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): **May 15, 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 2 – FINANCIAL INFORMATION

Item 2.02 Results of Operations and Financial Condition.

On May 15, 2024, Galectin Therapeutics Inc. ("Galectin Therapeutics") issued a press release announcing its results of operations and financial condition as of and for the three months ended March 31, 2024 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated May 15, 2024 (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, 2023, 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.

Exhibit Number	Description
99.1	Press Release dated May 15, 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: May 15, 2024

By: /s/ Jack W. Callicutt

Jack W. Callicutt
Chief Financial Officer

Galectin Therapeutics Reports Financial Results for the Quarter Ended March 31, 2024 and Provides Business Update

- *Fifth Data and Safety Monitoring Board (DSMB) meeting recommended the continuation, without modifications, of the Phase 2b/3 NAVIGATE study of belapectin in liver cirrhosis due to metabolic dysfunction-associated steatohepatitis (MASH)*
- *NAVIGATE trial remains on track for interim top-line readout late in the fourth quarter of 2024*

NORCROSS, Ga., May 15, 2024 (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 quarter ended March 31, 2024.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, said "This quarter we remained laser-focused on progressing the NAVIGATE Phase 2b/3 trial of belapectin, which has a Fast Track Designation from the U.S. Food & Drug Administration. As recently reported, we had another positive outcome from the fifth meeting of our independent DSMB, recommending the continuation of the trial without any modifications. This fifth recommendation is another testament to belapectin's encouraging safety profile, which is key considering the patient population in this trial. We look forward to sharing the top-line interim analysis readout from the Phase 2b portion of the NAVIGATE trial late in the fourth quarter of 2024."

Pol Boudes, M.D., Chief Medical Officer added, “We are deeply saddened by the recent passing of Dr. Stephen A. Harrison. Stephen was involved in the belapectin clinical program since its inception. As the coordinating investigator of NAVIGATE, he was also a driving force to change the way we are designing clinical research in cirrhotic patients. Most notably, Stephen championed the prevention of esophageal varices as a clinical outcome that is both less subjective and more closely related to real world clinical practice than liver biopsies. We are forever grateful for his contributions to Galectin and will remember his exemplary qualities as we continue his legacy to bring hope to cirrhotic patients.”

Belapectin Program Q1 2024 and Recent Highlights

Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of MASH and fibrosis.

MASH Cirrhosis

- The NAVIGATE Phase 2b/3 trial (NCT04365868) evaluating the efficacy and safety of belapectin for the prevention of esophageal varices in MASH in 357 patients across 14 countries on five continents is progressing as planned.
    - The fifth Data Safety and Monitoring Board (DSMB) meeting authorized the continuation of the trial as designed and without modifications.

- Interim top-line data readout from the Phase 2b portion of the trial is anticipated late in the fourth quarter of 2024.

Corporate Updates

- Appointed Khurram Jamil, M.D. as Vice President of Clinical Development.

Q1 2024 Financial Highlights

- As of March 31, 2024, the Company had $23.6 million of cash and cash equivalents. Additionally, the Company has $10 million remaining available under a $60 million line of credit provided by its chairman of the board to fund operations and $10 million available from a more recently executed line of credit also provided by our chairman. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through May 15, 2025.

- Research and development expenses for the quarter ended March 31, 2024 were $8.1 million compared with $8.8 million for the same period in 2023. The decrease was primarily due to timing of incurrence of expenditures related to our NAVIGATE clinical trial.

- General and administrative expenses for the quarter ended March 31, 2024 were $1.6 million, compared to $1.5 million for the quarter ended quarter ended March 31, 2023.

- For the quarter ended quarter ended March 31, 2024, the Company reported a net loss applicable to common stockholders of $11.5 million, or ($0.19) per share, compared to a net loss applicable to common stockholders of $11.5 million, or ($0.19) per share for the quarter ended March 31, 2023.

- These results are included in the Company's Quarterly Report on Form 10-Q as of and for the period ended March 31, 2024, 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, 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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Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	$ 8,054	$ 8,799
General and administrative	1,594	1,543
Total operating expenses	9,648	10,342
Total operating loss	(9,648)	(10,342)
Other income (expense):		
Interest income	80	44
Interest expense	(1,052)	(460)
Change in fair value of derivatives	(869)	(769)
Total other income	(1,841)	(1,185)
Net loss	$ (11,489)	$ (11,527)
Preferred stock dividends	(8)	0
Net loss applicable to common stock	$ (11,497)	$ (11,527)
Basic and diluted net loss per share	$ (0.19)	$ (0.19)
Shares used in computing basic and diluted net loss per share	61,976	59,480

Condensed Consolidated Balance Sheet Data

	March 31, 2024	December 31, 2023
	(in thousands)	
Cash and cash equivalents	$ 23,555	$ 25,660
Total assets	25,890	28,200
Total current liabilities	12,633	15,676
Total liabilities	96,976	88,441
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity (deficit)	$ (72,809)	$ (61,964)

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