



March 28, 2017

Galectin Therapeutics Reports 2016 Financial Results and Provides Business Update

NORCROSS, Ga., March 28, 2017 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results for the year ended December 31, 2016. 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 www.sec.gov.

Galectin Therapeutics management will host a conference call at 9:00 a.m. Eastern time March 28, 2017 to discuss this press release.

To access the conference call dial 844-899-6544 and provide the operator with Pin Number 89964111.

Galectin also invites all interested parties to listen to its conference call via webcast at <http://edge.media-server.com/m/p/exukm2jh>. The webcast will also be available on the investor relations portion of the Company's website at <http://galectintherapeutics.com/>. The webcast will be archived on the Company's website within two hours of the live call. The webcast will be available on the Company's website at www.galectintherapeutics.com for 90 days.

Management Commentary

"Galectin Therapeutics achieved a number of significant milestones in the development of our lead compound, GR-MD-02, during 2016," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "Furthermore, we've recently completed equity financings that have generated sufficient funding to cover currently planned expenditures through 2017.

"While non-alcoholic steatohepatitis (NASH) cirrhosis remains GR-MD-02's primary disease target, a number of additional trials have provided encouraging early results that provide additional insight on the clinical effect of GR-MD-02. In total, what we have seen in our early trials in moderate-to-severe plaque psoriasis and severe atopic dermatitis have consistently shown that GR-MD-02 demonstrates clinically significant, biological activity in humans.

"NASH cirrhosis represents a large unmet medical need with no currently approved therapies, and we are very pleased with our progress in the NASH-CX trial. A drug that can halt progression of, or reverse existing fibrosis, in NASH cirrhosis patients would be a breakthrough therapeutic intervention that may prevent complications, alleviate the need for liver transplant, and even prevent death.

"Our Phase 2b NASH-CX clinical trial enrollment exceeded its target and, to date, 71 patients have completed all 52 weeks of infusions with GR-MD-02, and 155 patients have completed 26 weeks of infusions. More than 3,400 infusions (or 85% of the maximum infusions in the trial) have been administered, with no drug-related serious adverse reactions and a dropout rate that is below the rate included in the trial design. The top-line data readout of the NASH-CX trial remains on track for early December 2017.

"The Providence Cancer Center is continuing two investigator-initiated Phase 1 clinical trials of GR-MD-02 used in combination with approved immunotherapies, Yervoy[®] and Keytruda[®] in patients with advanced melanoma, oral/head and neck cancer (OHN) and non-small cell lung cancer (NSCLC). There have been no safety concerns in either of these studies. Of the five patients with advanced melanoma who underwent combination therapy with GR-MD-02 (2 mg/kg) and Keytruda[®], one had an impressive partial response, heading towards a complete response, and one had a mixed response.

"Galectin Therapeutics also announced positive results in studies of GR-MD-02 for patients with serious skin diseases. This is an encouraging new indication for GR-MD-02 and one of the previously mentioned demonstrations that the drug is biologically active in humans.

"A Phase 2, exploratory study of GR-MD-02 in patients with severe plaque psoriasis showed all five patients enrolled had significant clinical improvement (mean of 52% improvement) as measured by an objective measurement, the PASI (Psoriasis Area and Severity Index). After receiving 8 mg/kg doses of GR-MD-02 for up to 24 weeks, the fifth patient, who also had the most severe baseline disease, had an 82% PASI improvement approximately one month following the full thirteen infusions (24 weeks).

"In an investigator-initiated protocol, GR-MD-02 was also used to treat three adult patients with severe atopic dermatitis,

each of whom had been recalcitrant to multiple therapies over many years. All three patients have had a marked clinical effect with near resolution of pruritus, or itching, and regression of skin lesions. Two patients achieved a 64% and 74% reduction in Eczema Area and Severity Index (EASI), after only 6 weeks and 3 drug infusions. These findings are believed to demonstrate a clinically significant effect of this novel investigational drug in this patient population."

"In summary, we believe that Galectin is in a solid position from clinical, financial and leadership perspectives," Dr. Traber concluded.

Financial Results

For the year ended December 31, 2016, the Company reported a net loss applicable to common stockholders of \$22.4 million, or \$0.76 per share, compared with a net loss applicable to common stockholders of \$21.1 million, or \$0.88 per share, for 2015. The increase is largely due to higher research and development expenses primarily related to the Phase 2 clinical program.

Research and development expense for 2016 was \$15.3 million, compared with \$13.1 million for 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 2016 was \$6.2 million, compared with \$7.0 million for 2015, primarily due to a decrease in stock based compensation.

As of December 31, 2016, the Company had \$15.4 million of non-restricted cash and cash equivalents. In January and February 2017, the Company raised a total of \$1.5 million in net proceeds from issuance of common stock. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through December 31, 2017.

About Galectin Therapeutics

Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver and skin diseases and cancer. Galectin's lead drug (GR-MD-02) is a carbohydrate-based drug that inhibits the galectin-3 protein which is directly involved in multiple inflammatory, fibrotic, and malignant diseases. The lead development program is in non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH related fibrosis. This is the most common liver disease and one of the largest drug development opportunities available today. Additional development programs are in treatment of severe atopic dermatitis, moderate-to-severe plaque psoriasis, and in combination immunotherapy for advanced melanoma and other malignancies. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. 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, 2016, 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

Year Ended
December 31,
2016 **2015**
(in thousands, except per share data)

Operating expenses:

Research and development	\$ 15,325	\$ 13,114
General and administrative	6,156	6,965
Total operating expenses	<u>21,481</u>	<u>20,079</u>
Total operating loss	<u>(21,481)</u>	<u>(20,079)</u>
Other income:		
Interest and other	45	52
Total other income	<u>45</u>	<u>52</u>
Net loss	<u>\$ (21,436)</u>	<u>\$ (20,027)</u>
Preferred stock dividends and accretion costs	(914)	(1,097)
Net loss applicable to common stock	<u>\$ (22,350)</u>	<u>\$ (21,124)</u>
Basic and diluted net loss per share	\$ (0.76)	\$ (0.88)
Shares used in computing basic and diluted net loss per share	29,216	24,120

Condensed Consolidated Balance Sheet Data

	December 31,	December 31,
	2016	2015
	<u>(in thousands)</u>	
Cash and cash equivalents	\$ 15,362	\$ 25,846
Total assets	15,795	26,408
Total current liabilities	3,780	1,360
Total liabilities	3,780	1,360
Total redeemable, convertible preferred stock	1,723	7,008
Total stockholders' equity	\$ 10,292	\$ 18,040

Contacts:

Jack Callicutt, Chief Financial Officer

(678) 620-3186

ir@galectintherapeutics.com.

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Source: Galectin Therapeutics

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