Galectin Therapeutics Reports 2025 Financial Results and Provides Business Update

03/31/26

NORCROSS, Ga., March 31, 2026 (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, 2025.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, said “We are at an important juncture for the belapectin development program. During 2025, we made meaningful progress advancing the belapectin program and continuing our analysis of the NAVIGATE dataset in patients with MASH cirrhosis and portal hypertension. We are encouraged by the signals observed, including additional biomarkers from the NAVIGATE dataset, and remain focused on evaluating the data as we engage with regulators, potential partners, and leading experts to determine the optimal path forward for the program.

Importantly, we also improved the Company’s financial position during the year, including securing an additional $10 million line of credit from our Chairman, Dick Uihlein, to extend our projected cash runway through April 2027. Also, just very recently, we have strengthened our Board with the appointment of Dr. Henry Brem, an internationally recognized neurosurgeon-scientist and leader in translational medicine, whose clinical development experience will be valuable as we advance the program. With no approved therapies currently available for patients with MASH cirrhosis, we believe belapectin has the potential to address a significant unmet medical need and look forward to discussing the program with FDA.”

Khurram Jamil, M.D., Chief Medical Officer, added “The NAVIGATE dataset continues to provide encouraging insights supporting belapectin’s potential role in patients with MASH cirrhosis and portal hypertension. In addition to the previously reported clinical finding of reduced varices incidence in the per-protocol population, additional biomarker analyses have demonstrated consistent signals across specialized markers of fibrosis and noninvasive measures of liver stiffness, supporting belapectin’s potential antifibrotic activity and disease-modifying effect. These findings have been well received by the scientific community and were recently discussed by leading hepatology experts during our March 10, 2026 virtual KOL event, where the data were reviewed in the context of disease progression and portal hypertension category risk in MASH cirrhosis. Taken together, these results further strengthen the biological rationale for galectin-3 inhibition and support continued evaluation of belapectin as a potential therapy for patients with MASH cirrhosis, a population for whom there are currently no approved treatment options. We are excited about our upcoming FDA meeting in the second quarter of 2026 to align on the next steps for advancing the program. We are pleased to announce that multiple abstracts from the NAVIGATE program have been accepted for presentations at the upcoming EASL Congress, including one oral presentation. This builds on our momentum from last year’s late-breaker presentation at EASL and oral presentation at AASLD 2025 and reflects the continued interest from the scientific community in our unique and comprehensive dataset.”

Belapectin Program Highlights
Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein involved in fibrosis and inflammation associated with MASH and portal hypertension.

MASH Cirrhosis

- NAVIGATE Phase 2b/3 trial (NCT04365868) is a global, randomized, double-blind, placebo-controlled study evaluating belapectin administered intravenously at 2 mg/kg or 4 mg/kg of lean body mass (LBM) versus placebo every two weeks for 18 months for the prevention of esophageal varices in patients with MASH cirrhosis.
- The NAVIGATE trial demonstrated:
    - In the intent-to-treat population (n=355), the incidence of varices at 18 months was 43.2% lower in patients treated with belapectin 2 mg/kg compared with placebo, although the composite endpoint did not reach statistical significance.
    - In the per-protocol population (n=287), belapectin 2 mg/kg reduced the incidence of varices by 49.3% versus placebo (nominal p = 0.04).
    - In U.S. patients within the per-protocol population (n=186), belapectin 2 mg/kg reduced the incidence of varices by 68.1% compared with placebo (p = 0.02).
    - Safety results showed a similar proportion of treatment-emergent adverse events, serious adverse events, and discontinuations across treatment groups, with no drug-related serious adverse events observed.
    - Additional 18-month NAVIGATE biomarker analyses presented in 2025 demonstrated consistent effects across multiple non-invasive markers of fibrosis and disease progression, including FibroScan® liver stiffness measurement, ELF score, and PRO-C3, further supporting belapectin’s potential antifibrotic and disease-modifying activity in patients with compensated MASH cirrhosis and portal hypertension.
    - Additional mechanistic analyses, including YKL-40 and PRO-C4, further supported belapectin’s biological activity, with findings consistent with reduced inflammation and fibrogenesis.
    - Analyses using validated Baveno VII criteria suggested belapectin treatment was associated with improvements in portal hypertension risk categories and a reduced risk of hepatic decompensation compared with placebo.
- In March 2026, the Company hosted a virtual KOL event featuring leading hepatology experts who reviewed additional NAVIGATE biomarker findings and discussed their implications for disease progression and portal hypertension risk in MASH cirrhosis.

- The Company will present new NAVIGATE trial analyses at EASL 2026 (May 27–30, 2026), including an oral presentation on reduced varices based on favorable changes in markers of fibrosis formation and resolution (PRO-C3/CTX-III), and a poster presentation on risk reduction in clinically significant portal hypertension in advanced MASH cirrhosis.

Full Year 2025 Financial Highlights

- As of December 31, 2025, the Company had $17.7 million of unrestricted cash and cash equivalents in addition to $10 million available under a line of credit provided by our chairman to fund future operations. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through April 2027.

- Research and development expenses for the year ended December 31, 2025 were $14.3 million compared with $36.6 million for the year ended December 31, 2024. The decrease 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, 2025 were $5.8 million, compared to $5.9 million for the year ended December 31, 2024.

- For the year ended December 31, 2025, the Company reported a net loss applicable to common stockholders of $31.0 million, or ($0.48) per share, compared to a net loss applicable to common stockholders of $47.2 million, or ($0.76) per share, for the year ended December 31, 2024. The decrease is largely due to a decrease in research and development costs due to the conclusion of 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 produce 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, 2025, 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 belapectin.

Condensed Consolidated Statements of Operations

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	$ 14,290	$ 36,571
General and administrative	5,795	5,862
Total operating expenses	20,085	42,433
Total operating loss	(20,085)	(42,433)
Other income (expense):		
Interest income	126	336
Interest expense	(7,329)	(5,540)
Change in fair value of derivatives	(3,548)	590
Total other income	(10,751)	(4,614)
Net loss	$ (30,836)	$ (47,047)
Preferred stock dividends	(138)	(153)
Warrant modification		
Net loss applicable to common stock	$ (30,974)	$ (47,200)
Basic and diluted net loss per share	$ (0.48)	$ (0.76)
Shares used in computing basic and diluted net loss per share	63,903	62,309

Condensed Consolidated Balance Sheet Data

	December 31, 2025	December 31, 2024
	(in thousands)	
Cash and cash equivalents	$ 17,720	$ 15,120
Total assets	19,532	17,495
Total current liabilities	8,030	35,409
Total liabilities	145,727	120,565
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity (deficit)	$ (127,918)	$ (104,793)