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

NORCROSS, Ga., May 10, 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 months ended March 31, 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.

Management Commentary

"The year got off to an active start as we advanced our lead compound GR-MD-02 through multiple clinical trials including non-alcoholic steatohepatitis, or NASH, and psoriasis. In parallel we worked to educate the investment community and the general public about Galectin and the significant and growing problem of NASH," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "We are pleased with the pace of enrollment in our two NASH studies. We expect to report top-line data from our 30-patient NASH-FX trial in NASH patients with fibrosis by the end of September, and we remain on track to report top-line data from our 156-patient NASH-CX trial in NASH patients with cirrhosis by the end of 2017.

"NASH represents a global market estimated to reach \$35 billion by the middle of the next decade. The increasing attention being paid by the consumer press, including a recent feature article in *Newsweek*, and the growing number of companies working to develop therapies with various mechanisms of action directed at different stages of the disease, all underscore the urgency to address this condition. GR-MD-02 has been shown to reverse fibrosis and cirrhosis in preclinical models, and should our clinical development programs be successful we are confident that our focus on advanced fibrosis and cirrhosis will be commercially viable."

Dr. Traber added, "A large percentage of NASH patients also suffer from psoriasis, possibly because both NASH and psoriasis are diseases with increased galectin-3 activity. Given that GR-MD-02 is a galectin-3 inhibitor, and based on a patient in our Phase 1 safety study showing resolution of her psoriasis for 17 months, we embarked last year on 10-patient Phase 2 open-label clinical trial with GR-MD-02 in patients with moderate-to-severe plaque psoriasis. We look forward to reporting interim data from this study in the near future.

"In addition, our partners at the Providence Portland Cancer Center continue to study GR-MD-02 in combination with the checkpoint inhibitors Yervoy® and Keytruda® in two separate Phase 1b trials in patients with advanced metastatic melanoma. We are pleased to provide GR-MD-02 for these investigator-sponsored trials and note that Providence Portland is funding the studies. They have indicated that data from the Yervoy combination trial should be available by the end of the year."

Financial Results

For the three months ended March 31, 2016, the Company reported a net loss applicable to common stockholders of \$7.0 million, or \$0.24 per share, compared with a net loss applicable to common stockholders of \$5.1 million, or \$0.22 per share, for the three months ended March 31, 2015. The increase is largely due to higher research and development expenses primarily related to the Phase 2 clinical program in NASH.

Research and development expense for the three months ended March 31, 2016 was \$4.4 million, compared with \$3.1 million for the three months ended March 31, 2015. 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 quarter was \$2.4 million, compared with \$1.7 million for the prior year, with the increase being primarily related to severance and non-cash stock compensation associated with the termination of the executive chairman in January 2016.

As of March 31, 2016, the Company had \$22.4 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.

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 forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

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Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2016	2015
	(in thousands, except per share data)	
Operating expenses:		
Research and development	\$ 4,377	\$ 3,136
General and administrative	2,437	1,704
Total operating expenses	<u>6,814</u>	<u>4,840</u>
Total operating loss	<u>(6,814)</u>	<u>(4,840)</u>
Other income:		
Interest and other	14	14
Total other income	<u>14</u>	<u>14</u>
Net loss	<u>\$ (6,800)</u>	<u>\$ (4,826)</u>

Preferred stock dividends and accretion costs		(210)		(248)
Net loss applicable to common stock	\$	(7,010)	\$	(5,074)
Basic and diluted net loss per share	\$	(0.24)	\$	(0.22)
Shares used in computing basic and diluted net loss per share		28,827		23,062

Condensed Consolidated Balance Sheet Data

	March 31, 2016		December 31, 2015	
	<u>(in thousands)</u>			
Cash and cash equivalents	\$	22,356	\$	25,846
Total assets		22,788		26,408
Total current liabilities		3,250		1,360
Total liabilities		3,250		1,360
Total redeemable, convertible preferred stock		7,066		7,008
Total stockholders' equity	\$	12,472	\$	18,040