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 11, 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 (§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 11, 2018, 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, 2018 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated May 11, 2018 (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, 2017, 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 11, 2018

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 11, 2018

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

Galectin Therapeutics Reports 2018 First Quarter Financial Results and Provides Business Update

NORCROSS, Ga. (May 11, 2018) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results for the three months ended March 31, 2018, and provided a business update. 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.

"Three additional analyses conducted on the results of the NASH-CX trial since we published initial, top-line trial results further support our belief that GR-MD-02 is the first compound to demonstrate clinically meaningful positive effects in patients with NASH cirrhosis without esophageal varices. First, a statistically significant correlation was identified between the decrease in portal pressure (HVPG, or hepatic venous pressure gradient) and the improvement in hepatocyte ballooning treatment with GR-MD-02 at 2 mg/Kg. Second, an *ad hoc* analysis examining the PK-PD (pharmacokinetics-pharmacodynamics) correlation between human data and mouse NASH model showed that the apparent lack of a dose response in the 8 mg/Kg dose group (GR8) may be due to very high levels of GR-MD-02 in the bloodstream. Finally, results from the ^{13}C-Methacetin Breath Test, a measure of liver function, conducted as part of the trial found that results for patients without baseline varices mirrored the results for changes in HVPG. This additional analysis further supports our original report of the NASH-CX findings which demonstrated a significant improvement in HVPG in patients without varices and has been provided to the FDA as part of our proposed plan for a Phase 3 trial," said Dr. Peter Traber, CEO and Chief Medical Officer of Galectin Therapeutics.

"About half of the total population of patients with NASH cirrhosis do not have esophageal varices. In addition, endoscopy to evaluate for varices is part of the standard of care for patients with newly diagnosed NASH cirrhosis. Consequently, the sub-group of NASH patients that may

benefit from our compound is clear at initial diagnosis. Because the sub-group that had a statistically significant response to GR-MD-02 is routinely identified, we believe there is sound logic to pursue further investigation."

Summary of Key Development Programs and Updates

- Since reporting the initial NASH-CX trial results in December 2017, continued analysis of the data has led to three additional findings:
  - The findings from the ^{13}C-Methacetin Breath Test conducted as part of the trial found that results for patients without baseline varices mirrored the results for changes in HVPG. This further supports our findings as well as represents a significant finding in the search to discover an effective non-invasive test for liver function and NASH.
  - Reinforcing the positive effects of GR-MD-02, a statistically significant ($p=0.04$) correlation was identified between the decrease in portal pressure (HVPG) and the improvement in hepatocyte ballooning (viz., representing a decrease in liver cell death) upon treatment with GR-MD-02 at 2 mg/Kg. This suggests an important pathophysiological link between the improvement in liver biopsy and reductions in HVPG. To our knowledge, this is the first time that such a correlation has been demonstrated in a human clinical trial in patients with NASH cirrhosis.
  - An *ad hoc* analysis examining the PK-PD correlation between human data and mouse NASH model showed that the apparent lack of a dose response in the 8 mg/Kg dose group (GR8) may be due to very high levels of GR-MD-02, where excessive levels of GR-MD-02 are less effective. This was supported when a statistically significant difference was observed between the GR8 patient group with high serum drug levels (> 12,000 μg*hr/mL) and those with lower (< 12,000 μg*hr/mL) serum drug levels, where those with the lower serum drug levels had a positive response on HVPG.
- The Company made an oral presentation at the International Liver Meeting in April 2018 in Paris. Dr. Naga Chalasani, one of the principal investigators on the NASH-CX clinical trial, led a session entitled, "A multicenter, randomized, double-blind, PLB-controlled trial of Galectin-3 inhibitor (GR-MD-02) in patients with NASH cirrhosis and portal hypertension."

- The company continues to enroll cohort 3 (GR-MD-02 8 mg/kg) of the pembrolizumab (KEYTRUDA) combination immunotherapy clinical trial, which will include at least 10 patients with melanoma, to provide a larger group of patients to evaluate. It is hoped additional data can be reported in mid-2018, when we anticipate a decision on progressing to phase 2.

Financial Results

For the three months ended March 31, 2018, the Company reported a net loss applicable to common stockholders of $4.5 million, or $0.12 per share, compared with a net loss applicable to common stockholders of $5.2 million, or $0.15 per share, for the three months ended March 31, 2017. The decrease is largely due to lower research and development expenses as our Phase 2 clinical program is winding down, somewhat offset by higher non-cash stock-based compensation expense in the three months ended March 31, 2018.

Research and development expense for the three months ended March 31, 2018, was $2.3 million, compared with $3.8 million for first quarter of 2017. The decrease primarily relates to the winding down of the NASH-CX Phase 2b clinical trial.

General and administrative expense for the three months ended March 31, 2018, was $1.9 million, compared with $1.2 million for first quarter of 2017, with the increase primarily due to an increase in non-cash stock-based compensation expense and an increase in business development and investor relations expenses.

As of March 31, 2018, the Company had $4.0 million of non-restricted cash and cash equivalents in addition to a $10 million line of credit which has not yet been used. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through at least March 31, 2019.

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 is believed to be 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 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 the treatment of severe atopic dermatitis, moderate-to-severe plaque psoriasis and in cancer immunotherapy. 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; the Company's 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 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.

Contacts:
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(678) 620-3186
ir@galectintherapeutics.com.

Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
	2018	2017
	(in thousands, except per share data)	
Operating expenses:		
Research and development	$ 2,298	$ 3,772
General and administrative	1,880	1,174
Total operating expenses	4,178	4,946
Total operating loss	(4,178)	(4,946)
Other income:		
Interest income	4	9
Interest expense	(84)	—
Total other income	(80)	9
Net loss	$ (4,258)	$ (4,937)
Preferred stock dividends and accretion costs	(285)	(272)
Net loss applicable to common stock	$ (4,543)	$ (5,209)
Basic and diluted net loss per share	$ (0.12)	$ (0.15)
Shares used in computing basic and diluted net loss per share	37,284	33,928

Condensed Consolidated Balance Sheet Data

	March 31, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	$ 3,988	$ 3,053
Total assets	4,931	4,161
Total current liabilities	2,283	2,968
Total liabilities	2.283	2,968
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 925	$ (530)

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