

Galectin Therapeutics Reports Third Quarter 2016 Financial Results and Provides Business Update

NORCROSS, Ga., Nov. 08, 2016 (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, 2016. These results are included in the Company's Form 10-Q, which has been filed with the U.S. Securities and Exchange Commission and is available at www.sec.gov.

Summary of Key Development Programs, Updates and Anticipated Milestones

- | At The Liver Meeting® in Boston, Massachusetts on November 11-15, 2016, Dr. Peter Traber, president, chief executive officer and chief medical officer of Galectin Therapeutics and co-investigator of these studies, will present two posters that demonstrate the use of alternative non-invasive tests on the progression of cirrhosis and fibrosis in patients with nonalcoholic steatohepatitis (NASH), highlighting the potential utility of non-invasive imaging methods in the development of novel therapies in this patient population and adding momentum in this area of medicine.
- | In the recently completed NASH-FX study, GR-MD-02 was found to be safe and well tolerated among the patient population with no serious adverse events.
- | In August, the Company reported on a study that demonstrated clinically meaningful results in a human disease with GR-MD-02, where four patients who received 24 weeks of therapy experienced an average of 48% improvement in their plaque psoriasis. In October, a fifth patient reached 72% improvement at his 13th infusion visit with one more assessment to be completed by the end of November. Dr. Stephen Harrison, the co-chief investigator in our NASH-CX trial, stated that he was especially encouraged that GR-MD-02 has demonstrated an [improved clinical effect in moderate-to-severe psoriasis](#), suggesting the compound has activity in a human disease that can occur in association with NASH.
- | The full report of our Phase 1 study in NASH patients with advanced fibrosis, which demonstrated GR-MD-02 was safe and defined dosing for Phase 2 trials, was published on October 25, 2016, in the peer-reviewed scientific journal, *Alimentary Pharmacology and Therapeutics* (<http://bit.ly/2f3Zng3>).
- | In support for continued funding of the NASH-CX trial, a private placement financing for \$1.5 million was secured from a single source.
- | Dr. William L. Redmond, Ph.D., of Earle A. Chiles Research Institute of Providence Portland Medical Center will present pre-clinical and clinical data regarding use of GR-MD-02 in combination with immunotherapy, specifically with Yervoy and Keytruda, at the GTCbio 9th Immunotherapeutics & Immunomonitoring Conference, to be held on February 6-7, 2017, in San Diego, California.

Management Commentary

"As noted by our co-lead investigators, Dr. Stephen Harrison and Dr. Naga Chalasani, it is important to complete our ongoing NASH-CX Phase 2b trial focused on the treatment of NASH cirrhosis, as one year may provide an appropriate length of therapy and the endpoints may serve as a surrogate for outcomes for registration trials in this patient population," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "NASH cirrhosis has always been, and remains, the lead indication for GR-MD-02. Presently, we are the only company with a compound for NASH cirrhosis in an active Phase 2 clinical trial.

"The market seemingly recognizes the concerns about the rising incidence of NASH and the need for therapies to counter a potential health epidemic as Allergan's \$1.7 billion purchase of Tobira appears to have been motivated by a NASH drug in clinical trials.

"The NASH-CX trial is a one year of treatment, multi-center trial in patients with NASH cirrhosis that is being conducted at 36 outstanding liver centers in the United States. It completed enrollment one month early with 162 well-compensated patients with NASH cirrhosis (Child-Pugh-Turcotte Class A) with elevated portal pressure (HVPG \geq 6 mmHg). Only five patients of the 162 enrolled have dropped out of the trial thus far, with this low attrition rate highlighting the importance, urgency and need for patients suffering from NASH cirrhosis to find an effective medical treatment. And, a total of 2,240 drug infusions (including placebo) have been given in this trial, representing 53% of the total number of infusions in the entire trial. We are quite pleased that this trial is well along in its development and on track for reporting of top-line results in December of 2017.

"As a company, Galectin Therapeutics' attention has always been focused on completing the NASH-CX clinical trial and

reporting results in a timely fashion. With an outstanding safety profile, inhibition of galectin-3 with GR-MD-02 remains a potential treatment of NASH cirrhosis and provides us encouragement about our continuation of the NASH-CX clinical trial."

Financial Results

For the three months ended September 30, 2016, the Company reported a net loss applicable to common stockholders of \$5.6 million, or \$0.19 per share, compared with a net loss applicable to common stockholders of \$6.2 million, or \$0.26 per share, for the three months ended September 30, 2015. The decrease is largely due to lower non-cash stock based compensation expense and timing of research and development expenses related to the Phase 2 clinical program in NASH.

Research and development expense for the three months ended September 30, 2016, was \$3.3 million, compared with \$4.4 million for the three months ended September 30, 2015. The decrease primarily relates to timing of research and development expenses related to the Phase 2 clinical program in NASH.

General and administrative expense for this quarter was \$1.2 million, compared with \$1.4 million for the prior year, with the decrease being primarily related to non-cash stock compensation. As of September 30, 2016, the Company had \$16.1 million of non-restricted cash and cash equivalents. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through August, 2017.

About Galectin Therapeutics

Galectin Therapeutics is developing promising 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.

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 and those regarding the hope that our lead compounds will be successful in connection with cancer immunotherapy. 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 current or future 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, 2015, 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.

Yervoy® is a registered trademark of Bristol-Myers Squibb

Keytruda® is a registered trademark of Merck & Co.

Condensed Consolidated Statements of Operations

<u>Three Months</u>		<u>Nine Months</u>	
<u>Ended</u>		<u>Ended</u>	
<u>September 30,</u>		<u>September 30,</u>	
<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>

(in thousands, except per share data)

Operating expenses:

Research and development	\$ 3,289	\$ 4,464	\$ 11,892	\$ 10,200
General and administrative	1,248	1,435	4,990	5,196
Total operating expenses	<u>4,537</u>	<u>5,899</u>	<u>16,882</u>	<u>15,396</u>
Total operating loss	<u>(4,537)</u>	<u>(5,899)</u>	<u>(16,882)</u>	<u>(15,396)</u>
Other income:				
Interest and other	11	12	37	40
Total other income	<u>11</u>	<u>12</u>	<u>37</u>	<u>40</u>
Net loss	\$ (4,526)	\$ (5,887)	\$ (16,845)	\$ (15,356)
Preferred stock dividends and accretion costs	(119)	(265)	(637)	(801)
Deemed dividend related to beneficial conversion feature of convertible preferred stock	(991)	-	(991)	-
Net loss applicable to common stock	<u>\$ (5,636)</u>	<u>\$ (6,152)</u>	<u>\$ (18,473)</u>	<u>\$ (16,157)</u>
Basic and diluted net loss per share	\$ (0.19)	\$ (0.26)	\$ (0.64)	\$ (0.69)
Shares used in computing basic and diluted net loss per share	29,282	23,793	29,045	23,531

Condensed Consolidated Balance Sheet Data

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
	<u>(in thousands)</u>	
Cash and cash equivalents	\$ 16,059	\$ 25,846
Total assets	16,115	26,408
Total current liabilities	4,087	1,360
Total liabilities	4,087	1,360
Total redeemable, convertible preferred stock	12,028	7,008
Total stockholders' equity	\$ 16,115	\$ 18,040

Contacts:

Jack Callicutt, Chief Financial Officer
(678) 620-3186
ir@galectintherapeutics.com