# 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, 2020**

# 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))

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** |

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. ☐

**SECTION 7 – REGULATION FD**

**Item 7.01 Regulation FD Disclosure.**

On December 3, 2020, 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, 2020 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**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, 2020

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

Thanks Kevin.

I want to thank Jack and Beth for putting together our virtual annual meeting, and to all those joining us on the call, I appreciate your participation today. Since we cannot be in Atlanta together, I wanted to personally welcome and wish you a joyous, and most importantly, a healthy holiday season. I look forward to seeing you next year in person.

This has been a challenging year for all of us. Regardless of those challenges, I am pleased that the Company is progressing in a positive direction. Joel and the team keep me updated on a regular basis, and I am pleased with the reports they have been providing me. Our management transition this year has been seamless, and I have every confidence that we have the right team in place.

Once again, thank you for joining us this morning, and I will now hand the call over to Joel and Pol for our corporate update.

Joel.

Thanks Dick.

And thank you to everyone joining us virtually today. I am grateful that you are listening, and I sincerely look forward to seeing you in person in Atlanta next year. 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.

Since this is the forum for today due to Covid-19, and I have been the CEO for precisely one quarter, I think it's important for me to discuss the Company in a new way. Shortly, I will turn the discussion over to Pol to give the update on two of our trials. Yes, we actually have three trials — our phase 2b/3 adaptive NASH cirrhosis trial, an investigator-initiated phase 1 extension cancer trial evaluating Keytruda in combination with belapectin, and finally our Hepatic Impairment study. However, before I ask Pol to give the update on the first two trials, I wanted to speak to you about the Company, as well as the third trial.

I get asked all the time about my vision for the Company. My opinion is that vision is an overused term, especially in biotech. It also implies that the person delivering his or her vision, is a visionary, which I believe is entirely presumptuous. Sadly, in my experience, the only visionaries that are ever discussed are people who have already achieved something. They also happen to be the only ones worth discussing. As a fellow shareholder, I think it's pretty safe to say that we all have the same vision, most commonly defined as the future position of our Company.

Instead, I think it is far more useful for me to speak about our mission. On our website, we say "Galectin Therapeutics develops novel therapies to improve the lives of patients with chronic liver disease and cancer". Today I want to take a broader approach. Our mission is to monetize our intellectual property as quickly as possible, by maximizing the use of our limited resources.

There are several strategies we are deploying to achieve that mission. First and foremost, our internal focus is on our adaptive phase 2b/3 NASH cirrhosis trial. Next, we are awaiting the results of the extension cohort of our investigator-initiated combination cancer immunotherapy trial, being conducted at Providence Portland Cancer Center. The results of this cancer immunotherapy trial will inform our decision on how we move forward in contemplating a multi-center phase 2 cancer trial. Finally, we are conducting other R&D efforts.

Pol will discuss the status of two of our trials, but I wanted to take a moment to discuss our R&D efforts and our Hepatic Impairment Study in the context of achieving our mission. This is mostly due to the ever-increasing research on the implication of Galectin-3 in numerous diseases. Additionally, this is an area in which I get many inquiries, especially this year.

During my transition and after becoming CEO, we have had numerous internal discussions around this topic. Part of how we are approaching our R&D efforts relates to our NASH cirrhosis program. As I mentioned, in connection with our NASH-RX trial, we are also conducting an open-label pharmacokinetic hepatic impairment study. While this study is related to the cirrhotic population we are targeting for belapectin, we intend to fully utilize the knowledge we gain from the data derived from the study, not only for regulatory interaction, but to help create a roadmap for future research. I encourage you to read the details of our study on Cinicaltrials.gov.

In addition to the data we will capture from the Hepatic Impairment study in the U.S., we are also conducting the NASH-RX trial in countries around the world, all of which have their own regulatory frameworks. Since we are new to those regulatory agencies, as expected, we have received many inquiries with respect to our data from both pre-clinical and clinical studies. While many leaders might view this as an inconvenience, those inquiries are actually causing us to undertake one of the most important things for any organization, a critical introspective analysis of the Company.

This is where we are extremely fortunate. Having Pol as our new Chief Medical Officer not only brings us the experience and expertise necessary to achieve our mission, it also provides us a fresh set of eyes on all of our data, including data we will be analyzing from all of our studies — past, present and future. While we do not have a specific roadmap to share with you today, I felt it was imperative for you to hear the methodology we are using to create that agenda. Our discussions have included topics related to hepatic/renal interaction, overexpression of macrophages in liver and other organs, and cancers in which immuno-oncology therapies are indicated. The message I want you to understand today is that our detailed process will focus on the areas where we have knowledge and data.

In the future when we are ready to discuss a roadmap for additional research, it will be undertaken in a manner that will help us to exploit our data and achieve our mission. I have a fiduciary obligation to you and the Board, and I fully intend on maximizing our limited resources to achieve our mission of monetizing our intellectual property.

Now I would like to turn the discussion over to Pol to discuss our other trials. Pol.

Thanks Joel,

I will provide a brief update on the progress of our seamless, adaptive clinical phase 2b/3 of belapectin to prevent the development of esophageal varices in patients with compensated NASH cirrhosis. As a reminder, we screened the first patient in June and randomized this first patient in August. This was done in accordance with our previously communicated expectations.

Please realize that the time it takes for a patient to sign a consent to participate, which is the beginning of the screening process, and the randomization for treatment, when all the eligibility criteria have been verified, including the qualifying esophagogastric endoscopy, is up to a maximum of 8 weeks.

Now, our goal is to randomize the last 315th patient by the end of next summer.

The study has started in the US and sites are actively screening patients for participation in the study. The processes of US sites initiation are ongoing, and we planned to have a total of approximately 60 sites there.

The study has not yet started outside of the United States where we expect to have approximately 70 sites in multiple countries, in Canada, Mexico, Europe, Israel, South Korea and Australia.

Compared to the US, as expected, the site initiation process ex-US takes longer. Each ex-US country, and we are currently planning 11 countries, needs to go through a registration process that is an equivalent to a US Investigational New Drug application (the so-called IND), in addition to Ethics Committees approvals -many of which have been already received- and import licenses applications. We anticipate the first ex-US site will be in a position to screen a patient before the end of this year.

We get questions on the impact of the COVID-19 pandemic on the initiation and the conduct of the study, so let me briefly address this. Overall, and until very recently, we have not faced major issues. The situation is however very dynamic and varies from countries to countries, and within a country from clinical site to clinical site. We are addressing issues on a site by site basis as they arise with the wellbeing of our patients and the team taking care of them being the absolute priority. Luckily, so far, we have not seen an impact on the care of patients who have been enrolled in the study. Recently, we have seen our first widespread disruption of the study due to a shortage of laboratory kits from our central laboratory. This potentially could impact screening of new patients, and we are trying to minimize the impact of this shortage, which we were told was related to a disruption of the supply chain due to COVID-19. We are hopeful this will be quickly resolved.

I also want to provide you with an update on the cancer immunotherapy trial being conducted with belapectin in combination with Keytruda® at Providence Portland Cancer center. We previously reported on the first cohort of 20 patients, and a manuscript is in preparation. Following the positive results of this first cohort showing a 50% objective response observed in melanoma and 33% objective response in head and neck cancer, an expansion cohort has been initiated. To date, an additional 13 patients have been enrolled, and 2 more are in screening. The recruitment of this cohort will stop at the end of the year, and we anticipate that enough follow-up will be available on the last patient to report these additional results in the second quarter of 2021. The expansion cohort will also comprise patients with advanced melanoma and patients with head and neck cancer, and we anticipate having twice as many patients with melanoma than with head and neck cancer.

Even though patients in the expansion cohort appear to be more advanced in their disease, we are already encouraged by the apparent good tolerance and safety profile seen in the expansion cohort. This seems to confirm and reinforce what we saw in the initial cohort. As you may know, PD-1 inhibitors such as Keytruda®, can be remarkably efficacious, but these lifesaving treatments might have to be stopped because of immune-mediated toxicities. Based on the documented safety profile our investigators have seen so far; we can be hopeful that the combination of belapectin with Keytruda may indeed decrease the incidence of these auto-immune toxicities.

Our colleagues at Providence have already concluded that a phase 2 combination program where the combination of belapectin to Keytruda could be compared to Keytruda alone would be justified, first to confirm the efficacy of the combination but also to test the hypothesis on the reduction of auto-immune toxicities associated with PD-1 inhibitor monotherapy. We are currently evaluating the best options regarding the financing as well as the operational conduct of such a study that could identify an important advance for patients affected with these cancers.

And with this I will turn the call back over to Joel.

Thanks Pol.

I wanted to quickly summarize some of Pol's points.

With respect to the NASH-RX trial, despite Covid-19 creating some administrative challenges, our goal was and remains to complete enrollment by the end of next summer. We monitor enrollment on a daily basis including site start-up and patient screenings, and we are making sure the process continues to move forward.

On the investigator-initiated combination cancer trial, our investigators are optimistic. Recruitment of the trial will end on December 31, and it is expected to take until the second quarter of next year to fully analyze all of the data. As Pol mentioned, the participants in the extension cohort are more advanced in their disease progression, than were the participants in the first cohort. While we do not know the efficacy results, the researchers have expressed that the favorable side-effect profile appears similar to the first cohort. Despite the fact that full results are not expected until the second quarter of next year, we have had preliminary discussions surrounding a potential multi-center phase 2 trial.

As we continue our discussions with them and learn more tangible information, we will update you.

Thank you again for joining us today.

Keytruda® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co.

**Forward Looking Statements**

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements concerning our anticipated operating results, research and development, clinical trials, regulatory proceedings, and financial resources, and can be identified by use of words such as, for example, “anticipate,” “estimate,” “expect,” “project,” “intend,” “plan,” “believe” and “would,” “should,” “could”, “may” 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 currently planned clinical trial and any future clinical studies as modified to meet the requirements of the FDA (or comparable foreign regulatory agencies) 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; challenges presented by the COVID-19 pandemic; and 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 the COVID-19 pandemic may limit access to NASH patient populations around the world 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, 2019, 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.