

May 11, 2015

Galectin Therapeutics Reports First Quarter 2015 Financial Results, Provides Business Update Including Phase 2 NASH Program

NORCROSS, Ga., May 11, 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 three months ended March 31, 2015. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the U.S. Securities and Exchange Commission.

Management commentary

"We made excellent progress during the quarter and recent weeks toward the imminent commencement of our Phase 2 program with GR-MD-02 for the treatment of nonalcoholic steatohepatitis (NASH) with advanced fibrosis and cirrhosis," said Peter G. Traber, M.D., president and chief executive officer. "As previously announced, our Phase 2 program consists of studies in two different NASH fibrosis indications, the NASH-CX trial in patients with NASH cirrhosis and the NASH-FX trial in NASH patients with advanced fibrosis, but not cirrhosis. Following communication with the U.S. Food and Drug Administration (FDA) we have a clear design for our program and understanding of the Agency's current view of the regulatory pathway to bring a new treatment to patients with NASH cirrhosis.

"The NASH-CX trial will enroll 156 patients with NASH cirrhosis and will evaluate 2 mg/kg of GR-MD-02 and 8 mg/kg of GR-MD-02 and placebo, with patients randomized 1:1:1. In collaboration with our contract research organization, we have identified 45 study sites in North America, held an Investigator Meeting, obtained central institutional review board (IRB) approval, and are working to secure site IRB approvals and contracts necessary to begin enrolling subjects. The primary endpoint will be change in hepatic venous pressure gradient (HVPG) compared with placebo, and now secondary endpoints will include fibrosis stage on biopsy as well as the percent of collagen on biopsy at one year of treatment. Correlation of HVPG with liver biopsy will continue to be studied, as planned. Additionally, the HVPG and liver biopsy measurements will be correlated with non-invasive measurements of liver fibrosis and function including FibroScan and ¹³C-methacetin breath test. We expect to screen the first patients by the end of the second quarter of 2015, with top-line data readout at the end of 2017. We submitted a special protocol assessment (SPA) with the FDA and received very useful feedback for the design of the study and the overall development program. At this time, and in order to move forward as quickly as possible and to take advantage of the myriad preparations in place, we have decided to proceed with the trial as a Phase 2 program, rather than resubmit the SPA to attempt to obtain designation as a Phase 3 trial currently."

Dr. Traber continued, "The NASH-FX study will be a shorter, four-month trial in 30 NASH patients with advanced fibrosis, but not cirrhosis, randomized 1:1 to either 8 mg/kg of GR-MD-02 or placebo." This study is entitled "Phase 2 Study to Evaluate Non-Invasive Imaging Methods in Efficacy Assessment of GR-MD-02 for the Treatment of Liver Fibrosis in Patients With NASH With Advanced Fibrosis," and details can be found [here](#).

"The non-invasive assessments included in this trial include LiverMultiScan (a multi-parametric nuclear magnetic resonance imaging method developed by Perspectum Diagnostics™) as the primary endpoint compared with magnetic resonance elastography and FibroScan as secondary endpoints. This study is expected to begin enrolling patients in July 2015, and will be performed at Brooke Army Medical Center in Fort Sam Houston in Texas, with top-line data readout in the second half of 2016."

He added, "Our Phase 2 program is supported by data generated with GR-MD-02 in our Phase1b study along with preclinical work. During the first quarter I had the privilege of presenting both our human and preclinical data at the American Association for the Study of Liver Diseases Industry Colloquium. There was a major focus on NASH at the Colloquium, as nearly 28 million Americans are afflicted with NASH, including up to 6 million with advanced fibrosis and a very poor prognosis. Thus there is keen interest from the medical community on drugs that can both halt and reverse fibrosis and cirrhosis."

Dr. Traber then stated, "In addition to the NASH fibrosis program, we have initiated an exploratory, open-label Phase 2a trial in patients with moderate-to-severe plaque psoriasis. This is based on the known increase in galectin-3 in the skin of psoriatic patients and a patient in the Phase 1 trial with psoriasis who had an apparent remission of psoriasis while receiving GR-MD-02. Determination of future development in this indication will depend on results of this exploratory study." Details of the trial can be found [here](#).

Dr. Traber concluded, "Immune checkpoint blockade therapies have generated a great deal of interest in recent years, as evidence grows for the efficacy of this approach in oncology, both in blood cancers and in solid tumors. We are excited to be

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 these therapies with this mechanism of action. A Phase 1b study with GR-MD-02 in combination with YERVOY® is ongoing, with successful completion of three patients in the first dosing group, and two patients enrolled in the second dosing group. Another, a Phase 1b study in combination with KEYTRUDA® is expected to be initiated in the coming months. 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, and we look forward to receiving human clinical data."

Financial Results

For the three months ended March 31, 2015, the Company reported a net loss applicable to common stockholders of \$5.1 million, or (\$0.22) per share, compared with a net loss applicable to common stockholders of \$5.4 million, or (\$0.27) per share, for three months ended March 31, 2014. The decrease in net loss applicable to common stockholders is largely due to a decrease in stock-based compensation expense of \$0.7 million partially offset by higher research and development expenses related to our clinical programs.

Research and development expense for the three months ended March 31, 2015, was \$3.1 million, compared with \$2.8 million for three months ended March 31, 2014. The increase primarily relates to increased costs related to preclinical and drug manufacturing costs and in planning activities in preparation for our Phase 2 clinical program.

General and administrative expense for the three months ended March 31, 2015 was \$1.7 million, compared with \$2.1 million for the three months ended March 31, 2014. The primary reason for the decrease was a reduction in stock-based compensation expense of \$0.4 million.

As of March 31, 2015, the Company had \$29.3 million of non-restricted cash and cash equivalents available to fund future operations. The Company believes that cash on hand as of March 31, 2015, is sufficient to fund its currently planned 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.

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(Tables to follow)

Condensed Consolidated Statements of Operations

	Three Months Ended	
	March 31,	
	2015	2014
	(in thousands, except per share data)	
Operating Expenses:		
Research and development	\$ 3,136	\$ 2,772
General and administrative	1,704	2,072
Total operating expenses	4,840	4,844
Total operating loss	(4,840)	(4,844)
Other Income (expense):		
Interest	14	4
Loss from equity method investment	--	(270)
Total other income (expense)	14	(266)
Net loss	\$ (4,826)	\$ (5,110)
Preferred stock dividends and accretion costs	(248)	(298)
Net loss applicable to common stock	\$ (5,074)	\$ (5,408)
Basic and diluted net loss per share	\$ (0.22)	\$ (0.27)
Shares used in computing basic and diluted net loss per share	23,062	20,270

Condensed Consolidated Balance Sheet Data

	March 31, 2015	December 31, 2014
	(in thousands)	
Cash and cash equivalents	\$ 29,349	\$ 29,128
Total assets	29,974	29,677
Total current liabilities	1,291	1,703
Total liabilities	1,291	1,703
Total redeemable, convertible preferred stock	6,836	6,779
Total stockholders' equity	\$ 21,847	\$ 21,195

CONTACT: Jack Callicutt, Chief Financial Officer

(678) 620-3186

ir@galectintherapeutics.com

LHA

Kim Golodetz

(212) 838-3777

kgolodetz@lhai.com



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