Galectin Therapeutics Reports Financial Results for the Quarter Ended March 31, 2020, and Provides Business Update

May 11, 2020

NASH-RX Clinical Trial Protocol Filed with FDA; First Patient Currently Expected to be Enrolled in Second Quarter 2020

Filed a New Form S-3 Shelf Registration Statement Which Replaces the Company's Existing Shelf Registration Statement, which Expires on June 1, 2020

NORCROSS, Ga., May 11, 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 March 31, 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 recently submitted the NASH-RX clinical trial protocol to the U.S. Food and Drug Administration (FDA). Taken together, the adaptations in this protocol should optimize the conduct of the NASH-RX trial to give belapectin (GR-MD-02) the best opportunity to show a positive therapeutic effect. Most notably, 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 large pharmaceutical company. While the filing currently anticipates clinical trials will begin in the second quarter of this year, this is a particularly challenging time to start a new clinical trial. Factors beyond our control, specifically related to the COVID-19 pandemic, may delay the trial's initiation. Notwithstanding that, we remain optimistic in moving forward. The unmet medical need for an effective treatment for patients with NASH cirrhosis remains an important motivation."

Richard E. Uihlein, Chairman of the Board, added, "I am very proud of our entire team at Galectin Therapeutics. Their efforts, along with invaluable assistance from our Co-Primary Investigators and based on input received from the FDA, resulted in a trial protocol which is designed to give our drug the best chance of demonstrating efficacy and safety. Additionally, it should also help to maximize patient retention and enhance participation. Our goal of slowing or otherwise preventing the development of new varices in our target clinical trial patient population, NASH patients with compensated cirrhosis, if attained, can help patients to avoid further cirrhosis complications. These include variceal bleeding and other decompensating events accompanying disease progression, which could ultimately lead to liver failure. Since there are currently no treatment options for NASH cirrhosis, liver transplantation is the only viable option. Alternatively, a reduction in the number of patients who progress to liver failure has the potential to save many lives."

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.

NASH-RX Trial Update

The NASH-RX trial will use an adaptive design, 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.

- The protocol for a seamless adaptively-designed Phase 2b/3 clinical study, the NASH-RX trial, was submitted to the U.S. Food and Drug Administration (FDA) on April 30, 2020. Details are available at www.clinicaltrials.gov NCT 04365868
- The filing currently anticipates clinical trials will begin in the second quarter of this year.
- The design of this trial reflects the unmet medical needs of the target patient population for belapectin treatment: NASH patients with compensated cirrhosis who develop esophageal varices. Bleeding varices are a cause of death in about one-third of cirrhotic patients. Currently, there is no approved treatment for preventing varices in these patients. The development of new varices reflects the progression of hepatic cirrhosis and thus portends the development of other cirrhosis complications and outcomes such as significant ascites, hepatic encephalopathy, and eventual liver failure.
- In addition on March 31, 2020, the Company also filed with the FDA a protocol for the hepatic impairment study (www.clinicaltrials.gov NCT04332432), with the study also currently anticipated to begin in the second quarter of this year.

Galectin Therapeutics will share more details about the protocol at the time the clinical trial begins.

Other Updates

- Pol F. Boudes, M.D. has now joined the company as Chief Medical Officer, where his background in NASH and other liver disease drug development has proven instrumental to the filing of the NASH-RX protocol and is expected to add significantly to the conduct of the trial.

New Articles Published to the Company's Website

- Shamseddeen H, Vilar-Gomez E, Chalasani N, Myers RP, Subramanian GM, Shlevin HH, Allgood AE, Orman ES (2020) Spontaneous Fluctuations in Liver Biochemistries in Patients with Compensated NASH Cirrhosis: Implications for Drug Hepatotoxicity Monitoring. Drug Safety 43:281–290. doi.org/10.1007/s40264-019-00896-1
    - Patients with cirrhosis may have spontaneous fluctuations in liver enzymes, which may confound the detection of drug-induced liver injury (DILI), but these fluctuations have not been described.
    - Study concluded that spontaneous liver enzyme abnormalities are common in patients with NASH cirrhosis in clinical trials, and these abnormalities rarely met criteria for DILI suspicion. Further work to better define these abnormalities and continued vigilance to detect DILI in this population is needed.

- Chalasani N, Abdelmalek MF, Garcia-Tsao G, Vuppalanchi R, Alkhouri N, Rinella M, Noureddin M, Pyko M, Shiffman M, Sanyal A, Allgood A, Shlevin H, Horton R, Zomer E, Irish W, Goodman Z, Harrison SA, Traber PG (2019) Effects of Belapectin, an Inhibitor of Galectin-3, in Patients with Nonalcoholic Steatohepatitis With Cirrhosis And Portal Hypertension. Gastroenterology S0016-5085(19)41895-7.

Shelf Registration Statement

The Company has filed a “shelf” registration statement on Form S-3 (the “Registration Statement”) with the Securities and Exchange Commission (the “SEC”) for the registration of up to $100.0 million of any combination of shares of the Company’s common stock, warrants, or rights (collectively, the “Securities”). The Registration Statement is being filed to replace the Company’s current “shelf” registration statement, which expires on June 1, 2020.

When the Registration Statement is declared effective by the SEC, Securities may be offered, separately or together, from time to time and in one or more offerings. A prospectus supplement related to the offer and sale of shares of common stock to be sold pursuant to an At The Market Issuance Sales Agreement with H. C. Wainwright & Co., LLC, is included within the Registration Statement. The terms of any other offering, including the specific terms and prices of the Securities, will be determined at the time of such offering and be made solely by means of the prospectus included in the Registration Statement and any prospectus supplement that may be filed with the SEC relating to such offering.

The Registration Statement has been filed with the SEC but has not yet become effective. The Securities may not be sold, nor may offers to buy the Securities be accepted, prior to the time the Registration Statement becomes effective. This press release shall not constitute an offer to sell or the solicitation of an offer to buy, nor shall there be any sale of the Securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities law of any such state.

Financial Results

For the three months ended March 31, 2020, the Company reported a net loss applicable to common stockholders of $3.6 million, or ($0.06) per share, compared to a net loss applicable to common stockholders of $9.1 million, or ($0.20) per share for the three months ended March 31, 2019. The decrease is largely due to a one-time, non-cash $6.6 million charge in the period ended March 31, 2019, related to extending the life of warrants held by the holder of the Company’s Series B preferred stock in connection with the conversion of all the Series B preferred stock into common stock, somewhat offset by an increase in 2020 research and development expense related to the Company’s planned NASH-RX trial.

Research and development expense for the three months ended March 31, 2020, was $2.1 million compared with $0.6 million for the three months ended March 31, 2019. The increase was primarily due to costs related to our NASH-RX clinical trial planning and site start-up and qualification processes globally, along with preparations and some preclinical activities incurred in support of the planned clinical program, such as development and reproductive toxicity studies, clinical supplies and other supportive activities. General and administrative expenses for the three months ended March 31, 2020, were $1.4 million, down from $1.7 million for the three months ended March 31, 2019, primarily due to a decrease in legal expenses partially offset by an increase in insurance expenses.

As of March 31, 2020, the Company had $43.3 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. 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 $125 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 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 GR-MD-02 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 March 31,	
	2020	**2019**
Operating expenses:		
Research and development	$ 2,144	$ 646
General and administrative	1,440	1,721
Total operating expenses	3,584	2,367
Total operating loss	(3,584)	(2,367)
Other income (expense):		
Interest income	50	14
Interest expense	(22)	(22)
Total other income	28	(8)
Net loss	$ (3,556)	$ (2,375)
Preferred stock dividends	6	(96)
Warrant modification	-	(6,622)
Net loss applicable to common stock	$ (3,550)	$ (9,093)
Basic and diluted net loss per share	$ (0.06)	$ (0.20)
Shares used in computing basic and diluted net loss per share	56,956	44,975

Condensed Consolidated Balance Sheet Data

	March 31, 2020	**December 31, 2019**
	(in thousands)	
Cash and cash equivalents	$ 43,328	$ 47,480

Total assets	44,111	48,467
Total current liabilities	1,316	2,820
Total liabilities	1,358	2,872
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 41,030	$ 43,872

Source: Galectin Therapeutics Inc.