March 18, 2015

Galectin Therapeutics Reports 2014 Financial Results, Provides Business Update

NORCROSS, Ga., March 18, 2015 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (Nasdaq:GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today reported financial results for the year ended December 31, 2014. These results are included in the Company's Annual Report on Form 10-K, which has been filed with the U.S. Securities and Exchange Commission.

"I am pleased with our many accomplishments during 2014 as we continue to advance programs with GR-MD-02 for the treatment of nonalcoholic steatohepatitis (NASH) with advanced fibrosis. We completed a successful Phase 1 clinical trial and announced final data in January 2015 that were supportive of our plans to begin a Phase 2 program with GR-MD-02 in advanced fatty liver disease, or NASH with fibrosis and cirrhosis," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "As announced last month, we submitted the Phase 2 clinical trial protocol to the U.S. Food and Drug Administration (FDA) to evaluate the safety and efficacy of GR-MD-02 for the treatment of liver fibrosis and resultant portal hypertension in patients with NASH cirrhosis, the primary endpoint being to determine the change in the hepatic venous pressure gradient (HVPG) as compared with placebo. The FDA has indicated that HVPG may serve as a surrogate primary endpoint for NASH cirrhosis. We submitted a request for a Special Protocol Assessment with the clinical protocol for this trial. Additionally, we are planning to conduct a separate, shorter Phase 2 trial in NASH patients with advanced fibrosis. We expect to begin enrolling patients in both trials during the second quarter of 2015."

Dr. Traber continued, "We are also supporting independent research with GR-MD-02 in combination with two commercial melanoma drugs, as preclinical research has shown our compound enhances the efficacy of immune checkpoint blockade therapies. Currently GR-MD-02 is in a Phase 1b study in combination with Yervoy®, and a Phase 1b study in combination with Keytruda® is expected to be initiated in the second quarter of 2015. Preclinical work in mouse cancer models with GR-MD-02 added to checkpoint inhibitors shows a boost in anti-tumor immunity, a reduction in tumor size and increased survival.

"We have an exciting year ahead of us, and we look forward to advancing GR-MD-02 through various clinical trials with the goal of providing a new treatment to the nearly 28 million Americans afflicted with NASH, of which up to 6 million have advanced fibrosis," Dr. Traber concluded.

For the year ended December 31, 2014, the Company reported a net loss applicable to common stockholders of $17.0 million, or ($0.78) per share, compared with a net loss applicable to common stockholders of $21.9 million, or ($1.30) per share, for 2013. The decrease in net loss applicable to common stockholders is largely due to an $8.8 million or ($0.53) per share one-time, non-cash charge related to the modification of certain warrants recorded in the second quarter of 2013 and an unrelated one-time, non-cash stock compensation charge of $1.0 million or ($0.06) per share recorded in the third quarter of 2013, which were partially offset by increased research and development expenses primarily related to our clinical program.

Research and development expense for the 2014 was $8.4 million, compared with $5.7 million for 2013. The increase primarily relates to increased costs for our Phase 1 clinical trial, which was completed in 2013, and increases in preclinical and drug manufacturing costs, and in planning activities in preparation for our Phase 2 clinical program.

General and administrative expense for 2014 was $7.0 million, compared with $6.4 million for 2013. The primary reasons for the increase were related to increased legal and insurance expense.

As of December 31, 2014, the Company had $29.1 million of non-restricted cash and cash equivalents available to fund future operations. In January and February of 2015, the Company received $4.1 million in net proceeds from the issuance of common shares through its At-the-Market stock issuance program. The Company believes that cash on hand of $29.7 million as of March 13, 2015, is sufficient to fund its operations and research and development activities through September 30, 2016.

About Galectin Therapeutics

Galectin Therapeutics 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, which are key mediators of biologic function. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. The Company is pursuing a development pathway to clinical enhancement and commercialization for its lead compounds in liver fibrosis and cancer. Additional information is available at www.galectintherapeutics.com.

Forward Looking Statements

This press release contains 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 management's current expectations and are subject to factors and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include those regarding the hope that Galectin's development program for GR-MD-02 will lead to the first therapy for the treatment of fatty liver disease with cirrhosis. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of GR-MD-02 or any of its other drugs in development. The Company's current clinical trial and any future clinical studies may not produce positive results in a timely fashion, if at all, and could prove time consuming and costly. Plans regarding development, approval and marketing of any of Galectin's drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies. There is no certainty that FDA and Company will agree on a SPA or that a SPA would ultimately be acceptable to FDA nor result in approval of GR-MD-02. Regardless of the results of any of its development programs, Galectin may be unsuccessful in developing partnerships with other companies or raising additional capital that would allow it to further develop and/or fund any studies or trials. Galectin has incurred operating losses since inception, and its ability to successfully develop and market drugs may be impacted by its ability to manage costs and finance continuing operations. For a discussion of additional factors impacting Galectin's business, see the Company's Annual Report on Form 10-K for the year ended December 31, 2014, and subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

Condensed Consolidated Statements of Operations

	Year Ended December 31,	
	2014	**2013**
	(in thousands, except per share data)	
Operating expenses:		
Research and development	$ 8,425	$ 5,688
General and administrative	7,005	6,416
Total operating expenses	15,430	12,104
Total operating loss	(15,430)	(12,104)
Other income:		
Interest and other	(358)	16
Total other income	(358)	16
Net loss	$(15,788)	$(12,088)
Preferred stock dividends and accretion costs	(1,172)	(1,096)
Modification of warrants	--	(8,763)
Net loss applicable to common stock	$(16,960)	$(21,947)
Basic and diluted net loss per share	$ (0.78)	$ (1.30)
Shares used in computing basic and diluted net loss per share	21,849	16,874

Condensed Consolidated Balance Sheet Data

	December 31, 2014	December 31, 2013
	(in thousands)	
Cash and cash equivalents	$29,128	$10,489

Total assets	29,677	10,713
Total current liabilities	1,703	2,486
Total liabilities	1,703	2,486
Total redeemable, convertible preferred stock	6,779	6,746
Total stockholders' equity	$21,195	$1,481

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