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Galectin Therapeutics Reports First Quarter 2012 Financial Results

NEWTON, Mass.--(BUSINESS WIRE)--May. 11, 2012-- 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 first quarter, ended March 31, 2012. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the SEC.

"Galectin made important progress in its clinical programs as well as its operations in the first quarter. Notably, the preclinical development of Galectin's lead candidate for the treatment of fibrosis, GR-MD-02, continues on track and we expect to file an investigational new drug application with the US FDA by year end," said Peter G. Traber, M.D., Chief Executive Officer, President and Chief Medical Officer, Galectin Therapeutics. "Accordingly, we plan to initiate a Phase 1 clinical trial of GR-MD-02 in patients with NASH and fibrosis in early 2013 to assess safety and preliminary evidence of efficacy in humans with Phase 2 studies potentially beginning by the end of next year with expected top-line results by the end of 2014. The novel mechanism of GR-MD-02, in combination with compelling preclinical data, gives us great hope that this compound may ultimately meet the needs of these patients with this deadly disease that has no currently approved therapeutic options."

Traber continued, "As previously disclosed, the Company has refocused its pipeline of galectin inhibitors in cancer to reflect the highest likelihood of creating value in the near-term and is now developing GM-CT-01 in melanoma. This development strategy is based on compelling data demonstrating that GM-CT-01 can protect a patient's immune system from the "Galectin Effect"; whereby tumors secrete galectin proteins that block the body's efforts to fight tumors. We are collaborating with the Ludwig Institute, where the Galectin Effect was discovered, for a Phase 2 clinical evaluation of GM-CT-01 which is currently underway. We feel that melanoma is an ideal indication because it is an immunologically responsive tumor and there are newly approved therapies that we suspect will be synergistic with GM- CT-01."

"Our Colombian partner, PROCAPS, S.A., continues to attempt to gain approval of GM-CT-01 in Colombia. The Colombian effort originated after the Company was encouraged by a key oncologist at Colombia's National Cancer Institute, the government and a regional pharmaceutical company to seek approval for GM-CT-01 as an adjuvant to 5-FU, because the data that showed it may increase the efficacy of 5-FU and reduce its side effects. The time to receive a definitive answer regarding Colombian approval has clearly taken longer than we were originally led to believe. At this point, our corporate strategy for increasing the value of the Company is not dependent on approval in Colombia. We have not taken into account projections for revenues, so if this should be successful, it will all be upside. We currently take a guarded view of the prospects for an approval and hope to report more by the end of the second quarter."

"Finally, Galectin Therapeutics recently completed a fund raising and listing of our common stock on The NASDAQ Capital Market. Importantly, the proceeds from this offering are expected to provide us with the financial resources to fund our promising development programs through the end of 2013, including the initiation of Phase 2 trials of GR-MD-02. The listing on NADSDAQ should provide increased liquidity and access to Galectin stock," concluded Traber.

On March 28, 2012, the Company completed an underwritten public offering in which it sold 2,666,722 shares of common stock and related warrants for 1,333,361 shares of common stock for $12.0 million (net cash proceeds of $10.4 million). On March 23, 2012, the Company effected a one-for-six reverse split of its common stock and began trading on The NASDAQ Capital Market under the symbol GALT. At March 31, 2012, the Company had $15.3 million of non-restricted cash and cash equivalents available to fund future operations. The Company believes that with the funds on hand at March 31, 2012, there is sufficient cash to fund core operations and planned research and development through 2013.

For the first quarter of 2012, the Company reported a net loss applicable to common stock of $2.2 million, or ($0.17) per share, basic and diluted, compared with a net loss of $2.7 million, or ($0.24) per share for the same period in 2011. Included in the losses was $0.3 million in non-cash dividend and accretion expenses related to the preferred stock for both the 2012 and 2011 periods and a $0.4 million non-cash expense related to the change in fair value of warrant liabilities in 2011.

Research and development expense for the first quarter of 2012 was $0.9 million, compared with $0.7 million for the same period in 2011. The increase is due primarily to greater pre-clinical activity in our fibrosis program and our clinical program related to our GM and GR compounds offset by decreased stock-based compensation.

General and administrative expense for the first quarter of 2012 was $1.1 million, compared with $1.3 million for the same period in 2011. The decrease is due primarily to lower payroll costs, decreased business development costs related to our marketing efforts in South America and decreased legal and accounting costs, offset by increased stock-based compensation.

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. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others: incurrence of operating losses since our inception, uncertainty as to adequate financing of our operations, extensive and costly regulatory oversight that could restrict or prevent product commercialization, inability to achieve commercial product acceptance, inability to protect our intellectual property, dependence on strategic partnerships, product competition, and others stated in risk factors contained in our SEC filings. We cannot assure that we have identified all risks or that others may emerge which we do not anticipate. 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.

Source: Galectin Therapeutics Inc.

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