Galectin Therapeutics Reports 2024 Financial Results and Provides Business Update

03/31/25

NORCROSS, Ga., March 31, 2025 (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, 2024.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, said “In the U.S. approximately 5 million adults are affected by MASH cirrhosis and clinically significant portal hypertension. The need for new treatments that can prevent disease progression is more urgent than anticipated. The NAVIGATE trial’s per-protocol analysis in U.S. patients revealed a remarkable 68% reduction in the incidence of new varices, underscoring belapectin’s potential as a treatment for MASH cirrhosis and portal hypertension. The statistically significant results in per protocol population at 18 months are further reinforced by the favorable trend observed in available 36 month data. We look forward to sharing additional results, including specialized biomarkers analyses results, in the second quarter of 2025, and collaborating with potential partners and leading medical experts to define the optimal next steps in belapectin’s development. Finally, I want to thank Richard Uihlein, our chairman, for providing an additional $5 million line of credit this month that will allow us to extend our cash runway as we continue to analyze NAVIGATE results and prepare to discuss them with potential partners and the FDA.”

Khurram Jamil, M.D., Chief Medical Officer added “I am encouraged by the 2 mg belapectin data, which demonstrated an approximately 49% reduction in varices incidence in the per-protocol population and a 68% reduction in the per-protocol population of U.S. patients, further validating the findings of our previous Phase 2b (GT-026) trial. Additionally, a total of 57 subjects completed 36 months of treatment and the positive trend that was observed at 18 months for the belapectin 2 mg cohort was sustained at 36 months, with a lower incidence of varices compared to placebo (13.0% vs. 20.0%). These results further support the potential of the 2 mg dose in preventing varices in MASH cirrhosis patients with portal hypertension. I believe the results warrant further clinical development as belapectin could become a pivotal therapeutic option for these patients who currently do not have any treatment options. Our hope is that belapectin MASH program, which has a Fast Track Designation, will ultimately provide the first targeted treatment option for the increasing number of patients affected by MASH-associated liver cirrhosis.”

Belapectin Program Highlights
Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH and fibrosis.

NASH Cirrhosis

- NAVIGATE Phase 2b/3 trial (NCT04365868) is global, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of belapectin intravenously either belapectin 2mg/kg of lean body mass (LBM) (n=119), 4 mg/kg/LBM (n=118) or placebo (n=118) every other week for 18 months for the prevention of esophageal varices in MASH cirrhosis.
    - Topline data from the NAVIGATE trial showed that the incidence of varices at 18 months was 43.2% lower in patients treated with belapectin 2 mg vs placebo; however, the composite endpoint did not reach statistical significance in the intent-to-treat population (n=355).
    - In the per-protocol population (n=287), the incidence of varices was reduced by 49.3% in patients treated with belapectin 2 mg vs placebo (nominal p-value = 0.04).
    - The incidence of varices was significantly reduced by 68.1% (p=0.02) in the per-protocol patients enrolled in the U.S. treated with belapectin 2 mg vs placebo (n=186).
    - Patients in the U.S. had a higher percentage use of GLP-1 and statins than the rest of the world across three cohorts, and the belapectin cohorts performed much better than placebo in the U.S.
    - Similar proportion of subjects reported Treatment-Emergent Adverse Events (TEAEs), Treatment-Emergent Serious Adverse Events (TEASEs), and discontinuation across the 3 cohorts. No drug related Serious Adverse Events (SAE) were observed in NAVIGATE.
- The Company is currently conducting the full analysis of the NAVIGATE trial data and anticipates having additional biomarker data in the second quarter of 2025.

Full Year 2024 Financial Highlights

- As of December 31, 2024, the Company had $15.1 million of unrestricted cash and cash equivalents in addition to $6 million available under a line of credit provided by our chairman available to fund future operations. Additionally, in March 2025, we signed a new supplemental line of credit agreement with our chairman for an additional $5 million of available borrowings. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through August 2025.
- Research and development expenses for the year ended December 31, 2024 were $36.6 million compared with $32.1 million for the year ended December 31, 2023. The increase was primarily due to costs related to our NAVIGATE clinical trial and other supportive activities.
- General and administrative expenses for the year ended December 31, 2024 were $5.9 million, compared to $5.9 million for the year ended December 31, 2023.

- For the year ended December 31, 2024, the Company reported a net loss applicable to common stockholders of $47.2 million, or ($0.76) per share, compared to a net loss applicable to common stockholders of $44.5 million, or ($0.74) per share for the year ended December 31, 2023. The increase is largely due to an increase in noncash interest expense of $2.7 million and a increase in research and development costs due to the NAVIGATE trial.
- 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**.

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 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 metabolic dysfunction-associated steatohepatitis (MASH, formerly known as nonalcoholic steatohepatitis, or NASH) with cirrhosis, the most advanced form of MASH-related fibrosis. Liver cirrhosis is one of the most pressing medical need and a significant drug development opportunity. Additional development programs are in treatment of combination immunotherapy for advanced head and neck cancers 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", "look forward", "believe", "hope" 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 MASH, formerly known as NASH, 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, full analysis of the NAVIGATE trial data may not product positive data; 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 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, 2024, 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

	Year Ended December 31,	
	2024	2023
Operating expenses:		
Research and development	$ 36,571	$ 32,130
General and administrative	5,862	5,942
Total operating expenses	42,433	38,072
Total operating loss	(42,433)	(38,072)
Other income (expense):		
Interest income	336	230
Interest expense	(5,540)	(2,792)
Change in fair value of derivatives	590	(432)

Total other income	(4,614)	(2,994)
Net loss	$ (47,047)	$ (41,066)
Preferred stock dividends	(153)	(120)
Warrant modification		(3,619)
Net loss applicable to common stock	$ (47,200)	$ (44,805)
Basic and diluted net loss per share	$ (0.76)	$ (0.74)
Shares used in computing basic and diluted net loss per share	62,309	60,159

Condensed Consolidated Balance Sheet Data

	December 31, 2024	December 31, 2023
	(in thousands)	
Cash and cash equivalents ……	$ 15,120	$ 25,660
Total assets……	17,495	28,200
Total current liabilities……	35,409	15,676
Total liabilities……	120,565	88,441
Total redeemable, convertible preferred stock….	1,723	1,723
Total stockholders' equity (deficit) …..	$ (104,793)	$ (61,964)