# 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 17, 2019**

# 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))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol | Name of each exchange on which registered |
|---|---|---|
| **Common Stock $0.001 par value per share** | **GALT** | **The Nasdaq Capital Market** |

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

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 17, 2019, 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. The following exhibit is filed with this Report:

| Exhibit No. | 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 17, 2019

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

**Exhibit 99.1**

# Galectin Therapeutics, Inc. and Providence Cancer Institute Receive Patent on the Use of Belapectin (GR-MD-02) in Cancer Immunotherapy

NORCROSS, Ga., September 17, 2019 (GLOBE NEWSWIRE) — Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, and Providence Cancer Institute announced today they have received notice of issuance of U.S. Patent Number 10,398,778 titled "Method for Enhancing Specific Immunotherapies in Cancer Treatment." The patent's principal claims cover method of use of Galectin's drug candidate, belapectin (GR-MD-02), as a means to enhance the effectiveness of specific immunotherapies in cancer treatment. The patent is expected to provide broad protection for the use of belapectin for compositions, methods of using and methods of manufacturing compositions used alone or in combination with other targeted immunotherapies in treating cancer. The patent coverage extends to 2033.

"This is an important patent that protects the use of belapectin in cancer immunotherapy," said Harold Shlevin, Ph.D., CEO and President of Galectin Therapeutics. "Immunotherapy holds great potential for treating advanced cancers, but response to treatment is highly variable. Providence Cancer Institute is conducting groundbreaking research using belapectin in combination with cancer immunotherapy, with indications that belapectin may boost the effectiveness of treatment. This patent expands the IP portfolio of Galectin to capture the importance of this work for the benefit of the Company and its stockholders, and for Providence Cancer Institute."

The patent is the result of work done by Providence Cancer Institute in a Phase 1B investigator-initiated trial using belapectin in combination with KEYTRUDA® to treat advanced melanoma as well as head and neck cancer. Data from this early open-label study shows a 50% objective response rate in advanced melanoma with belapectin in combination with KEYTRUDA. The published data on KEYTRUDA alone have shown an objective response rate of 33% in this patient population.

"Belapectin shows strong results when given with checkpoint blockade (anti-PD-1) immunotherapy. The response rates to combination therapy observed overall in advanced melanoma and head and neck cancer patients were better than with KEYTRUDA alone, 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," 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. "In addition to the encouraging clinical responses to combination therapies involving belapectin with KEYTRUDA, we continue to make progress on identifying immunological biomarkers that correlate with favorable responses."

The methods and compositions of the invention relate to the enhancement of specific immunotherapies in cancer treatment. In particular, aspects of the invention relate to novel approaches to boost immune function using a complex carbohydrate pharmaceutical compound alone or in combination with other targeted immunotherapy to increase the efficacy of cancer immunotherapy.

**About Belapectin (GR-MD-02)**

Belapectin (also known as 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 belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis. Belapectin also has robust efficacy in pre-clinical cancer models in combination with immunotherapy agents.

**About Galectin Therapeutics**

Galectin Therapeutics 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, 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.

**About Providence Cancer Institute**

Providence Cancer Institute, a part of Providence St. Joseph Health, offers the latest in cancer services, including diagnostic, treatment, prevention, education, support and internationally-renowned research. Providence Cancer Institute is home to the Earle A. Chiles Research Institute, a world-class research facility located within the Robert W. Franz Cancer Center in Portland, Oregon, and is a recognized leader in the field of cancer immunotherapy since 1993. Visit providenceoregon.org/cancer to learn more.

**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 belapectin (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 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 belapectin; 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, 2018, 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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