# 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): May 17, 2021**

# 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 $0.001par value per share** | **GALT** | **The Nasdaq Stock 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 2 – FINANCIAL INFORMATION**

**Item 2.02 Results of Operations and Financial Condition.**

On May 17, 2021, Galectin Therapeutics Inc. ("Galectin Therapeutics") issued a press release announcing its results of operations and financial condition as of and for the three months ended March 31, 2021 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated May 17, 2021 (the "Press Release"), a copy of which is attached hereto as Exhibit 99.1.

Except for the historical information contained in this report, the statements made by Galectin Therapeutics are forward looking statements that involve risks and uncertainties. All such statements are subject to the safe harbor created by the Private Securities Litigation Reform Act of 1995. Galectin Therapeutics' future financial performance could differ significantly from the expectations of management and from results expressed or implied in the Press Release. Forward-looking statements in the Press Release are subject to certain risks and uncertainties described in the Press Release. For further information on other risk factors, please refer to the "Risk Factors" contained in Galectin Therapeutics' Annual Report on Form 10-K for the fiscal year ended December 31, 2020, as filed with the Securities and Exchange Commission, and its subsequent filings with the SEC.

The information in this Item 2.02 is being furnished, not filed, pursuant to Item 2.02 of Form 8-K. Accordingly, the information in Item 2.02 of this report, including the Press Release attached hereto as Exhibit 99.1, will not be incorporated by reference into any registration statement filed by Galectin under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference.

**SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS**

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated May 17, 2021 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**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: May 17, 2021

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

**D R A F T**

**Galectin Therapeutics Reports Financial Results for the Quarter Ended March 31, 2021, and Provides Business Update**

*Continued Favorable Developments in both NAVIGATE and Cancer Combination Immunotherapy Trials*

**NORCROSS, Ga., May 17, 2021 (GLOBE NEWSWIRE)** – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results and provided a business update for the quarter ended March 31, 2021. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the U.S. Securities and Exchange Commission and is available at **www.sec.gov**.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, said, "The start to the new year has been an exciting and productive time for Galectin Therapeutics in both our NAVIGATE Phase 2b/3 clinical trial in NASH cirrhosis as well as the cancer, combination immunotherapy trial being conducted in collaboration with the Providence Cancer Institute in Portland, Oregon. In addition, since the beginning of the year, we have raised fresh capital and brought on

Dr. Ben Carson, Sr., a world-renowned physician and former Secretary of Housing and Urban Development, as a special consultant. We very much look forward to working with Dr. Carson.

“In support of our innovative NAVIGATE study,” continued Lewis, “we launched NAVIGATEnash.com, a new information resource about NASH cirrhosis for both patients and physicians. NASH cirrhosis is still largely overlooked and remains a major unmet medical need. I’ve been deeply moved by the determination of this community of NASH cirrhosis patients and the physicians who treat them.

“In our cancer, combination immunotherapy trial, results of the Phase 1 trial were published in the highest ranked fully open access peer-reviewed immunology journal. The study suggests combination therapy with belapectin results in a better objective response rate with fewer adverse events than pembrolizumab (KEYTRUDA®) alone. Brendan Curti, M.D., the first author of the paper, noted galectin-3 is an important driver of tumor-induced immunosuppression. This clinical study constitutes proof-of-concept that the addition our galectin-3 inhibitor, belapectin, to a PD-1 inhibitor can benefit cancer patients.

“Of course,” concluded Lewis, “I would be remiss if I did not thank our Chairman, Mr. Richard Uihlein, who continues to demonstrate his strong support and provided additional funding to help advance our NAVIGATE trial, and for which we are deeply grateful.”

Richard E. Uihlein, Chairman of the Board, added, “This quarter has been an important one for Galectin Therapeutics, and having Dr. Ben Carson on our team is an investment in the future. The progress being made in both our NASH

cirrhosis study and our collaboration on cancer immunotherapy demonstrates the important science behind what we are doing. Galectin-3 is involved in a wide range of human diseases, and my recent investment in the company underscores my commitment to develop belapectin to its full potential."

**Dr. Ben Carson, Sr., Engaged as Special Consultant**

- Engaged Ben Carson, Sr., M.D., a world-renowned neurosurgeon and the 17th Secretary of the U.S. Department of Housing and Urban Development, as a special consultant to assist with development of the Company's galectin-3 inhibitor, belapectin, as a treatment for NASH cirrhosis and in combination with immunotherapy for the treatment of cancers. In particular, Dr. Carson will help increase awareness of Galectin Therapeutics including our ongoing Phase 2b/3 NAVIGATE clinical trial in NASH cirrhosis, our continuing research in combination with cancer immunotherapy, and its potential in addressing other fibrotic diseases. Dr. Carson will also assist in the formation of a scientific advisory committee for the Company, recruit potential members of the committee, and identify potential strategic commercial and/or academic partners for the Company.

**Recent Financings**

- Raised $10 million in a convertible debt financing with Richard E. Uihlein, the Company's Chairman and largest individual stockholder. The debt is unsecured and bears interest at a rate of 2% compounded annually. Additional interest of 2.5% per quarter will accrue but will only be paid if the debt and interest are converted into shares of the Company's common

stock, at Mr. Uihlein's option, on or prior to maturity, which is four years from the date of the loan. The conversion price of the debt and interest is fixed at $5.00 per share of common stock.

**NAVIGATE Trial Update**

- Launched NAVIGATEnash.com, a trial website dedicated to educating patients and physicians about liver cirrhosis resulting from non-alcoholic steatohepatitis (NASH) as well as support NAVIGATE, the Company's innovative, seamless adaptive Phase 2b/3 study in NASH cirrhosis.
- Galectin Therapeutics continues to actively recruit patients into NAVIGATE, its seamless, adaptive Phase 2b/3 study of belapectin for the prevention of esophageal varices in NASH cirrhosis.

**Peer-reviewed publications, Scientific Presentations and Conferences**

- Published in the *Journal for ImmunoTherapy of Cancer (JITC)*, the highest ranked fully open access immunology journal, a peer-reviewed paper entitled, "Enhancing Clinical and Immunological Effects of anti-PD-1 with Belapectin, a Galectin-3 Inhibitor" (doi:10.1136/jitc-2021-002371), provided further clinical evidence that using belapectin, a potent galectin-3 inhibitor, in combination with pembrolizumab (KEYTRUDA®), a PD-1 inhibitor, significantly enhances tumor response to immunotherapy in patients with advanced metastatic melanoma (MM) and head and neck squamous cell carcinoma (HNSCC). The paper describes results from an ongoing Phase 1 clinical study, a collaboration between Galectin

Therapeutics and Providence Cancer Institute in Portland, Oregon. An objective response was observed in 50% of MM (7/14) and 33% of HNSCC (2/6) patients. This compares favorably to published response rates on pembrolizumab alone.

- At the 4th Global NASH Congress, which took place virtually on April 29, 2021, Pol F. Boudes, M.D., Chief Medical Officer, reviewed Galectin Therapeutics' scientific and clinical activities in NASH cirrhosis in a presentation entitled, "An innovative clinical development program: belapectin for NASH cirrhosis."

**Financial Results**

For the three months ended March 31, 2021, the Company reported a net loss applicable to common stockholders of $6.3 million, or ($0.11) per share, compared to a net loss applicable to common stockholders of $3.6 million, or ($0.06) per share for the three months ended March 31, 2020. The increase is largely due an increase in 2021 research and development expenses related to the Company's NAVIGATE trial.

Research and development expense for the three months ended March 31, 2021 was $4.9 million compared with $2.1 million for the three months ended March 31, 2020. The increase was primarily due to costs related to our NAVIGATE clinical trial and other supportive activities. General and administrative expenses for the three months ended March 31, 2021, were $1.4 million, compared to $1.4 million for the three months ended March 31, 2020.

As of March 31, 2021, the Company had $20.8 million of cash and cash equivalents. On April 16, 2021, the Company received $10,000,000 in proceeds from an unsecured convertible promissory note from its Board Chairman, Richard E. Uihlein. The Company also has a $10 million unsecured line of credit, under which no borrowings have been made to date. The Company believes it has sufficient cash, including availability under the line of credit, to fund currently planned operations and research and development activities through at least September 30, 2022.

The Company expects that it will require more cash to fund operations after September 30, 2022 and believes it will be able to obtain additional financing as needed. Currently, we expect to require an additional approximately $35-$40 million to cover costs of the trial to reach the planned interim analysis estimated to occur in the second half of 2023 along with drug manufacturing and other scientific support activities and general and administrative costs. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us.

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

Belapectin (GR-MD-02) is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH 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. Belapectin binds to galectin-3 and disrupts its function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis. A Phase 2 study showed belapectin may prevent the development of esophageal varices in NASH

cirrhosis, and these results provide the basis for the conduct of the NAVIGATE trial. The NAVIGATE trial (NAVIGATEnash.com), entitled “A Seamless Adaptive Phase 2b/3, Double-Blind, Randomized, Placebo-controlled Multicenter, International Study Evaluating the Efficacy and Safety of Belapectin (GR-MD-02) for the Prevention of Esophageal Varices in NASH Cirrhosis” began enrolling patients in June, 2020, and is posted on www.clinicaltrials.gov (NCT04365868). Galectin-3 also has a significant role in cancer, and the Company is supporting a Phase 1 study in combined immunotherapy of belapectin and KEYTRUDA® in treatment of advanced melanoma and in head and neck cancer.

**About Fatty Liver Disease with Advanced Fibrosis and Cirrhosis**

Non-alcoholic steatohepatitis (NASH) has become a common disease of the liver with the rise in obesity and other metabolic diseases. NASH is estimated to affect up to 28 million people in the U.S. It is characterized by the presence of excess fat in the liver along with inflammation and hepatocyte damage (ballooning) in people who consume little or no alcohol. Over time, patients with NASH can develop excessive fibrosis, or scarring of the liver, and ultimately liver cirrhosis. It is estimated that as many as 1 to 2 million individuals in the U.S. will develop cirrhosis as a result of NASH, for which liver transplantation is the only curative treatment available. Approximately 8,890 liver transplants are performed annually in the U.S. There are no drug therapies approved for the treatment of liver fibrosis or cirrhosis.

**About Galectin Therapeutics**

Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver disease and cancer. Galectin's lead drug belapectin (formerly known as 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, for which it has Fast Track designation by the U.S. Food and Drug Administration. 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 combination immunotherapy for advanced melanoma and other malignancies. Advancement of these additional clinical programs is largely dependent on finding a suitable partner. 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 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 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 and in other therapeutic indications. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that trial endpoints required by the FDA may not be achieved; Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of belapectin or any

of its other drugs in development; the Company may not be successful in scaling up manufacturing and meeting requirements related to chemistry, manufacturing and control matters; the Company's currently planned clinical trial and any future clinical studies as modified to meet the requirements of the FDA may not produce positive results in a timely fashion, if at all, and could require larger and longer trials, which would be 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. Global factors such as coronavirus may continue to impact NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs. 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, 2020, 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.

**Company Contact:**

Jack Callicutt, Chief Financial Officer
(678) 620-3186
ir@galectintherapeutics.com

**Condensed Consolidated Statements of Operations**

| | Three Months Ended March 31, | |
|---|---|---|
| | 2021 | 2020 |
| Operating expenses: | | |
| Research and development | $ 4,899 | $ 2,144 |
| General and administrative | 1,418 | 1,440 |
| Total operating expenses | 6,317 | 3,584 |
| Total operating loss | (6,317) | (3,584) |
| Other income (expense): | | |
| Interest income | 1 | 50 |
| Interest expense | (22) | (22) |
| Total other income | (21) | 28 |
| Net loss | $ (6,338) | $ (3,556) |
| Preferred stock dividends | 2 | 6 |
| Net loss applicable to common stock | $ (6,340) | $ (3,550) |
| Basic and diluted net loss per share | $ (0.11) | $ (0.06) |
| Shares used in computing basic and diluted net loss per share | 57,132 | 56,956 |

**Condensed Consolidated Balance Sheet Data**

| | March 31, 2021 | December 31, 2020 |
|---|---|---|
| | (in thousands) | |
| Cash and cash equivalents | $ 27,760 | $ 27,142 |
| Total assets | 22,897 | 29,600 |
| Total current liabilities | 4,663 | 5,399 |
| Total liabilities | 4,663 | 5,407 |
| Total redeemable, convertible preferred stock | 1,723 | 1,723 |
| Total stockholders' equity | $ 16,511 | $ 22,470 |

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