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): **December 20, 2024**

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 8 – OTHER ITEMS

Item 8.01 Other Items.

On December 20, 2024, Galectin Therapeutics Inc. (the "Company) issued the press release attached hereto as Exhibit 99.1, and incorporated herein 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 December 20, 2024

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: December 20, 2024

By: /s/ Jack W. Callicutt

Jack W. Callicutt
Chief Financial Officer

Galectin Therapeutics Announces Top-Line Results of NAVIGATE Clinical Trial Evaluating Belapectin in Patients with Cirrhotic Portal Hypertension Caused by MASH

- **In the pre-specified per-protocol population, belapectin showed a statistically significant reduction (p-value < 0.05) in development of esophageal varices in 2mg/kg cohort compared to placebo**
- **While there was a favorable trend for incidence of varices in the primary end point intent-to-treat population, belapectin did not achieve statistical significance**
- **Belapectin was overall well tolerated with no safety signals; incidence of adverse events and serious adverse events were comparable across the three cohorts**
- **Additional data to be presented in early 2025**

NORCROSS, Ga., December 20, 2024 (GLOBE NEWSWIRE) – Galectin Therapeutics, Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today announced results from its global clinical trial NAVIGATE evaluating belapectin in patients with Metabolic Dysfunction-Associated Steatohepatitis (MASH) cirrhosis and portal hypertension.

The NAVIGATE trial (NCT04365868) is a global, multicenter, randomized, double-blind, placebo-controlled study conducted in over 130 sites in 5 continents, across 15 countries including the U.S., Canada, Mexico, Australia, U.K, France, Germany, Korea and Israel. 355 patients were randomized 1:1:1 to receive intra-venously either belapectin 2mg/kg of lean body mass (LBM) (n=119), belapectin 4 mg/kg/LBM (n=118) or placebo (n=118) every other week for 18 months. The primary endpoint was defined as the prevention of varices, assessed as a composite clinical outcome that included subjects with any varices, those with intercurrent events, or those without an endoscopy or intercurrent events at 18 months. Intercurrent events were defined as any liver-related complication, treatment discontinuation due to adverse events, use of non-selective beta-blockers (NSBB) or GLP-1 agonists for more than 12 months or undergoing a TIPS procedure. The most common intercurrent event was prolonged use of NSBB or GLP-1 agonists.

In the intent-to-treat (ITT) population (N=355), while the incidence of varices was 43.2% reduced in the belapectin 2 mg/kg dose group vs placebo, the composite endpoint did not reach statistical significance. The per-protocol population (PPP) was pre-defined as subjects who completed 18 months of therapy with upper endoscopy performed at both baseline and 18 months. In the PPP (n=290), the incidence of varices was reduced by 48.9% (compared to the targeted 52.5% reduction) in the belapectin 2 mg/kg dose group (p-value < 0.05). These clinical outcomes (lower incidence of varices) were supported by non-invasive measures, where liver stiffness assessed by Fibroscan® indicated a 50% lower number of subjects with worsening stiffness (defined as an increase of ≥5 kPa or ≥25%; thresholds associated with worse clinical outcomes).

As in prior trials, the safety profile of belapectin remains highly encouraging with incidence of adverse events and serious adverse events comparable across the three cohorts. Rates of discontinuation, adverse events (AEs), and serious adverse events (SAEs) were comparable to placebo, with no drug-related SAEs reported in the NAVIGATE trial.

Dr. Khurram Jamil, Chief Medical Officer at Galectin Therapeutics, stated “While we had hoped that the NAVIGATE trial would meet its composite primary endpoint, we are highly encouraged by trends we have seen at only 18 months of treatment in the ITT population and by the statistically significant 48.9% reduction in new varices noted in the per-protocol population with belapectin 2 mg. All enrolled subjects transitioned into a 36-month treatment period, with approximately 50 subjects completing the full 36 months to date. We are still analyzing the extensive data from the trial and anticipate providing multiple clinical updates from the subjects completing 36-month therapy, as well as additional biomarker data in Q1 2025.”

Joel Lewis, Chief Executive Officer at Galectin Therapeutics, added “We remain optimistic about belapectin's potential as an important therapy for patients with MASH cirrhosis and portal hypertension, a population with an unmet medical need that we believe is much larger than current estimates suggest. I would like to extend our gratitude to the investigators, their staff, and the patients and their caregivers who participated in the NAVIGATE trial for their commitment and dedication. We look forward to sharing the additional results in the first quarter of 2025 and engaging with potential pharmaceutical partners and medical experts to determine the optimal next steps in belapectin’s development.”

Dr. Naim Alkhouri, Chief Medical Officer and Director of the Steatotic Liver Program at Arizona Liver Health, added “I am encouraged by the results demonstrating an approximately 49% reduction in the development of varices in patients with MASH cirrhosis with the previously studied belapectin dose of 2 mg in such a large, global trial. I believe the results warrant further clinical development as belapectin could become a pivotal therapeutic option for these patients that currently do not have any treatment options.”

Dr. Naga Chalasani, David W. Crabb Professor of Gastroenterology and Hepatology and Adjunct Professor of Anatomy, Cell Biology & Physiology at Indiana University School of Medicine, stated: “I have been involved with the belapectin development program in MASH cirrhosis since the beginning and am very pleased to see that prevention of esophageal varices in patients with MASH cirrhosis in this large NAVIGATE clinical trial confirmed the results that were seen in the previous trial conducted by Galectin in the 2 mg/kg cohort. Belapectin clearly is offering a reproducible benefit and should be continued in clinical development as there is a significant unmet need for patients with MASH cirrhosis.”

Based on results from previous clinical and preliminary nonclinical studies, as well as preliminary data from the NAVIGATE trial, the lack of increased efficacy at the 4 mg dose of belapectin is likely due to saturable binding dynamics and interactions with Galectin-3 proteins. Specifically, the 2 mg dose may provide optimal therapeutic effects, while the 4 mg and greater doses may provide more available circulating belapectin but will not lead to greater binding and an increase in pharmacodynamic effects, leading to saturable drug disposition and the appearance of reduced efficacy. The Company is performing further analysis on the pharmacodynamic data from the NAVIGATE trial.

Additionally, the Company is currently conducting the full analysis of the NAVIGATE trial data and anticipates having additional data from approximately 50 patients that have completed 36-months of treatment with belapectin in early 2025. Once available, Galectin will provide clinical updates and determine next steps for belapectin development.

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 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, 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, 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 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, 2023, 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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