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Galectin Therapeutics Provides Phase 2 NASH Program Update and Reports Second Quarter 2015 Financial Results

NORCROSS, Ga., Aug. 10, 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 and six months ended June 30, 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

"The second quarter and recent weeks were very exciting for Galectin, and were highlighted by the commencement of our Phase 2 program with GR-MD-02 for the treatment of nonalcoholic steatohepatitis (NASH) with advanced fibrosis and cirrhosis," said Jim C. Czirr, executive chairman. "As anticipated, in June we began screening patients for the NASH-CX trial, which will ultimately enroll 156 patients with NASH cirrhosis and will evaluate 8 mg/kg of GR-MD-02 and 2 mg/kg of GR-MD-02 and placebo, with patients randomized 1:1:1."

Peter G. Traber, M.D., president, chief executive officer, and chief medical officer said, "Although it is very early in the study, we are pleased with our progress and continue to expect top-line data readout by the end of 2017. The primary endpoint for this trial is change in hepatic venous pressure gradient (HVPG) compared with placebo, with secondary endpoints of fibrosis stage on biopsy as well as the percent of collagen on biopsy at one year of treatment. Additionally, the HVPG and liver biopsy measurements will be correlated with non-invasive measurements of liver fibrosis and function using FibroScan and ¹³C-methacetin breath test, respectively."

Dr. Traber added, "We are also preparing to begin a second trial in NASH fibrosis, our NASH-FX study, and expect to begin enrolling patients during the third quarter. As previously discussed, that study will be a four-month treatment trial in 30 NASH patients with advanced fibrosis (stage 3), but not cirrhosis, randomized 1:1 to either 8 mg/kg of GR-MD-02 or placebo. The primary goal of this study is to evaluate the efficacy of GR-MD-02 treatment by assessing the change in inflammation/fibrosis as assessed by a proprietary magnetic resonance imaging test called LiverMultiScan; the study is powered at 80% to detect a 20% difference in this measurement. The secondary goal is to compare the primary endpoint of LiverMultiScan with two secondary endpoints which are non-invasive measures of liver stiffness that correlate with fibrosis, magnetic resonance elastography and FibroScan. We expect data readout from the NASH-FX trial by the end of 2016."

LiverMultiScan is a multi-parametric nuclear magnetic resonance imaging method developed by Perspectum Diagnostics™.

Galectin notes that during the second quarter it released positive results of a drug-drug interaction study between GR-MD-02 and midazolam, a commonly used sedative, in which there was no interaction observed. "This suggests an additional layer of safety for GR-MD-02, while broadening the potential patient population for inclusion in our Phase 2 program. We are pleased with our overall progress thus far as we work to provide a drug for up to 6 million people in the U.S. with NASH, and advanced fibrosis and cirrhosis, a leading cause of liver transplants," Dr. Traber stated.

"We also expect to begin screening patients with moderate-to-severe plaque psoriasis in a proof-of-concept open-label Phase 2a trial with GR-MD-02, treating 10 patients with a dosing regimen of 8mg/kg every 2 weeks over 90 days. This study rationale is based on the known increase in galectin-3 in the skin of psoriasis patients and a subject in the Phase 1 GR-MD-02 NASH trial with psoriasis who had an apparent remission of psoriasis while receiving 4 mg/kg of the study drug. Determination of future development in this indication will depend on the results of this exploratory study."

Dr. Traber continued, "Last week, Galectin began an expansion of its initiative to communicate with investors and other interested parties with the commencement of a blog on our website, entitled *CEO Perspectives*. Our goal is to provide a forum through which we may help investors and members of the public understand our programs and answer questions that we routinely receive. I am enthusiastic about this opportunity to discuss the exciting activities not only at Galectin in NASH, but also in the study of other fibrotic and immunogenic diseases where our compounds might be tested. We will be posting to the blog on a regular basis."

Financial Results

For the three months ended June 30, 2015, the Company reported a net loss applicable to common stockholders of \$4.9 million, or (\$0.21) per share, compared with a net loss applicable to common stockholders of \$3.7 million, or (\$0.17) per share,

for three months ended June 30, 2014. The increase in net loss applicable to common stockholders is largely due to higher research and development expenses related to its clinical programs.

Research and development expense for the three months ended June 30, 2015 was \$2.6 million, compared with \$1.6 million for three months ended June 30, 2014. The increase is primarily due to increased costs related its recently initiated Phase 2 clinical program.

General and administrative expense for the three months ended June 30, 2015 was \$2.1 million, compared with \$1.8 million for the three months ended June 30, 2014. The primary reason for the increase related to timing of certain expenses in the three months ended June 30, 2015 verses 2014.

As of June 30, 2015, the Company had \$26.4 million of non-restricted cash and cash equivalents available to fund future operations. The Company believes that its cash on hand as of June 30, 2015 is sufficient to fund 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. 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.

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

(Tables to follow)

Condensed Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Operating expenses:				
Research and development	\$ 2,600	\$ 1,594	\$ 5,736	\$ 4,366
General and administrative	2,057	1,781	3,761	3,853
Total operating expenses	4,657	3,375	9,497	8,219
Total operating loss	(4,657)	(3,375)	(9,497)	(8,219)

Other income (expense):				
Interest and other	14	13	28	17
Loss from equity method investment	--	(67)	--	(337)
Total other income (expense)	14	(54)	28	(320)
Net loss	\$(4,643)	\$(3,429)	\$(9,469)	\$(8,539)
Preferred stock dividends and accretion costs	(288)	(302)	(536)	(600)
Net loss applicable to common stock	\$(4,931)	\$(3,731)	\$(10,005)	\$(9,139)
Basic and diluted net loss per share	\$ (0.21)	\$ (0.17)	\$ (0.43)	\$ (0.42)
Shares used in computing basic and diluted net loss per share	23,731	21,983	23,398	21,570

Condensed Consolidated Balance Sheet Data

	June 30, December 31,	
	2015	2014
	(in thousands)	
Cash and cash equivalents	\$ 26,362	\$ 29,128
Total assets	26,679	29,677
Total current liabilities	1,908	1,703
Total liabilities	1,908	1,703
Total redeemable, convertible preferred stock	6,894	6,779
Total stockholders' equity	\$ 17,877	\$ 21,195

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