Galectin Therapeutics Reports Q3 2019 Financial Results

November 12, 2019

Provides Update on NASH-RX Trial Plan

NORCROSS, Ga., Nov. 12, 2019 (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 three months ended September 30, 2019. 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, “Our team continues to vigorously pursue the implementation of additional trials of our proprietary compound, belapectin (GR-MD-02), including constructive, ongoing dialogue with the Food and Drug Administration (FDA). Representative of our most recent progress, Covance, our clinical research organization, has identified over 125 clinical trial sites in 11 countries interested in the trial, many of which have been qualified by pre-study visits. It is an exciting time at Galectin. We are well-prepared to advance the investigation of this valuable compound, which is the first drug to show positive results in a clinical trial in patients with compensated NASH cirrhosis without esophageal varices.”

Richard E. Uihlein, Chairman of the Board, added, “The growing, global incidence of NASH has raised the stakes in finding effective means to treat this debilitating disease. With our valuable science, which has shown positive results in a clinical trial in patients with compensated NASH cirrhosis without esophageal varices, and our world-class scientific team, we have the extensive and experienced resources needed to help develop therapies that have the potential to save lives.”

NASH-RX Trial Update

The NASH-RX Trial was initially designed as a Phase 3 trial of belapectin in NASH cirrhosis patients based on United States Food and Drug Administration (FDA) feedback from a February 2019 meeting between the Company and the FDA. The trial design is being refined as a result of further input received from the FDA in late October 2019 and ongoing input from the FDA.

The late October 2019 FDA comments are being evaluated by the Company in conjunction with its external hepatology experts and medical and other experts at Covance. In its comments, the FDA seemingly is departing from its earlier implied potential support of the use of progression to varices as a surrogate endpoint for accelerated approval. A follow-up call with the FDA is scheduled for later in November to clarify aspects of its communication. The FDA also made additional constructive comments and suggestions mostly of an operational nature. Based on updated feedback, the Company is redesigning the trial protocol. We will continue to seek approval in a manner consistent with the data derived from the results of the trial. The pathway pursued will be based on the assessment of that data.

Currently, as a result of the Agency’s feedback and after consultation with external experts, the Company plans to conduct an adaptive-designed trial that confirms dose selection and data observed in the NASH-CX trial and where, in a seamless fashion with pre-planned adaptations, an interim analysis informs the larger Phase 3 trial component. The adaptive design being considered allows pre-planned adjustments of the trial which may include, amongst other factors, optimization of dose selection, confirmation of efficacy and proof of concept, optimized sizing and statistical powering of the Phase 3 component, and possible inclusion of more advanced cirrhotic patients. We believe that these adaptations taken together should optimize conduct of the NASH-RX trial giving belapectin the best opportunity to show a positive therapeutic effect. Existing patients in the first component of the trial are expected to be seamlessly transitioned to the Phase 3 trial component. An important aspect of the adaptive design is potential early termination of the study for futility after evaluation of the results from the first part of the trial, thereby saving the company resources that it could expend on other trials. Conversely, if the final results of the NASH-RX trial are compelling, there could be the potential for FDA approval and/or partnership opportunity with a large pharmaceutical company.

In the Phase 3 component of this trial, the primary endpoint would likely be a composite clinical outcomes endpoint, including varices requiring treatment (development of large varices or varices with a red wale), decompensated events, all-cause mortality, MELD score increase as defined earlier and liver transplant. Patient selection would be based on clinical criteria indicative of clinically significant portal hypertension, amongst others, including presence or absence of varices, platelet count, spleen size and evidence of collaterals by imaging. In addition, in parallel, a hepatic impairment study in patients with Child-Turcotte-Pugh (CTP) classes A, B, and C would be conducted to potentially allow inclusion of patients with CTP Class B and/or C who are at increased risk of decompensating. Subject to additional assessments to assure appropriate study sizing and other operational considerations, these changes are believed to be relatively straight-forward modifications of the protocols submitted to the Agency in July 2019, and we believe the changes will increase the likelihood of success of the Phase 3 component of the study. These current plans are subject to modification after discussion with FDA. The final study design will be announced when available.

The focus and goal of the therapeutic program is to stop the progression of and reverse the fibrosis and/or portal hypertension in the liver and thereby improve liver function and prevent the development of varices and clinical complications of fibrosis/cirrhosis and liver-related mortality in patients. Based on the results of the NASH-CX trial and subject to confirmation in later-stage clinical trials, we believe that this goal is achievable in a significant portion of the NASH cirrhosis patient population, i.e. those NASH cirrhosis patients with portal hypertension.

The key milestones and associated target dates for the NASH-RX trial will be announced as elements of design of the trial are finalized based on the recent FDA feedback. However, we currently expect the first patient to be enrolled in the first quarter of 2020. The study likely will involve at least 500 patients at up to approximately 130 sites in 11 countries in North America, Europe, Asia, and Australia and will continue for at least two years of dosing.

Other Updates

- Along with Providence Cancer Institute, received a notice of issuance of a U.S. patent titled "Method for Enhancing Specific Immunotherapies in Cancer Treatment" to cover the method of use of belapectin (GR-MD-02) as a means to enhance the effectiveness of specific immunotherapies in cancer treatment. The patent coverage extends to 2033.

- Revamped the corporate and investor websites to increase transparency and improve mobile accessibility.

Scientific Presentations and Conferences

- An abstract based on results obtained in a subsequent *ad hoc* analysis of Galectin Therapeutics' NASH-CX Phase 2 Clinical Trial by investigators at the University of Indiana was presented at The Liver Meeting (AASLD) in Boston, Massachusetts on November 8-12. The poster presentation was titled "Enhanced liver fibrosis (ELF) score significantly predicts 52-week liver decompensation in patients with compensated NASH cirrhosis."

- Eliezer Zomer, Vice President, will present at the 3rd Annual Anti-Fibrotic Drug Development Summit (AFDD) on November 19, 2019, in Cambridge, Massachusetts. Dr. Zomer's presentation, titled "Therapeutic Integrin Inhibition," will discuss the next generation of Galectin-3 inhibitors as well as the discovery of functional allosteric inhibitors as part of efforts of Galectin Sciences LLC, our majority-owned subsidiary.

Financial Results

For the three months ended September 30, 2019, the Company reported a net loss applicable to common stockholders of $2.8 million, or $0.05 per share, compared to a net loss applicable to common stockholders of $3.0 million, or $0.07 per share, for the three months ended September 30, 2018. The decrease in net loss per share was primarily due to an increase in weighted average shares outstanding in the current period compared to the prior-year period.

Research and development expense for the three months ended September 30, 2019, was $1.5 million compared with $1.5 million for the three months ended September 30, 2018. There was an increase of about $0.3 million in clinical and pre-clinical development expenses which was offset by a similar amount of decrease in non-cash stock-based compensation expense. General and administrative expense for the three months ended September 30, 2019, were $1.4 million, compared to $1.2 million for the three months ended September 30, 2018, primarily due to increases in legal and business development expenses.

As of September 30, 2019, the Company had $50.3 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, and potential additional capital under its At the Market common stock issuance agreement. The Company believes there is sufficient cash, including availability of the line of credit, to fund currently planned operations at least through December 31, 2020. The Company expects that it will require more cash to fund operations after December 31, 2020, and believes it will be able to obtain additional financing as needed. The total cost of the planned trial, including general overhead, is estimated to be approximately $100 to $115 million; however, the costs and timing of such trial are not yet completely finalized. These costs will require additional funding. There can be no assurance that we will be successful in obtaining financing to support our operations beyond December 31, 2020, or, if available, that any such financing will be on terms acceptable to us.

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. 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, 2018, 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 1,503	$ 1,505	$ 3,671	$ 5,279
General and administrative	1,360	1,175	4,579	5,338
Total operating expenses	2,863	2,680	8,250	10,617
Total operating loss	(2,863)	(2,680)	(8,250)	(10,617)
Other income (expense):				
Interest income	101	15	158	23
Interest expense	(22)	(87)	(65)	(256)
Total other income	79	(72)	93	(233)
Net loss	$ (2,784)	$ (2,752)	$ (8,157)	$ (10,850)
Preferred stock dividends	(35)	(294)	(198)	(848)
Warrant modification			(6,622)	
Net loss applicable to common stock	$ (2,819)	$ (3,046)	$ (14,977)	$ (11,698)
Basic and diluted net loss per share	$ (0.05)	$ (0.07)	$ (0.27)	$ (0.30)
Shares used in computing basic and diluted net loss per share	56,631	40,921	55,493	38,822

Condensed Consolidated Balance Sheet Data

	September 30, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents	$ 50,337	$ 8,253
Total assets	50,760	9,006
Total current liabilities	1,216	2,108
Total liabilities	1,278	2,108
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 47,759	$ 5,175

Source: Galectin Therapeutics Inc.