UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **May 15, 2025**

GALECTIN THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Nevada	**001-31791**	**04-3562325**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

4960 PEACHTREE INDUSTRIAL BOULEVARD, STE 240
NORCROSS, GA 30071
(Address of principal executive office) (zip code)

Registrant's telephone number, including area code: **(678) 620-3186**

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock $0.001par value per share	GALT	The Nasdaq Stock Market

SECTION 2 – FINANCIAL INFORMATION

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2025, Galectin Therapeutics Inc. ("Galectin Therapeutics") issued a press release announcing its results of operations and financial condition as of and for the three months ended March 31, 2025 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated May 15, 2025 (the "Press Release"), a copy of which is attached hereto as Exhibit 99.1.

Except for the historical information contained in this report, the statements made by Galectin Therapeutics are forward looking statements that involve risks and uncertainties. All such statements are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. Galectin Therapeutics' future financial performance could differ significantly from the expectations of management and from results expressed or implied in the Press Release. Forward-looking statements in the Press Release are subject to certain risks and uncertainties described in the Press Release. For further information on other risk factors, please refer to the "Risk Factors" contained in Galectin Therapeutics' Annual Report on Form 10-K for the fiscal year ended December 31, 2024, as filed with the Securities and Exchange Commission, and its subsequent filings with the SEC.

The information in this Item 2.02 is being furnished, not filed, pursuant to Item 2.02 of Form 8-K. Accordingly, the information in Item 2.02 of this report, including the Press Release attached hereto as Exhibit 99.1, will not be incorporated by reference into any registration statement filed by Galectin under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference.

SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release dated May 15, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, Galectin Therapeutics Inc. has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Galectin Therapeutics Inc.

Date: May 15, 2025

By: /s/ Jack W. Callicutt
Jack W. Callicutt
Chief Financial Officer

Galectin Therapeutics Reports 2024 Financial Results and Provides Business Update

NORCROSS, Ga., May 15, 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 months ended March 31, 2025.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, stated "This quarter, we remained laser-focused on advancing additional analyses for belapectin. I was extremely encouraged by the feedback we received last week at the European Association for the Study of the Liver (EASL), specifically that we successfully demonstrated a clinically significant response in a key biomarker (Fibroscan®) that is used to support outcomes in MASH trials at every stage of disease progression. In December 2024, as part of the topline results from the NAVIGATE trial, we reported that the 2 mg/kg dose of belapectin led to a significantly lower incidence of new varices compared to placebo in the per protocol population—validating the findings from our earlier Phase 2 study where 2 mg/kg dose showed significant reduction in portal pressure and new varices in cohort of patients without varices at baseline.

Based on these results from the NAVIGATE trial presented at EASL, we continue to believe that belapectin has the potential to offer a much-needed new treatment option for the growing number of patients with MASH-associated liver cirrhosis and portal hypertension — a significant area of unmet medical need."

Khurram Jamil, M.D., Chief Medical Officer, added “We were pleased to present the analysis of the NAVIGATE trial coupled with biomarker analysis to the scientific community and industry stakeholders at EASL. We are particularly encouraged by the liver stiffness measure (LSM), which showed that approximately double the number of patients demonstrated worsening of liver stiffness on placebo compared to on belapectin. We also showed that the difference in new varices between the 2 mg/kg dose and placebo was primarily driven by a reduction in medium and large varices, rather than small ones. This is relevant for clinicians since it’s medium or large size varices that are more likely to bleed and or require additional treatment. We also demonstrated that the proportion of patients who experienced a significant worsening of LSM were significantly higher in the placebo group compared to the 2 mg/kg belapectin group, thus reinforcing the relationship between disease progression and development of varices.

These findings further support the potential clinical efficacy of belapectin. With Fast Track Designation in place, we are hopeful that the belapectin program will ultimately deliver the first targeted treatment for patients with MASH cirrhosis and portal hypertension.”

Mr. Lewis added, “We are pleased to share that after a complete analysis of all existing valid Fibroscan data, we observed several important findings. First, the total baseline Fibroscan data was normally distributed (n=269). Additionally, the 2 mg/kg population (n=94) and the 4 mg/kg population (n=87) showed statistically significant changes from baseline on Fibroscan data, while the placebo population (n=88) did not show a statistically significant change from baseline. Most importantly, on several clinical endpoints indicating increased severity of LSM worsening, the 2 mg/kg population significantly outperformed the placebo group (see below). We look forward to sharing more biomarker data as it becomes available.”

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

MASH 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 2 mg/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.
- Following the topline data announced in December 2024, the NAVIGATE trial data and additional biomarker data was presented at the European Association for the Study of the Liver (EASL) Congress on May 10, 2025.
- Liver stiffness measurements (LSM), assessed using FibroScan®, were analyzed using a commonly used analytical method for this test i.e. Mixed Model for Repeated Measures (MMRM), incorporating all clean and verified assessments collected throughout NAVIGATE.
  Statistically significant reductions in liver stiffness from baseline were observed in the belapectin 2 mg/kg treatment arm at Week 26, Week 52 and Week 78:

Belapectin 2 mg/kg (absolute kPa change from baseline)

- Week 26 - LSM Mean Change from Baseline = -3.48; p = 0.005
- Week 52 - LSM Mean Change from Baseline = -4.60; p = < 0.0001
- Week 78 - LSM Mean Change from Baseline = -2.72; p = 0.0197

This finding indicates that belapectin treatment may lead to regression of liver stiffness in this high-risk population, while placebo-treated patients continued to show no improvement.

In addition, significantly fewer patients with >30% worsening in liver stiffness were observed in the 2 mg/kg belapectin groups compared to placebo:

- Placebo: 21/88 (23.9%) patients
- Belapectin 2 mg/kg: 11/94 (11.7%) patients (51% fewer cases than placebo; p=0.03)
- Belapectin 4 mg/kg: 13/87 (14.9%) patients

Further, compared to the 2 mg/kg group, 64% more patients in the placebo group experienced an absolute increase in LSM of >10 kPa (p=0.02). Additionally, 62.5% more patients in the placebo group experienced both worsening of > 10 kPa and >30% increase (p=0.04) over 18 months, thus reinforcing the progression of disease in the absence of treatment.

	placebo	2 mg/kg belapectin	4mg/kg belapectin
	N=88	N=94	N=87
>10 increase in kPa from baseline	11	4	9
Percentage	12.5%	4.3%	10.3%
>30% increase from baseline	21	11	13
Percentage	23.9%	11.7%	14.9%
>10 kPa + 30% increase from baseline	10	4	9
	11.4%	4.3%	10.3%

These thresholds of increases are clinically meaningful since they are based on published trials in MASH populations where categorical increases meeting these thresholds result in significantly increased rates of liver complications.[1]

Q1 2025 Financial Highlights

- As of March 31, 2025, the Company had $7.4 million of cash and cash equivalents. Additionally, the Company has $11 million remaining available under two lines 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 August 2025.

- Research and development expenses for the quarter ended March 31, 2025 were $6.5 million compared with $8.1 million for the same period in 2024. The decrease was primarily due to timing of incurrence of expenditures related to our NAVIGATE clinical trial.

- General and administrative expenses for the quarter ended March 31, 2025 were $1.4 million, compared to $1.6 million for the quarter ended quarter ended March 31, 2024.

- For the quarter ended quarter ended March 31, 2025, the Company reported a net loss applicable to common stockholders of $9.6 million, or ($0.15) per share, compared to a net loss applicable to common stockholders of $11.5 million, or ($0.19) per share for the quarter ended March 31, 2024.

- These results are included in the Company's Quarterly Report on Form 10-Q as of and for the period ended March 31, 2025, which has been filed with the U.S. Securities and Exchange Commission and is available at **www.sec.gov**.

1 Gawrieh S, Vilar-Gomez E, Wilson LA, Pike F, Kleiner DE, Neuschwander-Tetri BA, Diehl AM, Dasarathy S, Kowdley KV, Hameed B, Tonascia J, Loomba R, Sanyal AJ, Chalasani N; NASH Clinical Research Network. Increases and decreases in liver stiffness measurement are independently associated with the risk of liver-related events in NAFLD. J Hepatol. 2024 Oct;81(4):600-608. doi: 10.1016/j.jhep.2024.05.008. Epub 2024 May 16. PMID: 38762169; PMCID: PMC11410523.

Loomba R, Huang DQ, Sanyal AJ, et al Liver stiffness thresholds to predict disease progression and clinical outcomes in bridging fibrosis and cirrhosis Gut 2023;72:581-589.

van Doorn DJ, Holleboom AG, Takkenberg RB, Verheij J, Lantinga MA. Can liver stiffness measurement accurately predict disease progression and clinical outcome in patients with metabolic dysfunction-associated steatotic liver disease and bridging fibrosis or cirrhosis? Hepatobiliary Surg Nutr. 2023 Dec 1;12(6):912-915. doi: 10.21037/hbsn-23-445. 2023 Oct 30. PMID: 38115935; PMCID: PMC10727830.

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 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 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.

Company Contact:

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Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2025	2024
Operating expenses:		
Research and development	$ 6,485	$ 8,054
General and administrative	1,412	1,594
Total operating expenses	7,897	9,648
Total operating loss	(7,897)	(9,648)
Other income (expense):		
Interest income	35	80
Interest expense	(1,744)	(869)
Change in fair value of derivatives	(25)	(1,052)
Total other income	(1,734)	(1,841)
Net loss	$ (9,631)	$ (11,489)
Preferred stock dividends	26	(8)
Net loss applicable to common stock	$ (9,605)	$ (11,497)
Basic and diluted net loss per share	$ (0.15)	$ (0.19)
Shares used in computing basic and diluted net loss per share	63,204	61,976

Condensed Consolidated Balance Sheet Data

	March 31, 2025	December 31, 2024
	(in thousands)	
Cash and cash equivalents	$ 7,431	$ 15,120
Total assets	9,528	17,495
Total current liabilities	110,840	35,409
Total liabilities	121,789	120,565
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity (deficit)	$ (113,984)	$ (104,793)

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