

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): August 14, 2025

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 2 – FINANCIAL INFORMATION

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2025, Galectin Therapeutics Inc. (“Galectin Therapeutics”) issued a press release announcing its results of operations and financial condition as of and for the six months ended June 30, 2025, and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated August 14, 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated August 14, 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: August 14, 2025

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



Galectin Therapeutics Reports Financial Results for the quarter ended June 30, 2025 and Provides Business Update

NORCROSS, Ga., August 14, 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 and six months ended June 30, 2025.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, stated “We are encouraged by the continued analysis of data from our NAVIGATE trial , which further supports the clinical profile of belapectin in patients with MASH cirrhosis. At the European Association for the Study of the Liver (EASL) in May, we presented a clinically significant response in Fibroscan® (a key biomarker in MASH) and additional Fibroscan® data outcomes supporting the NAVIGATE trial’s primary endpoint, the prevention of esophageal varices after 18 months of treatment with belapectin. We believe it is especially promising that these findings remain robust in patients who received belapectin beyond 18 months, reinforcing our belief in the potential of belapectin to modify disease progression in this high-risk population. We are also analyzing additional biomarkers and expect to present those results later this year.”

“In June, we hosted a webcast featuring two prominent key opinion leaders, Dr. Naga Chalasani and Dr. Naim Alkhouri, who provided valuable insight into the NAVIGATE data and evolving treatment landscape. Looking ahead, we remain focused on engaging with the U.S Food and Drug Administration later this year to discuss potential next steps for our program, while also continuing to explore strategic partnership opportunities.

As stated previously, we continue to believe that belaepectin 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. Lastly, I again thank Mr. Richard E. Uihlein, our chairman, for his continued support through the additional \$10 million debt financing announced in early July, which is expected to fund our current planned operations through second half of 2026.”

Khurram Jamil, M.D., Chief Medical Officer, added, “The 18-month analysis showed a lower incidence of both liver stiffness progression and varices in the 2 mg belaepectin arm compared to placebo — an encouraging signal, given that increasing liver stiffness is a well-established predictor of liver-related complications.

We are pleased that these effects were maintained in patients who continued into the second 18-month treatment period. Using all available data and LOCF (Last Observation Carried Forward) methodology, the updated analysis confirms less progression in the belaepectin group, further supporting FibroScan® as a meaningful predictive biomarker in this setting.”

Recent Highlights

- In June, Galectin hosted a KOL event featuring two key opinion leaders, Dr. Naga Chalasani and Dr. Naim Alkhouri, who discussed NAVIGATE trial results and the unmet need and current treatment landscape for metabolic dysfunction-associated steatohepatitis (MASH) cirrhosis and portal hypertension.

- In May, Galectin presented NAVIGATE trial results at the European Association for the Study of the Liver (EASL) 2025 Congress. The updated analysis includes subjects who completed the 18 months of treatment, had an endoscopy assessment (i.e., completers) and had at least one FibroScan® assessment during the stage 2 portion of the study. As a reminder, while endoscopy assessments were conducted at months 18 and 36, FibroScan® evaluations were performed every six months throughout the study.
 - **Belaepectin shows sustained efficacy in reducing liver stiffness:** In patients who entered the second 18 months of treatment, belaepectin 2 mg continued to significantly reduce progression in liver stiffness compared to placebo. Using the LOCF (Last Observation Carried Forward) method, the analysis confirms the durability of effect beyond the initial 18-month period.
 - **Fewer patients experienced clinically meaningful worsening:** A lower proportion of patients in the belaepectin arm had >5 kPa or >30% increases in liver stiffness from baseline, reinforcing the drug’s ability to slow disease progression. This was consistent across both thresholds, as assessed using LOCF.
 - **Liver stiffness outcomes align with reduced varices incidence:** The updated FibroScan® findings mirror previously reported reductions in esophageal varices, supporting belaepectin’s potential to reduce the risk of portal hypertension-related complications.
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- o **Longitudinal FibroScan® data strengthens clinical confidence:** Regular assessments every six months, combined with LOCF methodology, provided a robust dataset across both phases of treatment, enhancing confidence in the consistency and durability of the observed biomarker trends.

Q2 2025 Financial Highlights

- As of June 30, 2025, the Company had \$13.8 million of cash and cash equivalents. Additionally, on July 8, 2025, the Company entered into a new \$10 million line 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 June 30, 2026.
- Research and development expenses for the quarter ended June 30, 2025 were \$3.3 million compared with \$9.8 million for the same period in 2024. The decrease was primarily due to timing of incurrence of expenditures related to our NAVIGATE clinical trial which ended in the first quarter of 2025.
- General and administrative expenses for the quarter ended June 30, 2025 were \$1.4 million, compared to \$1.5 million for the quarter ended quarter ended June 30, 2024.
- For the quarter ended June 30, 2025, the Company reported a net loss applicable to common stockholders of \$7.6 million, or (\$0.12) per share, compared to a net loss applicable to common stockholders of \$12.4 million, or (\$0.20) 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 June 30, 2025, which has been filed with the U.S. Securities and Exchange Commission and is available at www.sec.gov.

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 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 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.

Company Contact:

Jack Callicutt, Chief Financial Officer
(678) 620-3186
ir@galactintherapeutics.com

Investors Relations Contacts:

Kevin Gardner
kgardner@lifesciadvisors.com

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.

Condensed Consolidated Statements of Operations

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2025	2024	2025	2024
	(in thousands, except per share data)			
Operating expenses:				
Research and development	\$ 3,261	\$ 9,813	\$ 9,746	\$ 17,867
General and administrative	1,364	1,478	2,776	3,072
Total operating expenses	4,625	11,291	12,522	20,939
Total operating loss	(4,625)	(11,291)	(12,522)	(20,939)
Other income (expense):				
Interest income	26	80	62	160
Interest expense	(1,826)	(1,269)	(3,570)	(2,321)
Change in fair value of derivative	(1,096)	109	(1,122)	(760)
Total other income	(2,896)	(1,080)	(4,630)	(2,921)
Net loss	\$ (7,521)	\$ (12,371)	\$ (17,152)	\$ (23,860)
Preferred stock dividends	(63)	(64)	(37)	(72)
Warrant modification				
Net loss applicable to common stock	\$ (7,584)	\$ (12,435)	\$ (17,189)	\$ (23,932)
Basic and diluted net loss per share	\$ (0.12)	\$ (0.20)	\$ (0.27)	\$ (0.39)
Shares used in computing basic and diluted net loss per share	63,447	62,233	63,326	62,104

Condensed Consolidated Balance Sheet Data

	June 30, 2025	December 31, 2024
	(in thousands)	
Cash and cash equivalents	\$ 13,771	\$ 15,120
Total assets	15,602	17,495
Total current liabilities	10,774	35,409
Total liabilities	132,769	120,565
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity (deficit)	\$ (118,890)	\$ (104,793)

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