# 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): October 10, 2013

### 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)  ${\bf r}$ 

ollo	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 wing 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 October 10, 2013, Galectin Therapeutics Inc. (the "Company) issued the attached press release, which is being furnished and not filed, and is 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.

(a) Financial Statements of Businesses Acquired.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Shell Company Transactions.

Not applicable.

(d) Exhibits.

Exhibit Number Description

99.1 Press Release dated October 10, 2013

#### **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: October 10, 2013

By: /s/ Peter G. Traber, M.D.

Peter G. Traber, M.D.
President, Chief Executive Officer &
Chief Medical Officer



## Galectin Therapeutics' Preclinical Data Published in *PLOS ONE* Show Its Galectin Inhibitors Reverse Cirrhosis and Significantly Reduce Fibrosis and Portal Hypertension

## Findings Suggest Role for GR-MD-02 and GM-CT-01 in Treatment of Liver Fibrosis and Cirrhosis in Humans

**Norcross, GA, October 10, 2013** – Galectin Therapeutics (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today announced that new preclinical data show its galectin inhibitors, GR-MD-02 and GM-CT-01, have significant therapeutic effects on fibrosis regression and cirrhosis reversal. Results were published in an article titled "Regression of Fibrosis and Reversal of Cirrhosis in Rats by Galectin Inhibitors in Thioacetamide-Induced Liver Disease" in *PLOS ONE*, an international, open-access journal with rigorous peer review.

In the preclinical study, fibrosis was induced in rats by injecting thioacetamide (TAA) into the abdominal cavity. Rats were then treated with GR-MD-02 (galactoarabino-rhamnogalaturonan) or GM-CT-01 (galactomannan). In the initial part of the study, rats that completed eight weeks of thioacetamide injections were given four weeks of treatment with GR-MD-02; results showed an almost 50 percent reduction in collagen content, a marker of chronic fibrosis. Rats were then exposed to additional thioacetamide injections and developed extensive fibrosis (cirrhosis); treatment with four once weekly doses of GR-MD-02 or GM-CT-01 while continuing treatment with the toxin TAA led to marked reduction in fibrosis and reversal of cirrhosis. Overall, the study demonstrated that GR-MD-02 or GM-CT-01 led to significantly reduced fibrosis, reversal of cirrhosis and a significant reduction in portal hypertension.

"These preclinical data suggest a potential role for GR-MD-02 and GM-CT-01 in the treatment of liver fibrosis and cirrhosis in humans," said Peter G. Traber, MD, President, Chief Executive Officer and Chief Medical Officer, Galectin Therapeutics Inc. "There are currently no approved therapies for fibrosis. Encouraging data like these published in *PLOS ONE* increase the body of scientific knowledge of galectin inhibitors and add momentum to Galectin Therapeutics' development program. We recently announced that GR-MD-02 received Fast Track designation from the FDA for fatty liver disease with advanced fibrosis."

The preclinical study was conducted predominantly at the Icahn School of Medicine at Mount Sinai in New York City. The senior author, Dr. Scott Friedman of Mount Sinai, is an international expert in the pathogenesis and treatment of liver fibrosis. The *PLOS ONE* article can be found online at <a href="http://dx.plos.org/10.1371/journal.pone.0075361">http://dx.plos.org/10.1371/journal.pone.0075361</a>

GM-CT-01 and GR-MD-02 are proprietary molecules, which are generated from naturally occurring carbohydrate polymers using proprietary processes, and possess the property of binding to and inhibiting galectin proteins, predominantly galectin-3. In July, the Company successfully dosed the first patient in a Phase 1 clinical trial of GR-MD-02 and enrollment is ongoing.



#### **About Galectin Therapeutics**

Galectin Therapeutics (NASDAQ: GALT) 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, key mediators of biologic function. We are leveraging extensive scientific and development expertise as well as established relationships with external sources to achieve cost effective and efficient development. We are pursuing a clear development pathway to clinical enhancement and commercialization for our lead compounds in liver fibrosis and cancer. Additional information is available at www.galectintherapeutics.com.

#### **Forward Looking Statements**

This press release contains, in addition to historical information, 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 our current expectations and are subject to factors and uncertainties which could cause actual results to differ materially from those described in the statements. These statements include those regarding the potential role for GR-MD-02 and GM-CT-01 in the treatment of liver fibrosis and cirrhosis in humans. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that our plans, expectations and goals regarding any potential therapeutic uses and benefits of our drugs and any future pre-clinical or clinical studies are subject to factors beyond our control. Future clinical studies may not begin or 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 our drugs are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies. Regardless of the results of current or future studies, we may be unsuccessful in developing partnerships with other companies or obtaining capital that would allow us to further develop and/or fund any studies or trials. To date, we have incurred operating losses since our inception, and our ability to successfully develop and market drugs may be impacted by our ability to manage costs and finance our continuing operations. For a discussion of additional factors impacting our business, see our Annual Report on Form 10-K for the year ended December 31, 2012, and our subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause our v

#### Contact

Galectin Therapeutics Inc.
Peter G. Traber, MD, 678-620-3186
President, CEO, & CMO
<u>ir@galectintherapeutics.com</u>