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 3, 2021**

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 3, 2021, 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 3, 2021

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 3, 2021

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

Thanks Kevin.

And thank you to everyone joining us virtually today. Unfortunately, we are still unable to hold our annual meeting in person due to Covid-19. Hopefully, this will not be the case next year. Regardless, I am grateful that you are listening. 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 and at the end of the transcript of this presentation.

Before I turn the discussion over to Pol to discuss our drug development programs in more detail, I wanted to share my observations about the Company, since I spoke to you last year. At that time, I mentioned that our mission is to monetize our intellectual property as quickly as possible, by maximizing the use of our limited resources. Without hesitation that is precisely what we are doing. While it might not be apparent to the market yet, Galectin Therapeutics has been transformed into a new company compared to a year ago today.

Starting with an internal analysis of our goals and contemplating a roadmap for the future of the Company, senior management and I resolved to change our corporate culture. Our Company was perceived as, and frankly had been, an early-stage Company. However, with our global registration NASH cirrhosis trial, along with the potential to move into a phase 2 oncology program, Galectin Therapeutics in our view is better characterized as a late-stage company. To best align our culture to our reality and to establish an environment to realize our potential value, the strategy was straightforward: expand and strengthen the talent on our team—whether employees or consultants.

We referenced potential industry partners in the videos released on our website over the summer. I touch on it briefly in my presentation, but in part 2 of our panel discussion, we go into more detail. What I would like investors to understand is partnerships may actually require a similar level of scrutiny as regulatory approval in what I would describe as an accelerated process. In any due diligence discussions, a potential partner will fully evaluate a company's pathway to approval. Before an investment is made, a potential partner not only looks at data but also at every potential regulatory hurdle. They contemplate every possible scenario -- ranging from bioanalytics, to preclinical studies, to CMC, and to the Company's potential pipeline, just to name the most obvious.

To make sure we were prepared for these scenarios, we undertook multiple parallel paths over the past year. Not only did we retain Dr. Ben Carson as a strategic consultant, we hired four executives in key leadership positions. I encourage you to read their bios on our website. I am confident you will see that we have covered major areas with respect to any due diligence process that will be required by potential partners. Our expanded team possesses large pharma experience including being part of due diligence and registration teams in their past experiences. Collectively, they possess operational expertise in virtually every aspect of drug development. As I mentioned in my last press release, we will continue to look for talent to further enhance our ability and add value to the Company. In all the years I have been associated with Galectin Therapeutics, which is over a decade, I do not believe we have ever possessed this level of experience or capability internally. And in the relatively short time I have worked with our new Team, I am pleased to tell you that the level of professionalism has surpassed even my own expectations.

Our development programs have continued to progress over the past year. While Covid19 did present challenges almost everywhere earlier in the year, and challenges currently still exist in Europe with NAVIGATE, our global adaptive phase 2b/3 NASH Cirrhosis trial, we are optimistic we will be able to fully enroll our trial. In addition to hiring an Executive Director of Clinical Operations, we also added several staff members in clinical operations comprising a full team of experienced professionals. This team has worked together in the past on multiple large NASH trials and has built relationships with staff members at many of our investigational sites. As we continue to recruit patients, we plan on adding more support for trial participants and investigator sites.

In July, we released additional top line extension data from an investigator-initiated combination immuno-oncology trial in advanced metastatic melanoma and head and neck cancer patients. As we have mentioned in the past, we were encouraged by the results and at the request of our Chairman, Richard Uihlein, as well as the Board, we have been exploring potential pathways for Company-sponsored cancer trials. We are pleased to announce that we have retained as consultants Dr. Chetan Bettegowda from Johns Hopkins, Dr. Nishant Argawal and Dr. Ari Rosenberg both from University of Chicago Medical Center. I will let Pol speak in more detail about our goals and objectives, but I wanted to give a brief overview of our current strategy.

In my remarks last year, I mentioned that our detailed process would focus on areas where we have knowledge and data in order to develop a roadmap to achieve our mission by maximizing our limited resources. With that goal and our desire to optimize value, in our initial discussions with Dr. Bettegowda we considered the landscape in immuno-oncology. Those discussions caused us to re-evaluate both patient populations included in the phase 1 investigator-initiated trial. After several discussions and introductions to Dr. Argawal and Dr. Rosenberg, our current strategy is to focus primarily on head and neck cancer patients while continuing discussions for other indications conditional on partnership collaboration. This decision is informed by several factors, including current front-line treatments, current active trials, response rates to available therapies, and potential regulatory pathways. After multiple discussions, we believe that this patient population presents the most direct path forward to achieve our mission. While we still intend on pursuing other oncology indications, at present our internal resources will be directed towards the most expedient strategy with the highest medical need. We have already had initial discussions on potential protocols, and we will keep you updated on our progress.

Before I turn the program over to Pol, I wanted to share one more thought with you. Biotech in general has had a difficult year in 2021. Although the Company has performed well compared to Biotech indices year to date, we were not immune from market pressure. While there is substantial evidence that galectin-3 plays a role in many disease mechanisms, and there have been numerous scientific papers published underscoring that hypothesis, the Company currently has clinical data in hepatology and oncology indications. Highlighting this fact, I encourage you to read the peer reviewed oncology articles published this year, as well as the six presentations that we made at AASLD. Senior management and the Board are committed to carefully allocating our limited resources to the areas in which the Company is in a leadership position and has the best potential.

On a personal note, my belief in our Company and our technology was only a part of my rationale for my compensation package. By taking 80% of my compensation in stock, I also wanted to invest in the Company directly, preserving limited resources to enable us to achieve our potential. This is the same position I had previously taken with my Board compensation before I became CEO. A summary of my compensation strategy is listed in a footnote in every Form 4 filed around every pay period and effectively says I am purchasing shares equivalent to 80% of my salary, no matter the share price.

I want to thank our Chairman, Richard Uihlein, for his commitment including his time and multiple investments this year. Also, I want to thank the entire Board for its efforts and, more importantly, for their confidence in me in reshaping our Company. I am extremely proud of senior management and our entire team. We will build on our accomplishments from this year by expanding our internal capabilities and continuing to advance our programs.

Now I would like to turn the discussion over to Pol to go into more details of our NASH cirrhosis and oncology programs. Pol.

Thank you, Joel.

As a quick reminder, NAVIGATE is “A Seamless, Adaptive, Phase 2b/3, Double-Blind, Randomized, Placebo-controlled, Multicenter, International Study Evaluating the Efficacy and Safety of Belapectin for the Prevention of Esophageal Varices in NASH Cirrhosis.” For the phase 2b part of the NAVIGATE study, we plan to enroll approximately 315 patients, and, in addition to safety, the main outcome for evaluating efficacy is the incidence of esophageal varices after 18 months of treatment. Esophageal varices are evaluated by a central review of recorded endoscopic videos. We will compare the incidence of varices between two belapectin treatment groups and the placebo group.

The trial design is very innovative and is a first for the hepatology community. We believe it represents a significant advance for the treatment of NASH cirrhosis. As a testimony of this innovation, we were able to present this new study concept at the congress of the American Association for the Study of Liver Diseases, the premier US Hepatology congress, a few weeks ago.

What is also important to understand is that the target population of NAVIGATE -- patients with NASH cirrhosis who do not have yet decompensated their disease but have developed portal hypertension -- is a population who is at risk of developing a clinical event, such as esophageal varices. The development of an esophageal varix is a very concerning event in the life of a cirrhotic patient because this varix can bleed and, in that case, the bleeding can immediately become life threatening. Focusing on the prevention of esophageal varices allows us to evaluate a relevant clinical outcome without having to perform liver biopsy, which, now, if you closely follow NASH clinical development, is a very controversial and problematic way to evaluate NASH drugs.

It is also important to understand that esophageal endoscopies, contrary to liver biopsy, is part of the standard clinical surveillance of a cirrhotic patient. Hence, NAVIGATE is not only an innovative trial, it is also a very pragmatic clinical trial.

We have now initiated NAVIGATE in all countries we originally selected for participation. As we communicated, the process of country initiation and site start-up has been impacted by the COVID-19 pandemic, particularly outside of the US. But the last country that was originally planned, namely South Korea, is now on board.

In anticipation of this pandemic impact, we made the decision some months ago to initiate additional countries to be able to balance risks, should this be necessary. These additional countries are on the verge of being initiated and will very soon contribute to our global recruitment effort.
While the pandemic situation remains challenging, we have made good progress with our recruitment campaign. As could be anticipated, for a new design targeting a new population, very different from any other NASH studies, sites had to learn what were the best recruitment practices. Thanks to their feedback and the ongoing analysis of our screening and randomized population, we have been able to make technical adjustments to the protocol that, we are convinced, will further improve recruitment.
Based on the feedback we receive from our investigators, there is no question in our mind that the study is considered an important milestone by the medical community. NAVIGATE should further trigger the interest of clinical researchers for cirrhosis in general, and NASH cirrhosis in particular, something that is also part of our mission at Galectin Therapeutics. As we previously communicated, our objective is now to complete the recruitment of the phase 2b part of the study by the end of June 2022.

Now, turning to the oncology program, we have recently conducted a strategic review of the field with our consultants, particularly the immunotherapy of cancer. On one hand, we want to continue to build our program on top of the encouraging clinical data we have produced; on the other hand we have to make sure we are targeting the population that is in the highest need of new treatment. These are two necessary conditions to fulfill our objective, which is to provide access to belapectin as quickly as possible, including a registration as the ultimate goal.

This is why, as Joel mentioned, we want to prioritize our internal effort towards the Head and Neck cancer indication. Thanks to the results of our previous clinical study, we believe Galectin Therapeutics remains the oncology leader for the clinical translation of the anti-galectin-3 mechanism of action. While we think that the melanoma indication is certainly justified by our positive phase 1 data, this field is very competitive, particularly for clinical study recruitment, and we would only venture there with the support of a partner for a phase 2 multicenter study.

Consequently, with the help of our consultants, we are now also developing a phase 2 belapectin protocol for Head and Neck cancer patients and will provide further information on our operational plans as quickly as possible. I now turn it back to Joel.

Thanks Pol. Once again thank you all for attending this morning. We are looking forward to significant achievements in our development programs in 2022 and will keep you informed of our progress.

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, 2020, 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.