

Galectin Therapeutics Reports Third Quarter 2012 Financial Results

NORCROSS, Ga.--(BUSINESS WIRE)--Nov. 9, 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 the third quarter and first nine months ended September 30, 2012. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the SEC.

"We have continued to make progress with our primary candidate, GM-CT-01 in melanoma, part of our pipeline of galectin inhibitors in cancer," said Peter G. Traber, M.D., Chief Executive Officer, President and Chief Medical Officer, Galectin Therapeutics. "There is strong *in vitro* data that demonstrates that GM-CT-01 can protect immune cells from the 'Galectin Effect'; whereby tumors secrete galectin proteins that block the body's efforts to fight tumors. The trial, being conducted in collaboration with the Cancer Centre at the Cliniques Universitaires Saint-Luc and the Ludwig Institute for Cancer Research (LICR) in Brussels, is evaluating GM-CT-01 in combination with a Ludwig Institute peptide vaccine. In May, the first patient was dosed in a Phase 1/2 trial evaluating the safety and efficacy of GM-CT-01 in combination with a peptide tumor vaccine in metastatic melanoma. This trial is being conducted in two stages, and the results of the first stage will determine the timing and conduct of the second stage. We expect to have top-line clinical results for the first group of patients from the first stage of this trial in the second quarter of 2013."

"The preclinical development of Galectin's lead candidate for the treatment of liver fibrosis, GR-MD-02, continues on track and we expect to file an investigational new drug application (IND) with the US FDA by January 2013. Following the filing of the IND, we plan to initiate a Phase 1 clinical trial of GR-MD-02 in patients with nonalcoholic steatohepatitis (NASH) and fibrosis in early 2013 followed by a Phase 2 study potentially beginning by early 2014 with expected top-line clinical results by the end of 2014 or early 2015. 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."

At September 30, 2012, the Company had \$11.1 million of non-restricted cash and cash equivalents available to fund future operations. The Company believes that with the funds on hand at September 30, 2012, there is sufficient cash to fund core operations and planned research and development activities through 2013.

For the third quarter of 2012, the Company reported a net loss applicable to common stock of \$3.0 million, or (\$0.19) per share, basic and diluted, compared with a net loss applicable to common stock of \$2.3 million or (\$0.19) per share for the same period in 2011. For the nine months ended September 30, 2012, the Company reported a net loss applicable to common stock of \$8.2 million, or (\$0.55) per share, basic and diluted, compared with a net loss of \$9.0 million, or (\$0.77) per share for the same period in 2011. The weighted average number of shares used to calculate loss per share increased for the 2012 periods compared to the 2011 periods due primarily to the March 2012 offering of 2.7 million common shares as well as the payment of dividends in common stock.

Research and development expense for the third quarter of 2012 increased to \$1.4 million, compared with \$0.7 million for the same period in 2011, due primarily to increased preclinical activities related to preparations for filing an IND for GR-MD-02. General and administrative expense for the third quarter of 2012 increased to \$1.5 million, compared with \$1.4 million for the same period in 2011, due primarily to increased stock-based compensation, partially offset by decreased legal expenses.

Research and development expense for the nine-months ended September 30, 2012, increased to \$3.5 million compared with \$2.7 million for the same period in 2011, due primarily to increased activity in clinical and preclinical programs related to our Phase 1/2 clinical trial for GM-CT-01 and our work related to preparing for filing the IND for GR-MD-02, partially offset by decreased stock-based compensation expense. General and administrative expense for the nine-months ended September 30, 2012, decreased to \$4.0 million compared with \$4.3 million for the same period in 2011, due primarily to decreased legal and business development expenses, partially offset by increased stock-based compensation and overhead costs.

In October, the Company reported that it had terminated its agreement with PROCAPS, S.A. (PROCAPS) to gain approval of GM-CT-01 in Columbia. The Company has no current plans to continue attempts to gain approval of GM-CT-01 in Columbia. As a result of the termination of the PROCAPS agreement, the Company recognized \$0.2 million of deferred income in Other Income during the three and nine-month periods ended September 30, 2012. No further income is expected related to this agreement and a future revenue stream from this terminated agreement had not been taken into account in any of Galectin's financial projections. The results for the nine-months ended September 30, 2011, included \$0.5 million in Other Income of non-cash expense related to the change in the fair value of warrants.

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. These statements include Company plans and expectations regarding clinical trials, expectations regarding the effectiveness and potential benefits of our products, and expectations regarding the sufficiency of cash to fund core operations and planned research and development activities through 2013. 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, potential delays in our ability to initiate and successfully complete clinical trials, possible negative results from our clinical trials, 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 Annual Report on Form 10-K for the year ended December 31, 2011 and our subsequent 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.

Galectin Therapeutics
Tom McGauley, 678-620-3186
Acting Chief Financial Officer
ir@galectintherapeutics.com