Galectin Therapeutics Reports Financial Results for the Quarter Ended September 30, 2021, and Provides Business Update

11/15/21

Board approves exploration of a Company-sponsored belapectin oncology program complementing our ongoing NASH cirrhosis program

Leading oncology experts engaged to consult on strategic planning and operational direction in the development of belapectin in cancer immunotherapy

Management team strengthened with the appointment of Hugh Huang, Ph.D., as Vice President, CMC Pharmaceutical Development

NORCROSS, Ga., Nov. 15, 2021 (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 September 30, 2021. 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**.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, said, “I am extremely impressed with our new team members and our continuing progress this quarter. Building on our previous announcements of additional financing from our Chairman, Richard E. Uihlein, and positive results from a cancer immunotherapy extension trial of belapectin in combination with KEYTRUDA®, we are pleased to inform you about the progress we have made in working with Dr. Ben Carson, our strategic consultant. I am grateful to Board members and to Dr. Carson, who previously noted that belapectin has broad potential applications as it pertains to galectin-3 inhibition, including in oncology, where data has demonstrated the role that galectin-3 plays in the tumor micro-environment to stimulate tumor progression. Through Dr. Carson’s introductions, we met and retained new oncology consultants who are each affiliated with prestigious university medical centers. These consultants will assist us with strategic planning for the development of belapectin in cancer indications. Such a Company-sponsored oncology program would complement our existing NASH cirrhosis program and leverage belapectin’s potential as a galectin-3 inhibitor. Galectin-3 plays a major role in liver cirrhosis and is also strongly associated with cancer progression. Last week, the Board approved this important first step in exploring Company-sponsored oncology programs, and I hope to have more details at our annual meeting in December. At our most recent Board meeting, immediately after the Board approved Mr. Uihlein’s generous financing, I expressed to Dick and Rick Zordani, our audit committee chairman, that my goal was to assemble a highly qualified team and be able to have further discussions about an oncology program at our Annual Meeting in December. I intend to achieve that goal.

“The NAVIGATE trial for NASH cirrhosis is progressing, and we have seen increases in activity in the United States over the past several months. While this program is strongly supported by the hepatology and gastroenterology community, activity in Europe, South Korea and Latin America remains slower than we anticipated due to lingering effects of the COVID-19 pandemic and the emergence of new COVID-19 variants. These activities include clinical trial applications, clinical research site start-ups, patient screenings and randomizations. Over the past few weeks our team has thoroughly analyzed these dynamics. While we do need to extend the estimated completion of enrollment in the Phase 2b portion of the NAVIGATE trial by six months to around the end of the second quarter of 2022, we only need to extend the anticipated initial top-line results by three months, until the end of the first quarter of 2024. This is in large measure due to the additional capacity and expertise of my team. We have added talented and experienced professionals in key leadership roles this year that have and will continue to strengthen the Company. This strategy will progress until we believe we have the best team in place, giving us the critical mass we need for success.”

Richard E. Uihlein, Chairman of the Board, added, “I am pleased with the additional management personnel that have been recently attracted to join the Company and believe they will assist in continuing to move us forward. While we are similar to many other companies who have experienced slower than planned clinical trial enrollment during the pandemic, I am encouraged by the recent acceleration that we will fully enroll the NAVIGATE trial. Finally, I am gratified by the interest shown in our combination cancer immunotherapy program by the esteemed physicians that are now collaborating with us. I look forward to hearing their insights, as well as sharing them with you.”

Program Review

Cancer Immunotherapy

In our cancer immunotherapy program, we previously announced positive top-line results in our Phase 1b investigator initiated clinical trial extension of belapectin in combination with KEYTRUDA in advanced metastatic melanoma and head and neck cancer. The study provided further clinical evidence that using belapectin, a potent galectin-3 inhibitor, in combination with pembrolizumab (KEYTRUDA), a PD-1 inhibitor, significantly enhances tumor response to immunotherapy in patients with advanced metastatic melanoma (MM) and head and neck squamous cell carcinoma (HNSCC).

In furtherance of this program, the Company engaged three new key oncology opinion leaders as consultants to assist the Company in formulating our strategic and operational directions. Additional information will be provided in the near future.

NAVIGATE Study (NASH Cirrhosis)

A protocol amendment adopted in the third quarter, aimed at refining criteria for patients with portal hypertension and based on input from investigators, has been approved by institutional review boards and implemented globally. This protocol amendment has resulted in an improved quality of screening and, importantly, more patients qualifying for enrollment.

Our innovative NAVIGATE study web portal, NAVIGATEnash.com, continues to be a useful resource for patients and physicians interested in the trial, NASH cirrhosis, and portal hypertension. The site provides a steady stream of new information about NASH cirrhosis, the diagnosis and consequences of portal hypertension, and the NAVIGATE study. NAVIGATEnash.com is also attracting significant activity as we build a community

where NASH cirrhosis patients and physicians can share information.

Corporate Development

The Company continues to build its management team to achieve its goal of advancing belapectin and recently welcomed Hugh Huang, Ph.D., as Vice President, Chemical Manufacturing and Controls (CMC) Pharmaceutical Development. Dr. Huang has broad and successful product development experiences in parenteral and non-parenteral formulations and has had roles of increasing responsibility in both large and mid-sized pharma companies. Dr. Huang received his Ph.D. in biochemistry from Ohio State University.

Additionally, as previously announced, several other key leadership positions have been recently filled, including Dakshina Reddy, MSM, as Executive Director, Regulatory Affairs; Ezra R. Lowe, Ph.D., as Executive Director, Clinical and Preclinical Pharmacology; Marla Mills-Wilson, as Executive Director, Clinical Operations; and Jessica Kopaczewski, as Associate Director, Clinical Operations.

These strategic appointments strengthen the company's clinical, regulatory, CMC, and operational efforts across its ongoing programs in cancer immunotherapy and NASH cirrhosis. The Company expects to add additional key senior resources in the near future.

On September 21, the company announced that it had entered into a $20 million convertible debt financing agreement with Richard E. Uihlein, the Company's Chairman and largest individual stockholder. The loan agreement comprises two separate $10 million convertible notes, the first of which closed and funded on September 17, 2021, and the second of which is expected to close on or before December 17, 2021.

Scientific Presentations

The Company presented six scientific abstracts at The Liver Meeting™ 2021, hosted by the American Association for the Study of Liver Diseases (AASLD), held virtually from November 12 to 15, 2021.

Financial Results

For the three months ended September 30, 2021, the Company reported a net loss applicable to common stockholders of $8.6 million, or ($0.14) per share, compared to a net loss applicable to common stockholders of $6.0 million, or ($0.10) per share for the three months ended September 30, 2020. The increase is largely due to an increase in 2021 research and development expenses related to the Company's NAVIGATE trial.

Research and development expenses for the three months ended September 30, 2021, was $6.6 million compared with $4.8 million for the three months ended September 30, 2020. The increase was primarily due to costs related to our NAVIGATE clinical trial and other supportive activities. General and administrative expenses for the three months ended September 30, 2021, were $1.6 million, compared to $1.1 million for the three months ended September 30, 2020.

As of September 30, 2021, the Company had $36.6 million of cash and cash equivalents. On September 17, 2021, the Company received $10 million in proceeds from an unsecured convertible promissory note from its Board Chairman, Richard E. Uihlein. The Company also has an agreement for an additional $10 million unsecured promissory note from Mr. Uihlein to close in December 2021. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through at least March 31, 2023.

The Company expects that it will require more cash to fund operations after March 31, 2023, and believes it will be able to obtain additional financing as needed. Currently, we expect to require an additional approximately $30-$35 million to cover costs of the NAVIGATE trial to reach the planned interim analysis estimated to occur around the end of the first quarter of 2024, along with drug manufacturing and other scientific support activities and general and administrative costs. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us.

About Belapectin

Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH 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. Belapectin binds to galectin-3 and disrupts its function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis. A Phase 2 study showed belapectin may prevent the development of esophageal varices in NASH cirrhosis, and these results provide the basis for the conduct of the NAVIGATE trial. The NAVIGATE trial (www.NAVIGATEnash.com), titled "A Seamless Adaptive Phase 2b/3, Double-Blind, Randomized, Placebo-controlled Multicenter, International Study Evaluating the Efficacy and Safety of Belapectin (GR-MD-02) for the Prevention of Esophageal Varices in NASH Cirrhosis," began enrolling patients in June 2020, and is posted on www.clinicaltrials.gov (NCT04365868). Galectin-3 has a significant role in cancer, and the Company has supported a Phase 1b study in combined immunotherapy of belapectin and KEYTRUDA in advanced melanoma and in head and neck cancer. This trial provided a strong rationale for moving forward into a Company-sponsored Phase 2 development program, which the company is exploring.

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 current 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 continue to impact 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, 2020, 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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Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc. Belapectin is the USAN assigned name for Galectin Therapeutics’ galectin-3 inhibitor GR-MD-02.

Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 6,613	$ 4,780	$ 17,962	$ 11,605
General and administrative	1,631	1,146	4,792	4,007
Total operating expenses	8,244	5,926	22,754	15,612
Total operating loss	(8,244)	(5,926)	(22,754)	(15,612)
Other income (expense):				
Interest income	1	5	3	64
Interest expense	(111)	(22)	(217)	(65)
Change in fair value of derivative	(166)	-	- (338)	-
Total other income	(276)	(17)	(552)	(1)
Net loss	$ (8,520)	$ (5,943)	$ (23,306)	$ (15,613)
Preferred stock dividends	(37)	(12)	(104)	(72)
Warrant modification				
Net loss applicable to common stock	$ (8,557)	$ (5,955)	$ (23,410)	$ (15,685)
Basic and diluted net loss per share	$ (0.14)	$ (0.10)	$ (0.40)	$ (0.28)
Shares used in computing basic and diluted net loss per share	59,290	57,047	58,253	57,013

Condensed Consolidated Balance Sheet Data

	September 30, 2021	December 31, 2020
	(in thousands)	
Cash and cash equivalents	$ 36,600	$ 27,142
Total assets	38,038	29,600
Total current liabilities	8,299	5,399
Total liabilities	28,789	5,407
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 7,526	$ 22,470