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Galectin Therapeutics Reports Second Quarter 2012 Financial Results

NEWTON, Mass.--(BUSINESS WIRE)--Aug. 10, 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 second quarter and first six months ended June 30, 2012. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the SEC.

"Galectin has continued to make progress with its 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. 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. The trial, being conducted in collaboration with the Cancer Centre at the Cliniques Universitaires Saint-Luc and the Ludwig Institute for Cancer Research (LICR), is evaluating GM-CT-01 in combination with a Ludwig Institute peptide vaccine. We expect top line results from stage 1 of this study by the end of 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 U.S. FDA by year end. Following the filing of the IND we plan to initiate a Phase 1 clinical trial of GR-MD-02 in patients with non-alcoholic steatohepatitis (NASH) with fibrosis in early 2013, followed by a Phase 2 study potentially beginning by the end of 2013 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."

"In July, we received a notice of issuance from the U.S. Patent and Trademark Office for the patent 'Galactose-prolonged polysaccharides in a formulation for antifibrotic therapies'. This patent covers key methods of derivation and use for our carbohydrate-based galectin inhibitor compound for use in patients with chronic liver disease associated with the development of fibrosis, established liver fibrosis or end-stage scarring, or cirrhosis. The major claim is for a method of obtaining the galectin inhibitor compound, obtaining a composition for parenteral administration in an acceptable pharmaceutical carrier and administering to a subject having at least one of the following: chronic liver disease associated with the development of fibrosis, established liver fibrosis or cirrhosis. The use covers inhibiting or slowing the progression of fibrosis or the reversal of fibrosis. GR-MD-02 is covered by this patent, and it provides opportunities for development of additional compounds in the class."

"Our Colombian partner, PROCAPS, S.A., continues to attempt to gain approval of GM-CT-01 in Colombia; however, INVIMA has indicated that additional clinical trial data will be required before such approval may be granted. We are working with PROCAPS and INVIMA to design a Phase 3 clinical trial that would evaluate the ability of GM-CT-01 to reduce adverse events (e.g., mucositis and diarrhea) of 5-FU containing a chemotherapy regimen in metastatic colorectal cancer. The timing of such a clinical trial is under discussion and would be financed, at least in large part, by PROCAPS as per our agreement, outside of Galectin providing study drug. We have not taken into account projections for any potential revenues from this agreement in our financing plans."

At June 30, 2012, the Company had \$13.1 million of non-restricted cash and cash equivalents available to fund future operations. The Company believes that with the funds on hand at June 30, 2012, there is sufficient cash to fund core operations and planned research and development through 2013.

For the second 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 \$3.9 million or (\$0.34) per share for the same period in 2011. Research and development expense for the second quarter of 2012 decreased to \$1.2 million, compared with \$1.3 million for the same period in 2011, due primarily to decreased stock-based compensation, offset by increased clinical and preclinical activities. General and administrative expense for the second quarter of 2012 decreased to \$1.5 million, compared with \$1.7 million for the same period in 2011, due primarily to decreased stock-based compensation and legal expenses.

For the six months ended June 30, 2012, the Company reported a net loss applicable to common stock of \$5.2 million, or (\$0.36) per share, basic and diluted, compared with a net loss of \$6.7 million, or (\$0.59) per share for the same period in 2011. The results for the six-months ended June 30, 2011, included \$0.5 million of non-cash expense related to the change in the fair value of warrants. Research and development expense for the six-months ended June 30, 2012, increased to \$2.1 million compared with \$2.0 million for the six-months ended June 30, 2011, due primarily to increased activity in clinical and preclinical programs offset by decreased stock-based compensation expense. General and administrative expense for the six-months ended June 30, 2012, decreased to \$2.5 million compared with \$3.0 million for the six-months ended June 30, 2011, due

primarily to decreased stock-based compensation expense and legal costs.

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.

Galectin Therapeutics
Tom McGauley, 617-559-0033
Acting Chief Financial Officer
ir@galectintherapeutics.com