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): **June 23, 2026**

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

Item 7.01 Regulation FD Disclosure.

On June 23, 2026, Galectin Therapeutics Inc. (the "Company") issued a press release announcing results from its recent Type C meeting with the U.S. Food and Drug Administration (FDA), furnished hereto as Exhibit 99.1. and incorporated herein by reference.

In accordance with General Instruction B.2 of Form 8-K, the information furnished under this Item 7.01 of this Current Report on Form 8-K and the exhibit furnished hereto are deemed to be "furnished" and shall not be deemed "filed" for the purpose of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall such information and exhibit be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

This Current Report on Form 8-K and Exhibit 99.1 hereto contain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibits 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Exhibit Description
99.1	Press release dated June 23, 2026
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: June 23, 2026

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

Exhibit 99.1

Galectin Therapeutics Announces Positive Type C Meeting with the FDA for Belapectin in Patients with MASH Cirrhosis and Portal Hypertension

- Galectin has reached agreement with the FDA on the primary endpoint and regulatory path forward for the potential full approval of belapectin
- Company intends to file the Phase 3 protocol in Q3 2026 and is actively exploring strategic and financial partnership opportunities to support the continued development and commercialization of belapectin

NORCROSS, Ga., June 23, 2026 – Galectin Therapeutics Inc. (NASDAQ: GALT), a biotechnology company focused on developing therapies for patients with advanced liver disease, today announced positive feedback from its recent in person Type C meeting with the U.S. Food and Drug Administration (FDA), supporting the advancement of belapectin for the treatment of patients with metabolic dysfunction-associated steatohepatitis (MASH) cirrhosis and portal hypertension.

Joel Lewis, Chief Executive Officer of Galectin Therapeutics, said "We are pleased to have reached agreement with FDA on the key elements of our planned Phase 3 program for belapectin. Alignment on the study design, primary endpoint, and regulatory framework provides important clarity, as we advance the program with renewed confidence. We are initiating preparations for the Phase 3 trial and in parallel are evaluating development pathways alongside potential strategic partnership opportunities. We remain committed to patients with MASH cirrhosis and portal hypertension facing the highest risk of life-threatening decompensation events, who currently are excluded from enrolling in other ongoing drug development efforts. Additionally, FDA acknowledged the substantial unmet medical need in this patient population during our meeting, which strengthened our dedication to continuing the development of belapectin and our Phase 3 trial. We look forward to submitting the final Phase 3 protocol in the third quarter of 2026."

The Phase 3 trial will assess the safety and efficacy of belapectin for the prevention of disease progression in a randomized, double-blind, placebo-controlled design in patients with metabolic dysfunction-associated steatohepatitis (MASH) cirrhosis and portal hypertension. Alignment was reached on the following:

Primary Endpoint: Alignment was reached on a composite liver outcome as the primary endpoint, including prevention of development of large esophageal varices (>5 mm), a clinically meaningful manifestation of worsening portal hypertension and disease progression in patients with compensated MASH cirrhosis. Importantly, the Company plans to incorporate the development of large esophageal varices as one component of composite clinical outcome endpoints in the planned Phase 3 study.

Central Endoscopy Review Methodology: FDA accepted the Company's proposed blinded central review process for endoscopic assessment of esophageal varices. This methodology builds upon the approach successfully implemented in the global Phase 2b/3 NAVIGATE trial and is designed to ensure standardized, objective, and consistent assessment of endoscopic outcomes across study sites.

Galectin recently published details of the central review methodology and operational framework developed for NAVIGATE, highlighting the rigor and reproducibility of the process in a large multinational clinical trial.

Planned registration trial to evaluate single dose: Based on the robust efficacy observed with the 2 mg dose across prior clinical studies, the Company plans to evaluate a single 2 mg dose of belapectin in its planned Phase 3 trial. The Company believes that the planned Phase 3 study, together with the totality of existing clinical data, has the potential to support a full approval application for belapectin in patients with MASH cirrhosis and portal hypertension.

Given the similarity of the intended study population to the NAVIGATE trial, including patients with MASH cirrhosis and portal hypertension, and the evaluation of a single belapectin dose, the Company currently expects the planned Phase 3 trial to be of a size generally comparable to the NAVIGATE trial.

Regulatory Pathway: Consistent with FDA guidance, the Company understands that approval in the MASH cirrhosis population will require a traditional pathway, unlike earlier-stage MASH populations where accelerated approval based on histologic endpoints may be available. The FDA confirmed that the proposed composite outcome endpoints, including the development of large varices, and study framework are appropriate for a full approval pathway. Based on FDA's recent communication regarding use of a single, adequate and well-controlled confirmatory trial for marketing approval, the Company believes the planned phase 3 trial provides a clear regulatory path toward a broad indication focused on preventing progression of MASH cirrhosis.

Khurram Jamil, M.D., Chief Medical Officer of Galectin Therapeutics, commented "FDA's acceptance of our centralized endoscopy review process underscores the scientific rigor and operational robustness of the methodology that Galectin pioneered, and successfully implemented in the NAVIGATE trial. Standardized, blinded assessment of esophageal varices is critical to ensuring reliable and reproducible endpoint evaluation in global studies. Importantly, the Agency's feedback supports the advancement of belapectin towards full approval, which we believe offers the opportunity to pursue a broad indication focused on preventing disease progression in patients with MASH cirrhosis."

Galectin is advancing Phase 3 planning and is actively pursuing potential strategic and financial partners. Phase 3 protocol submission is anticipated in the third quarter of 2026.

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 belapectin 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, 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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