

Galectin Therapeutics Reports First Quarter 2014 Financial Results

NORCROSS, Ga., May 13, 2014 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today reported its financial results for the quarter ended March 31, 2014. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the Securities and Exchange Commission.

"We continued to make significant progress in our liver fibrosis development program through the first quarter of 2014. We announced the successful results of the first cohort of patients in our Phase 1 clinical trial for patients with NASH with advanced fibrosis, which demonstrated that GR-MD-02 was safe and well tolerated. Additionally, the results demonstrated positive changes in biomarkers, suggesting a therapeutic effect on fibrosis. More recently, we announced on April 23, 2014, that we have completed the enrollment of all of the required patients in cohort 2 of this Phase 1 clinical trial, and we expect to announce the results around the end of July 2014," said Peter G. Traber, M.D., Chief Executive Officer, President and Chief Medical Officer, Galectin Therapeutics. "This Phase 1 first-in-man study is evaluating the safety, tolerability, pharmacokinetics and exploratory biomarkers for efficacy for single and multiple doses of GR-MD-02 when administered to patients with fatty liver disease with advanced fibrosis."

The company also has an active cancer development program using its galectin-3 inhibitor GR-MD-02 in cancer immunotherapy of advanced melanoma. In collaboration with Providence Portland Medical Center, an investigator sponsored Phase 1 clinical trial has been initiated to evaluate the combination of Bristol-Myers Squibb's Yervoy® (ipilimumab) and GR-MD-02 in patients with metastatic melanoma. This trial is based on pre-clinical data obtained in collaboration with Dr. Will Redmond at the center which demonstrated that the combination of immune checkpoint inhibitors like ipilimumab with GR-MD-02 enhances the antitumor effect in syngeneic mouse cancer models. This trial is listed on clinicaltrials.gov (http://www.clinicaltrials.gov/ct2/show/NCT02117362?term=NCT02117362&rank=1) and is actively recruiting patients.

At March 31, 2014, the Company had \$36.6 million of non-restricted cash and cash equivalents which it believes will be sufficient to fund currently planned future operations, research and development through 2015.

For the quarter ended March 31, 2014, the Company reported a net loss applicable to common stock of \$5.4 million, or (\$0.27) per share, basic and diluted, compared with a net loss applicable to common stock of \$3.5 million or (\$0.22) per share, basic and diluted, for quarter ended March 31, 2013. The increase in net loss applicable to common stock in the quarter ended March 31, 2013 is primarily due to an increase in pre-clinical and clinical development expenses and an increase in non-cash stock-based compensation expense.

Research and development expense for the first quarter of 2014 was \$2.8 million, compared with \$1.8 million for first quarter of 2013. The increase in research and development expense in the first quarter of 2014 over 2013 primarily relates to increased costs for our Phase 1 clinical trial and pre-clinical activities associated with preparations for a Phase 2 clinical trial.

General and administrative expense for the first quarter of 2014 was \$2.1 million, compared with \$1.5 million for the first quarter of 2013. The primary reasons for the increase were non-cash stock-based compensation and legal expense.

About Galectin Therapeutics

Galectin Therapeutics (Nasdaq:GALT) is developing promising carbohydrate-based therapies for the treatment of fibrotic liver disease and cancer based on the Company's unique understanding of galectin proteins, key mediators of biologic function. We are leveraging extensive scientific and development expertise as well as established relationships with external sources to achieve cost effective and efficient development. We are pursuing a clear development pathway to clinical enhancement and commercialization for our lead compounds in liver fibrosis and cancer. Additional information is available at www.galectintherapeutics.com.

Forward-Looking Statements

This press release contains, in addition to historical information, forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future financial performance, and use words such as "may," "estimate," "could," "expect" and others. They are based on our current expectations and are subject to factors and uncertainties which could cause actual results to differ materially from those described in the statements. These statements include those regarding our plans, expectations and goals regarding clinical trials, including our expectation that

clinical data from the second cohort should be available in July-August 2014, plans regarding a Phase 2 clinical trial, potential benefits and therapeutic effects of GR-MD-02 in liver fibrosis or cancer, and plans regarding future funding alternatives and the sufficiency of cash on hand to fund future operations and planned research and development through 2015. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that our plans, expectations and goals regarding any clinical trial or any future trials are subject to factors beyond our control and there is no guarantee that we will avoid delays in the development of our drug products or receive FDA approval for any of our drugs in development. Any current clinical trials and any future trials may not produce positive results in a timely fashion, if at all, and any necessary changes during the course of a trial could prove time consuming and costly. We may have difficulty in enrolling candidates for testing, which would impact our estimates regarding timing, and we may not be able to achieve the desired results. Upon receipt of FDA approval, we may face competition with other drugs and treatments that are currently approved or those that are currently in development, which could have an adverse impact on our ability to achieve revenues from any proposed indications. Plans regarding development, approval and marketing of any of our drugs, including GR-MD-02, are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies, and any changes to our plans could materially impact our cash on hand and our projections regarding liquidity and sufficiency of cash on hand. To date, we have incurred operating losses since our inception, and our ability to successfully develop and market drugs may be impacted by our ability to manage costs and finance our continuing operations. For a discussion of additional factors impacting our business, see our Annual Report on Form 10-K for the year ended December 31, 2013, and our subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause our views to change, we disclaim any obligation to update forward-looking statements.

Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc.

	Quarter Ended March 31,	
	2014	2013
	(in thousands, except per share data)	
Operating expenses:		
Research and development	\$2,722	\$1,752
General and administrative	2,072	1,456
Total operating expenses	4,844	3,208
Total operating loss	(4,844)	(3,208)
Other income (expense):		
Interest and other	4	5
Loss from equity method investment	(270)	
Total other income (expense)	(266)	5
Net loss	\$ (5,110)	\$ (3,203)
Preferred stock dividends and accretion costs	(298)	(269)
Net loss applicable to common stock	\$ (5,408)	\$ (3,472)
Basic and diluted net loss per share	\$ (0.27)	\$ (0.22)
Shares used in computing basic and diluted net loss per share	20,270	16,079

Condensed Consolidated Statements of Operations

Condensed Consolidated Balance Sheet Data

	March 31, 2014 De	<u>March 31, 2014</u> <u>December 31, 2013</u> (in thousands)	
	(in thous		
Cash and cash equivalents	\$ 36,594	\$ 10,489	
Total assets	36,899	10,713	
Total current liabilities	1,937	2,486	

Total liabilities	1,937	2,486
Total redeemable, convertible preferred stock	6,696	6,746
Total stockholders' equity	\$ 28,266	\$ 1,481

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