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): June 30, 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 8 – OTHER ITEMS

Item 8.01 Other Items.

On June 30, 2020, the Company issued the press release attached hereto as Exhibit 99.1.

SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits. The following exhibit is filed with this Report:

Exhibit No.	Description
99.1	Press release

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: June 30, 2020

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

Galectin Therapeutics Announces Commencement of patient enrollment of the Adaptively-Designed Phase 2b/3 Trial of Belapectin in NASH Cirrhosis

Clinical Trial for patients with NASH cirrhosis who have the highest need for effective therapy

Belapectin has previously shown ability to prevent the development of esophageal varices in this patient population

Compelling NASH-RX trial result could potentially lead to accelerated FDA approval and/or partnership opportunities and fulfill an acute unmet medical need

NORCROSS, Ga., June 30, 2020 (GLOBE NEWSWIRE) -- Galectin Therapeutics, the leading developer of therapeutics that target galectin proteins, announced today that it has enrolled its first patients in the NASH-RX trial. NASH-RX is an international, seamless, adaptively-designed Phase 2b/3 trial of its galectin-3 inhibitor belapectin (GR-MD-02), the company's lead compound, in nonalcoholic steatohepatitis (NASH) cirrhosis patients who have clinical signs of portal hypertension and are at risk of developing esophageal varices. Belapectin had previously been shown that it could prevent the development of new varices in this patient population in the Phase 2 NASH-CX clinical trial (Gastroenterology 2020;158:1334–1345 or https://doi.org/10.1053/j.gastro.2019.11.296).

NASH-RX is expected to enroll approximately 315 NASH patients in the Phase 2b part of the trial at approximately 130 sites in 12 countries in North America, Europe, Asia and Australia. During the Phase 2b part of the trial, two belapectin doses, 2 mg/kg of lean body mass (LBM) and 4 mg/kg LBM, will be compared to placebo. Prior trials have demonstrated the good tolerance profile and apparent safety of belapectin with doses of up to 8 mg/kg LBM, notably for up to 52 weeks of treatment in patients with NASH cirrhosis (Phase 2b NASH-CX Study).

The study design provides for a prespecified interim analysis (IA) of efficacy and safety data conducted after all planned subjects in the Phase 2b component have completed at least 78 weeks (18 months) of treatment and a gastro-esophageal endoscopic assessment. This adaptive design allows for patients to seamlessly transition from the Phase 2b component into the Phase 3 stage, as well as helps determine the optimal dose, bolsters the efficacy signal, and re-evaluates the sample size and statistical power for the Phase 3 stage of the trial. These adaptations are designed to increase the statistical power for detecting a successful outcome. The IA also provides for adjustment in the randomization ratio, refinement of inclusion/exclusion criteria and the potential termination of the study for overwhelming efficacy or for futility.

“The unmet medical need for an effective treatment for patients with NASH cirrhosis remains a compelling motivation to vigorously pursue our therapy,” commented Harold H. Shlevin, Ph.D., President and Chief Executive Officer of Galectin Therapeutics. Moreover, if the results of the NASH-RX trial are compelling, there could be the potential for accelerated FDA approval and/or partnership opportunities.”

Unlike most other clinical trials focused primarily on earlier stages of NASH, the NASH-RX study population will comprise patients with compensated liver cirrhosis. Based on the results of the NASH-CX trial, NASH-RX is focused on patients who have not yet developed esophageal varices but are at increased risk of developing these potentially life-threatening complications. Consequently, patient selection for both Phase 2b and Phase 3 will be based on clinical signs of portal hypertension such as a depressed platelet count (thrombocytopenia), an enlargement of the spleen (splenomegaly) and/or evidence of collateral vessels.

The primary endpoint of the trial is to assess the effect of belapectin on the incidence of new varices. A centralized review system of video recording of esophagogastroduodenoscopy (EGD) has been put in place, and the primary endpoint will be adjudicated by expert EGD readers. Key secondary endpoints will assess the type of varices (sizes and/or bleeding) and other clinical events, such as ascites, hepatic encephalopathy, listing for liver transplantation or death.

NASH-RX was designed in accordance with advice from the U.S. Food and Drug Administration (FDA) and with key contributions from our NASH-RX co-primary study investigators, Dr. Naga Chalasani and Dr. Stephen Harrison, both widely recognized expert hepatologists for NASH, biostatistical experts and numerous other collaborators at Covance, the CRO for the study. The design of the NASH-RX trial optimizes patient enrollment and retention and minimizes the need for invasive tests.

Pol Boudes, M.D., Chief Medical Officer for Galectin commented, “Once liver fibrosis has progressed to cirrhosis, NASH patients can no longer expect significant improvements from changes in their lifestyle. These patients are in dire need of new options, and this trial may prove pivotal in improving their condition. The study’s seamless and adaptive design is very innovative, and the primary endpoint minimizes the inconvenience for patients while being relevant to real life medical practice. We are extremely excited to start the study and give thanks in advance to all the patients who will participate and the medical teams that will support them”.

Details on the trial, entitled “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” are posted on www.clinicaltrials.gov (NCT04365868) and WHO’s trial registry platform.

About Belapectin (GR-MD-02)

Belapectin (GR-MD-02) is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of fatty liver disease 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. The drug binds to galectin proteins and disrupts their function. Preclinical data in animals have shown that GR-MD-02 has robust treatment effects in reversing liver fibrosis and cirrhosis.

About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis

Non-alcoholic steatohepatitis (NASH), also known as fatty liver disease, has become a common disease of the liver with the rise in obesity rates. NASH is estimated to affect up to 28 million people in the U.S. Fatty liver disease is characterized by the presence of fat in the liver along with inflammation and damage in people who consume little or no alcohol. Over time, patients with fatty liver disease can develop fibrosis, or scarring of the liver, and it is estimated that as many as 1-2 million individuals in the U.S. will develop cirrhosis, a severe liver disease for which liver transplantation is the only treatment available. Approximately 6,300 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis.

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 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 NASH-RX trial and any future clinical studies 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 complete the NASH-RX trial or further develop and/or fund additional 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 limit access to 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, 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.

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