this report, 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 approaching \$300 million, while Galectin's enterprise value is below \$20 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.

Galectin Therapeutics, Inc.

Table 3: 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 Non-alcoholic steatohepatitis sufferers	450,000 67,500	453,825 70,875	457,683 74,419	461,573 78,140	465,496 82,047	469,453 86,149	473,443 90,456	477,468 94.979	481,526 99.728	485,619 104.715	489,747 109.950	493,910 115,448	498,108 121,220	502,342 127,281	506,612 133,645	510,918 140,328	515,261 147,344	519,640 154,711	524,057 162,447
GR-MD-02 Penetration	07,500	0%	, -	0%	0%	3%	7%	9%	11%	15%	18%	21%	23%	25%	23%	21%	18%	17%	
GR-MD-02 Penetration	0%	0%	0%	0%	0%	3%	170	9%	1176	15%	10%	2170	23%	25%	23%	21%	10%	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						=00.000													
Cirrhosis population Non-alcoholic steatohepatitis sufferers	600,000 84,000	615,000 86,100	630,375 88,253	658,742 92,224	691,679 96,835	726,263 101,677	762,576 106,761	800,705 112,099	840,740 117,704	882,777 123,589	926,916 129,768	973,262 136,257	1,021,925	1,073,021 150,223	1,126,672 157,734	1,183,006 165,621	1,242,156 173,902	1,304,264 182,597	1,369,477 191,727
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 4: 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.

Galectin Therapeutics, Inc.

Table 5: Galectin Therapeutics (GALT) – Historical Income Statements, Financial Projections

FY end December 31

\$ in thousands, except per share data

			_		2012	<b>=</b>		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 18-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.

We, Raghuram Selvaraju and Yi Chen, the authors of this research report, certify that the views expressed in this report accurately reflect our personal views about the subject securities and issuers, and no part of our compensation was, is, or will be directly or indirectly tied to the specific recommendations or views contained in this research report.

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., Ampio Pharmaceuticals, Inc. and Neuralstem, Inc. within the past 12 months.

Aegis Capital Corp. makes a market in Ampio Pharmaceuticals, Inc..

	;	Investment Banking Services/Past 12 Mos.						
Rating	Percent	Percent						
BUY [BUY]	95.45	33.33						
HOLD [HOLD]	4.55	0.00						
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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