

Galectin Therapeutics Reports 2015 Financial Results and Provides Business Update

Conference Call to Begin at 8:30 a.m. ET Today

NORCROSS, Ga., March 15, 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 year ended December 31, 2015. These results are included in the Company's Annual Report on Form 10-K, which has been filed with the U.S. Securities and Exchange Commission and is available at <u>www.sec.gov</u>.

Management Commentary

"Numerous clinical advancements during 2015 with our lead compound GR-MD-02 form the basis for a productive 2016, and we look forward to reporting on a number of important development milestones throughout the year," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "Of particular note, during 2015 we began two Phase 2 studies with GR-MD-02 in non-alcoholic steatohepatitis, or NASH, a disease that has been gaining considerable awareness not only among clinicians, but also among the general population. NASH is a significant and growing problem, and treatment will require considerable healthcare resources. Our compound is being investigated in NASH with cirrhosis in our NASH-CX trial, and in NASH with advanced fibrosis in our NASH-FX trial. We expect to report top-line data from our NASH-FX trial by the end of September of this year. Enrollment in our NASH-CX trial is on schedule and we expect to report top-line data by the end of 2017. We are very excited about the potential for GR-MD-02 in the treatment paradigm of a global market estimated to reach \$35 billion by the middle of the next decade."

Dr. Traber continued, "In addition to data from the NASH-FX trial, we expect to report data from a 10-patient Phase 2 openlabel study with GR-MD-02 in moderate-to-severe plaque psoriasis in September 2016. Also, our partners at the Providence Portland Cancer Center are studying GR-MD-02 in combination with the checkpoint inhibitors Yervoy® and Keytruda® in two separate Phase 1b studies in advanced metastatic melanoma. We look forward to initial data from select cohorts in both studies later this year, but are dependent on the Providence Portland Cancer Center to conduct and fund these trials. Preclinical work in cancer models with GR-MD-02 added to checkpoint inhibitors showed a boost in anti-tumor immunity, a reduction in tumor size and increased survival, and we are eager to learn if this activity will be duplicated in humans.

"We strengthened our U.S. patent position during 2015 and more recently obtained an extension of coverage for method of use patents of pectin compounds in a number of fibrotic diseases, including pulmonary fibrosis. We are formulating plans to leverage our intellectual property. Also in recent weeks we named lead independent director Marc Rubin, M.D. as chairman of our board of directors. Dr. Rubin is a leading bioscience industry executive with more than 25 years of senior management and board experience in the development and commercialization of pharmaceuticals.

"In January 2016, we announced that the United States District Court for Northern Georgia had dismissed all claims against it and certain officers, directors and shareholder 10X Fund L.P. alleged in a Consolidated Securities Class Action originally filed in July 2014 and all claims against certain officers and directors alleged in a Consolidated Shareholder Derivative Action originally filed in August 2014. The Court entered final judgments of dismissals in both actions, that is, dismissals 'with prejudice,' based on the Court's finding that any further amendment of the complaints would be futile. Plaintiffs have filed notice of intent to appeal in both matters. On March 3, 2016, the Nevada State Court dismissed a shareholder derivative complaint filed against the Company's officers and directors in Nevada and entered a final judgment in favor of the defendants. The plaintiff has 30 days to appeal after the final judgment order. We are pleased that these matters appear very close to final resolution in favor of the Company and our officers and directors."

"In summary, we believe that Galectin is in a solid position from clinical, financial and leadership perspectives. I look forward to continuing consistent outreach to the investment community via frequent <u>CEO Perspective</u> blog postings and conference participation, among other activities to keep our shareholders informed of our plans, accomplishments and milestones," Dr. Traber concluded.

Financial Results

For the year ended December 31, 2015, the Company reported a net loss applicable to common stockholders of \$21.1 million, or \$0.88 per share, compared with a net loss applicable to common stockholders of \$17.0 million, or \$0.78 per share, for 2014. The increase is largely due to higher research and development expenses primarily related to the Phase 2 clinical program.

Research and development expense for 2015 was \$13.1 million, compared with \$8.4 million for 2014. The increase primarily relates to costs for the Phase 2 clinical trials begun in 2015, partially offset by lower preclinical costs.

General and administrative expense for 2015 was \$7.0 million, compared with \$7.0 million for 2014.

As of December 31, 2015, the Company had \$25.8 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 March 31, 2017.

Conference Call and Webcast

Galectin Therapeutics management will host a conference call at 8:30 a.m. Eastern time today to provide a business update and discuss fourth quarter financial results.

To access the conference call, U.S.-based listeners should dial 844-236-5620 and international listeners should dial 330-863-3454. All listeners should provide the following passcode: 65873987. Individuals interested in listening to the live conference call via the Internet may do so by logging on to the Company's website at <u>www.galectintherapeutics.com</u>.

Following the conclusion of the conference call, a replay will be available through March 21, 2016 and can be accessed by dialing (855) 859-2056 from within the U.S. or (404) 537-3406 from outside the U.S. All listeners should provide passcode 65873987. The webcast will be available on the Company's website at <u>www.galectintherapeutics.com</u> for 90 days.

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 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, 2015, and subsequent filings with the SEC. You should not place undue reliance on forwardlooking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

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or

LHA Kim Golodetz (212) 838-3777 Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc.

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Condensed Consolidated Statements of Operations

	<u>Year Ended</u> December 31,		
	<u>2015</u>	<u>2014</u>	
	(in thousands, except		
	per share data)		
Operating expenses:			
Research and development	\$ 13,114 \$	\$ 8,425	
General and administrative	6,965	7,005	
Total operating expenses	20,079	15,430	
Total operating loss	(20,079)	(15,430)	
Other income:			
Interest and other	52	(358)	
Total other income	52	(358)	
Net loss	\$ (20,027) \$	\$ (15,788)	
Preferred stock dividends and accretion costs	(1,097)	(1,172)	
Net loss applicable to common stock	\$ (21,124) \$	\$ (16,960)	
Basic and diluted net loss per share	\$ (0.88) \$	6 (0.78)	
Shares used in computing basic and diluted net loss per share	e 24,120	21,849	

Condensed Consolidated Balance Sheet Data

		December 31, 2015	December 31, 2014	
		(in thousands)		
Cash and cash equivalents	\$	25,846	\$ 29,128	
Total assets		26,408	29,677	
Total current liabilities		1,360	1,703	
Total liabilities		1,360	1,703	
Total redeemable, convertible preferred	stock	7,008	6,779	
Total stockholders' equity	\$	18,040	\$ 21,195	