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 16, 2022**

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 16, 2022, 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, 2022 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated May 16, 2022 (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, 2021, 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 16, 2022

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 16, 2022

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

Exhibit 99.1

Galectin Therapeutics Reports Financial Results for the Quarter Ended March 31, 2022 and Provides Business Update

NORCROSS, Ga., May 16, 2022 (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 months ended March 31, 2022. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the U.S. Securities and Exchange Commission and is available at **www.sec.gov**.

Dr. Pol Boudes, Chief Medical Officer, stated: "As we hear more about difficulties of reading and interpreting liver biopsies in pre-cirrhotic NASH, the feedback we get from our investigators reinforces our belief that using the prevention of esophageal varices as our primary outcome of efficacy in NAVIGATE is the appropriate efficacy outcome. Patients that are enrolled in our program have advanced to the cirrhotic stage of NASH and have developed portal hypertension, a severe complication of cirrhosis that impacts their prognosis. This also means that many of our patients have low platelet counts, and because this increases the risk of bleeding, it makes a liver biopsy far too dangerous. These are some of the reasons why we do not believe that biopsies are appropriate for patient selection or endpoints in our target population and is also why we even removed the requirement for baseline biopsies in our NAVIGATE trial. Preventing the development of an esophageal varix, on the other hand, is a very relevant and pragmatic clinical outcome. Unfortunately, too many cirrhotic patients bleed from these varices, and this can be a life-threatening event. Preventing the development of varices eliminates this potentially significant adverse outcome related to cirrhosis. We believe the design of the NAVIGATE study is truly innovative and allows us to move clinical research for liver cirrhosis forward."

Joel Lewis, Chief Executive Officer and President, said: “I am proud of our team and their accomplishments this quarter. Most importantly, as a Company, we achieved an extremely significant milestone. Our previous phase 2 trial, NASH-RX, indicated a favorable safety profile for belapectin over one year of treatment. As of today, due to the length of our adaptively designed phase 2b/3 NAVIGATE trial, our safety profile has been further evaluated by an independent data safety monitoring board who recommended the trial continue as designed. Additionally, our innovative trial design allows trial participants to move directly into the phase 3 treatment course for an additional 18 months. As these and additional patients continue receiving treatment, we continue to expand our data on the safety profile of belapectin. The significance of this safety profile in a severely compromised patient population cannot be overstated.

“We continued to make progress towards our primary goal of completing enrollment in our adaptively designed Phase 2b/3 NAVIGATE trial for the prevention of esophageal varices in patients with NASH cirrhosis. Our strategy to further expand our trial sites in Mexico and Latin America is well underway. We recently conducted a very productive in-person investigator meeting in Mexico where we have added more than 10 new sites. I attended the meeting with my clinical operations staff, and we are extremely enthusiastic about the ability of these sites to quickly enroll patients. I am grateful to all of our investigators and their teams, as well as our consultants in Mexico, for their time and dedication to our trial. Enrollment in the United States continued steadily; however, enrollment in Europe still lags far behind our expectations. We currently expect enrollment to conclude for the Phase 2b portion around the end of the third quarter of this year.”

Mr. Lewis continued: “Additionally, we are making progress and are working to compile an Investigational New Drug (IND) package, including the development of a phase 2 trial protocol, with the objective for the Company to file an IND with the FDA oncology division for the treatment of recurrent or metastatic head and neck cancer for belapectin in combination with Keytruda®, an immune checkpoint inhibitor. The lack of current treatments for these patients, the low response rates of monotherapy with check-point inhibitors, the limited number of therapies in development, and the resulting very high medical need make this an important area for new combination therapies.”

Financial Results

For the three months ended March 31, 2022, the Company reported a net loss applicable to common stockholders of $9.9 million, or ($0.17) per share, compared to a net loss applicable to common stockholders of $6.3 million, or ($0.11) per share for the three months ended March 31, 2021. The increase is largely due to an increase in 2022 research and development expenses related to the Company’s NAVIGATE trial.

Research and development expenses for the three months ended March 31, 2022, was $8.1 million compared with $4.9 million for the three months ended March 31, 2021. The increase was primarily due to costs related to our NAVIGATE clinical trial and other supportive activities. General and administrative expenses for the three months ended March 31, 2022, were $1.9 million, compared to $1.4 million for the three months ended March 31, 2021. The increase was primarily due to non-cash stock-based compensation expense.

As of March 31, 2022, the Company had $31.6 million of cash and cash equivalents. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through at least May 16, 2023.

The Company expects that it will require more cash to fund operations after May 16, 2023, and believes it will be able to obtain additional financing as needed. Currently, we expect to require an additional approximately $40-$45 million to cover costs of the NAVIGATE trial to reach the planned interim analysis estimated to occur in mid-2024, along with drug manufacturing and other research and development activities and general and administrative costs. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us.

About Belapectin

Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH and fibrosis. Galectin-3 plays a major role in diseases that involve scarring of organs, including fibrotic disorders of the liver, lung, kidney, heart and vascular system. Belapectin binds to galectin-3 and disrupts its function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis. A Phase 2 study showed belapectin may prevent the development of esophageal varices in NASH cirrhosis, and these results provide the basis for the conduct of the NAVIGATE trial. The NAVIGATE trial (www.NAVIGATEnash.com), titled "A Seamless Adaptive Phase 2b/3, Double-Blind, Randomized, Placebo-controlled Multicenter, International Study Evaluating the Efficacy and Safety of Belapectin (GR-MD-02) for the Prevention of Esophageal Varices in NASH Cirrhosis," began enrolling patients in June 2020, and is posted on www.clinicaltrials.gov (NCT04365868). Galectin-3 has a significant role in cancer, and the Company has supported a Phase 1b study in combined immunotherapy of belapectin and KEYTRUDA in advanced melanoma and in head and neck cancer. This trial provided a strong rationale for moving forward into a Company-sponsored Phase 2 development program, which the company is exploring.

About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis

Non-alcoholic steatohepatitis (NASH) has become a common disease of the liver with the rise in obesity and other metabolic diseases. NASH is estimated to affect up to 28 million people in the U.S. It is characterized by the presence of excess fat in the liver along with inflammation and hepatocyte damage (ballooning) in people who consume little or no alcohol. Over time, patients with NASH can develop excessive fibrosis, or scarring of the liver, and ultimately liver cirrhosis. It is estimated that as many as 1 to 2 million individuals in the U.S. will develop cirrhosis as a result of NASH, for which liver transplantation is the only curative treatment available. Approximately 9,000 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis or cirrhosis.

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 (formerly known as GR-MD-02) 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 non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH-related fibrosis. This is the most common liver disease and one of the largest drug development opportunities available today. Additional development programs are in treatment of combination immunotherapy for advanced melanoma 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” 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 fatty liver disease 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 as modified to meet the requirements of the FDA 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. Global factors such as coronavirus may continue to impact NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs. 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, 2021, 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:

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Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2022	2021
Operating expenses:		
Research and development	$ 8,058	$ 4,899
General and administrative	1,877	1,418
Total operating expenses	9,935	6,317
Total operating loss	(9,935)	(6,317)
Other income (expense):		
Interest income	1	1
Interest expense	(227)	(22)
Change in fair value of derivatives	229	—
Total other income	3	(21)
Net loss	$ (9,932)	$ (6,338)
Preferred stock dividends	16	(2)
Net loss applicable to common stock	$ (9,916)	$ (6,340)
Basic and diluted net loss per share	$ (0.17)	$ (0.11)
Shares used in computing basic and diluted net loss per share	59,354	57,132

Condensed Consolidated Balance Sheet Data

	March 31, 2022	December 31, 2021
	(in thousands)	
Cash and cash equivalents	$ 31,606	$ 39,648
Total assets	33,615	41,827
Total current liabilities	9,535	9,033
Total liabilities	39,808	39,211
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' (deficit) equity	$ (7,916)	$ 893

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