Galectin Therapeutics Reports Fiscal 2020 Financial Results and Provides Business Update

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NORCROSS, Ga., March 31, 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 year ended December 31, 2020. These results are included in the Company's Annual Report on Form 10-K, 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 very encouraged by the progress achieved in fiscal 2020, and remain extremely optimistic for 2021. Given the current challenging environment, I am proud of our success, highlighted by site activations and ongoing enrollment of our innovative NAVIGATE study. This global program continues to be the only active late-stage trial of patients with compensated NASH cirrhosis, where the medical need is greatest and with a clinically meaningful endpoint. Our concurrent hepatic impairment study will also provide important information on belapectin tolerance, safety and exposure in advanced cirrhotic patients.

Over the course of the last year at the Board’s direction we have taken aggressive steps to strengthen our organization, adding Pol Boudes as Chief Medical Officer, as well as Mr. Richard Zordani and Dr. Elissa Schwartz to our Board of Directors. These changes informed my decision to accept the role of Chief Executive Officer, and they afforded me the confidence to receive 80% of my compensation in the form of Galectin stock. Additionally, I believe this breadth of talent reinvigorated Galectin and placed the Company in a position to monetize our assets. This has served to strengthen my commitment to my compensation strategy, which aligns my interests with all shareholders.

More recently, the peer-reviewed publication of a well-recognized mouse model has shown that the combination of belapectin, a galectin-3 inhibitor, with immunotherapy reprograms the tumor microenvironment. This favors anti-tumor immunity, results in better anti-tumor activity, and most importantly, brings further rationale for our ongoing cancer trial combining belapectin with Keytruda®, a potent PD-1 inhibitor. Providence Cancer Institute is currently conducting the study and preliminary results suggest improved activity and, potentially, improved tolerance of this regimen.

I am extremely confident in our science, our team, and our progress,” concluded Lewis. The upcoming year will be dedicated to advancing our trial in NASH cirrhosis and supporting investigations of belapectin’s safety and efficacy in other indications, such as the ongoing cancer trial in conjunction with the Providence Cancer Institute. I also want to recognize the outstanding efforts of our entire team, who persevered through the challenges precipitated by COVID-19 in the interest of developing a therapy for NASH cirrhosis, a critical, unmet medical need. Let me once again thank the investigators and patients participating in our NAVIGATE trial, where a positive outcome would be very clinically relevant for patients with NASH cirrhosis.”

Richard E. Uihlein, Chairman of the Board, added, “I want to echo Joel’s sentiment and thank Pol, Jack and our entire team for their dedication throughout this past year, especially their commitment to initiating our exciting NAVIGATE trial under less than optimal circumstances due to the global pandemic. Joel has proven to be the leader we all expected, and I am pleased with the progress he has achieved since assuming the role and confident in his ability to unlock the value of our proprietary compound, belapectin. Peer-reviewed research, such as that recently published in *OncoImmunology*, clearly confirms our basic scientific premise regarding belapectin’s anti-inflammatory characteristics in a broad range of fibrosis as well as its ability to potentially enhance the efficacy of cancer therapies. As such, the NAVIGATE trial represents an opportunity to further demonstrate the anti-inflammatory activity of belapectin, which would open up vast new opportunities to investigate other indications and establish our compound as a foundation for a platform technology.”

NAVIGATE Trial Update

- The NAVIGATE trial uses a seamless, adaptive design to confirm dose selection and reaffirm the observed efficacy of belapectin to prevent the development of esophageal varices in the NASH-CX trial. Pre-planned adaptations will inform the larger Phase 3 trial component.
- Key clinical study milestones:
  - First patient randomized August 2020
  - 130+ sites, 12 countries in North America, Europe, Asia and Australia
  - Phase 2b part to Interim Analysis will be ~315 patients
  - Recruiting period for phase 2b portion now expected to conclude around the end of 2021 due to COVID-19 impact on recruitment
  - Key inclusion criteria - NASH cirrhosis (baseline or historical liver biopsy), clinical sign of portal hypertension, no esophageal varices (esophago-gastro endoscopy)
  - Interim analysis expected late 2023

Peer-reviewed publication, Scientific Presentations and Conferences

- *OncoImmunology* published a peer-reviewed article describing how belapectin, a potent galectin-3 inhibitor, in combination with an anti-OX40 (CD134) monoclonal antibody, reduces tumor progression compared to either agent alone. The paper, titled “Galectin-3 inhibition with belapectin combined with anti-OX40 therapy reprograms the tumor microenvironment to favor anti-tumor immunity,” describes results from a collaboration between Galectin Therapeutics and Providence Cancer

Institute highlighting the mechanism of action of the combination which is explained by a reduction in myeloid-derived suppressor cell infiltration and function coupled to an increase in T-cell effector function. For many years, galectin-3 has been known to play a key role in the control of tumor-induced immunosuppression. Galectin-3 acts to maintain tumor growth, in part, by supporting the generation of suppressive macrophages and inhibiting T cell function. This creates an attractive rationale for the use of a galectin-3 inhibitor, such as belapectin, to improve anti-tumor activities of multiple cancer therapies.

Financial Results

For the year ended December 31, 2020, the Company reported a net loss applicable to common stockholders of $23.6 million, or ($0.41) per share, compared to a net loss applicable to common stockholders of $20.2 million, or ($0.39) per share for the full year 2019. The increase is largely due to an increase in research and development expenses related to our NAVIGATE clinical trial, partially offset by a non-cash, one-time warrant modification charge of $6.6 million in 2019.

Research and development expense for 2020 was $18.0 million compared with $7.5 million for 2019. The increase was primarily due to costs related to our NAVIGATE 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 2020 were $5.5 million, down from $6.0 million for the full year 2019, primarily due to decreases in legal, investor relations and non-cash stock-based compensation expenses partially offset by an increase in insurance expenses.

As of December 31, 2020, the Company had $27.1 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 March 31, 2022.

The Company expects that it will require more cash to fund operations after March 31, 2022, and believes it will be able to obtain additional financing as needed. The currently planned operations include costs related to our adaptively designed NAVIGATE Phase 2b/3 clinical trial. Currently, we expect to require an additional approximately $45-$50 million to cover costs of the trial to reach the planned interim analysis estimated to occur in the second half of 2023 along with drug manufacturing and other scientific support activities and general and administrative costs and further amounts to complete the Phase 3 portion of the trial. 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 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 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.

Company Contact:
Jack Callicutt, Chief Financial Officer
(678) 620-3186
ir@galectintherapeutics.com.

Condensed Consolidated Statements of Operations

	Year Ended December 31,	
	2020	2019
Operating expenses:		
Research and development	$ 17,976	$ 7,467
General and administrative	5,468	5,971
Total operating expenses	23,444	13,438
Total operating loss	(23,444)	(13,438)
Other income (expense):		
Interest income	66	231
Interest expense	(87)	(87)
Total other income	(21)	144
Net loss	$ (23,465)	$ (13,294)
Preferred stock dividends	(137)	(263)
Warrant modification	-	(6,622)
Net loss applicable to common stock	$ (23,602)	$ (20,179)
Basic and diluted net loss per share	$ (0.41)	$ (0.39)
Shares used in computing basic and diluted net loss per share	57,029	52,238

Condensed Consolidated Balance Sheet Data

	December 31, 2020	December 31, 2019
	(in thousands)	
Cash and cash equivalents	$ 27,142	$ 47,480
Total assets	29,600	48,467
Total current liabilities	5,399	2,820
Total liabilities	5,407	2,872
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 29,600	$ 43,872