

# INSTITUTIONAL RESEARCH

# Healthcare & Biotechnology COMPANY UPDATE

Estimates

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F2011E F2012E

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

**BUY** 

**Targeting Hot Liver Disorder Area** 

Galectin Therapeutics is developing liver fibrosis and cancer therapeutics

### **Investment Highlights**

- 1) Galectin Therapeutics (Galectin) provided a progress update earlier this month in coordination with the release of their third quarter 2011 earnings results. The Company made significant clinical progress during the recently completed third quarter, specifically: 1) Submitting and having accepted an abstract analyzing Galectin's pre-clinical data on treating fatty liver disease and fibrosis, to be presented next month at the European Association for the Study of the Liver (EASL) in Portugal; and 2) Finalizing a collaboration, supply, marketing and distribution agreement with partner PROCAPS S.A. for the use of GM-CT-01 in metastatic colorectal cancer in Colombia. Subsequent to the quarter end in early November, Galectin further advanced its liver fibrosis clinical program with the establishment of a Liver Fibrosis Clinical Trial Advisory Board, consisting of five US-based key opinion leaders.
- 2) The Company also reported financial results for Q3/2011 earlier this month, including a net loss of \$2.3 million or (\$0.03) per share. Major expenses in the quarter included \$655,000 for R&D, up from \$313,000 in the prior year period, \$1.4 million in general and administrative expense, an increase over \$900,000 spent in Q3/2010, and \$311,000 in preferred stock dividends and accretion costs, which was less than the \$790,000 recorded in Q3/2010. We estimate that net cash burn for Galectin during the third quarter was approximately \$1.3 million, which was nearly offset by net proceeds from the exercise of stock options and warrants during the quarter. Thus, Galectin retained \$7.9 million in cash and equivalents at the end of September, or approximately six quarters (1.5 years) worth of operating funding at current levels of cash burn, enough to last through the first quarter of 2013.
- 3) In addition to the clinical progress achieved in the last quarter, investors have a lot to look forward to from Galectin in the near future as well. First, in the Company's **tumor immunology program**,

Current Price \$0.78
Price Target \$4.00

Revenues(\$000s) EPS	\$0 (\$0.15)	\$0 (\$0.16)	\$9,000 (\$0.07)		
Stock Data					
52-Week Range Shares Outstanding (mil.)		\$0	\$0.63-\$1.57 77.1		

F2010A

Market Capitalization (mil.) \$60.1 Enterprise Value (mil.) \$52.1 Debt to Capital (9/11) 0.0% Book Value/Share (9/11) \$0.01 Price/Book N/A x Average Trading Volume (3-Month) 80,000 Insider Ownership Institutional Ownership 0.1% 240,000 Short interest Dividend / Yield \$0.00/0.0%



<u>Price target and ratings changes over the past 3 yrs:</u> Initiated - September 6, 2011 - Buy -Price Target \$4.00



Galectin expects their clinical partners (The Ludwig Institute and the Universitaires Saint-Luc in Brussels) to begin a Phase I/II trial in late 2011 or early 2012, with top-line results on the first stage of this trial using GM-CT-01 in metastatic melanoma patients available as early as Q4/2012. Second, the Company's partner PROCAPS is targeting Q2/2012 for final approval in **Colombia** for GM-CT-01 in combination with 5-FU for the treatment of metastatic colorectal cancer, with potential product launch to occur later in 2012, as well as potential regulatory filings in additional countries in South and Central America this year. Finally, Galectin is on track to advance its **Liver Fibrosis clinical program** in 2012, starting off with completion of pre-clinical assessment, and followed by initiation of Phase II trials for GM-CT-01 and Phase I and Phase II trials for GR-MD-02. (See Page 4 for a more complete Clinical Program timeline).

**4**) Going forward, we are projecting that Galectin will incur a net loss of \$2.5 million or (\$0.03) per share in Q4/2011 (due out early next year), similar to the financial results from the third quarter, making a net loss of \$11.5 million or (\$0.16) per share for the 2011 year as a whole. Next year, we anticipate that initial license fees, royalties and product sales from international partnerships totaling \$9.0 million will help reduce net losses for Galectin to \$6.0 million, or (\$0.07) per share in 2012E.

#### Conclusion/Stock Valuation

Galectin has experienced management, a strong balance sheet, a solid track record of tight cost control and close monitoring of operating cash outflows, and most importantly a deep clinical pipeline with several programs targeting major medical indications (including the currently "hot" liver disorder area) with near-term potential catalysts looming as well. Thus, we are maintaining our BUY rating on GALT shares and 18-24 month price target of \$4.00 per share, based on projected revenues of \$250 million in 2015E, multiplied by a price/revenues multiple of 4.0X and discounted by a 40% annual rate to reflect regulatory and marketing risks. (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, 2010, Galectin held five patents in the US 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 2013, 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 80,000 shares per day. As such, news regarding Galectin, its target market, and/or competitors could lead to significant volatility in the stock price. In addition, GALT shares currently trade on the Nasdaq Over-the-Counter Bulletin Board, and there can be no assurance that these shares will be able to move up to a larger, more active exchange in the future.

2012E

2013E

2011E



FYE December

Preferred stock

TOTAL LIAB & EQ

Stockholders' equity (deficiency)

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

2010A

2009A

Robert M. Wasserman

2015E

2014E

		1	l I		1	1 1	1 1	1 1
Revenues LIS		\$0	\$0	\$0	\$0	\$0	\$0	\$85,000
Product revenues - US Product revenues - International		0	0	0	4.000	7,000	48,000	140,000
							,	2.5
License fees, royalties & other		<u>0</u> 0	<u>0</u> 0	<u>0</u> 0	5,000	<u>5,000</u>	10,000	25,000
Total revenues		0	0	U	9,000	12,000	58,000	250,000
Cost of goods sold					1,000	1,750	12,000	<u>56,250</u>
Gross profit					8,000	10,250	46,000	193,750
Expenses				2.500	4.500	0.000	40.000	24,000
Research and development		1,110	1,066	3,500	4,500	9,000	18,000	36,000
General and administrative		4,983	3,817	5,750	7,500	15,000	30,000	60,000
One-time and other		0	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	0	<u>0</u>
Total operating expenses		6,093	4,883	9,250	12,000	24,000	48,000	<u>96,000</u>
Loss from operations		(6,093)	(4,883)	(9,250)	(4,000)	(13,750)	(2,000)	97,750
Interest income		3	6	20	50	50	50	50
Interest expense		0	0	0	0	0	0	0
Other expense, net		(1,372)	(752)	(520)	(500)	(500)	(500)	(500)
Net income (loss) before taxes		(7,462)	(5,629)	(9,750)	(4,450)	(14,200)	(2,450)	97,300
Income taxes		<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	0	38,920
Net income (loss)		(7,462)	(5,629)	(9,750)	(4,450)	(14,200)	(2,450)	58,380
Preferred stock dividends and accretion		(1,957)	(3,080)	(1,750)	(1,500)	(1,500)	(1,500)	(1,500)
Net loss applicable to common stockhold	ers	(9,419)	(8,709)	(11,500)	(5,950)	(15,700)	(3,950)	56,880
Basic and diluted income (loss) per share		(\$0.20)	(\$0.15)	(\$0.16)	(\$0.07)	(\$0.17)	(\$0.04)	\$0.57
Basic and diluted shares outstanding		48,274	56,301	72,000	85,000	90,000	95,000	100,000
Key ratios:								
Revenue growth						33.3%	383.3%	331.0%
Gross Margin					75.0%	75.0%	75.0%	75.0%
R&D/revenues					50.0%	75.0%	31.0%	14.4%
General & admin/revenues					83.3%	125.0%	51.7%	24.0%
Tax Rate					N/A	N/A	N/A	40.0%
Cash Flow/share		(\$0.12)	(\$0.06)	(\$0.09)	(\$0.01)	(\$0.12)	\$0.01	\$1.01
		l		10 0 0000	75 117500 1 150		1	l I
	Balance Sheets			Investor Cata	lyst Timeline	272 0000		and a training
	(\$000s)					<u>2010</u>	2011E	2012E
Assets:	12/31/10							
Cash and equivalents	\$5,891	\$7,944		Cancer Thera				
Grant receivable	234	0			- Colombia - Co			
Prepaid expenses & other assets	<u>70</u>	<u>51</u>		Submission of	of regulatory app	proval	Q4/11	
Total current	6,195	7,995		Marketing ap	proval			Q2/12
Property & equip., net	7	7						
Restricted cash	59	64		US - GM-CT-	<u>01</u>			
Intangible assets and other	<u>39</u>	<u>37</u>		Phase III prof	tocol approval	Q4/10		
TOTAL ASSETS	\$6,300	\$8,103		Phase III trial	l initiated			Mid-2012
Liabilities:								
Accounts payable	\$125	\$198		Liver fibrosi	<u>s</u>			
Accrued expenses & other	585	417		GM-CT-01				
Deferred revenue	200	200		Pre-IND mee	eting			Q2/12
Warrant liabilities &other	861	0		Submit IND				Q3/12
Total current	1,771	815		Initiate Phase	e II			Q4/12
Other long-term liabilities	12	0						
Draforrad stook	6 211	6.165		CM MD 02				

Phase I/II trial initiated

Tumor Immunology Program

Q4/11orQ1/12 Top-line results released

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

6,211

(1,694)

\$6,300

6,465

\$8,103

823

GM-MD-02

Submit IND

Initiate Phase I

Initiate Phase II

Pre-IND meeting

Q2/12

Q3/12

Q4/12

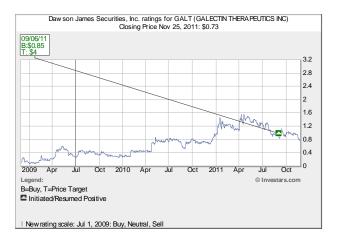
Q4/12

Q4/12



#### **Important Disclosures:**

#### **Price Chart:**



Price target and ratings changes over the past 3 years: Initiated – September 6, 2011 – Buy – Price Target \$4.00

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	Company Co	verage	Investment Banking		
Ratings Distribution	# of Companies	% of Total	# of Companies	% of Totals	
Buy	27	84%	8	30%	
Neutral	4	13%	3	75%	
Sell	1	3%	0	0%	
Total	32	100%	11	34%	

Information about valuation methods and risks can be found in the "STOCK VALUATION" and "RISKS" sections of this report.

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