Galectin Therapeutics Reports Financial Results for the Quarter Ended September 30, 2023 and Provides Business Update

11/13/23

NORCROSS, Ga., Nov. 13, 2023 (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, 2023. 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: “Recently, two significant events occurred that we believe demonstrate confidence in our ongoing mission to bring to market a therapy for NASH cirrhosis patients where none currently exists. First, in late September 2023, our Board Chairman, Richard E. Uihlein, exercised 2,236,204 common stock purchase warrants for cash proceeds to the Company of $10 million. The price paid per share of $4.49 was significantly higher than the market price on the transaction date of $1.81. Additionally, as previously announced, Dr. Benjamin S. Carson, Sr. agreed to accept a nomination to join our Board of Directors. Dr. Carson has had an extraordinary career in medicine, business, and public service, and we are extremely pleased and gratified that he accepted the nomination. The support of Mr. Uihlein and Dr. Carson uniquely positions the Company to achieve our goals.”

Dr. Pol Boudes, Chief Medical Officer stated: “We continue to see an apparent positive safety and tolerance profile of belapectin, with some patients now having been dosed for 36 months. We remain on schedule to obtain the interim analysis results for NAVIGATE in the fourth quarter of 2023. Finally, I am proud of our team for having five scientific abstracts presented at the American Association of Liver Diseases Meeting going on this week. This is an outstanding accomplishment by our team.”

Financial Results

For the three months ended September 30, 2023, the Company reported a net loss applicable to common stockholders of $14.0 million, or ($0.24) per share, compared to a net loss applicable to common stockholders of $8.6 million, or ($0.14) per share for the three months ended September 30, 2022. Included in the loss applicable to common stockholders in the three months ended September 30, 2023, is a one-time, non-cash deemed dividend in the amount of $3.6 million related to the modification of certain common stock purchase warrants to extend the expiration dates through September 2026. In exchange for this modification, the cashless exercise provision was removed from the warrants. Additionally, the provision enabling the holder of the warrants to nominate a director for the board was eliminated among other terms. The net loss from operations increased by $1.0 million for the three months ended September 30, 2023 compared to 2022 primarily due to expenses related to hiring of additional personnel and activities associated with our belapectin program.

Research and development expenses for the three months ended September 30, 2023, were $7.7 million compared with $6.6 million for the three months ended September 30, 2022. The increase was primarily due to the hiring of additional employees to support our clinical trial program and other activities associated with belapectin. General and administrative expenses for the three months ended September 30, 2023, were $1.4 million, compared to $1.5 million for the three months ended September 30, 2022.

As of September 30, 2023, the Company had $20.4 million of cash and cash equivalents. Additionally, the Company has $30 million remaining available under a $60 million line of credit provided by its chairman to fund operations. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through at least December 31, 2024.

The Company expects that it will require more cash to fund operations after December 31, 2024, and believes it will be able to obtain additional financing as needed. 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 when it has progressed to the liver cirrhosis stage as well as advanced cancers. Galectin-3 is produced by activated macrophages, a key inflammatory cell, and plays a major role in diseases that involve scarring of organs, including fibrotic disorders of the liver, lung, kidney, heart, as well as in the cancerous tumor microenvironment. Belapectin binds to galectin-3 and disrupts its function. Belapectin, because of its unique structure, is also captured by activated macrophages and exerts its activity directly at the source of galectin-3 production. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis associated with liver cirrhosis, a disease that is characterized by an invasion of activated macrophages into the liver parenchyma. 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 for the Prevention of Esophageal Varices in NASH Cirrhosis,” completed randomization of 357 patients in February 2023 with top-line data expected from the Phase 2b portion in the fourth quarter of 2024, and is posted on www.clinicaltrials.gov (NCT04365868). Galectin-3 has a significant role in cancer, in making the tumor microenvironment resistant to immunological treatment, and the Company has supported a Phase 1b study in combined immunotherapy of belapectin and Keytruda in advanced melanoma and in head and neck cancers. 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), a complication of fatty liver disease, 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 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 9,000 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, 2022, 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,	
	2023	2022	2023	2022
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 7,732	$ 6,598	$ 23,902	$ 22,730
General and administrative	1,434	1,524	4,609	4,989
Total operating expenses	9,166	8,122	28,511	27,719
Total operating loss	(9,166)	(8,122)	(28,511)	(27,719)
Other income (expense):				
Interest income	62	18	156	22
Interest expense	(835)	(269)	(1,945)	(725)
Change in fair value of derivative	(489)	(224)	(769)	280
Total other income	(1,262)	(475)	(2,558)	(423)
Net loss	$ (10,428)	$ (8,597)	$ (31,069)	$ (28,142)
Preferred stock dividends	6	16	(57)	(32)

Warrant modification	(3,619)		(3,619)	
Net loss applicable to common stock	$ (14,041)	$ (8,581)	$ (34,745)	$ (28,174)
Basic and diluted net loss per share	$ (0.24)	$ (0.14)	$ (0.58)	$ (0.47)
Shares used in computing basic and diluted net loss per share	59,704	59,396	59,590	59,380

Condensed Consolidated Balance Sheet Data

	September 30, 2023	December 31, 2022
	(in thousands)	
Cash and cash equivalents	$ 20,362	$ 18,592
Total assets	22,163	21,285
Total current liabilities	10,522	13,012
Total liabilities	73,036	53,479
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity (deficit)	$ (52,596)	$ (33,917)