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 7, 2023**

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 7, 2023, 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 7, 2023

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 7, 2023

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

Exhibit 99.1

Thanks Kevin and thank you to everyone joining us today. 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.

As I thought about 2023 from the perspective of Galectin Therapeutics, the Board and our shareholders, I couldn't help but reflect on the significant changes in the NASH landscape. So, before I discuss the Company, I wanted to make a few comments on NASH in general and Galectin's unique position in the space.

In late October I was interviewed by Matt Miller and Paul Sweeny on Bloomberg radio. Since I had very little time to respond to their questions, I felt that it was important to expand on a few of the points I made, as I believe they are integral to Galectin and our programs. Several days before the interview I watched a video presented by the Fatty Liver Foundation from October 18th, and I referenced it in answering one of the questions posed to me. Galectin has always supported patient advocacy groups including Fatty Liver Foundation and their amazing team. I want to thank them and the presenters, as their message underscores the importance of our shared goal, specifically, improving patient outcomes.

While I learned many things from the presentation, and I urge you to watch it, there were several points that struck me as extremely important. Using an analysis of insurance claims data and risk factors associated with NASH, the implied population of patients with Steatosis, or fat in their liver, that has progressed to NASH in the U.S. is greater than 16 million out of the 100 million people in the U.S. estimated to have Steatosis according to their analysis. Of those implied patients, 97% are only seen in primary care, not by specialists. Also, since this was an -analysis of insurance claims, we believe that the patient population is actually much larger, since not everyone has insurance or is regularly seen by a physician.

This is highlighted by two other points made in their presentation. From 2002 through 2019 the composition of patients on the liver transplant list as a result of cirrhosis caused by NASH has increased fivefold. Additionally, a separate insurance claims analysis study showed that a greater number of newly diagnosed patients are presenting with cirrhosis compared to those with pre-existing NASH. Concerningly, newly diagnosed patients presenting without cirrhosis, may experience complications from progression to cirrhosis in under a year, which is a shorter time than previously thought.

So, I am sure you are asking the obvious question, “why is he telling me this”? From my perspective, when patient advocacy groups and KOLs make these types of presentations, I pay particular attention. Typically, biotechs do not have the luxury of allocating resources to claims data analyses for a myriad of reasons. And this is especially the case when they are conducting pivotal trials. Instead, we tend to leverage the academic endeavors of others. In this particular case the themes derived from their analyses were clear and poignant; there are a massive number of patients, they are not being diagnosed effectively, and when they are diagnosed, it seems to be trending towards the late stage of disease progression, which is liver cirrhosis.

One other topic discussed that I wanted to mention is the new nomenclature being used for liver disease. You will begin to hear the terms MASLD or Metabolic Dysfunction-Associated Steatotic Liver Disease instead of NAFLD, and MASH Metabolic Dysfunction-Associated Steatohepatitis instead of NASH. For a time, these terms will be used synonymously, especially in biotech, and Galectin is no exception. However, I believe the genesis of the name change further underscores the current landscape. The move away from the term “non-alcoholic” to “metabolic” is significant, as is the movement away from “fatty-liver disease” to “steatotic liver disease”. When words change from a negative connotation to something more clinical in nature, it begs the question, why? It is not a trivial development. Effectively, when clinicians, patient advocates, professional organizations, experts and regulatory authorities undertake such a monumental change, it says one thing. This is a serious problem, and we need to pay attention now.

Admittedly, I feel this validates the course of Galectin’s clinical development program in cirrhosis caused by NASH or MASH. Using the term “Metabolic Dysfunction-Associated” in both new definitions further distinguishes Galectin, especially in year that could easily be called “the year of the GLP1s”. To summarize the current NASH landscape today, when Galectin, the only Company conducting trial with a clinical endpoint designed to measure the reduction of the effects of portal hypertension in cirrhosis, I would list the following:

1. There is a shift underway to focus on the metabolic nature of the cause of NASH and cirrhosis caused by NASH, including obesity, especially around the waist, and type 2 diabetes.

2. There is confirmation that our patient population is large and being diagnosed late in disease progression, and there will be initiatives to both identify and treat this population.

3. While GLP1s at weight loss dosage might impact early stage NAFLD and NASH, Galectin is only focused on a population who has progressed to cirrhosis with portal hypertension.

As previously communicated, we expect to present data from the interim analysis of NAVIGATE in about one year from now. While I wish I could take credit for the backdrop in which we plan to present data next year, instead I have to simply say, sometimes things just align in your favor. I honestly couldn't envision a better environment for our phase 2b readout.

The Company achieved several key milestones this year. In February we randomized the last patient for the phase 2b portion of Navigate with a total of 357 patients, which was above our objective of 315 patients. Navigate is the first study in patients with cirrhosis caused by NASH that have advanced to develop portal hypertension with a clinical outcome of preventing esophageal varices, a clinically concerning complication resulting from portal hypertension.

The Company reported positive outcomes in both our third and fourth Data Safety Monitoring Board Meetings for Navigate, including patients who have completed up to 36 months of treatment. This achievement further strengthens our confidence that belapectin can offer a favorable risk-benefit profile due to the nature of our patient population. Specifically, including patients diagnosed with the cirrhotic process, as well as the multiple co-morbidities of the metabolic syndrome, such as hypertension, type 2 diabetes and obesity. Any drug candidate designed for this population must be safe and well-tolerated, and we are encouraged that belapectin continues to achieve that high standard.

Additionally, the Company presented at multiple conferences culminating in five scientific presentations at the Liver Meeting, hosted by AASLD last month. It is unique for a company of our size to continuously make this many presentations at one of the most significant liver meetings in the world. I personally want to thank everyone on my team for their contributions.

As we move forward towards our planned readout next year, we have and will continue to make strategic additions to our staff. While several of these are highlighted on our website, many are not. Senior management and the Board are committed to ensuring we have the right people and consultants in place to efficiently lock the database and present the results of the interim analysis of NAVIGATE as soon as possible. This will also include an enhanced effort over the next year to increase our communication with the scientific and investment communities as we approach interim top line data.

I also want to acknowledge and thank Dr. Ben Carson for accepting our Board nomination. We are grateful for Dr. Carson's enhanced commitment to the Company and our programs. Dr. Carson has a distinguished career in medicine, becoming the youngest director of a major division at Johns Hopkins Hospital when he was named chief of pediatric neurosurgery at the age of 33. He served as the program's director until his retirement in 2013, and subsequently served as the 17th Secretary of Housing and Urban Development. After spending time with Dr. Carson over the last few years as a Senior Advisor, I am confident that his addition to the Board will be a seamless transition that will make an immediate impact.

Finally, we continue to explore options for our oncology program. While I have no updates today, the Company will release information as it becomes available.

Once again, thank you for attending this morning. 2024 will be the most consequential year in Galectin's history and I look forward to keeping you informed of our progress.