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): August 5, 2019

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 8 – OTHER ITEMS

Item 8.01 Other Items.

On August 5, 2019, 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: August 5, 2019

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

Exhibit 99.1

GALECTIN THERAPEUTICS SUBMITS PHASE 3 NASH-RX PROTOCOL IN NASH CIRRHOSIS TO FDA

NORCROSS, Ga. (August 5, 2019) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today announced it has submitted for assessment the Phase 3 protocol for using belapectin (GR-MD-02) for the treatment of compensated non-alcoholic steatohepatitis (NASH) cirrhosis without esophageal varices (the NASH-RX trial). The plans were put forward via a Type C Written Response Only submission to the U.S. Food and Drug Administration (FDA) with the goal of finalizing the Phase 3 protocol and initiating the clinical trial in the fourth quarter of this year.

Galectin provided its Phase 3 protocol and statistical analysis plan for FDA review. In support of the Phase 3 protocol, at the request of the Agency, Galectin has also submitted its current clinical development plan, a draft Phase 4 study synopsis, a draft SAP for the Phase 4 study, an esophagogastroduodenoscopy (EGD) procedure manual to standardize centralized evaluation of the primary and key secondary esophageal varices endpoints. Additional components of the submission are an updated Investigator Brochure suitable for international studies, as well as complete responses to the FDA's comments from the previous meeting, including the justification for dose selection and foregoing a dedicated hepatic impairment study.

"The Galectin team is excited about the submission of the Phase 3 NASH-RX protocol, and the other requested information including the draft Phase 4 synopsis to the FDA. We have traveled a long road to get to this point, and we are proud of the tremendous effort put forth by the entire team, both inside and outside the company. This is a momentous milestone in our development of belapectin for the treatment of NASH cirrhosis," said Harold Shlevin, Ph.D., president and CEO of Galectin.

"After months of thorough evaluation and consideration of six top contract research organizations (CROs) in a rigorous bid defense process, we selected a leading global CRO, with deep experience in NASH cirrhosis and operations in more than 60 countries worldwide, to partner with us on our Phase 3 program," continued Dr. Shlevin. "Our CRO's extensive experience in conducting clinical trials in our therapeutic area was certainly an important consideration in evaluating CROs. We are particularly impressed by its work with clinical trials involving assessment and adjudication of video endoscopies, the critical variable of the primary endpoint in our Phase 3 trial. The CRO has already begun extensive work on site and vendor startup activities. We are also including a NASH-specific site network to accelerate site startup and patient enrollment for this trial. The global medical team at our CRO, together with our two co-primary investigators, Dr. Naga Chalasani and Dr. Stephen Harrison, who are key opinion leaders in NASH, dedicated considerable time and effort to design and optimize the study design for success and maximize the likelihood of attracting and retaining patients during the two years of extensive assessments and treatments. With the continued support of the medical, patient, and investment communities we are excited to be advancing this new drug toward treating the millions of people globally with NASH cirrhosis."

In a joint statement, Drs. Harrison and Chalasani said, “We are honored to have been chosen as co-principal investigators on this very important study. Having worked with Galectin Therapeutics in prior trials, we are encouraged by the results achieved in preclinical and clinical studies which support further testing belapectin to improve outcomes in patients with NASH cirrhosis in a registration trial. In addition, we have been actively involved in the design of these upcoming trials and believe that this study could further the understanding of NASH and the role Galectin-3 inhibition may play in the treatment of this growing epidemic.”

The NASH-RX trial is designed as an international, multicenter, randomized, placebo-controlled, double-blind, parallel-group, Phase 3 study with approximately 500 patients at up to 128 sites in 11 countries in North America, Europe, Asia, and Australia. The study is designed to evaluate the safety and efficacy of two doses of belapectin for the treatment of compensated NASH cirrhosis with clinical evidence of clinically significant portal hypertension without esophageal varices. Enrollment is expected to commence in the fourth quarter of 2019 with an estimated 12-14 months to achieve full enrollment. The treatment period for Phase 3 is two years and topline data readout is expected in late 2022.

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 developing promising carbohydrate-based therapies for the treatment of fibrotic liver disease and cancer based on the Company’s unique understanding of galectin proteins, which are key mediators of biologic function. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. The Company is pursuing a development pathway to clinical enhancement and commercialization for its lead compounds in liver fibrosis and cancer. 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 the treatment of severe atopic dermatitis, moderate-to-severe plaque psoriasis and 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 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 may not produce positive results in a timely fashion, if at all, and could prove 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 completely 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. 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, 2018, 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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