

November 9, 2015

## **Galectin Therapeutics Reports Third Quarter 2015 Financial Results and Provides Business Update**

NORCROSS, Ga., Nov. 9, 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 nine months ended September 30, 2015 and provided a business update. 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**

"Galectin Therapeutics has never been in a better position advancing the development of our galectin-3 inhibitor in non-alcoholic steatohepatitis (NASH) and other therapeutic indications," said Jim C. Czirr, executive chairman of the company. "Our pipeline has progressed considerably during the third quarter and recent weeks, and we now have five clinical studies underway with our proprietary compound, GR-MD-02, in four different indications.

"We began a second Phase 2 study in NASH with advanced fibrosis, the NASH-FX study, during the quarter, and we continued to enroll patients in our Phase 2 study in NASH with cirrhosis, the NASH-CX study. We also began a pilot study to evaluate the potential efficacy of GR-MD-02 in patients with moderate-to-severe plaque psoriasis. More recently, after the close of the quarter we announced that the Providence Portland Medical Center submitted an Investigational New Drug (IND) application to study GR-MD-02 in combination with Keytruda® in metastatic melanoma. This is in addition to its ongoing study of GR-MD-02 in combination with Yervoy® in the same indication. To support this increased activity at Galectin, during the quarter we hired an industry veteran, Adam E. Allgood, Pharm.D., R.Ph. as executive director of clinical development," Mr. Czirr added.

Peter G. Traber, M.D., president, chief executive officer and chief medical officer, said, "NASH has been a topic of keen interest within the medical community as this disease appears to be overtaking hepatitis C as the number one cause of liver transplants, affecting up to 6 million people in the U.S. We are very excited about the potential of GR-MD-02 to treat the fibrosis and cirrhosis that can accompany NASH, and we are working hard to make efficacious treatment a reality.

"We are very pleased with the pace of our clinical studies and remain on track with our stated timelines," added Dr. Traber. "The NASH-CX trial, which if successful has potential to be a component of a pivotal study, began enrolling patients with NASH cirrhosis, with 156 patients in total to be enrolled. Patients are being evaluated with either 8 mg/kg of GR-MD-02, 2 mg/kg of GR-MD-02 or placebo, and are being randomized 1:1:1. 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 <sup>13</sup>C-methacetin breath test, respectively. We expect top-line data readout by the end of 2017."

Dr. Traber continued, "The NASH-FX trial in 30 patients with NASH with advanced fibrosis, but not cirrhosis, is proceeding as planned. This four-month treatment trial will evaluate the efficacy of 8 mg/kg of GR-MD-02 versus placebo, using non-invasive endpoints. LiverMultiScan, a multi-parametric nuclear magnetic resonance imaging method developed by Perspectum Diagnostics™, will be used to measure the change in inflammation and fibrosis as a primary endpoint. The secondary goal is to compare the primary endpoint of LiverMultiScan with two secondary endpoints that 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 in the third quarter of 2016.

"We have also begun screening patients with moderate-to-severe plaque psoriasis in a proof-of-concept, open-label Phase 2a trial. In this trial 10 patients will be treated with 8mg/kg of GR-MD-02 every 2 weeks over 90 days. Research has shown that galectin-3 is increased in the skin of psoriasis patients, thus we have good support for the mechanism of action of our compound. In addition, as previously disclosed, one subject in our Phase 1 NASH study had an apparent remission of psoriasis. As such, we believe it is worthwhile to explore this indication further in this small study.

"We expect that the Portland Cancer Center will begin enrolling patients in its Phase 1b study of GR-MD-02 in combination with Keytruda within the coming weeks, following the filing of its IND in October. Keytruda is an immune checkpoint inhibitor indicated for patients whose melanoma had progressed after treatment with Yervoy or targeted therapy in melanomas that have a BRAF mutation. Preclinical data show that GR-MD-02 holds potential to increase the effectiveness of other therapies and represents a promising approach to enhance cancer immunotherapy. GR-MD-02 is also the subject of an ongoing study in combination with Yervoy being conducted by same investigators at the Portland Cancer Center. We are very pleased to be supplying our

compound to the investigators," Dr. Traber concluded.

Additional information about the Company's clinical development program and clinical trials is available on the CEO Perspectives website at <http://perspectives.galectintherapeutics.com/articles/>.

## Financial Results

For the three months ended September 30, 2015, the Company reported a net loss applicable to common stockholders of \$6.2 million, or (\$0.26) per share, compared with a net loss applicable to common stockholders of \$3.9 million, or (\$0.17) per share, for three months ended September 30, 2014. The increase in net loss applicable to common stockholders is largely due to higher research and development expenses related to the Company's Phase 2 clinical program.

Research and development expense for the three months ended September 30, 2015 was \$4.5 million, compared with \$2.0 million for three months ended September 30, 2014. The increase is primarily due to increased costs related to the Company's Phase 2 clinical program.

General and administrative expense for the three months ended September 30, 2015 was \$1.4 million, compared with \$1.5 million for the three months ended September 30, 2014. The primary reason for the decrease was related to a decrease in stock-based compensation expense in the three months ended September 30, 2015, compared with 2014.

For the nine months ended September 30, 2015, the Company reported a net loss applicable to common stockholders of \$16.2 million, or (\$0.69) per share, compared with a net loss applicable to common stockholders of \$13.0 million, or (\$0.60) per share, for the nine months ended September 30, 2014. The increase in net loss applicable to common stockholders is largely due to higher research and development expenses related to the Company's Phase 2 clinical program.

Research and development expense for the nine months ended September 30, 2015 was \$10.2 million, compared with \$6.3 million in the prior year's period. The higher research and development expense is related to increased expenses associated with the Company's Phase 2 clinical studies.

General and administrative expense for the nine months ended September 30, 2015 was \$5.2 million, compared with \$5.4 million for the nine months ended September 30, 2014. The decline was due to lower stock-based compensation expense.

As of September 30, 2015, the Company had \$21.3 million of non-restricted cash and cash equivalents available to fund future operations. The Company believes that its cash on hand as of September 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](http://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		Nine Months	
	Ended September 30,		Ended September 30,	
	2015	2014	2015	2014
	(in thousands, except per share data)			
Operating expenses:				
Research and development	\$ 4,464	\$ 1,979	\$ 10,200	\$ 6,345
General and administrative	1,435	1,498	5,196	5,351
Total operating expenses	5,899	3,477	15,396	11,696
Total operating loss	(5,899)	(3,477)	(15,396)	(11,696)
Other income (expense):				
Interest and other	12	12	40	29
Loss from equity method investment	--	(53)	--	(390)
Total other income (expense)	12	(41)	40	(361)
Net loss	\$ (5,887)	\$ (3,518)	\$ (15,356)	\$ (12,057)
Preferred stock dividends and accretion costs	(265)	(335)	(801)	(935)
Net loss applicable to common stock	\$ (6,152)	\$ (3,853)	\$ (16,157)	\$ (12,992)
Basic and diluted net loss per share	\$ (0.26)	\$ (0.17)	\$ (0.69)	\$ (0.60)
Shares used in computing basic and diluted net loss per share	23,793	22,051	23,531	21,732

### Condensed Consolidated Balance Sheet Data

	September 30, December 31,	
	2015	2014
	(in thousands)	
Cash and cash equivalents	\$ 21,319	\$ 29,128
Total assets	21,512	29,677
Total current liabilities	1,726	1,703
Total liabilities	1,726	1,703
Total redeemable, convertible preferred stock	6,951	6,779
Total stockholders' equity	\$ 12,835	\$ 21,195

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Source: Galectin Therapeutics, Inc.

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