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): August 16, 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 August 16, 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 June 30, 2021 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated August 16, 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 August 16, 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: August 16, 2021

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

Galectin Therapeutics Reports Financial Results for the Quarter Ended June 30, 2021, and Provides Business Update

Considering options for a Combination Cancer Immunotherapy trial based on encouraging results of Phase 1b trial which strengthened the rationale to conduct a larger, randomized controlled Phase 2 study

NORCROSS, Ga., August 16, 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 June 30, 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, "Galectin continued its progress on our strategic initiatives this quarter, actively working towards achieving our goals for the Company, which include advancing our NASH cirrhosis program through global registration trials and expanding our research. We reported positive new results in a cancer immunotherapy extension trial of belapectin in combination with KEYTRUDA® in a patient cohort with more advanced disease compared to earlier results, and our NASH cirrhosis trial continues to initiate new sites and increase enrollment despite the continued

challenges arising from COVID-19. Organizationally, we have added and will continue to add talented and experienced professionals in key leadership roles that will strengthen the company, preparing us for significant new milestones. As my new team, including employees and external consultants, reshapes our culture internally, we continue to engage our strategic consultant, Dr. Ben Carson, in formulating new opportunities. These are exciting times, and we expect the second half of the year to bring continued success." Richard E. Uihlein, Chairman of the Board, added, "I am excited by the idea that we have the opportunity to potentially save thousands of lives, not just in NASH cirrhosis but in cancer and other areas where galectins have been implicated. I encourage you to visit our website to study and learn more from Dr. Carson and our talented team, who have just created a series of new videos to help educate our various constituencies and provide a better understanding of why our work is so important."

Program Review

Cancer Immunotherapy

In our cancer immunotherapy program, we announced on July 9, 2021, positive top-line results in our Phase 1b clinical trial extension of belapectin in combination with KEYTRUDA in advanced metastatic melanoma and head and neck cancer. The study 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 results demonstrated that belapectin potentially improves treatment response while simultaneously reducing adverse effects often seen with KEYTRUDA alone. Most impressive, these results were obtained despite the patients in this extension cohort having a significantly higher tumor burden when enrolled as compared to the initial study – especially the melanoma patients. Furthermore, there were no toxicities deemed related, probably related, or possibly related to belapectin and the severity of toxicities in this trial were less than the anticipated toxicity with KEYTRUDA alone. Dr. Brendan Curti, M.D., the study's principal investigator at the Earle A. Chiles Research Institute, a division of Portland Providence Cancer Institute, observed that these results highlight the potential benefit and immunological effects of this combination and were sufficiently encouraging to strengthen the rationale to conduct a larger, randomized controlled Phase 2 study.

NAVIGATE Study (NASH Cirrhosis)

Enrollment in our NAVIGATE trial in NASH cirrhosis continues, with new sites coming online in both the U.S. and Europe. A protocol amendment aimed at refining criteria for patients with portal hypertension, based on input from investigators, has been approved by institutional review boards and implemented globally resulting in an improved quality of screening and, importantly, more patients qualifying for enrollment.

Our relationship with Dr. Ben Carson as a Senior Consultant is helping increase awareness of Galectin Therapeutics, which is expected to help attract additional clinical trial sites and patients.

Our innovative NAVIGATE study web portal, NAVIGATEnash.com, has experienced a strong response. Many clinicians from our various study sites have registered for the site's steady stream of new information and resources about NASH cirrhosis and the NAVIGATE study for both patients and physicians. NAVIGATEnash.com is also attracting significant web traffic as we build a community where NASH cirrhosis patients and the physicians can share information.

Corporate Development

The Company has been aggressively building out its management team and is in the process of making a number of key hires. Ezra R. Lowe, Ph.D. has joined as Executive Director, Clinical and Preclinical Pharmacology. Ezra Lowe brings a depth of experience in clinical pharmacology, drug metabolism, and pharmacokinetics. He has a broad base of experience working with various drug formats across a diverse array of therapeutic areas. Prior to Galectin, Ezra was Senior Director, Clinical Pharmacology in Global R&D with the Bausch Health Companies. He previously held Clinical and Nonclinical Pharmacology positions at Salix Pharmaceuticals, Bausch+Lomb, and Valeant Pharmaceuticals International, Inc. and spent time as Lead Scientist in Biotransformation and Toxicology at The Dow Chemical Company. In the course of his career, he has completed 10 different global drug approvals. The Company expects to add additional key senior resources in the remainder of 2021.

As a strategic consultant, Dr. Carson will also help amplify our story, by raising awareness with key constituencies. During a recent television appearance, in fact, he was asked about new and interesting projects he was working on, and he took the opportunity to discuss his involvement and support of Galectin. In addition, Dr. Carson was very much involved in a recent meeting of key members of the company's leadership, where he participated in the taping of a number of videos discussing Galectin, belapectin, the management team and the road forward. His vision for the company can be seen on these videos on the company's website at https://galectintherapeutics.com//video-library.

Evolving Areas of Interest

Clinical and pre-clinical research shows the recently demonstrated mechanism of action for belapectin in cancer immunotherapy reinforces the potential for belapectin in NASH cirrhosis and other diseases driven by galectin-3. This has led to Galectin being approached by researchers from a variety of unrelated specialties that are interested in initiating collaborative research.

Dr. Carson observed, "Belapectin has broad potential applications as it pertains to galectin-3 and the whole family of galectins, which affect almost every organ system. Not just in oncology, where data has demonstrated the nefarious role that galectin-3 plays in the tumor micro-environment to stimulate tumor progression, but also in areas such as heart disease. Clearly, there are a whole host of processes that are affected, particularly those where the fibrotic and immunologic impact of galectin-3 are clinically relevant."

Mr. Lewis commented, "Having a respected physician and leader such as Dr. Carson is strategic. He is a great resource and uniquely qualified to seek out partnerships, such as collaborations that could rapidly advance additional trials in cancer immunotherapy where we already have strong Phase 1b data that encourages further study."

Financial Results

For the three months ended June 30, 2021, the Company reported a net loss applicable to common stockholders of $8.5 million, or ($0.15) per share, compared to a net loss applicable to common stockholders of $6.2 million, or ($0.11) per share for the three months ended June 30, 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 June 30, 2021, was $6.5 million compared with $4.7 million for the three months ended June 30, 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 June 30, 2021, were $1.7 million, compared to $1.4 million for the three months ended June 30, 2020.

As of June 30, 2021, the Company had $31.6 million of cash and cash equivalents. On April 16, 2021, the Company received $10 million 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 $30-$35 million to cover costs of the NAVIGATE 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 has a significant role in cancer, and the Company has supported a Phase 1b study in combined immunotherapy of belapectin and KEYTRUDA in advanced melanoma and in head and neck cancer. This trial provided a strong rationale for moving forward into a Phase 2 development program which the company is considering.

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 current 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:

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Condensed Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 6,450	$ 4,681	$ 11,349	$ 6,825
General and administrative	1,743	1,421	3,161	2,861
Total operating expenses	8,193	6,102	14,510	9,686
Total operating loss	(8,193)	(6,102)	(14,510)	(9,686)
Other income (expense):				
Interest income	1	9	2	59
Interest expense	(85)	(21)	(107)	(43)
Change in fair value of derivative	(172)	—	(172)	—
Total other income	(256)	(12)	(277)	16
Net loss	$ (8,449)	$ (6,114)	$(14,787)	$ (9,670)
Preferred stock dividends	(65)	(66)	(67)	(60)
Warrant modification				
Net loss applicable to common stock	$ (8,514)	$ (6,180)	$(14,854)	$(12,158)
Basic and diluted net loss per share	$ (0.15)	$ (0.11)	$ (0.26)	$ (0.17)
Shares used in computing basic and diluted net loss per share	58,312	57,035	57,725	56,995

Condensed Consolidated Balance Sheet Data

	June 30, 2021	December 31, 2020
	(in thousands)	
Cash and cash equivalents	$ 31,598	$ 27,142
Total assets	33,405	29,600
Total current liabilities	6,054	5,399
Total liabilities	16,289	5,407
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 15,393	$ 22,470

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