

# GALECTIN THERAPEUTICS INC

## **FORM 8-K** (Current report filing)

Filed 02/07/17 for the Period Ending 02/07/17

Address	4960 PEACHTREE INDUSTRIAL BOULEVARD SUITE 240 NORCROSS, GA 30071
Telephone	678-620-3186
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Symbol	GALT
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 7, 2017**

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**GALECTIN THERAPEUTICS INC.**

(Exact name of registrant as specified in its charter)

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**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)

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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 February 7, 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release

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**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 7, 2017

By: /s/ Peter G. Traber  
Peter G. Traber, M.D.  
Chief Executive Officer

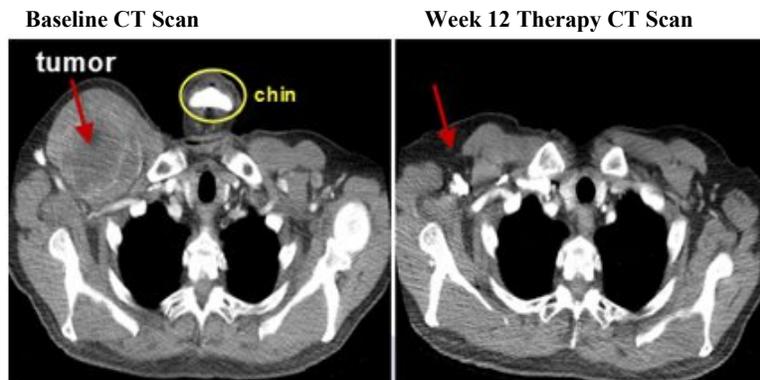
**Combination Immunotherapy with Galectin-3 Inhibitor GR-MD-02 Enhances  
Effects in Pre-clinical Models and Early Results of Phase 1 Clinical Trials**

*First-in-human data presented at GTCBio 9th Immunotherapeutics & Immunomonitoring Conference*

**NORCROSS, Ga. (February 7, 2017)** – **Galectin Therapeutics Inc. (NASDAQ: GALT)**, the leading developer of therapeutics that target galectin proteins, and the Providence Cancer Center today announced the presentation of preclinical and early clinical data from two investigator-initiated Phase 1 clinical trials of GR-MD-02 used in combination with approved cancer immunotherapies. Data presented today at the 9<sup>th</sup> GTCBio Immunotherapeutics & Immunomonitoring Conference in San Diego, CA by Dr. William L. Redmond, Providence Cancer Center, has been posted.

“Preclinical results in mouse models of multiple types of cancers showed important anti-tumor and increased survival effects of combining GR-MD-02 with different types of immune modulators, providing a compelling case for progressing studies into human patients with cancer” said William L. Redmond, Ph.D., Associate Member, Laboratory of Cancer Immunotherapy, and Director, Immune Monitoring Laboratory, Earle A. Chiles Research Institute, Providence Cancer Center, Portland, OR. “We are pleased that our translational medicine team is conducting two phase 1 clinical trials which were initiated under the direction of principal investigator Brendan D. Curti, M.D., Director of the Providence Biotherapy Program at Providence Cancer Center.”

GR-MD-02 was combined with pembrolizumab (KEYTRUDA<sup>®</sup>) in patients with advanced melanoma, and this study has been expanded to patients with oral/head and neck cancer (OHN) and non small cell lung cancer (NSCLC) (<https://clinicaltrials.gov/ct2/show/NCT02575404?term=GR-MD-02&rank=1>). Six subjects with advanced melanoma have been enrolled in the lowest dose cohort (2 mg/kg) with no safety concerns related to GR-MD-02. To date, one partial response and one mixed response has been observed. Below is a chest CT scan of the patient with a partial response showing a marked reduction in tumor size at week 12 of therapy, after 3 doses of combined GR-MD-02 and pembrolizumab.



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GR-MD-02 was also combined with ipilimumab (Yervoy<sup>®</sup>) in patients with advanced melanoma (<https://clinicaltrials.gov/ct2/show/NCT02117362?term=GR-MD-02&rank=6>). Seven subjects treated with the lowest two dose cohorts of GR-MD-02 (1 and 2 mg/kg) have been completed with no safety signals identified due to GR-MD-02. In these low dose initial cohorts, there were no notable changes in the peripheral immune signature. Due to changes in the standard of care for metastatic melanoma (i.e., approval of KEYTRUDA<sup>®</sup>), recruitment has been slowed significantly.

“We are encouraged by these early safety results and look forward to further data on the safety and efficacy of GR-MD-02 used in combination with pembrolizumab (KEYTRUDA<sup>®</sup>) in patients with metastatic melanoma, OHN, or NSCLC”, said Dr. Curti. “While we cannot conclude from the one partial response in the pembrolizumab study that the response was related to GR-MD-02, it provides us with a clinically relevant signal to follow as GR-MD-02 doses are escalated. We hope to report additional data in early 2018 when we anticipate a decision on progressing to phase 2. This decision will be based on the response rate of the combination of pembrolizumab with GR-MD-02 as compared to historical response rates to pembrolizumab alone.”

#### **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, skin 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](http://www.galectintherapeutics.com).

#### **About Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute (EACRI), Providence Cancer Center, Providence Portland Medical Center, Portland Oregon**

Providence Cancer Center, a part of Providence Health & Services, offers the latest in cancer services, including diagnostic, treatment, prevention, education, support and internationally renowned research. The Robert W. Franz Cancer Research Center in the Earle A. Chiles Research Institute is a world-class research facility located within Providence Cancer Center. The Institute’s main area of investigation is cancer immunotherapy, a specialized field of study focused on triggering the immune system to fight cancer. Visit [www.providence.org/cancer](http://www.providence.org/cancer).

#### *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, and use words such as “may,” “estimate,” “could,” “expect” and others. They are based on 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 a therapy for the treatment of fibrotic liver disease and/or an additional therapy*

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*for the treatment of cancer when used in combination with pembrolizumab. 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. 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. Forward Looking Statements*

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