

Galectin Therapeutics Reports Second Quarter 2013 Financial Results

NORCROSS, Ga., Aug. 14, 2013 (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 second quarter and first six months ended June 30, 2013. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the Securities and Exchange Commission.

"During the second quarter, we continued preparing for our Phase 1 clinical trial of GR-MD-02 for patients with nonalcoholic steatohepatitis (NASH or fatty liver disease) with advanced fibrosis and in July, we successfully dosed the first patient. Additionally, we recently announced the FDA has granted Fast Track status for GR-MD-02 for NASH. The successful first patient dosing in the clinical trial of GR-MD-02 and Fast Track designation are critical milestones in Galectin's development program and there are currently no treatments for fatty liver disease with advanced fibrosis; these milestones take us closer to bringing a first-in-class treatment to the millions of Americans suffering from this silent epidemic," said Peter G. Traber, M.D., Chief Executive Officer, President and Chief Medical Officer, Galectin Therapeutics. "This first-in-man study will evaluate the safety, tolerability, 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, and we expect top line clinical results for Phase 1 sometime late in 2013 or early 2014."

At June 30, 2013, the Company had \$5.1 million of non-restricted cash and cash equivalents available to fund future operations. Subsequent to quarter end, the Company received \$2.4 million from the exercise of warrants. The Company believes that the cash on hand at quarter end and received subsequently is sufficient to fund operations and planned research and development through the first quarter of 2014. The Company is currently exploring and evaluating several alternatives for obtaining additional funding.

For the second quarter of 2013, the Company reported a net loss applicable to common stock of \$11.6 million, or (\$0.72) per share, basic and diluted, compared with a net loss applicable to common stock of \$3.0 million or (\$0.19) per share for the same period in 2012. The increase in net loss applicable to common stock is primarily due to an \$8.8 million or (\$0.54) per share one-time, non-cash charge related to the extension of the exercisable period of certain warrants. Research and development expense for the second quarter of 2013 was \$1.3 million, compared with \$1.2 million for the same period in 2012. The increase is due primarily to clinical program expenses related to the Phase I clinical trial. General and administrative expense for the second quarter of 2013 was \$1.2 million, compared with \$1.5 million for the same period in 2012. The primary reasons for the decrease are due to decreased stock-based compensation and rent, offset by increased legal expenses.

For the six months ended June 30, 2013, the Company reported a net loss applicable to common stock of \$15.1 million, or (\$0.94) per share, basic and diluted, compared with a net loss of \$5.2 million, or (\$0.36) per share for the same period in 2012. The increase in net loss applicable to common stock is primarily due to an \$8.8 million or (\$0.54) per share non-cash charge as disclosed above. Research and development expense for the six-months ended June 30, 2012 increased to \$3.1 million compared with \$2.1 million for the same period in 2012, due primarily to clinical program expenses related to the Phase I clinical trial. As we continue to enroll patients in the Phase I trial, we expect our clinical activities costs may increase and fluctuate from quarter to quarter as the trial progresses. General and administrative expense for the six-months ended June 30, 2013 increased to \$2.7 million compared with \$2.5 million for the same period in 2012, due primarily to increased legal expenses related to ongoing litigation with the Company's former CEO and investor relations expenses, offset by decreased rent expense due to our relocation to Georgia in October 2013.

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 the clinical trial, our Fast Track submission and the potential benefits of a Fast Track designation, and the sufficiency of cash on hand to fund future operations and planned research and development into the first guarter of 2014. 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 the clinical trial are subject to factors beyond our control and that the receipt of a Fast Track designation from FDA is no guarantee that we avoid delays in the development of our drug product and provide no assurance of FDA approval of our drug development plans. Our clinical trial may not produce positive results in a timely fashion, if at all, and any necessary changes during the course of the 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 this proposed indication. 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. 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, 2012, 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 trademark of Galectin Therapeutics Inc.

×

×

CONTACT: Jack Callicutt Chief Financial Officer 678-620-3186 ir@galectintherapeutics.com