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): September 20, 2018

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

SECTION 8 – OTHER ITEMS

Item 8.01 Other Items.

On September 20, 2018, the Company issued the press release attached hereto as Exhibit 99.1.

SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
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: September 20, 2018

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

Galectin Therapeutics, Inc. Announces Positive Preliminary Results from Phase 1b Clinical Trial of GR-MD-02 and KEYTRUDA® in Advanced Melanoma and Expansion of the Trial

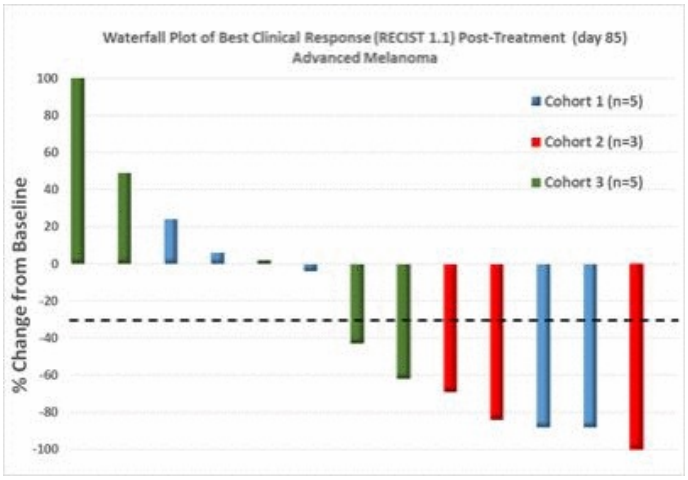
- *Combination immunotherapy of GR-MD-02 and KEYTRUDA for all cohorts reported shows an Objective Response Rate of 50% (seven of fourteen patients).*
- *The published response rate of KEYTRUDA alone is 33% in melanoma*
- *Providence Portland principal investigator, Dr. Brendan Curti, encouraged by the results and plans to add more patients to the study*
- *Both Advanced Melanoma and Head and Neck Cancer being studied*

NORCROSS, Ga., September 20, 2018 (GLOBE NEWSWIRE)—**Galectin Therapeutics Inc.** (NASDAQ:GALT), the leading developer of therapeutics that target galectin proteins, and Providence Cancer Institute, today announced additional preliminary clinical data from cohort 3 of an investigator-initiated Phase 1b clinical trial of GR-MD-02 used in combination with KEYTRUDA® (pembrolizumab) in patients with metastatic melanoma for which KEYTRUDA is indicated or those patients whose melanoma progressed during or recently after KEYTRUDA monotherapy.

The Providence Cancer Institute (Portland, OR) translational medicine team is conducting this phase 1b clinical trial, initiated under direction of principal investigator Brendan D. Curti, M.D., Director, Providence Melanoma Program. The objectives of this study were to determine a safe dose of GR-MD-02 used in combination with KEYTRUDA and to measure the response rate to combined therapy. “We are very encouraged by the objective response rate and the disease control rate observed in patients with advanced melanoma. These response rates were higher than expected with KEYTRUDA alone,” said Dr. Curti. “An objective response rate of seven out of fourteen patients (50%) and a disease control rate of nine out of fourteen patients (64%) with advanced melanoma is very encouraging. The published objective response rates in randomized studies using KEYTRUDA in patients with advanced melanoma range from 21% in patients who have had prior therapy to 39% in patients who had not received prior systemic therapy. Importantly, the combination was also very well tolerated, and treatment appears to be associated with fewer adverse events than expected with KEYTRUDA alone.”

When aggregated with the cohorts previously reported, the data shows a 50% objective response rate in advanced melanoma with GR-MD-02 in combination with KEYTRUDA and a significant decrease in the frequency of suppressive myeloid-derived suppressor cells (MDSC) following treatment in the responding patients (on day 85 post-treatment) was observed. The published data on KEYTRUDA alone have shown an objective response rate of 33% in this patient population.

Fourteen advanced melanoma patients across three dose cohorts now have Objective Response Rate (ORR) and Disease Control Rate (DCR) data. Six patients in cohort 3 (8 mg/kg GR-MD-02) have now been added to the three patients in cohort 2 (4 mg/kg GR-MD-02) and the five patients in cohort 1 (2 mg/kg GR-MD-02). Cohorts 1 and 3 each had two patients with an objective response. All three patients in cohort 2 had an objective response.



N=13; 1 patient in cohort 3 not depicted due to clinical progression prior to scans. Dotted line at -30% change from baseline indicates the RECIST 1.1 threshold for definition of partial response.

Generally, the U.S. Food and Drug Administration has defined objective response rate as the sum of partial responses plus complete responses. Disease control rate is the objective responses plus those with stable disease.

In addition to the fourteen advanced melanoma patients, six patients with head and neck cancer were enrolled in this phase 1b trial with a 33% objective response rate and a 67% disease control rate. Dr. Curti states “the response rates observed overall in advanced melanoma and head and neck cancer patients were better than expected with KEYTRUDA alone and are the basis for moving forward with both tumor types, particularly given the low response rates of anti-PD-1 monotherapy in head and neck cancer. There is a significant clinical need for better options for these patients and our initial objective response rates were encouraging enough to warrant inclusion of additional patients to help determine whether we should also pursue these challenging patient populations in a phase 2 trial. Taken together with the observed favorable safety and tolerability of the combination, these results provide a compelling rationale to move forward with this approach.” Given that all three melanoma patients (100%) were responders at 4 mg/kg dose, the investigators plan to continue the trial with expansion of the 4 mg/kg GR-MD-02 and KEYTRUDA cohort to include additional advanced melanoma patients and additional head and neck cancer patients.

“In addition to the encouraging clinical responses seen thus far, we continue to make progress on identifying immunological biomarkers that correlate with favorable responses,” said William L. Redmond, Ph.D., Associate Member, Laboratory of Cancer Immunotherapy, and Director, Immune Monitoring Laboratory at the Earle A. Chiles Research Institute, a division of Providence Cancer Institute. “We have observed a significant decrease in the frequency of suppressive myeloid-derived suppressor cells (MDSC) following treatment in the responding patients (on day 85 post-treatment). Comprehensive laboratory studies are being performed to further identify the biological mechanisms associated with this response.”

"Galectin Therapeutics is very pleased with our continuing collaboration with Providence Cancer Institute, and we are encouraged that Dr. Curti and his team are expanding the trial to include additional patients," said Harold Shlevin, Ph.D., CEO and President of Galectin Therapeutics. "The planned expansion of the size of the 4 mg/kg dose cohort, and inclusion of both advanced melanoma patients and patients with head and neck cancer, will permit further evaluation that the use of GR-MD-02 in combination with KEYTRUDA has a better objective response rate and fewer adverse events than KEYTRUDA alone. We believe this collaboration with Providence to be a fruitful approach to helping to determine the potential of GR-MD-02 in combination immuno-therapy, and it also leverages our ability to collect additional data related to the immunological monitoring of these patients before potentially proceeding to the next phase of development."

Additional information about this clinical trial may be found at www.clinicaltrials.gov/ct2/show/NCT02575404

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-3 proteins and disrupts its function. Preclinical data in animals have shown that GR-MD-02 has robust treatment effects in reversing liver fibrosis and cirrhosis. GR-MD-02 also has robust efficacy in pre-clinical cancer models in combination with immunotherapy agents.

About Galectin Therapeutics

Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver and cancer. Galectin's lead drug (GR-MD-02) is a carbohydrate-based drug that inhibits the galectin-3 protein that 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 is believed to be one of the largest drug development opportunities available today. Additional exploratory development programs are 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.

About Earle A. Chiles Research Institute, a division of Providence Cancer Institute, at the Robert W. Franz Cancer Center, in Portland, Ore.

Providence Cancer Institute, a part of Providence Health & Services, offers the latest in cancer services, including diagnostic, treatment, prevention, education, support and internationally-renowned research. The Earle A. Chiles Research Institute, a division of Providence Cancer Institute, is a world-class research facility located within the Robert W. Franz 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.chilesresearch.org.

About RECIST Criteria. RECIST is a set of published rules that define when tumors in cancer patients improve ("respond"), stay the same ("stabilize"), or worsen ("progress") during treatment. The criteria were published in February 2000 by an international collaboration including the European Organisation for Research and Treatment

of Cancer (EORTC), National Cancer Institute of the United States, and the National Cancer Institute of Canada Clinical Trials Group. Today, the majority of clinical trials evaluating cancer treatments for objective response in solid tumors use RECIST. In solid tumors, tumor response measures the changes in tumor mass, growth (progression) or shrinkage (response) and it is often assessed using the RECIST criteria (Response Evaluation Criteria in Solid Tumor). Although it is still the object of criticism (e.g. the definition of cut-off used to define the response and the progression), RECIST provides a simplified set of criteria for evaluating tumors response via an anatomical approach using a unidimensional measure of tumor burden.

Further information on RECIST criteria is available at:

https://ctep.cancer.gov/protocolDevelopment/docs/recist_guideline.pdf

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 fatty liver disease with cirrhosis and those regarding the hope that our lead compounds will be successful in cancer immunotherapy. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that the current management leadership may not be as effective as the predecessor management team; for the clinical trials in cancer immunotherapy, Galectin has relied on the trials undertaken by Providence, which limits the number of patients included in the trials; Galectin may be unsuccessful in expanding the scope of the cancer immunotherapy trials, and the results of expanded trials may not be positive; Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of GR-MD-02; manufacturing of drug product now in scale-up may not be successful or meet regulatory expectations, the Company’s Phase 3 clinical trial for the treatment of fatty liver disease, now in the initial planning stages, and any future clinical studies, including those in connection with cancer immunotherapy may not proceed and 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 further develop and/or fund any 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, 2017, 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.

KEYTRUDA® is a registered trademark of Merck & Co., Inc

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