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): **March 29, 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 March 29, 2024, Galectin Therapeutics Inc. ("Galectin Therapeutics") issued a press release announcing its results of operations and financial condition as of and for the year ended December 31, 2023 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated March 29, 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 March 29, 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: March 29, 2024

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

Galectin Therapeutics Reports 2023 Financial Results and Provides Business Update

NORCROSS, Ga., March 29, 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 year ended December 31, 2023.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, said "We have been focused on advancing our Metabolic Dysfunction-Associated Steatohepatitis (MASH, formerly known as NASH) cirrhosis program. We completed enrollment and randomization for the NAVIGATE Phase 2b/3 trial in 2023, and belapectin has consistently shown an encouraging safety profile, which was determined by our independent Data and Safety Monitoring Board on multiple reviews.

We are pleased with the recent addition of Khurram Jamil, M.D., to our team. Dr. Jamil's extensive experience in advanced liver disease, specifically for late-stage cirrhotic patients, is a tremendous asset to our program. Echoing Dr. Boudes' comments from early March, Dr. Jamil's breadth of expertise in clinical development and regulatory interactions will be critical for the Company as we continue to execute the trial. We look forward to sharing the top-line interim analysis readout from NAVIGATE in Q4 2024.

Finally, we are pleased to report that, once again, our Chairman, Mr. Richard Uihlein, has provided significant financing for the Company via an additional $10 million credit facility to the Company. This funding extends our cash runway through March 2025. On behalf of the Board and management I want to thank Mr. Uihlein for his confidence in our team and our program."

Pol Boudes, M.D., Chief Medical Officer added, "We were pleased by the very recent U.S. Food and Drug Administration approval of resmetirom for the treatment of patients with MASH with moderate to advanced liver fibrosis; this will bring renewed attention to the field. However, the population of patients in our NAVIGATE trial of belapectin have progressed beyond advanced liver fibrosis, to liver cirrhosis and portal hypertension and have the most pressing medical need. Currently, for them, the only curative treatment is liver transplantation, a process whose access is severely limited, highly complex and very costly. Our hope is that our belapectin MASH program, which has a Fast Track Designation, will for the first time offer a new medical treatment option for the increasing number of patients affected with MASH associated liver cirrhosis. We look forward to the upcoming interim analysis of the adaptive Phase 2b/3 NAVIGATE study which, we believe, has the potential to demonstrate belapectin's ability to stop the progression of portal hypertension in cirrhotic patients and prevent the development of esophageal varices, which are a leading cause of morbidity and mortality in this population."

Q4 2023 Belapectin Program Highlights

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

NASH Cirrhosis

- The NAVIGATE Phase 2b/3 trial (NCT04365868) evaluating the efficacy and safety of belapectin for the prevention of esophageal varices in MASH cirrhosis completed randomization of 357 patients in 14 countries on five continents.
    - The fourth Data Safety and Monitoring Board (DSMB) meeting authorized the continuation of the trial as designed and without modifications.
    - Upcoming milestone remains on track for top-line data readout from NAVIGATE interim analysis in Q4 2024.
- Presented five posters at the Liver Meeting™ 2023 of the American Association for the Study of Liver Diseases (AASLD) including the safety profile of belapectin and the fact that its pharmacokinetics properties are not affected by the degree of liver impairment.

Corporate Updates

- Appointed Benjamin S. Carson, Sr., M.D. as a new member of the Board of Directors, following his service as a senior advisor to the Company since 2021.

Full Year 2023 Financial Highlights

- As of December 31, 2023, the Company had $25.7 million of cash and cash equivalents. Additionally, the Company has $20 million remaining available under a $60 million line of credit provided by its chairman to fund operations and a newly executed $10 million 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 March 31, 2025.

- Research and development expenses for the year ended December 31, 2023 were $32.1 million compared with $31.7 million for the year ended December 31, 2022. The increase was primarily due to costs related to our NAVIGATE clinical trial and other supportive activities.

- General and administrative expenses for the year ended December 31, 2023 were $5.9 million, compared to $6.6 million for the year ended December 31, 2022. The decrease was primarily due to non-cash stock-based compensation expense.

- For the year ended December 31, 2023, the Company reported a net loss applicable to common stockholders of $44.8 million, or ($0.74) per share, compared to a net loss applicable to common stockholders of $38.9 million, or ($0.65) per share for the year ended December 31, 2022. The increase is largely due to an increase in noncash interest expense of $1.8 million and a noncash charge related to modification of common stock purchase warrants of $3.6 million.

- These results are included in the Company's Annual Report on Form 10-K, 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 need 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.

Company Contact:

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

Investors Relations Contacts:
Kevin Gardner
kgardner@lifesciadvisors.com

Chris Calabrese
ccalabrese@lifesciadvisors.com

Condensed Consolidated Statements of Operations

	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	$ 32,130	$ 31,737
General and administrative	5,942	6,615
Total operating expenses	38,072	38,352
Total operating loss	(38,072)	(38,352)
Other income (expense):		
Interest income	230	52
Interest expense	(2,792)	(1,033)
Change in fair value of derivatives	(432)	557
Total other income	(2,994)	(424)
Net loss	$ (41,066)	$ (38,776)
Preferred stock dividends	(120)	(97)
Warrant modification	(3,619)	
Net loss applicable to common stock	$ (44,805)	$ (38,873)
Basic and diluted net loss per share	$ (0.74)	$ (0.65)
Shares used in computing basic and diluted net loss per share	60,159	59,391

Condensed Consolidated Balance Sheet Data

	December 31, 2023	December 31, 2022
	(in thousands)	
Cash and cash equivalents	$ 25,660	$ 18,592
Total assets	28,200	21,285
Total current liabilities	15,676	13,012
Total liabilities	88,441	53,479
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity (deficit)	$ (61,964)	$ (33,917)

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