GALECTIN THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	4960 PEACHTREE INDUSTRIAL BOULEVARD SUITE 240 NORCROSS, GA 30071
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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 1, 2017**

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 1, 2017, 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 1, 2017

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

Exhibit 99.1

Galectin Therapeutics Announces Achievement of Key Milestones Related to NASH-CX Clinical Trial

NORCROSS, Ga. (February 1, 2017) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today announced it has generated sufficient financing to cover currently planned expenditures through 2017 and it remains on track to present top line data from its NASH-CX Phase 2 clinical trial by early December 2017.

Through the sale of common stock via the Company's At-The Market sales agreement, and previously announced private placements in September and December 2016, the Company has reached a financing milestone and believes it now has sufficient funding to cover currently planned expenditures through 2017, most notably its NASH-CX trial.

Additionally, the Company has reached important clinical milestones in its NASH-CX trial, a double blind, placebo-controlled Phase 2b clinical trial which has enrolled 162 NASH cirrhosis patients into the treatment phase. To date, 47 patients have completed all 52 weeks of infusions with the company's lead compound, GR-MD-02, and 122 patients have completed 26 weeks of infusions. In the NASH-CX clinical trial, more than 3,000 infusions (or 75% of the maximum infusions in the trial) have been administered with no drug-related serious adverse reactions. Only 8 patients have discontinued participation in the clinical trial before their scheduled completion dates, and none of the discontinuations were due to drug-related serious adverse events. Currently, the approximate 5% dropout rate is significantly below the 25% included as part of the trial design. The top-line data readout of the NASH-CX trial remains on track for early December 2017.

"NASH cirrhosis represents a large unmet medical need with no currently approved therapies, and we are very pleased with our progress in the NASH-CX trial," said Dr. Peter Traber, President, Chief Executive Officer and Chief Medical Officer of Galectin Therapeutics. "A drug that can halt progression of, or reverse existing fibrosis, in NASH cirrhosis patients would be a breakthrough therapeutic intervention that may prevent complications, alleviate the need for liver transplant, and even prevent death.

"The NASH-CX trial is designed to assess the efficacy of our lead compound, GR-MD-02, in patients with NASH cirrhosis. The trial is being conducted with a primary endpoint that the U.S. Food and Drug Administration views may be a surrogate for outcomes for registration trials in this patient population," added Dr. Traber. "As previously disclosed, the significant biological activity of GR-MD-02 in humans has been demonstrated in patients with moderate to severe plaque psoriasis, a disease which occurs with increased frequency in patients with NASH." (See press release .)

In the NASH-CX trial, NASH-cirrhosis was confirmed both by liver biopsy and by confirmation of an elevated hepatic venous pressure gradient (HVPG). Enrolled patients are receiving either 8 mg/kg or 2 mg/kg of GR-MD-02 or placebo every other week for 52 weeks, for a total of 26 doses. The primary

study endpoint is a reduction in HVPG. Patients treated with GR-MD-02 will be evaluated to determine the change in HVPG as compared to patients treated with placebo. The importance of portal hypertension as measured by HVPG as a potential regulatory endpoint for cirrhosis trials has been discussed in a CEO Perspective. Secondary end-points include NASH fibrosis stage and percent of fibrotic tissue based on liver biopsy and other non-invasive measures including FibroScan and ^{13}C Methacetin breath test (see: www.clinicaltrials.gov for further details).

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 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 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 NASH, or fatty liver disease, with cirrhosis and/or an additional therapy for the treatment of cancer. 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. There may be additional expenditures required during 2017 or subsequently that are currently unknown that are not contemplated in the Company's current projections. 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 its current trials or further develop and/or fund further 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, 2015, 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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