Galectin Therapeutics Reports Financial Results for the Quarter Ended June 30, 2020, and Provides Business Update

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NASH-RX Trial Continues to Enroll New Patients

NORCROSS, Ga., Aug. 10, 2020 (GLOBE NEWSWIRE) -- Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results and provided a business update for the quarter ended June 30, 2020. 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 and is available at **www.sec.gov**.

Harold H. Shlevin, Ph.D., President and Chief Executive Officer of Galectin Therapeutics, said, “We are excited to have initiated the NASH-RX trial, having enrolled our first patient in June and continuing to enroll patients at several of our sites in our clinical trial of belapectin targeting cirrhotic NASH patients. If the results of the NASH-RX trial are compelling, there could be the potential for accelerated FDA approval and/or partnership opportunity with a pharmaceutical company. Later this quarter, we plan to host a conference call with the Investment Community for a more thorough discussion of the NASH-RX trial, its current status, our updated strategy, and to take questions.”

Richard E. Uihlein, Chairman of the Board, added, “The protocol of the NASH-RX trial has been designed to provide belapectin with the best chance to demonstrate efficacy and safety, and I am very pleased this trial is now underway. Belapectin is targeting NASH cirrhosis patients, those who can no longer expect to benefit from increased exercise or an improved diet as may benefit many of those with earlier stages of NASH. And, belapectin (formerly known as GR-MD-02) is the first drug that has been shown to prevent the development of esophageal varices in patients with compensated NASH cirrhosis. If confirmed, these results would constitute a significant benefit for patients. Consequently, we believe our drug targets NASH at a very critical point of its development, as it represents an opportunity to prevent the progression of liver damage, and thereby save lives.”

The NASH-RX trial will use an adaptive design to confirm dose selection and reaffirm the efficacy data observed in the NASH-CX trial and, with pre-planned adaptations, inform the larger Phase 3 trial component. In June 2020, we enrolled our first patients in the NASH-RX trial. NASH-RX is expected to enroll approximately 315 NASH patients in the Phase 2b part of the trial at approximately 130 sites in 12 countries in North America, Europe, Asia and Australia.

Galectin plans to host a conference call with the investment community in the third quarter to provide a more comprehensive description and update on the status of the trial and to take questions. The date and time of the call and how to participate will be published in advance of the planned call.

Financial Results

For the three months ended June 30, 2020, the Company reported a net loss applicable to common stockholders of $6.2 million, or ($0.11) per share, compared to a net loss applicable to common stockholders of $3.1 million, or ($0.06) per share for the three months ended June 30, 2019. The increase is due to 2020 research and development expense related to the Company’s NASH-RX trial.

Research and development expense for the three months ended June 30, 2020 was $4.7 million compared with $1.5 million for the three months ended June 30, 2019. The increase was primarily due to costs related to our NASH-RX clinical trial, along with preparations and some preclinical activities incurred in support of the clinical program, such as development and reproductive toxicity studies, clinical supplies and other supportive activities. General and administrative expenses for the three months ended June 30, 2020, were $1.4 million, down from $1.5 million for the three months ended March 31, 2019, primarily due to a decrease in stock-based compensation expenses.

As of June 30, 2020, the Company had $40.8 million of cash and cash equivalents. The Company also has a $10 million unsecured line of credit, under which no borrowings have been made to date. The Company believes it has sufficient cash, including availability under the line of credit, to fund currently planned operations and research and development activities through at least September 30, 2021.

The Company expects that it will require more cash to fund operations after September 30, 2021 and believes it will be able to obtain additional financing as needed. The total cost to obtain the interim analysis data of the planned trial, including general overhead, is currently estimated to be approximately $90 million. These costs will require additional funding. There can be no assurance that we will be successful in obtaining financing to support our operations beyond September 30, 2021, or, if available, that any such financing will be on terms acceptable to us.

About Belapectin (GR-MD-02)

Belapectin (GR-MD-02) is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of fatty liver disease and fibrosis. Galectin-3 plays a major role in diseases that involve scarring of organs including fibrotic disorders of the liver, lung, kidney, heart and vascular system. The drug binds to galectin proteins and disrupts their function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis.

About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis
Non-alcoholic steatohepatitis (NASH) has become a common disease of the liver with the rise in obesity and other metabolic diseases. NASH is estimated to affect up to 28 million people in the U.S. It is characterized by the presence of excess fat in the liver along with inflammation and hepatocyte damage (ballooning) in people who consume little or no alcohol. Over time, patients with NASH can develop excessive fibrosis, or scarring of the liver, and ultimately liver cirrhosis. It is estimated that as many as 1 to 2 million individuals in the U.S. will develop cirrhosis as a result of NASH,

for which liver transplantation is the only curative treatment available. Approximately 8,890 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis or cirrhosis.

About Galectin Therapeutics
Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver disease and cancer. Galectin's lead drug belapectin (formerly known as 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, for which it has Fast Track designation by the U.S. Food and Drug Administration. 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 combination immunotherapy for advanced melanoma and other malignancies. Advancement of these additional clinical programs is largely dependent on finding a suitable partner. 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 belapectin 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 cancer immunotherapy and in other therapeutic indications. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that trial endpoints required by the FDA may not be achieved; Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of belapectin or any of its other drugs in development; the Company may not be successful in scaling up manufacturing and meeting requirements related to chemistry, manufacturing and control matters; the Company's currently planned clinical trial and any future clinical studies as modified to meet the requirements of the FDA may not produce positive results in a timely fashion, if at all, and could require larger and longer trials, which would be 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. Global factors such as coronavirus may limit access to NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs. 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, 2019, 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 4,681	$ 1,522	$ 6,825	$ 2,168
General and administrative	1,421	1,498	2,861	3,219
Total operating expenses	6,102	3,020	9,686	5,387
Total operating loss	(6,102)	(3,020)	(9,686)	(5,387)
Other income (expense):				
Interest income	9	43	59	57
Interest expense	(21)	(21)	(43)	(43)
Total other income	(12)	22	16	14
Net loss	$ (6,114)	$ (2,998)	$ (9,670)	$ (5,373)
Preferred stock dividends	(66)	(67)	(60)	(163)
Warrant modification				(6,622)
Net loss applicable to common stock	$ (6,180)	$ (3,065)	$ (12,158)	$ (12,158)
Basic and diluted net loss per share	$ (0.11)	$ (0.06)	$ (0.17)	$ (0.26)
Shares used in computing basic and diluted net loss per share	57,035	50,301	56,995	47,653

Condensed Consolidated Balance Sheet Data

	June 30, 2020	December 31, 2019
	(in thousands)	
Cash and cash equivalents	$ 40,768	$ 47,480
Total assets	41,317	48,467
Total current liabilities	4,274	2,820
Total liabilities	4,305	2,872
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 35,289	$ 43,872

Source: Galectin Therapeutics Inc.