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 3, 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 Capital Market

SECTION 7 – REGULATION FD

Item 7.01 Regulation FD Disclosure.

On December 3, 2025, Galectin Therapeutics Inc. (the "Company) made a presentation after its Annual Meeting of Stockholders, a transcript of such is attached hereto as Exhibit 99.1.

The information in this report is being furnished pursuant to this Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933 or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this report.

SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Transcript of presentation, December 3, 2025

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 3, 2025

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

Exhibit 99.1

Thanks Kevin,

Since I became President and CEO of Galectin Therapeutics, I can honestly say that I have never been as excited as I am today, nor have I had the luxury of sharing such an extensive amount of meaningful information. As I am writing this to you, frankly, the only appropriate word I can think of is, wow!

Around a year ago, I think it's safe to say, we had many doubters. And while today we are trading at close to multi-year highs, even that metric does not properly articulate the state of Galectin. However, before I enthusiastically dive into my update for today, there are a few things I would like to address.

The combined efforts of many people, some very apparent and some behind the scenes, are why we are in this enviable position. I want to thank my entire staff, both employees and consultants, for their tireless efforts in mining the massive amount of data from Navigate. Additionally, I want to thank our KOLs for their support this year including Naga Chalasani, Naim Alkhouri and Raj Vuppalanchi for their review and interpretation of the NAVIGATE results, as well as all the investigators that helped us generate and present the data at EASL and AASLD conferences.

I also want to express my profound gratitude to our Chairman Richard Uihlein. Without his unwavering support and commitment to our program we would not have achieved the milestones that we have this year.

Finally, I want to acknowledge our Chief Medical Officer, Dr. Khurram Jamil. There are a select few doctors who have overseen drug approvals for compounds in late-stage liver disease. Not only were we fortunate enough to have Khurram, a member of that exclusive group, join the Company, his enthusiasm, work ethic and drive are beyond anything I have witnessed in biotech or anywhere else. I am honored to have Khurram on our team and thank him for getting us to this stage in our development. Without Khurram we simply would not be where we are today.

At the beginning of 2025 the Company was in a difficult position. We committed to presenting the top-line results from NAVIGATE in December of 2024 and did so without the benefit of any of our biomarker data, which had not been fully analyzed at that time. We believe that the top-line data alone does not provide a complete picture of the potential benefits of belapectin.

Just to remind everyone, NAVIGATE was designed as an adaptive trial. However, due to ongoing communication with FDA, the Company made the decision to unblind at the end of 2024, something that was not originally planned. As a result, a large volume of data was not centralized. During 2025, our team has been focused on consolidating and analyzing all available data including Fibroscan reports and blood samples from around the world. Each trial participant had many scans and blood samples, so the task was monumental for my small team.

Our perseverance yielded what we believe to be some extremely compelling results to date, and we are still continuing to analyze data from the trial. While I will let Khurram discuss results in more detail, most biomarkers we analyzed seem to support our primary endpoint data in the completer population with respect to prevention of varices. This ranged from analysis of Fibroscan, ELF, specialized biomarkers from Nodic Biosciences and even more general cytokine biomarkers.

During 2025, we also focused on educating both the scientific community and investor audiences on three key areas: the advance nature of patients enrolled in NAVIGATE, the use of a novel but meaningful clinical end point, and most importantly, biomarker data to confirm Belapectin's mechanism of action. Our participation at both EASL and AASLD with late-breaker, oral and poster presentations has allowed us to meaningfully re-engage with KOLs who are encouraged by our results. Near-term goals include additional KOL events with respect to our biomarker data, presentations at upcoming congresses, as well as peer reviewed publications from NAVIGATE. And finally, the unique nature of our patient population compared to other trials has led to what we view as groundbreaking discussions with respect to patients with MASH cirrhosis and portal hypertension. We are looking forward to continued engagement with clinicians in the coming months and sincerely appreciate their insight with respect to this extremely large, and unfortunately, growing patient population.

As I mentioned in our last quarterly update, we submitted our FDA package and are anticipating feedback soon. Additionally, we are continuing to explore strategic opportunities to maximize the value of our program. We believe this program has the potential to change the treatment landscape for a patient population that currently has no FDA approved therapy and will update you as more information becomes available.

Finally, before I turn the program over to Khurram, I would like to once again thank our Chairman, Richard Uihein, for extending our cash runway and enabling us to achieve what I believe was the best year in the Company's history. As we approach 2026, I believe we are stronger than ever, from both a scientific and strategic perspective.

Khurram.

Good morning, everyone, and thank you for joining us.

As many of you will recall, we announced the NAVIGATE topline results nearly a year ago. In that readout, the 2 mg dose of belapectin showed a lower rate of new varices compared with placebo after 18 months. While this was not statistically significant in the overall population, the effect *was* statistically significant in the group of patients who completed the protocol mandated18-month course of therapy and endoscopic evaluations at baseline and end of treatment called per protocol or completer population.

Throughout 2025, our goal has been to strengthen, validate, and communicate the full body of evidence supporting this clinical finding with belapectin. We analyzed widely used biomarker panels collected in NAVIGATE to better understand how belapectin works in patients with MASH cirrhosis and portal hypertension. We shared those results at major Hepatology symposia, via KOL webcasts, investor events, and during one-on-one scientific sessions, all with a consistent objective: to show the clinical and biological effects of belapectin in compensated MASH cirrhosis and portal hypertension.

Across all these analyses, the consistency between the clinical outcomes and the biomarker results strengthens our confidence in Belapectin's potential for slowing disease progression and improving clinical outcomes in this high-risk population.

Let me walk through some of the key findings.

1. Reducing progression of Fibrosis on FibroScan®

Using widely accepted and clinically meaningful cut-offs of either a ≥30% increase or an absolute ≥5 kPa rise, significantly fewer patients on belapectin 2 mg/kg experienced worsening of liver stiffness—compared with placebo. Since rising liver stiffness is closely linked to worsening of portal hypertension and risk of complications, this signals that belapectin likely stabilizes MASH cirrhosis over time.

2. Belapectin effects on FDA approved marker for fibrosis, ELF score

When patients were grouped by their fibrosis level using the validated FDA approved enhanced liver fibrosis or ELF test, belapectin consistently showed a lower rate of new varices across all categories. The largest benefit appeared in patients with ELF > 11.3, indicative of highly likely cirrhosis. In these patients, the incidence of new varices was 22.7% with belapectin versus 42.9% with placebo—a meaningful difference in those at greatest risk of developing complications.

3. Mechanistic biomarkers showing impact on fibrosis and inflammation

PRO-C3, a marker of active fibrogenesis, showed more than a 50% reduction from baseline at 18 months with belapectin 2 mg/kg compared with placebo. This supports a direct antifibrotic effect that aligns with belapectin's mechanism of action.

YKL-40, associated with Galectin-3 activity and liver inflammation, showed ≥20% reductions in a higher proportion of belapectin-treated patients than placebo. This indicates that belapectin may be reducing key inflammatory pathways that drive disease progression.

There are additional biomarker results that were shared with stakeholders and can be found in our latest corporate deck.

4. We also reported clinically meaningful changes in portal hypertension risk category on belapectin

Using the established criteria of Baveno expert consensus guidelines:

- Belapectin was associated with a reduced presence of CSPH at 18 months.
- More belapectin-treated patients moved from high risk CSPH or probable CSPH into the no/low-risk category compared with placebo.

5. Last, but not least,

Belapectin continued to show a favorable and consistent safety profile. There was

- No drug-related serious adverse events in the entire trial.
- Discontinuation rates were similar to placebo,

And No drug-induced liver injury was reported in NAVIGATE.

Across clinical findings, non-invasive markers, mechanistic biomarkers, and portal-hypertension metrics, the NAVIGATE data continue to reinforce belapectin's potential to slow disease progression and improve outcomes for patients with compensated MASH cirrhosis and portal hypertension. This is especially important because NAVIGATE enrolled one of the most advanced compensated MASH cirrhosis populations studied to date, with many patients already meeting clinically significant portal hypertension criteria at baseline.

As we finalize the remaining analyses, we look forward to working with the FDA to determine next steps for the program. In parallel, we continue active discussions with potential partners who share our commitment to advancing belapectin for patients who currently have no approved treatment options.

We remain grateful to our patients, investigators, and scientific collaborators for their essential contributions. We look forward to a productive year ahead—for the program, for our shareholders, and most importantly, for the patients we aim to serve.

Now I will turn it back over to Joel.

JOEL

Thank you Khurram. And thank you to everyone for your continued interest in Galectin Therapeutics and for your attention today. We look forward to sharing more updates as they become available.