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): February 24, 2015

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))

SECTION 7 – REGULATION FD

Item 7.01 Regulation FD Disclosure.

On February 24, 2015, Galectin Therapeutics Inc. (the "Company) issued the press release 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	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: February 24, 2015

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

Exhibit 99.1

FINAL DRAFT
FEBRUARY 23, 2015

Galectin Therapeutics Announces Details of the Design of its Phase 2 Program with GR-MD-02

- ***Program to include one trial to confirm the safety and therapeutic effect on fibrosis in NASH patients with cirrhosis, and a smaller trial to confirm the safety and therapeutic effect on NASH patients with advanced fibrosis***
- ***Both studies to begin in the second quarter of 2015***
- ***Company to submit a Special Protocol Assessment to the FDA by the end of the month***

NORCROSS, Ga. (February 24, 2015) – Galectin Therapeutics (Nasdaq: GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, announces details of the design of its Phase 2 program with GR-MD-02 in patients with advanced fatty liver disease, or nonalcoholic steatohepatitis (NASH) with cirrhosis.

The program includes two clinical studies. The first is a multicenter, randomized, placebo-controlled, double-blind, parallel-group Phase 2 trial to evaluate the safety and efficacy of GR-MD-02 for the treatment of liver fibrosis and resultant portal hypertension in patients with NASH cirrhosis (the NASH-CX trial). This trial is expected to commence in the second quarter of 2015 with data readout expected in the fourth quarter of 2017. In addition, the Company will conduct a smaller trial of shorter duration in NASH patients with advanced fibrosis (the NASH-FX trial).

The NASH-CX trial was designed with guidance from the U.S. Food and Drug Administration (FDA) received during an End-of-Phase 1 meeting. The NASH-CX trial will include 45 sites (and up to 60 sites, if necessary) in the U.S. and Canada and will enroll a total of 156 patients. It will be comprised of three parallel treatment arms of 52 patients each, with one arm receiving 8 mg/kg of GR-MD-02, the expected therapeutic dose, one arm receiving 2 mg/kg of GR-MD-02 and a third arm receiving placebo. Patients will receive a total of 26 infusions every other week for one year and will be evaluated to determine the change in the hepatic venous pressure gradient (HVPG) as compared with placebo.

The FDA has indicated that HVPG may serve as a surrogate primary endpoint for NASH cirrhosis. HVPG will be correlated with secondary endpoints of fibrosis on liver biopsy as well as with measurement of liver stiffness (FibroScan®) and assessment of liver metabolism (^{13}C-methacetin breath test, Exalenz), which are non-invasive measures of the liver that may be used in future studies.

Galectin is finalizing a submission to the FDA by the end of February for a Special Protocol Assessment (SPA) to accept this trial, if positive, as one of the required trials to support approval of the drug candidate. The FDA has previously agreed to review this study protocol for acceptance under an SPA.

Peter G. Traber, M.D., Galectin's chief executive officer, president and chief medical officer, said, "We are very excited to begin testing our drug candidate in a larger patient population, and we look forward to working with PPD, our contract research organization. There are no approved drugs to treat NASH, and fatty liver disease and NASH are stealth diseases that advance from early stages through to advanced disease without symptoms. When symptoms of any significance do occur, the disease is already full-blown cirrhosis of the liver and the damage is currently considered to be irreversible and the treatment is liver transplant. We are hopeful that GR-MD-02 will prove to be a solution to this significant health problem. As many as 28 million Americans are afflicted with NASH, of which up to 6 million have advanced fibrosis."

Dr. Traber added, "Our successful Phase 1 program showed GR-MD-02 to be safe and well-tolerated, and reached the targeted therapeutic range in the 8 mg/kg dose cohort. Patients in this group showed encouraging effects on a relevant biomarker of fibrotic liver disease and a potential signal indicating a reduction in liver stiffness. These findings are even more notable in light of the short, four-dose treatment regimen tested."

The NASH-FX trial is a 30-patient, randomized, placebo-controlled, blinded study to be conducted at Brooke Army Medical Center with enrollment expected to begin in mid-2015. Patients with NASH with advanced fibrosis will be randomized with 20 receiving 8 mg/kg GR-MD-02 and 10 receiving placebo every other week for 16 weeks, for a total of nine doses. Following the treatment period, the safety and the efficacy of GR-MD-02 on liver stiffness will be evaluated as assessed by magnetic resonance-elastography and FibroScan score, and on imaging of liver fibrosis using multi-parametric magnetic resonance imaging (LiverMultiScan®, Perspectum Diagnostics). Top-line data is expected to be available in mid-2016.

"We believe that this smaller study will provide important information that could inform future larger trials that ultimately may widen the target market for GR-MD-02," continued Dr. Traber. "This study will evaluate three promising non-invasive tests for assessment of liver fibrosis, while offering shorter treatment in a population of patients with advanced fibrosis, but not necessarily cirrhosis."

More details on the clinical trials can be found in Galectin's Corporate Presentation on our website, www.galectintherapeutics.com. Galectin anticipates that the cost of completing both studies will be approximately $20 million over the two and one-half year duration of the trials. As of December 31, 2014, Galectin had cash and cash equivalents of $29.1 million.

About GR-MD-02

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 scaring 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 will in the U.S. have 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 GR-MD-02 will lead to the first therapy for the treatment of fatty liver disease with cirrhosis. 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 GR-MD-02 or any of its other drugs in development. The Company's current 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. There is no certainty that FDA and Company will agree on a SPA or that a SPA would ultimately be acceptable to FDA nor result in approval of GR-MD-02. 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. 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, 2013, 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.

Contacts

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