

## INSTITUTIONAL RESEARCH

# Healthcare & Biotechnology COMPANY UPDATE

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### **Galectin Therapeutics (Nasdaq/GALT)**

BUY

September Symposium to Highlight Galectin-based Platform

Galectin Therapeutics is developing liver fibrosis and cancer therapeutics

### **Investment Highlights**

1) Galectin Therapeutics (Galectin or GALT) is moving ahead with its advanced metastatic melanoma therapeutic clinical program, announcing in May 2012 that the first patient was dosed in a Phase 1/2 trial using the Company's carbohydratebased galectin inhibitor compound, GM-CT-01 in combination with a peptide vaccine. In the Phase 1/2 study, patients will receive GM-CT-01 intravenously every three days in addition to an injection of either the MAGE-3 A.1 or NA17.A2 vaccine at three-week intervals. The study is being conducted at the Cliniques universitaires Saint-Luc and the Ludwig Institute for Cancer Research in Belgium and led by lead investigator Professor Jean-Francois Baurain. The Cliniques are funding the first stage of the trial (six patients in each of two arms), with the second stage of up to 17 patients to be funded through grants and/or by the Company. The primary endpoint of the Phase 1/2 trial is partial or complete response in these patients, who in the past have had limited success with currently available therapies. Top-line results for the 12 patients to be dosed in Stage 1 are expected to be available in the first quarter of next year. Galectin may subsequently ramp up partnership discussions for GM-CT-01 next year if Stage 1 results are positive, perhaps with an established pharmaceutical provider who already has a cancer immunotherapy drug on the market or one in late-stage clinical trials. With a large addressable market and short duration for potential positive news flow, this R&D program represents the best opportunity for a near-term catalyst for potential investors in Galectin.

2) Meanwhile, the Company is staying on course with its Liver Fibrosis clinical program, expecting to file an investigational new drug (IND) application with the US FDA for GR-MD-02 by the end of this year. Soon after this filing,

Current Price \$1.89
Price Target \$3.00

Estimates	F2010A	F2011E	F2012
Revenues(\$000s)	\$0	\$0	\$3.50

EPS	(\$0.93)	(\$1.06)	(\$0.68)		
Stock Data					
52-Week Range		\$1	.65-\$7.80		
<b>Shares Outstanding</b>		15.7			
Market Capitalization (mil.)			\$29.7		

Enterprise Value (mil.) \$14.2 Debt to Capital (3/12) 0.0% Book Value/Share (3/12) \$0.43 Price/Book 4.3 xAverage Trading Volume (3-Month) 44,000 Insider Ownership 15.0% Institutional Ownership 0.4% Short interest 49,700 Dividend / Yield \$0.00/0.0%



Price target and ratings changes over the past 3 yrs: Initiated - September 6, 2011 - Buy -Price Target \$4.00 (\$24.00 post-split)

Price target lowered to \$3.00 - July 6, 2012



Galectin plans to start a Phase 1 clinical trial using GR-MD-02 in patients with fibrotic liver disease associated with Non-alcoholic steatohepatitis (or NASH) in order to assess safety and preliminary evidence of efficacy in humans. Results from this Phase 1 trial could be released as soon as the fourth quarter of this year, and if positive, the Company plans on potentially beginning Phase 2 clinical trials by the end of next year, with top-line results expected approximately one year later.

- 3) GALT's upcoming September Symposium on Galectin Science and Therapeutic Applications may well be the near-term development which holds the greatest long-term potential for the Company. The 3-day Symposium, to be held in Boston, will bring together researchers and clinicians from 14 countries on five continents and will feature discussions on the following topics relating to the Galectin class of compounds:
  - Galectins and Galectin Blockers: Structural Aspects;
  - Galectin Functions: Intracellular and Extracellular Manifestations and implications;
  - Galectin-Dependent Pathologies;
  - Galectin-Based Therapy and Diagnostics: Preclinical and Clinical Data; and
  - Galectins and Diseases: Present and Future.

In addition to the primary Galectins-related R&D programs in cancer and liver disease already underway at the Company, Galectin Therapeutics holds a number of domestic and international patents (through at least 2020) related to Galectin-based compounds and applications, and the upcoming symposium will lay the groundwork for further development of a Galectins-based platform technology for the Company.

**4**) Galectin also recently held their annual shareholder meeting and reported financial results for their first quarter of 2012, ending March 31<sup>st</sup>. During the quarter, the Company reported operating expenses of \$2.0 million and a net loss of \$2.2 million or (\$0.17) per share, as compared with operating expenses of \$2.0 million, and a net loss of \$2.7 million or (\$0.24) per share in the prior year period. Bearing in mind the recent cost data for the Company as well as a delay in the potential approval of GM-CT-01 in combination with 5-FU for metastatic colorectal cancer in Colombia, we are revising our forecasts for Galectin for 2012E to revenues of \$3.5 million (from \$9.0 million) and to a net loss of \$10.2 million or (\$0.68) per share, as compared to a net loss of \$6.0 million or (\$0.42) per share previously. We are also reducing our revenue projections for Galectin for fiscal years 2013-2015, again due to the delay in approval in Colombia. However, at least for the near future, these reduced revenue expectations are not expected to over-stress the Company's balance sheet. Our projections for operating cash burn for Galectin for 2012E is approximately \$5.0-\$6.0 million; thanks to a recently completed equity placement, Galectin held over \$15.3 million in cash and equivalents on their balance sheet at the end of the most recent March 2012 quarter.

### Conclusion/Stock Valuation

Galectin Therapeutics shares have declined this year, following a delay in product approvals in International jurisdictions and a reverse stock split, but some anticipated positive scientific and clinical progress as well as a possible investor awakening to the current deep value of these current shares (less than 2X cash on hand) could point to a rebound in these shares this year. Thus, we are maintaining our BUY rating on GALT shares, although lowering our 18-24 month price target to \$3.00 per share (from \$24.00 split-adjusted previously), representing a price/revenue multiple of 1.5X projected revenues of \$43 million in 2015E discounted by 40% and a little less than 3.0X cash on hand. (See page 4 for projections through year 2015E and also our initiation report for GALT dated September 6, 2011.)



### **Risk Factors**

In addition to normal economic and market risk factors that impact most equities and the common risks shared by Galectin with other companies in the industry, we believe an investment in Galectin Therapeutics involves the following risks:

- **FDA and regulatory risks** Galectin is subject to regulatory review for its ongoing research and development activities, principally the US Food and Drug Administration but also potentially with other regulatory agencies as well, specifically in South and Central America and potentially Europe.
- **Reliance on joint venture partners** At present, Galectin has signed one marketing and development partnership, with PROCAPS S.A. for chemotherapy applications in Colombia. In the future, Galectin may sign additional marketing and/or development partnerships for other jurisdictions or pipeline products. Partnerships and joint ventures bring certain risks that are not present in internal operations, however, such as potential delays, company disagreements, or unforeseen financial difficulties at the partnering entity.
- Need to defend patents and other intellectual property At December 31, 2011, Galectin held six patents in the US and three international patents, with additional patents pending in the US as well as in foreign jurisdictions including Europe, Canada, Latin America and Asia. The Company may need to defend its patents in the US and overseas in the future, particularly if one or more products receive regulatory approval and are successfully marketed.
- Need to raise additional capital Currently, Galectin has enough cash on hand to fund ongoing research and marketing development programs into calendar 2014, approximately. However, the Company does not have a history of profitable operations and unforeseen events including potential delays in regulatory approvals and/or product launches could require Galectin to raise additional capital through the sale of equity within a shorter time-frame, therefore potentially diluting current shareholders.
- **Limited stock liquidity** Trading volume in Galectin stock is comparatively light at an average of approximately 40,000 shares per day. As such, news regarding Galectin, its target market, and/or competitors could lead to significant volatility in the stock price.



# Galectin Therapeutics, Inc. Consolidated Statements of Income (in \$000s, except EPS)

Robert M. Wasserman

FYE December	2009A	2010A	2011A	<u>2012E</u>	<u>2013E</u>	2014E	2015E
Revenues	I				Ĩ		
Product revenues - US	\$0	\$0	\$0	\$0	\$0	\$0	\$15,000
Product revenues - International	0	0	0	1,000	2,000	4,000	8,000
License fees, royalties & other	0	<u>0</u>	<u>o</u>	2,500	5,000	10,000	20,000
Total revenues	0	0	0	3,500	7,000	14,000	43,000
Cost of goods sold				<u>250</u>	<u>500</u>	1,000	5,750
Gross profit				3,250	6,500	13,000	37,250
Expenses							
Research and development	1,110	1,066	3,552	4,000	5,000	6,250	7,813
General and administrative	4,983	3,817	6,857	7,500	9,375	11,719	14,648
One-time and other	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>
Total operating expenses	6,093	4,883	10,409	11,500	14,375	17,969	22,461
Loss from operations	(6,093)	(4,883)	(10,409)	(8,250)	(7,875)	(4,969)	14,789
Interest income	3	6	18	50	50	50	50
Interest expense	0	0	0	0	0	0	0
Other expense, net	(1,372)	(752)	(524)	(500)	(500)	(500)	(500)
Net income (loss) before taxes	(7,462)	(5,629)	(10,915)	(8,700)	(8,325)	(5,419)	14,339
Income taxes	<u>O</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	0	5,740
Net income (loss)	(7,462)	(5,629)	(10,915)	(8,700)	(8,325)	(5,419)	8,599
Preferred stock dividends and accretion	(1,957)	(3,080)	(1,798)	(1,500)	(1,500)	(1,500)	(1,500)
Net loss applicable to common stockholders	(9,419)	(8,709)	(12,713)	(10,200)	(9,825)	(6,919)	7,099
Basic and diluted income (loss) per share	(\$1.17)	(\$0.93)	(\$1.06)	(\$0.68)	(\$0.62)	(\$0.33)	\$0.28
Basic and diluted shares outstanding	8,046	9,384	11,986	15,100	15,800	20,800	25,800
Key ratios:							
Revenue growth					100.0%	100.0%	207.1%
Gross Margin				75.0%	75.0%	75.0%	75.0%
R&D/revenues				114.3%	71.4%	44.6%	18.2%
General & admin/revenues				214.3%	133.9%	83.7%	34.1%
Tax Rate				N/A	N/A	N/A	40.0%
Cash Flow/share	(\$0.72)	(\$0.39)	(\$0.59)	(\$0.32)	(\$0.29)	(\$0.08)	\$0.70

	Balance Sl	<u>ieets</u>	Investor Catalyst Timeline		
	(\$000s)		<u>2010</u> <u>2011</u>	2012E	2013E
Assets:	12/31/11	3/31/12			
Cash and equivalents	\$6,397	\$15,314	Cancer Therapy		
Grant receivable	0	0	International - Colombia - Colorectal		
Prepaid expenses & other assets	<u>104</u>	115	Submission of regulatory approval Q4/11		
Total current	6,501	15,429			
Property & equip., net	6	5	<u>General</u>		
Restricted cash	69	69	Global Conference on Galectins in Disease &	Q3/12	
Intangible assets and other	<u>36</u>	35	Therapy		
TOTAL ASSETS	\$6,612	\$15,538			
Liabilities:			Liver fibrosis		
Accounts payable	\$384	\$669	<u>GM-CT-01</u>		
Accrued expenses	1,551	1,266	FDA IND filed for NASH	Q4/12	
Deferred revenue	200	200	Initiate Phase I NASH Trial		Q1/13
Accrued dividends payable	80	0	Results for Phase I NASH Trial		Q4/13
Total current	2,215	2,135	Initiate Phase II NASH Trial		Q4/13
Other long-term liabilities	0	0			
Preferred stock	6,522	6,579	Tumor Immunology Program (Melanoma)		
Stockholders' equity (deficiency)	(2,125)	6,824	Phase I/II trial initiated	Q2/12	
TOTAL LIAB & EQ	\$6,612	\$15,538	Top-line results released		Q1/13

Source: Dawson James Securities, Inc. estimates; Company documents



#### **Important Disclosures:**

### **Price Chart:**



<u>Price target and ratings changes over the past 3 years:</u>
Initiated – September 6, 2011 – Buy – Price Target \$4.00 (Split adjusted: \$24.00)
Price Target Lowered to \$3.00 – July 6, 2012

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- 1) **Buy**: the analyst believes the price of the stock will appreciate and produce a total return of at least 20% over the next 12-18 months;
- 2) **Neutra**l: the analyst believes the price of the stock is fairly valued for the next 12-18 months;
- 3) **Sel**I: the analyst believes the price of the stock will decline by at least 20% over the next 12-18 months and should be sold.

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	Company Co	overage	Investment Banking		
Ratings	# of	% of	# of	% of	
Distribution	Companies	Total	Companies	Totals	
Buy	18	67%	8	44%	
Neutral	8	30%	5	63%	
Sell	1	4%	0	0%	
Total	27	100%	13	48%	

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