
**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 25, 2016**

GALECTIN THERAPEUTICS INC.
(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-31791
(Commission File Number)

04-3562325
(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))
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SECTION 7 – REGULATION FD

Item 7.01 Regulation FD Disclosure.

On August 25, 2016, 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.

| <u>Exhibit Number</u> | <u>Description</u> |
|-----------------------|--------------------|
| 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 25, 2016

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

GALECTIN THERAPEUTICS ANNOUNCES RESULTS FROM 12-WEEK EXTENSION OF PHASE 2A PSORIASIS CLINICAL TRIAL

Meaningful activity of GR-MD-02 in treating psoriasis suggests promise in treatment of non-alcoholic steatohepatitis (NASH), the company's primary target

NORCROSS, Ga. (August 25, 2016) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, announces interim results from an exploratory, open-label, Phase 2a clinical trial with GR-MD-02 in patients with moderate-to-severe plaque psoriasis.

In May, the company announced significant improvement in PASI (Psoriasis Area and Severity Index) scores at the 12-week mark for all four patients in the study (7 infusions of 8 mg/kg every other week). These results prompted an extension of treatment for an additional 12 weeks at the same dose and dosing interval (13 total infusions). Four patients have now completed 24 weeks of therapy with GR-MD-02, and a fifth patient has completed 12 weeks. Despite the extension of treatment, the original four patients have experienced minimal additional improvement in their psoriasis beyond that first reported in May.

“We are pleased to report that there is clinically meaningful activity of GR-MD-02 for the treatment of moderate to severe psoriasis,” said Peter G. Traber, M.D., Galectin’s president, chief executive officer and chief medical officer. “Moreover, this activity in a human disease, strongly associated with NASH and increased galectin-3 expression, suggests that GR-MD-02 may also have activity in NASH, which remains the company’s primary target.

“While the improvement among the patients is significant, we have to consider the extent of improvement in the context of biological agents for psoriasis currently on the market or in development. The primary endpoint for these existing agents is a 75% improvement in PASI, and none of our patients reached that level of improvement at the dose level and duration administered in the study. There are potential advantages which GR-MD-02 might have over biological agents, such as safety and cost, and the current safety profile of GR-MD-02 does support the possibility of studying higher doses or a more frequent dosing regimen for psoriasis. However, without much more study, these potential advantages remain untested.”

Galectin Therapeutics conducted this small psoriasis study because of an unexpected positive effect on the psoriasis of a NASH patient in the Company’s Phase 1 trial in liver disease. Given the Company’s focus on the phase 2 program in NASH with advanced fibrosis and cirrhosis, additional studies to develop GR-MD-02 as a psoriasis treatment will not occur at this time. The Company may later conduct additional studies in psoriasis either directly or through a partner who may wish to take this forward.

“The results of the psoriasis trial confirm GR-MD-02 is active in a human disease,” concluded Traber. “The Company continues to pursue the application of GR-MD-02 for the treatment of NASH with liver fibrosis and cirrhosis which has always been the primary focus of our business.”

Results of the 24-week psoriasis trial are shown in the table below.

| Patient | Baseline PASI Score | After 7 Doses | | After 13 Doses | |
|---------|---------------------|---------------|-----------------------------------|----------------|-----------------------------------|
| | | PASI Score | Percent improvement from baseline | PASI Score | Percent improvement from baseline |
| 1 | 13.6 | 8.1 | 40% | 7.4 | 46% |
| 2 | 14.6 | 7.9 | 46% | 6.0 | 59% |
| 3 | 12.3 | 10.6 | 14% | 9.0 | 27% |
| 4 | 12.8 | 4.3 | 66% | 5.1 | 60% |
| 5 | 19.1 | 12.7 | 34% | NA | NA |

NA: Data not currently available

About Psoriasis

Psoriasis, which manifests most often as plaque psoriasis, is a chronic, relapsing, inflammatory skin disorder. Although plaque psoriasis is rarely life threatening, it often is intractable to treatment. According to the International Federation of Psoriasis Associations, about 3% of the world's population has some form of psoriasis. In the U.S. there are about 150,000 new cases every year, and psoriasis affects about 2% of the U. S. population, according to the Cleveland Clinic.

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 moderate to severe psoriasis and that positive results in treating psoriasis may have implications for the treatment of 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. 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.

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