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 1, 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 Capital Market

SECTION 7 – REGULATION FD

Item 7.01 Regulation FD Disclosure.

On December 1, 2022, 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 1, 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: December 1, 2022

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

Exhibit 99.1

Thanks Kevin, and thank you to everyone joining us today. Out of an abundance of caution, management and the Board made the decision to hold our meeting virtually due to uncertainty surrounding Covid-19 at the time of planning the meeting. Please note that certain statements made today are forward looking in nature. Please see the forward-looking statements disclaimer attached to the Agenda for the Annual Meeting at the end of the transcript of this presentation.

2022 has been a year of tremendous change at Galectin Therapeutics, in the NASH space generally, and more broadly in biotech against the backdrop of the overall market. I believe every achievement at the Company in the past year has not only advanced our programs but has strengthened our position from every perspective. While there have been challenges this year, I believe that, unfortunately, our accomplishments have gone largely unnoticed in the market.

First, I want to address the primary focus for the Company, completion of the enrollment of NAVIGATE, our phase 2b/3 registration trial in NASH Cirrhosis. It is important to note there are not any specific diagnostic codes that can simply identify our trial participants. This is especially the case for the most important criterion, the presence of portal hypertension prior to the development of esophageal varices. While there are codes for some inclusion criteria, there is not one, or even a unique combination of codes, that encompasses all of them. This creates a challenge at the site level and requires a learning curve, as well as both intellectual and creative thought processes to recruit ideal candidates.

We began releasing recruitment metrics this fall when we had confidence that the patients in screening had high probability for randomization. Consequently, we are very close to ending the screening process, and we continue to expect to complete enrollment by the end of the year as previously communicated. As of today, we have randomized 290 of the planned 315 patients with an additional 79 currently in screening. With this said, I want to express my sincere gratitude to trial participants, the investigators and their respective teams for their dedication and commitment to our NAVIGATE clinical trial. Thank you.

Since last year's annual meeting, my team and I have placed an emphasis on achieving the goals I articulated in press releases and at prior annual shareholder meetings. Specifically, we continue to reposition Galectin Therapeutics as a late-stage development company. But before I discuss our progress, I wanted to reiterate the most important financial milestone for the Company. Thanks to the commitment of our Chairman Richard Uihlein, in late July, we closed on a $60 million line of credit that is projected to cover all currently planned expenses through 2024. We believe, the financing terms were the most favorable among our peers during the current year. In analyzing several of the financings that occurred this year in the NASH space, our stated interest costs are more than 35% lower than the average. Additionally, since the funding was in the form of convertible debt with a price floor on conversion, potential dilution has been greatly reduced.

I cannot overemphasize the impact and importance of this financing. Apart from the terms that were more favorable than any potential market-based deal, securing the funds has allowed the Company to continue its momentum. This included increasing our staff by recruiting personnel in key functions. We will continue to expand and strengthen the talent on our team. This financing also provided us with the ability to operationalize and contract for many of the activities that will position the Company for the potential submission of a New Drug Application, if the Phase 2b data indicates a positive risk benefit ratio for patients suffering from NASH cirrhosis. Once again, I want to thank Mr. Uihlein for the confidence that he has shown in our team and in me.

Last year I indicated that the Company would focus on the areas in which we have scientific data that can serve as the foundation for a clinical program that can lead to a drug registration. As in prior years, there have been numerous publications this year with even more substantial evidence that galectin-3 plays a role in many disease mechanisms. As a Company, we remain focused on hepatology and oncology indications where we have pre-clinical and clinical data, as well as expertise. Earlier in the year we hired a VP of Clinical Development, Dr. Steven Schoenfeld, who has over 30 years of experience in both large pharma and biotech, including experience in NASH and Oncology. We also added a Director of Project Management, Sharisse Brutto, who brings over 10 years of biotech experience to Galectin. Both were integral in the completion of our second major accomplishment this year, filing an IND with the FDA Oncology Division and receiving a Study May Proceed letter for a Phase 2 clinical trial to study belapectin in combination with a checkpoint inhibitor in recurrent or metastatic head and neck cancer. Additionally, last month we hired a Director of Clinical Data Management and Programing to expand our internal capabilities. We have also hired a new VP of Regulatory Affairs who will join us in the coming weeks. Both have substantial biotech experience, including NDA filings.

While our intention is to focus on our core competencies, we do intend to broaden our research and development capabilities with respect to our small molecule galectin inhibitor patents. We are actively recruiting PhD's to assist Drs. Ezra Lowe and Hugh Huang with this endeavor. In advance of acquiring this staff, we expect to produce more compounds for experimentation and hope to have lead compounds for a new generation of orally administered galectin inhibitors from our broad intellectual property portfolio over the next year.

Apart from these activities, and with the imminent enrollment completion of NAVIGATE, I have been working with outside advisors on funding sources for our oncology program. As more capacity of our staff becomes available, we will deploy resources to attempt to engage the best partner for this study. Just as we were very deliberate with our IND submission, we intend to take the same approach with finding the right partner for the Company. In my discussions with outside advisors and senior management, we intend on developing a program that will create the most potential value.

Finally, we were able to attend several in-person conferences for the first time since Pol and I have been with Galectin. Unlike virtual meetings, we physically attended others' presentations, which is a much better environment to assess our standing. What I can say is that I sincerely believe we are in the best position in NASH cirrhosis and as a company in general. Some of our peers seem to be migrating to cirrhosis, a space we have occupied since the inception of this program. However, unlike others who are now looking to late-stage NASH as a strategy for conditional approval, our primary efficacy endpoint, contrary to the interpretation of liver biopsies, is straightforward and clinically relevant. We continue to communicate our scientific and regulatory objectives in multiple venues, most recently at the premier US liver meeting AASLD, and I am convinced we will get more credit for what we are trying to achieve for patients with NASH cirrhosis. I believe we are the leader in this field.

This became very apparent to me when I met with a group of our investigators at AASLD last month in Washington DC. One physician approached me and said, “I know you probably are not aware, but you are changing the lives of my patients”. Specifically, she was referring to the testing and frequency of visits in our protocol. Regardless of whether the patients are on belapectin or placebo, these patients are being regularly seen by her and her staff which likely wouldn’t be the case without our trial. Additionally, patients agreed to testing in order to be part of the trial, so even those with varices present are now aware of their condition. While these sentiments were not unexpected, the mere fact that a clinician made a point to say this to me as the CEO had a tremendous impact on me. The Company will shift our patient outreach towards advocacy groups to increase broad awareness in this patient community leading up to our phase 2b data readout.

On a personal note, I remain committed to our Company’s success. In connection with Mr. Uihlein’s financing, I extended my compensation structure of receiving 80% of my pay in stock. This plan was scheduled to end on December 31, 2022. However, I thought it was important to demonstrate the same confidence that Mr. Uihlein displayed in the Company, our development programs and our future. Instead of receiving all of my compensation in cash from the Company, I am reinvesting 80% of those funds into the Company to help ensure our success. Every pay period a Form 4 is filed showing my purchases, and I welcome you to view them and my compensation plan. I am confident that my investment is the correct choice for me and my family.

Once again, thank you for attending today. I look forward to a successful 2023 and will keep you informed of our progress.

Forward Looking Statements Disclaimer

This presentation may provide 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.