GALECTIN THERAPEUTICS INC

FORM 8-K
(Current report filing)

Filed 03/14/17 for the Period Ending 03/14/17

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Telephone	678-620-3186
CIK	0001133416
Symbol	GALT
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): March 14, 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 March 14, 2017, Galectin Therapeutics Inc. (the "Company) issued the press release attached hereto as Exhibit 99.1. Also, on March 14, 2017, Galectin Therapeutics Inc. posted on its website a "CEO Perspectives" blog article entitled "Galectin Inhibitor Therapy Effective in Severe Atopic Dermatitis (Eczema)", which is attached as Exhibit 99.2.

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
99.2	CEO Perspectives

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.

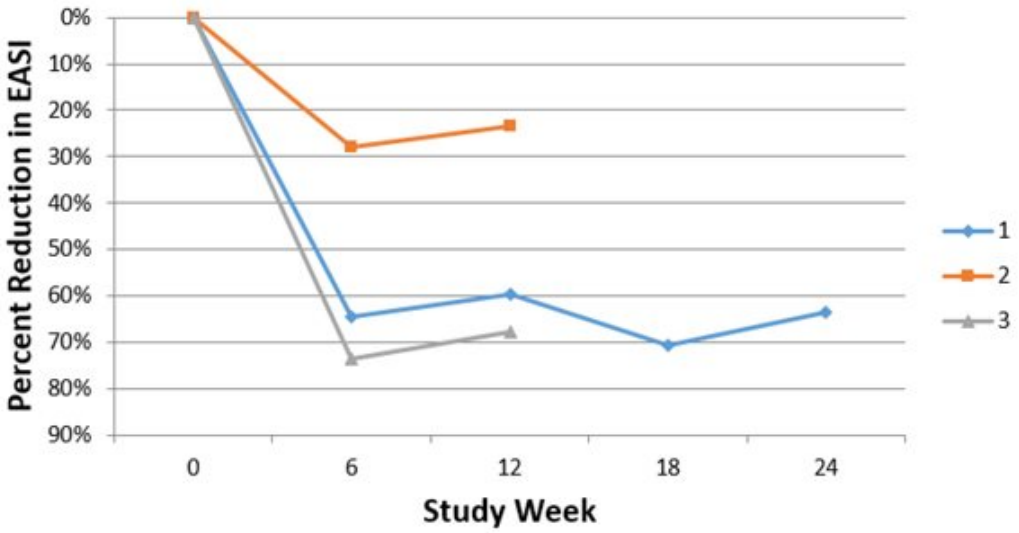
Date: March 14, 2017

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

Exhibit 99.1

GR-MD-02 Demonstrates Clinically Significant Effect in Patients with Severe and Refractory Atopic Dermatitis (Eczema)

NORCROSS, Ga. (March 14 , 2017) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today announced preliminary results for severe and refractory atopic dermatitis from a small, open label, investigator-initiated study with GR-MD-02 that has enrolled 3 patients. There were no serious adverse events observed. All three patients showed clinical response as determined by reduction of the Eczema Area and Severity Index (EASI) score at week 12 having received 6 every other week doses, with two patients achieving a 64% and 74% reduction in EASI, respectively, at six weeks after receiving only 3 doses of GR-MD-02 (see graph below). These findings are believed to demonstrate a clinically significant effect of this novel investigational drug in this patient population. More information and commentary on these findings can be found in a simultaneously released CEO Perspective (link to article here).



Simon A. Ritchie, M.D., FAAD, lead investigator and staff dermatologist, San Antonio Military Health System, Fort Sam Houston, TX, said “There is a lack of effective therapy currently on the market for patients with severe, refractory atopic dermatitis. As a galectin-3 inhibitor, GR-MD-02, represents a novel mechanism for treatment in patients with severe atopic dermatitis that have failed standard of care. The significant clinical effect we have seen from preliminary results in this investigator-initiated protocol is encouraging and warrants a phase 2 controlled trial with various doses and regimens to further explore the drug’s potential.”

The small, open label, investigator-initiated protocol treated three adult patients with severe atopic dermatitis. All three patients had failed a number of systemic therapies and would be classified as

refractory, meaning that they have not responded to medical treatment beyond topical steroids. The disease severity was determined using EASI, an objective scoring system in common use for atopic dermatitis studies. GR-MD-02 was given intravenously at a starting dose of 8 mg/kg at baseline and then every other week for 10 weeks (6 infusions) and then increased to 12 mg/kg every other week for an additional 7 infusions. All three patients experienced improvement in their atopic dermatitis, with patient 1 achieving a 64% reduction in EASI at 24 weeks, the time of his 13 th infusion. While patient 1 has completed the full 13 infusions, patients 2 and 3 have just started the higher dose of 12 mg/kg. It should be noted that patient 1 has elected to remain on 24 additional weeks of therapy because of the positive effect on his clinical symptoms.

“We are pleased by the results of this study demonstrating the safety and clinically significant effect in patients with severe atopic dermatitis, although because of the potential of a placebo effect in this disease, confirmation of the magnitude of the effect will require placebo-controlled trials,” said Peter G. Traber, M.D., president, chief executive officer and chief medical officer, Galectin Therapeutics. “Moreover, the activity of GR-MD-02 in these patients compares favorably with other drugs currently in development, and with minimal side effects as demonstrated by nearly 3,000 doses of our compound being administered in multiple completed and ongoing clinical trials with no severe adverse effects attributed to the drug.”

About Atopic Dermatitis

Atopic dermatitis, commonly called eczema, is a chronic inflammatory condition of the skin of caused by multiple factors that usually arises in early childhood, often in infancy. While it usually resolves by early teenage years, approximately 5-10% of patients have the disease extend into adulthood. Classic symptoms are itching and burning of the skin, resulting in thickening of the skin in response to the scratching. In some adults, it can be severe with debilitating itching, inability to sleep, and social stigmatization due to skin damage and thickening, often on the face.

Surveys suggest that up to 18% of the population have atopic dermatitis, up to 37% of those people seek medical care, and over 70% of those seeking care have mild disease that is handled by primary care physicians. Approximately 20% with mild and 2% with severe disease are referred to specialists. The national estimated cost of treatment is as high as $3.8 billion, as of 2012.

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 dedicated to developing novel therapies to improve the lives of patients with chronic liver and skin diseases and cancer. Galectin’s lead drug (GR-MD-02) is a carbohydrate-based drug that inhibits the galectin-3 protein which is directly involved in multiple inflammatory, fibrotic, and malignant diseases. The lead development program is in non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH related fibrosis. This is the most common liver disease and one of the largest drug development opportunities available today. Additional development programs are in treatment of severe atopic dermatitis, moderate-to-severe plaque psoriasis, and in combination immunotherapy for advanced melanoma and other malignancies. Galectin seeks to leverage extensive

scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. 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, and use words such as “may,” “estimate,” “could,” “believe”, “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 atopic dermatitis, psoriasis and other skin diseases, as well as fibrotic and 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. 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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# # #

Exhibit 99.2

Galectin Inhibitor Therapy Effective in Severe Atopic Dermatitis (Eczema)
By Dr. Simon Ritchie and Dr. Peter G. Traber

Guest Author

I welcome as a co-author to this Perspective, Dr. Simon Ritchie, our lead investigator in skin disease and staff dermatologist, at San Antonio Military Health System, Fort Sam Houston, TX. Dr. Ritchie conducted the clinical study in moderate-to-severe plaque psoriasis and will present the promising results of the effect of our galectin inhibitor GR-MD-02 in psoriasis at the Maui Derm meeting March 20-23. The progression of results in the treatment of psoriasis has been previously released on March 6, 2016 , May 16, 2016 , and November 10, 2016 .

What is atopic dermatitis (Eczema)

Atopic dermatitis, commonly called eczema, is a chronic inflammatory condition of the skin of caused by multiple factors that usually arises in early childhood, often in infancy. While it usually resolves by early teenage years, approximately 5-10% of patients have the disease extend into adulthood. As an allergic type of disorder, it is associated with asthma and seasonal allergies, which often occur in the same patient called the “atopic triad”. Atopic dermatitis is the itch that becomes a rash. Classic symptoms are itching and burning of the skin, resulting in thickening of the skin in response to the scratching. In some adults, it can be severe with debilitating itching, inability to sleep, and social stigmatization due to skin damage and thickening, often on the face.

How big a problem is atopic dermatitis?

Surveys suggest that up to 18% of the population have atopic dermatitis, up to 37% of those people seek medical care, and over 70% of those seeking care have mild disease that is handled by primary care physicians. Of those patients who seek medical care, approximately 20% have moderate and 2% have severe disease, which is generally referred to specialists. The national estimated cost of treatment is as high as $3.8 billion, as of 2012 (1).

No new therapies for difficult-to-treat atopic dermatitis in 30 years

Mild atopic dermatitis can be treated with skin moisturizers and topical steroid preparations, but there are fewer options for those that have more severe disease and do not respond. The only FDA approved systemic therapy is oral steroids, but multiple other drugs and approaches are often tried in clinical practice with limited efficacy and significant side effects including phototherapy, methotrexate, cyclosporine A, and mycophenolate mofetil. A number of newer drugs have been tried such as tofacitinib, apremilast, and ustekinumab with negative or modest effects, or significant side effects.

Therefore, there is an important unmet medical need for therapies in difficult-to-treat and severe atopic dermatitis. Some of the drugs in development will be discussed later in this article.

Galectin-3 Inhibition is a novel new mechanism that may be effective

Scientific studies show that there is a link between the galectin-3 protein and disease activity in atopic dermatitis. Galectin-3 protein is increased in the skin of patients, as well as animal models, of atopic dermatitis. Moreover, mice that lack the galectin-3 protein have much less skin disease when treated with a known trigger of atopic dermatitis (2). GR-MD-02, our galectin-3 inhibitor was used in patients because of these scientific data and the fact that there was a clinically significant effect in another inflammatory skin disease, psoriasis.

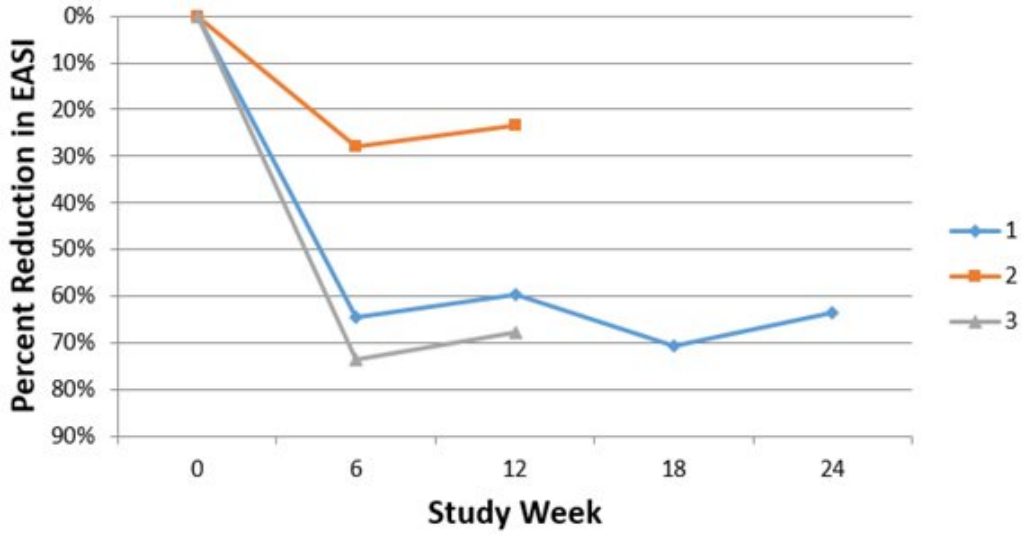
GR-MD-02's potential for a clinically meaningful effect in refractory, severe atopic dermatitis

Three adult patients with severe atopic dermatitis were treated with GR-MD-02 by Dr. Simon Ritchie under an investigator-initiated protocol. All of these patients had failed a number of systemic therapies as shown in the table below, and would be classified as refractory which means their disease has not responded to treatment beyond topical steroids alone. The disease severity was determined using a standard, objective scoring system in common use for atopic dermatitis studies, the Eczema Area and Severity Index (EASI).

The disease was more severe in our three patients as indicated by the baseline EASI (median 67, mean 60), than in two recent phase 3 trials in atopic dermatitis, in which the median baseline EASI ranged from 29 to 31.8 for various groups (3). Moreover, the three patients in our study were refractory to systemic therapies, whereas the patients in these phase 3 studies only were required to fail topical steroid therapy. Other scores such as SCORAD were also used, but did not change the conclusions so only EASI is reported here for clarity.

Patient	Gender	Age	Baseline EASI	Prior Therapies (failed or not tolerated)
1	M	36	67.6	Topical steroids, phototherapy, methotrexate, apremilast, omalizumab, tofacitinib, mycophenolate mofetil
2	F	23	67	Topical steroids, phototherapy
3	M	53	47	Topical steorids, cyclosporine, oral steroids, isotretinoin

GR47-MD-02 was given intravenously at a starting dose of 8 mg/kg every other week for 10 weeks (6 infusions) and then increased to 12 mg/kg every other week for an additional 7 infusions. All three patients experienced improvement in their atopic dermatitis, as shown below for the change in EASI scores. While patient 1 has completed the full 13 infusions, patients 2 and 3 have just started the higher dose of 12 mg/kg.



Patient 1, who completed the study, had a very significant reduction in disease activity and told Dr. Ritchie, “This is the best I have felt since I was diagnosed with atopic dermatitis 17 years ago”. In fact, the patient is so pleased with his therapy that it has been extended for another 24 weeks. It is also important to note that patient 1 had a significant improvement in the IGA scale (Investigator Global Assessment scale), starting with a score of 3 (0-4) and improving to a score of 1, an improvement that the FDA views as clinically significant in registration trials for atopic dermatitis. When patients 2 and 3 complete the additional therapy at the higher dose, we will report their final scores.

Patient 1’s skin was also visually improved with less thickness and scaling and re-growth of lateral eyebrows (lost from itching). However the cutaneous manifestations of atopic dermatitis are much more subtle and do not show well on photos (particularly in African American patients). This is the reason that photos are rarely, if ever, included in atopic dermatitis drug trial publications.

Importantly, there was no toxicity nor adverse events noted in the three patients.

How does GR-MD-02 treatment compare with other treatments in development?

GR-MD-02 seems to have had an important, clinically significant effect in this small open-label, investigator-initiated protocol. However, we caution that this is a very small sample of patients with no placebo treatment arm. In other documented trials, there has been a significant placebo response in atopic dermatitis (25% for a 50% improvement in EASI (called EASI-50) in dupilumab studies (3)), unlike in psoriasis trials where the placebo effect is usually less than 5%. On the other hand, all of these patients treated with GR-MD-02 had more severe baseline scores and refractory disease after multiple therapies, so it may be a more challenging group than those typical difficult-to-treat patients who have failed topical steroids only.

So, how does the effect we saw in this small study compare to other drugs in development? Dupilumab, a drug in development with successful phase 3 trials, averaged 64% of patients reaching an EASI-50 at week 16 of therapy (3). Two out of three of our patients reached an EASI-50 (reduction of EASI of 64% and 74%, respectively) at 6 weeks of therapy (3 doses of drug) which is a shorter period of time than with dupilumab. Moreover, as stated above, the baseline EASI score was more severe in our patients than in the phase 3 dupilumab studies and our patients had been on multiple systemic drugs, whereas those in the dupilumab studies had only to fail topical steroids.

Nemolizumab, another phase 3 drug asset, averaged 40% reduction in EASI at 12 weeks; patient 1 and 3 both exceeded this. Our patients 1 and 3 also faired favorably compared to tofacitinib, which has only been used in one small study, and there is not data on lebrikizumab which is currently in development.

Therefore, it appears that the effects on severe atopic dermatitis seen in our small, open label protocol, compares favorably with the other drugs currently in development.

What's next?

Several arguments suggest that GR-MD-02 has potential as a therapy for severe atopic dermatitis:

- It represents a new and novel mechanism of galectin-3 inhibition in the disease
- We have seen clinically relevant, preliminary results of GR-MD-02 in three refractory patients with severe atopic dermatitis.
- There is a lack of effective therapy for these patients currently on the market
- GR-MD-02 has apparently similar magnitude of clinical effect levels compared to drugs in development
- GR-MD-02 has a very strong safety profile, with nearly 3,000 doses of GR-MD-02 delivered in multiple completed and ongoing clinical trials with no severe adverse effects attributed to the drug
- While intravenous administration is a potential drawback, it is encouraging that patient 1 asked to continue on therapy for an additional 6 months.

Phase 2, randomized, placebo-controlled trials with various doses and regimens of administration will be necessary to explore this potential. Planning for such a program is ongoing, as the company explores partnership and other options to finance such a program.

Reference List

1. Arkwright PD, Motala C, Subramanian H, Spergel J, Schneider LC, Wollenberg A. Management of difficult-to-treat atopic dermatitis. J Allergy Clin Immunol Pract 2013 Mar;1(2):142-151.
2. Saegusa J, Hsu DK, Chen HY, Yu L, Fermin A, Fung MA, et al. Galectin-3 is critical for the development of the allergic inflammatory response in a mouse model of atopic dermatitis. Am J Pathol 2009 Mar;174(3):922-931.
3. Simpson EL, Bieber T, Guttman-Yassky E, Beck LA, Blauvelt A, Cork MJ, et al. Two Phase 3 Trials of Dupilumab versus Placebo in Atopic Dermatitis. N Engl J Med 2016 Dec 15;375(24):2335-2348.

These "CEO Perspectives" are a regular feature of our communication activities and may contain forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including whether GR-MD-02 may be effective in the treatment of severe atopic dermatitis, psoriasis, and other skin disease. These statements relate to future events and use words such as "may," "might," "could," "expect" and others. 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.