

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): **January 5, 2023**

**GALECTIN THERAPEUTICS INC.**

(Exact name of registrant as specified in its charter)

**Nevada**  
(State or Other Jurisdiction of Incorporation)

**001-31791**  
(Commission File Number)

**04-3562325**  
(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 \$0.001 par value per share | GALT           | The Nasdaq Stock Market                   |

## SECTION 8 – OTHER ITEMS

### Item 8.01 Other Items.

On January 5, 2023, Galectin Therapeutics Inc. (the “Company”) issued the press release attached hereto as Exhibit 99.1.

## SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits. The following exhibit is filed with this Report:

| <b>Exhibit<br/>No.</b> | <b>Description</b> |
|------------------------|--------------------|
| <a href="#">99.1</a>   | Press release      |

**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: January 5, 2023

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

**Galectin Therapeutics Announces the End of Enrollment of NAVIGATE, its Seamless, Adaptive Phase 2b/3 Study of Belapectin in Patients with Liver Cirrhosis Caused by Non-Alcoholic Steatohepatitis**

NORCROSS, Ga., January 5, 2023 (GLOBE NEWSWIRE) -- [Galectin Therapeutics, Inc.](#) (NASDAQ: GALT), the leading developer of therapeutics that target galectin-3, announced today that in late December 2022, it ended enrollment of NAVIGATE, its seamless, adaptive, phase 2b/3 study of belapectin in patients with liver cirrhosis caused by non-alcoholic steatohepatitis (NASH). NAVIGATE is the first study of its kind and is a global effort that recruited patients in 14 countries and on five continents. The main efficacy objective is the primary prevention of esophageal varices. Patients enrolled in the study have cirrhosis caused by NASH and, because of the advancing cirrhotic process, have already developed portal hypertension but have not yet developed dilated veins in the esophagus known as esophageal varices, a complication of portal hypertension. Portal hypertension is the consequence of the unrelenting inflammatory and fibrotic process occurring in the liver and dramatically increases the risk of developing esophageal varices, a potentially life-threatening complication of liver cirrhosis.

Dr. Pol Boudes, M.D., Chief Medical Officer of Galectin Therapeutics, said: “the Phase 2b portion of NAVIGATE was designed to study approximately 315 patients, randomized (1 to 1 to 1) either to 2 mg/kg of Lean Body Mass (LBM) or 4 mg/kg LBM of belapectin or placebo. We were pleased to close out the screening for this trial in December 2022. Currently, 309 patients have been randomized, and with the remaining patients in screening total randomizations are expected to reach 325 to 340 patients. The final patient is expected to be randomized no later than early March. The treatment period is 18 months; therefore, the results of the interim analysis are expected in the fourth quarter of 2024.”

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Dr. Stephen A. Harrison, co-principal investigator for NAVIGATE and Chairman, Summit Clinical Research, stated: “completing enrollment in NAVIGATE is an important milestone. This is a critical study for patients with NASH cirrhosis. Demonstrating prevention of progression to esophageal varices in these patients has important implications for long-term patient outcomes. In addition, the primary outcome measure of efficacy, as opposed to liver biopsies, is both practical and clinically relevant.”

Mr. Joel Lewis, the Company’s president and Chief Executive Officer said: “we are gratified to reach this important milestone. Completing enrollment will allow us to focus on efficiently executing our program and other stated goals for this year. I want to personally thank our investigators and their teams, along with all the patients in the trial for participating in this innovative study.”

#### **About Belapectin**

Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH and fibrosis. Galectin-3 plays a major role in diseases that involve scarring of organs, including fibrotic disorders of the liver, lung, kidney, heart and vascular system. Belapectin binds to galectin-3 and disrupts its function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis. A Phase 2 study showed belapectin may prevent the development of esophageal varices in NASH cirrhosis, and these results provide the basis for the conduct of the NAVIGATE trial. The NAVIGATE trial ([www.NAVIGATEnash.com](http://www.NAVIGATEnash.com)), titled “A Seamless Adaptive Phase 2b/3, Double-Blind, Randomized, Placebo-controlled Multicenter, International Study Evaluating the Efficacy and Safety of Belapectin (GR-MD-02) for the Prevention of Esophageal Varices in NASH Cirrhosis,” is posted on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT04365868). Galectin-3 has a significant role in cancer, and the Company has supported a Phase 1b study in combined immunotherapy of belapectin and KEYTRUDA in advanced melanoma and in head and neck cancer. This trial provided a strong rationale for moving forward into a Company-sponsored Phase 2 development program, which the company is exploring.

#### **About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis**

Non-alcoholic steatohepatitis (NASH) has become a common disease of the liver with the rise in obesity and other metabolic diseases. NASH is estimated to affect up to 28 million people in the U.S. It is characterized by the presence of excess fat in the liver along with inflammation and hepatocyte damage (ballooning) in people who consume little or no alcohol. Over time, patients with NASH can develop excessive fibrosis, or scarring of the liver, and ultimately liver cirrhosis. It is estimated that as many as 1 to 2 million individuals in the U.S. will develop cirrhosis as a result of NASH, for which liver transplantation is the only curative treatment available. Approximately 9,000 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis or cirrhosis.

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## **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 (formerly known as GR-MD-02) 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 non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH-related fibrosis. This is the most common liver disease and one of the largest drug development opportunities available today. Additional development programs are in treatment of combination immunotherapy for advanced melanoma 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](http://www.galectintherapeutics.com).

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### **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” 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 fatty liver disease 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, findings of safety of a drug candidate are not indicative of the drug candidate’s efficacy; 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 as modified to meet the requirements of the FDA 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. Global factors such as coronavirus may continue to impact NASH patient populations around the globe and further affect the trial and significantly impact associated costs. 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, 2021, 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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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 (GR-MD-02).

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