



Galectin Therapeutics Reports Financial Results for the quarter ended September 30, 2025, and Provides Business Update

11/14/25

NORCROSS, Ga., Nov. 14, 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 three and nine months ended September 30, 2025.

"The new NAVIGATE data presented at AASLD further strengthen the clinical and mechanistic profile of belapectin. We continue to see encouraging consistency across key biomarkers—including FibroSca®[®], ELF, and PRO-C3—all supporting belapectin's durable antifibrotic activity and potential to slow disease progression in patients with compensated MASH cirrhosis. We submitted the NAVIGATE data package to the FDA and requested feedback on proposed next steps, with guidance anticipated by year-end. As we move forward, our focus remains on advancing dialogue with FDA and exploring strategic opportunities to maximize the value of this promising program," said Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics.

Khurram Jamil, M.D., Chief Medical Officer, added, "Importantly, the concordant biomarker data across independent measures support the mechanistic rationale for Galectin-3 inhibition and highlight belapectin's potential to favorably alter disease trajectory in patients with advanced, high-risk MASH cirrhosis. From a clinical and mechanistic standpoint, these biomarker analyses provide compelling evidence of belapectin's biological activity and durability of effect. The data demonstrating reductions in Baveno VII defined portal hypertension risk categories are particularly encouraging, as they come from the sickest MASH cirrhosis patients studied to date. The results were consistent across both the overall and completer populations, with a clear dose-response observed, reinforcing the biological rationale. Taken together, these findings strengthen our confidence in belapectin's mechanism of action and its potential to positively impact disease progression in this high-risk population."

Recent Highlights

- Earlier in November, at the 2025 AASLD Annual Meeting, Galectin presented new 18-month biomarker analyses from the NAVIGATE trial, further supporting the antifibrotic and disease-modifying potential of belapectin in patients with compensated MASH cirrhosis and portal hypertension. The updated results reinforce and extend previously reported findings.
- Belapectin demonstrated consistent, meaningful effects across multiple key biomarkers in MASH cirrhosis. Fewer patients experienced clinically significant worsening of liver stiffness (LSM), while improvements in the ELF (Enhanced Liver Fibrosis) score suggested reduced fibrosis risk and potential improvement in liver function. Notably, the strongest impact was observed in the subgroup with the highest baseline risk (ELF score 11.3), underscoring belapectin's potential to benefit patients with advanced MASH cirrhosis. FibroScan®[®] derived liver stiffness measurement (LSM) and the ELF test are the most widely used noninvasive markers to assess fibrosis severity and the risk of complications in patients with MASH and MASH cirrhosis. PRO-C3 (which indicates active fibrosis) levels showed marked reductions, reflecting decreased fibrogenesis and aligning with observed reductions in new varices. Mechanistic support was provided by YKL-40 (a marker of inflammation), with a greater proportion of patients achieving significant reductions, consistent with Galectin-3 modulation. PRO-C4 data further indicated reduced fibrotic activity, distinguishing belapectin's impact versus placebo across both overall and completer populations. Together, these findings reinforce belapectin's antifibrotic mechanism of action in a very high-risk patient population.
- We also present new data showing that, using the validated Baveno VII criteria for portal hypertension, treatment with belapectin was associated with a reduced presence of clinically significant portal hypertension (CSPH) and a lower risk of hepatic decompensation at 18 months.
 - Belapectin reduced clinically significant portal hypertension category and risk of hepatic decompensation. Using Baveno VII criteria incorporating liver stiffness measurement (LSM) by transient elastography (FibroScan®[®]) and platelet count, belapectin treatment reduced the presence of clinically significant portal hypertension (CSPH) and lowered the risk of hepatic decompensation in patients with MASH cirrhosis. Notably, among recent MASH cirrhosis trials reported, NAVIGATE enrolled one of the most advanced patient populations, as evidenced by the high proportion of subjects meeting CSPH criteria at baseline.
 - All portal hypertension risk categories were improved comparing belapectin to placebo. Over 18 months, a higher proportion of patients treated with belapectin transitioned from the CSPH or probable CSPH categories to the no/low-risk category, compared to placebo.
 - i. CSPH category for placebo decreased from 34.2% to 32.9% (-3.8% change) while belapectin 2 mg/kg decreased 33.3% to 25.9% (-22.2% change).
 - ii. Probable category for CSPH decreased for placebo from 21.1% to 15.8% (-25.1% change) while belapectin 2

- mg/kg probable category for CSPH decreased from 24.7% to 17.3% (–30% change).
- iii. No/low-risk category for CSPH for placebo increased from 44.7% to 51.3% (14.8% change) while belapectin 2 mg/kg no/low-risk category for CSPH increased from 42.0% to 56.8% (35.2% change).

This data demonstrates a consistent improvement in portal hypertension risk. Similar trends were observed in both the overall and per-protocol populations. This data has been included in our corporate presentation, accessible on our website.

- o Belapectin improved composite liver risk scores based on AGILE-4 assessment. Using AGILE-4, a validated composite marker incorporating liver enzymes, FibroScan[®] measurements, gender, and diabetes status, patients treated with belapectin demonstrated favorable outcomes relative to placebo. At 18 months, ~32% fewer subjects in the belapectin 2 mg/kg group experienced a ≥20% worsening in AGILE-4 score, a threshold indicative of increased risk for liver complications. This improvement reflects a meaningful reduction in disease progression and is consistent with the clinical endpoint findings of a lower incidence of new varices in the NAVIGATE trial.
- The company has submitted the NAVIGATE data package to the FDA and requested feedback on proposed next steps, with guidance anticipated by year-end.
- The management team participated in H.C. Wainwright Investor Meeting in New York (September) and the H.C. Wainwright MASH Conference (October), where NAVIGATE data were presented, including new analyses on fibrosis biomarkers.

Q3 2025 Financial Highlights

- As of September 30, 2025, the Company had \$11.5 million of cash and cash equivalents. Additionally, on July 8, 2025, the Company entered into a new \$10 million line of credit provided by its chairman of the board to fund operations. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through June 30, 2026.
- Research and development expenses for the quarter ended September 30, 2025 were \$2.6 million compared with \$7.6 million for the same period in 2024. The decrease was primarily due to timing of incurrence of expenditures related to our NAVIGATE clinical trial which ended in the first quarter of 2025.
- General and administrative expenses for the quarter ended September 30, 2025 were \$1.6 million, compared to \$1.5 million for the quarter ended September 30, 2024.
- For the quarter ended September 30, 2025, the Company reported a net loss applicable to common stockholders of \$8.2 million, or (\$0.13) per share, compared to a net loss applicable to common stockholders of \$11.2 million, or (\$0.18) per share for the quarter ended September 30, 2024.
- These results are included in the Company's Quarterly Report on Form 10-Q as of and for the period ended September 30, 2025, 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) with cirrhosis, the most advanced form of MASH-related fibrosis. Liver cirrhosis is one of the most pressing medical needs 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 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, 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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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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2025	2024	2025	2024
	(in thousands, except per share data)			
Operating expenses:				
Research and development	\$ 2,611	\$ 7,595	\$ 12,357	\$ 25,462
General and administrative	1,587	1,471	4,363	4,543
Total operating expenses	<u>4,198</u>	<u>9,066</u>	<u>16,720</u>	<u>30,005</u>
Total operating loss	<u>(4,198)</u>	<u>(9,066)</u>	<u>(16,720)</u>	<u>(30,005)</u>
Other income (expense):				
Interest income	39	93	101	254
Interest expense	(1,820)	(1,494)	(5,390)	(3,815)
Change in fair value of derivative	(2,205)	(753)	(3,327)	(1,514)
Total other income	<u>(3,986)</u>	<u>(2,154)</u>	<u>(8,616)</u>	<u>(5,075)</u>
Net loss	<u>\$ (8,184)</u>	<u>\$ (11,220)</u>	<u>\$ (25,336)</u>	<u>\$ (35,080)</u>
Preferred stock dividends	<u>(39)</u>	<u>(18)</u>	<u>(76)</u>	<u>(90)</u>
Net loss applicable to common stock	<u>\$ (8,223)</u>	<u>\$ (11,238)</u>	<u>\$ (25,412)</u>	<u>\$ (35,170)</u>
Basic and diluted net loss per share	<u>\$ (0.13)</u>	<u>\$ (0.18)</u>	<u>\$ (0.40)</u>	<u>\$ (0.57)</u>
Shares used in computing basic and diluted net loss per share	64,205	62,278	63,623	62,163

Condensed Consolidated Balance Sheet Data

	September 30, 2025		December 31, 2024	
	(in thousands)			
Cash and cash equivalents	\$ 11,525	\$ 15,120		
Total assets	12,865	17,495		
Total current liabilities	136,445	35,409		
Total liabilities	136,445	120,565		
Total redeemable, convertible preferred stock	1,723	1,723		
Total stockholders' deficit	<u>\$ (125,303)</u>	<u>\$ (104,793)</u>		