# 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

May 3, 2012
Date of Report (Date of earliest event reported)

# 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.)

7 WELLS AVENUE NEWTON, MASSACHUSETTS 02459 (Address of principal executive offices) (Zip Code)

(617) 559-0033

(Registrant's telephone number, including area code)

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))

# Item 8.01. Other Events

On May 3, 2012, Galectin Therapeutics Inc. sent a letter to its shareholders (the "Shareholder Letter"). Exhibit 99.1 hereto, which is being furnished and not filed herewith, contains the text of the Shareholder Letter.

## Item 9.01. Financial Statements and Exhibits.

- (d) Exhibits
- 99.1 Shareholder Letter, dated May 3, 2012

# **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# GALECTIN THERAPEUTICS INC.

By: /s/ Peter G. Traber

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

Medical Officer

Date: May 3, 2012

#### May 3, 2012

### Dear Galectin Therapeutics Stockholder:

We are very pleased to report the progress that Galectin Therapeutics is making in its mission to create shareholder value and liquidity by developing new therapeutics based on its pioneering work in the area of galectin inhibition. In particular, we are pleased to announce since our last correspondence that we are now a NASDAQ listed company with the funds we need to conduct the current Phase II metastatic melanoma trial that has started in Belgium and conduct Phase I and initiate Phase II clinical trials for our fatty liver drug, GR-MD-02. We are executing the strategy we discussed in earlier correspondence which is designed to efficiently maximize the value of our unique scientific and medical leadership in this field in a short period of time. In this letter we would like to reflect on these accomplishments but, more importantly, summarize the current strategy and look forward to the value adding objectives we intend to achieve executing this strategy during the next two to three years.

#### Recent Stock Trading Platform and Balance Sheet Improvements

Galectin Therapeutics (GALT) completed a \$12.0 million public offering of its shares and "up listing" to the NASDAQ market system. In the course of this letter we want to answer questions from shareholders regarding the public offering and explain how the Company intends to use the approximate \$10.4 million of net proceeds received. We believe that the additional funding for progressing development programs and trading on NASDAQ should drive shareholder value. As a result of completing the offering, the Company now has funds required to make important progress on our two development programs. In melanoma, we will be able to finish the current Phase II clinical trial in patients with metastatic melanoma which has started in Belgium. In our liver fibrosis program, we will be able to finish pre-clinical development and conduct a Phase I clinical trial and initiate a Phase II clinical trial.

### QUESTIONS FROM SHAREHOLDERS WITH ANSWERS FROM MANAGEMENT

Question: Has the Company reduced its emphasis on treatment of cancer?

Answer: No, the Company has refocused the use of galectin inhibitors in a way that has the highest likelihood of creating value in the shortest period of time. Originally, the therapeutic focus was on adding GM-CT-01 (DAVANAT) to chemotherapy containing 5-FU for patients with colorectal cancer. Evaluation of this approach revealed that colorectal cancer is a very competitive area with multiple drugs on the market and in late stages of development, the development program was linked to an old chemotherapy that is not viewed as the future of cancer therapy, and the development program would have been very costly and taken at least 4 years. Now, the focus is on melanoma based on new and revolutionary data showing that GM-CT-01 can protect cancer patient's immune system from the "Galectin Effect"; whereby tumors secrete galectin proteins which block the effect of immune cells on the tumor.

Question: Why is Galectin Therapeutics conducting the melanoma clinical trial in Belgium?

Answer: The Ludwig Institute in Brussels Belgium discovered the "Galectin Effect" and has a long standing program in melanoma. In fact, the investigators at the Ludwig Institute and the University of Saint Luc Cancer Center are global opinion leaders in melanoma and tumor immunology. Melanoma is an ideal tumor for a treatment trial with GM-CT-01 because it is an immunologically responsive tumor and there are newly approved immunologic therapies that we suspect will be synergistic with GM-CT-01. Moreover, the investigators at the Ludwig Institute for Cancer Research, Brussels and Centre du Cancer des Cliniques Universitaires Saint-Luc are experienced in conducting melanoma clinical trials and are funding the first stage of the trial.

Question: What is the goal of the melanoma clinical trial?

Answer: Our Belgium collaborators previously used a peptide vaccine to treat melanoma with only minimal results on the tumor. The investigators hypothesize that the minimal effect may be due to the fact that melanoma cells secrete galectin proteins that bind to and inhibit T-cells thereby reducing their ability to kill the melanoma tumor cells. In the ongoing clinical trial, GM-CT-01 is being infused in combination with the peptide vaccine with the intent of inhibiting galectins and enhancing the ability of tumor specific T-cells to kill tumor cells. As a primary endpoint of the clinical trial, we are looking for reduction or disappearance of the tumors. A positive result in this study will not only be an important milestone for Galectin Therapeutics, but will also usher in a new therapeutic era of galectin inhibition in cancer therapy.

Question: How will positive results from the melanoma clinical trial increase the value of the company?

Answer: Tumor specific immunotherapy is a very active area of clinical research. There are currently two products on the market, Provenge for prostate cancer and Yervoy for melanoma, and there are over a hundred ongoing clinical trials. The market for tumor vaccines is expected to be over \$7 billion by 2015 and represents one of the most exciting new approaches for cancer therapy. Galectin inhibition will possibly be important for enhancing the tumor killing effect of the immune system in multiple cancers, regardless of the method by which the immune system is stimulated. A positive result in our melanoma clinical trial will be a proof of concept for inhibiting the galectin effect with GM-CT-01. We anticipate that there will be great interest from drug companies for this approach and our drug, making a partnership and/or licensing agreement a strong possibility.

Question: Why has the Company chosen to focus on treatment of liver fibrosis, and in particular fatty liver disease?

**Answer:** The driving factor for our commitment to galectin inhibition for fibrosis is the strong scientific evidence that galectin-3 is essential for the development of liver fibrosis in animals with or without fatty liver disease. Published data show that mice lacking the galectin-3 gene are incapable of developing liver fibrosis in response to toxin insult to the liver. This type of evidence is the strongest possible that a particular protein is critical for a disease process.

For this reason, we evaluated the ability of Galectin Therapeutics' carbohydrate drug candidates to block galectin-3 in animal models of liver fibrosis. The results were clear and exciting. In rats treated with a liver toxin, GR-MD-02 was able to reverse scar tissue in the liver. We also studied fatty liver, or non-alcoholic steatohepatitis (NASH) in mice. The Company's preclinical findings indicate that GR-MD-02 decreases the amount of fat, inflammation and fibrosis in diabetic mice with NASH diseased livers.

The possible application of GR-MD-02 for treatment of NASH represents a very large opportunity with relatively short time line to monetization. There are zero therapies on the market for NASH, a condition that leads to fibrosis and is estimated to effect up to 15,000,000 patients in the US and which is expected to become the leading reason for liver transplantation.

Question: What are the important milestones in the clinical development program for fatty liver disease and how will they increase the value of the Company?

**Answer:** Currently, the Company is conducting multiple pre-clinical efficacy and toxicology studies to prepare for a submission of an IND to the FDA by the end of 2012. In early 2013, it is planned to start a Phase I clinical trial with GR-MD-02 in patients with NASH to assess safety and preliminary evidence of efficacy in humans. By the end of 2013, we plan on initiating a Phase II clinical trial to assess the efficacy of GR-MD-02 in patients with NASH with expected top line results by the end of 2014. Because there are no currently approved therapies for NASH, results of these studies will be closely watched and positive results will elicit broad interest from the industry.

Phase I and II results in an unmet medical need like NASH can be very valuable to a small biotechnology company. One only needs to look at a recent example in the area of Hepatitis C, in which there are many fewer patients than NASH. Inhibitex was acquired for \$2.5 billion after completing Phase I clinical trials and Pharmasset was acquired by Gilead for \$11 billion during their Phase II clinical trials. While there is no guarantee that a company with a NASH drug at comparable points in development would sell for equivalent prices as either of these Hepatitis C drug companies recently did, it is worth making a few comparisons. Both diseases ultimately result in fibrotic scar tissue forming in the liver, resulting in failure of the organ. In the US, there are between 6,000,000 and 11,000,000 more patients with NASH than Hepatitis C and, while there are other treatments for Hepatitis C, there are no therapies for NASH. This suggests that a drug for Fatty Liver Disease could have a tremendous value with positive results from early clinical trials, long before FDA approval to market a drug.

Question: What is the view of the liver clinician community and key opinion leaders of GR-MD-02's potential value in therapy of liver fibrosis?

Answer: Our data on the pre-clinical efficacy of GR-MD-02 in NASH has been completely developed in house over the last year. As such, the information is only recently being disseminated into the research community. The first data was presented in December at a meeting of the European Association for the Study of the Liver in Lisbon Portugal. There will be another presentation at Digestive Disease Week in San Diego on May 21, 2012. The work has been very favorably received and we will be submitting the work to a peer reviewed journal for publication. In addition, the strength of the science has attracted the interest of leaders in the study of liver diseases. Specifically, our program for galectin inhibition to treat liver fibrosis has attracted Key Opinion Leaders (KOLs) from prominent institutions such as Harvard, Mount Sinai, Penn, Emory, Michigan, and Wisconsin. Moreover, Dr. Scott Friedman of Mount Sinai School of Medicine, one of the foremost authorities in liver fibrosis in the world, has recently agreed to a five year consulting agreement. These experts will be critical in disseminating information about our therapy, designing the best clinical trials, communicating with the FDA, and enrolling patients in clinical trials.

QUESTION: Why does Management feel the NASDAQ listing is going to be good for shareholders and create more liquidity in GALT shares?

**ANSWER:** The NASDAQ listing increases the number of stock brokers and investment organizations that can buy GALT shares. Most stock brokers and institutional investors have been prohibited from recommending GALT shares while they traded on the OTC Bulletin Board. The larger the number of brokers who can recommend GALT shares and the larger amount of money that is available to invest in the Company, the better the liquidity and the higher the price that GALT shares should be.

As a result of up listing to NASDAQ, GALT shares can now be purchased by institutional investors and recommended by nearly every stock broker who decides they like what we are doing. Institutional investors generally will buy much larger positions in company shares than individuals. To this point, an institutional investor that we met on the recent public offering road show made a purchase of 145,000 GALT Units (GALTU, consisting of two shares of common stock and one common stock warrant) in the market at a price greater than \$1.3 million following the public offering. Additionally, institutional investors will often invest more as a company achieves clinical milestones vs. individual investors who often sell shares because the share price increased to a price higher than they paid for shares after milestone achievements.

QUESTION: How does the reverse split affect me as a shareholder?

**ANSWER:** Everything gets adjusted so that there isn't any change in value or upside potential. Post reverse split the number of shares you own represents the SAME PERCENTANGE of the Company, worth the SAME AMOUNT OF MONEY as the moment before the reverse split. The only difference is the total number of shares that make up your percentage of the Company are 1/6 as many as before the split. While some people enjoy seeing a higher number of shares on their stock certificate, we ask you to remember that ultimately a purchaser of GALT will determine what they think GALT is worth based on some form of net

present value, risk adjusted valuation of GALT's technologies and that number will not have any correlation to the number of shares outstanding. Moreover, any purchase of the Company or its assets upon meeting milestones listed above will be made based on our market cap and not number of shares.

QUESTION: How significant is the combination of being listed on NASDAQ and adding approximately \$10.4 million to the company's balance sheet net after offering expenses.

ANSWER: The most common complaints management previously heard from stock brokers no longer exist post NASDAQ listing and post \$12.0 million public offering. Prior to the offering and NASDAQ listing management was told by brokers, "I can't trade or recommend GALT shares until they are traded on an exchange like NASDAQ or as long as they are traded on the OTC Bulletin Board". The most common concern management heard from the few brokers whose firms would allowed them to trade OTC Bulletin Board listed shares had to do with balance sheet strength. Management would hear, "GALT doesn't have enough money to last 18 months" "you don't have enough cash to achieve significant milestones that could cause a large drug company to want to acquire GALT", or "you don't have enough cash to last 24 months". All of these previous concerns have been eliminated by the combined NASDAQ listing and \$12.0 million Public Offering.

With trading barriers that prohibited stock brokers from soliciting trades in GALT shares removed and having the money to achieve clinical milestones in both Fatty Liver Disease and Cancer Immunotherapy enhancement between today and second quarter 2014, it will be much more likely a stock broker or money manager will take a position in GALT shares. Greater demand for shares means more liquidity and should mean higher share prices. Achievement of milestones should equate to greater shareholder value and greater interest by both stock brokers and money managers.

QUESTION: What is the status with GALT's Colombian partner's application to market GM-CT-01?

ANSWER: Our Colombian partner continues to attempt to gain approval of GM-CT-01 in Colombia. The Colombian effort originated after the Company was encouraged by a key oncologist at Colombia's National Cancer Institute, the government, and a regional pharmaceutical company to seek approval for GM-CT-01 as an adjuvant to 5-FU, because the data that showed it may increase the efficacy of 5-FU and reduce its side effects. The time to receive a definitive answer regarding Colombian approval has clearly taken longer than we were originally led to believe. At this point, our corporate strategy for increasing the value of the Company is not dependent on approval in Colombia. We have not taken into account projections for revenues, so if this should be successful, it will all be upside. Even though the president of PROCAPS, S.A., our Colombian partner, has taken personal responsibility for this effort, we currently take a guarded view of the prospects for an approval and hope to report more by the end of the second quarter.

We hope and expect to continue this excellent progress in 2012 and very much look forward to keeping you informed throughout the year.

Sincerely,

Peter G. Traber, M.D. CEO and President

James C. Czirr Executive Chairman