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):
March 6, 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))

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 March 6, 2019, Galectin Therapeutics Inc. ("Galectin Therapeutics") issued a press release announcing its results of operations and financial condition as of and for the year ended December 31, 2018 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated March 6, 2010 (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, 2018, 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 March 6, 2019

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: March 6, 2019

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

Galectin Therapeutics Reports Fiscal 2018 Financial Results and Provides Business Update

Planning for Phase 3 clinical trial (NASH-RX) nearing completion for GR-MD-02, the first drug to show positive results in a clinical trial in patients with compensated NASH cirrhosis

NORCROSS, Ga. (March 6, 2019) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results for the year ended December 31, 2018. These results are included in the Company's Annual Report on Form 10-K, which has been filed with the U.S. Securities and Exchange Commission and is available at **www.sec.gov**.

Harold H. Shlevin, Ph.D., President and Chief Executive Officer of Galectin Therapeutics, said, "Over the last year we have been positioning the company to undertake a Phase 3 clinical trial — the NASH-RX trial — with our proprietary compound GR-MD-02, the first drug to show positive results in a clinical trial in patients with compensated NASH cirrhosis without esophageal varices. Our trial will be noteworthy because it is investigating NASH cirrhosis, a condition that is more closely linked to liver failure and its life-threatening implications than earlier stages of NASH, which are the focus of the majority of NASH drugs in development. Leading NASH experts have been engaged throughout the process to provide advice and counsel to strengthen our plan for the NASH-RX Phase 3 clinical trial.

"Since presenting the results of the NASH-CX trial, the Company has had ongoing discussions with U.S. Food and Drug Administration (FDA), including a Type C Meeting with the Agency on February 6, 2019. At that meeting we discussed our proposal to use progression to varices as the primary surrogate endpoint in the NASH-RX trial. In this meeting, the FDA confirmed it is supportive of the use of progression to varices as a potential surrogate endpoint and progression to large varices as a component of a composite clinical benefit endpoint, pending additional requested information. Galectin will address and implement additional FDA requests and considerations for the Phase 3 trial, when and where possible. Given the newness of the endpoint and the new information to be generated in the trial, some information requests may not be able to be addressed fully until data from the NASH-RX Phase 3 trial is available. We are very pleased with the progress achieved thus far and anticipate that the plan that is now in the process of finalization will provide meaningful clinical outcomes.

"Beyond our NASH trial, we will continue to pursue other paths forward for GR-MD-02, such as the significant market for evolving new combination cancer therapies. Illustrative of these opportunities, investigators plan to expand a combination immunotherapy trial involving GR-MD-02 and KEYTRUDA as a result of the favorable Objective Response Rate (ORR) reported in the first 3 cohorts.

“Throughout fiscal 2018, we also continued to strengthen our global intellectual property portfolio with a number of new patents awarded and/or submitted. As the understanding of GR-MD-02 improves, it is becoming increasingly clear that galectins, and specifically galectin-3, play an important role in a number of critical pathologies, contributing value to our patent portfolio.

“Finally, we believe that our capital structure is substantially improved as a result of the recent conversion of the preferred stock by 10X Fund L.P. into common stock.”

Richard E. Uihlein, Chairman of the Board, added, “The work on our NASH-RX Phase 3 plan remains paramount. There is a clear need for a treatment for what the medical community has identified as an unmet need in the rising incidence of NASH around the world. Given the biological response GR-MD-02 has elicited in both the laboratory and in human trials, a well-planned NASH-RX Phase 3 trial informed by some of the top researchers on NASH can help ensure that hope is provided for the many cirrhotic patients who may benefit from the therapy once approved and for which there are no therapeutic options.”

Summary of Key Development Programs and Updates

- Continued to develop plans for its NASH-RX Phase 3 clinical trial program with the galectin-3 inhibitor GR-MD-02 in NASH cirrhosis, incorporating advice and guidance obtained in a meeting with the FDA and our external advisors. Details of the NASH-RX Phase 3 clinical trial design, including projected timings and costs, will be announced once the planning phase has been completed and the Company has a final clinical trial protocol.
- Received a three-year extension on the $10 million unsecured line of credit entered into on December 19, 2017, for both borrowings and maturity. The line of credit arrangement with Richard E. Uihlein, Chairman of the Board of Directors and a shareholder, originally provided for borrowings to occur through December 31, 2018, with all principal and any interest maturing and coming due on December 31, 2019. There were two amendments that extended borrowings through December 31, 2021 and maturity of principal and interest to December 31, 2022. To date, the Company has not made any borrowings under this line of credit.
- Announced that its largest institutional shareholder, 10X Fund L.P., has converted all of its Series B Convertible Preferred Stock into Common Stock of Galectin Therapeutics. All special voting rights and protective provisions that previously benefited the Series B Preferred Stock were extinguished by the conversion to Common Stock.

Scientific Presentations and Conferences

- Dr. Harold H. Shlevin presented at the 2nd Annual Anti-Fibrotic Drug Development Summit (AFDD) on November 29. In his presentation, titled “Physiological Control Systems Involving Galectins in the Treatment of Diseases,” Dr. Shlevin discussed the following: The significant involvement of galectins in various biological functions and pathologies and how

this has driven recent interest in therapeutic discovery and development for clinical intervention against fibrosis, cancer, and other disorders; and the role of galectins in mediating physiological control processes, including an understanding of structure-function relationships, the mechanisms of action at the molecular level, and the evolving clinical data on their role in the treatment of various diseases.

- Dr. Harold H. Shlevin will be presenting at the H.C. Wainwright Global Life Sciences Conference being held in London April 7 – 9, 2019.

Dr. Shlevin concluded, "Galectin Therapeutics continues to advance GR-MD-02 as a potential therapy for NASH cirrhosis where elevated levels of galectin protein and inflammation play key roles in the pathophysiology of the diseases. This past year has been a period of steady progress, culminating in the collaboration of a number of leading clinicians in the formulation of our NASH-RX Phase 3 trial plan in selected NASH cirrhosis patients and the recent meeting with the FDA. We believe this methodical approach to Phase 3 planning is the best path to build value in our galectin franchise in NASH and, secondarily, to maximize potential of this platform technology to treat other diseases."

Financial Results

For the year ended December 31, 2018, the Company reported a net loss applicable to common stockholders of $15.0 million, or $0.38 per share, compared to a net loss applicable to common stockholders of $17.5 million, or $0.49 per share, for the full year 2017. The decrease is largely due to lower preclinical and clinical costs somewhat offset by higher business development and non-cash stock-based compensation expenses. Research and development expense for 2018 was $6.5 million compared with $11.7 million for 2017. The decrease primarily relates to a reduction in costs for the NASH-CX Phase 2 clinical trial as it wound down, and lower preclinical costs. General and administrative expense for 2018 were $7.1 million, compared to $4.5 million for the full year 2017, primarily due to a increase in business development and non-cash stock-based compensation expenses. As of December 31, 2018, the Company had $8.3 million of cash and cash equivalents. In December 2017, the Company entered into a $10 million unsecured line of credit and received $4.5 million in proceeds in January 2018 from common stock warrant exercises. There have not been, and currently are no, borrowings under the line of credit. 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 March 31, 2020.

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 (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 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; 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 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 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 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 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 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.

Contact:
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ir@galectintherapeutics.com.

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Condensed Consolidated Statements of Operations

	Year Ended December 31,	
	2018	2017
	(in thousands, except per share data)	
Operating expenses:		
Research and development	$ 6,471	$ 11,721
General and administrative	7,131	4,526
Total operating expenses	13,602	16,247
Total operating loss	(13,602)	(16,247)
Other income:		
Interest and other	(298)	12
Total other income	(298)	12
Net loss	$(13,900)	$(16,235)
Preferred stock dividends	(1,147)	(1,232)
Net loss applicable to common stock	$(15,047)	$(17,467)
Basic and diluted net loss per share	$ (0.38)	$ (0.49)
Shares used in computing basic and diluted net loss per share	39,414	35,521

Condensed Consolidated Balance Sheet Data

	December 31, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	$ 8,253	$ 3,053
Total assets	9,006	4,161
Total current liabilities	2,108	2,968
Total liabilities.	2,108	2,968
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 5,175	$ (530)

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