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): November 13, 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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 November 13, 2018, Galectin Therapeutics Inc. ("Galectin Therapeutics") issued a press release announcing its results of operations and financial condition as of and for the three and nine months ended September 30, 2018 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated November 13, 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 November 13, 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: November 13, 2018

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

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

NORCROSS, Ga. (November 13, 2018) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results for its third fiscal quarter, which ended September 30, 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.

Harold H. Shlevin, Ph.D., President and Chief Executive Officer of Galectin Therapeutics, said, "Our central focus remains advancing our plan for a Phase 3 clinical trial program with GR-MD-02 in NASH cirrhosis, for which we continue to make progress. Importantly, we have been collaborating with leading NASH experts who have been enlisted to help strengthen the overall plan. We are simultaneously scaling-up manufacture of clinical supplies and conducting other required activities prior to starting the Phase 3 trial."

"In addition, we are pursuing other opportunities where our galectin-3 inhibitor GR-MD-02 has demonstrated encouraging clinical results. On September 20, 2018, we reported that the investigators were encouraged by the reported Objective Response Rate (ORR) of the GR-MD-02 and KEYTRUDA combination immunotherapy trial for all cohorts relative to the ORR from randomized studies with KEYTRUDA alone in patients with advanced melanoma. The investigators also reported on six patients with head and neck cancer that exhibited a 33% ORR and 67% Disease Control Rate (DCR). As a result of these encouraging preliminary findings, the investigators will be expanding the trial to include additional patients. Further details are available in that press release. As a company we are very pleased with our productive collaboration with Providence Cancer Institute.

"We continued to enhance the scope of our intellectual property protections and expand basic patent approvals in key markets and countries. During this quarter, we had the following patents either granted or allowed:

- Galactose-pronged carbohydrate compounds for the treatment of diabetic nephropathy and associated in Europe, Australia, and China
- Composition of novel carbohydrate drug for treatment of human disease in Japan
- Method for enhancing specific immunotherapies in China, Israel and Japan
- Compositions of novel carbohydrate drugs for treatment of NASH and NAFLD in Mexico and South Africa
- We also note that patent applications have been filed on behalf of Galectin Sciences LLC related to small molecule inhibitors of galectin-3 and various other activities.

“At quarter end, our funding is sufficient to support continued pursuit of this multi-pronged strategy, all based upon the strong foundation of our proprietary molecule and the potential it represents. Our goal is to unlock the value of our proprietary technology and capitalize on the pressing need for solutions to the growing NASH epidemic and other diseases where our anti-fibrotic compound can be therapeutic.”

Richard E. Uihlein, Chairman of the Board, added, “This has been another quarter of steady progress across the broad range of possibilities for GR-MD-02. I am pleased with the progress Dr. Shlevin and the team are making and look forward to the ultimate submission of our Phase 3 plan and the exciting opportunities it can create.”

Summary of Key Development Programs and Updates

- Continuing to develop plans for a Phase 3 clinical trial program with our 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 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 that is acceptable to the FDA.
- As highlighted above, in conjunction with Providence Cancer Institute, announced additional preliminary clinical data from cohort 3 of an investigator-initiated Phase 1b clinical trial of GR-MD-02 used in combination with KEYTRUDA® (pembrolizumab) in patients with metastatic melanoma for which KEYTRUDA is indicated or those patients whose melanoma progressed during or recently after KEYTRUDA monotherapy. Those results indicated:
    - Combination immunotherapy of GR-MD-02 and KEYTRUDA for all cohorts reported showed an Objective Response Rate of 50% (seven of fourteen patients). These response rates from this small cohort are encouraging as they were higher than expected with KEYTRUDA alone
    - A Disease Control Rate of nine out of fourteen patients (64%) with advanced melanoma, which the principal investigator characterized as ‘very encouraging’
    - The combination was also very well tolerated, and treatment appears to be associated with fewer adverse events than expected with KEYTRUDA alone
    - When aggregated with the cohorts previously reported, the data shows a 50% Objective Response Rate in advanced melanoma with GR-MD-02 in combination with KEYTRUDA whereas the published response rate of KEYTRUDA alone is 33% in advanced melanoma
- In addition to advanced melanoma patients, the Providence Cancer Institute clinical trial enrolled six patients with head and neck cancer in this Phase 1b trial with a 33% Objective Response Rate and a 67% Disease Control Rate
- Providence Portland will be expanding the size of the 4 mg/kg GR-MD-02 cohort including additional melanoma patients as well as head and neck cancer patients. These results together with earlier results will help guide decision on advancing development to Phase 2.

- Back Bay Life Science Advisors, under contract with the Company, continues to support the Company's exploration of strategic alternatives.

Upcoming Scientific Presentations and Conferences

- Dr. Harold H. Shlevin will be making a presentation, titled "Physiological Control Systems Involving Galectins in the Treatment of Diseases" at the 2nd Annual Anti-Fibrotic Drug Development Summit (AFDD) on November 29.
- A poster presentation titled "The noninvasive point of care MBT accurately predicts decompensation events better than MELD in compensated (MELD<15) NASH cirrhotics" authored by Naga Chalasani, et al. and based on results obtained from Galectin Therapeutics' NASH-CX Phase 2 Clinical Trial will be presented by Exalenz Bioscience at The Liver Meeting, the annual meeting of the American Association for the Study of Liver Diseases (AASLD) on November 9-13, 2018. The poster illustrates Exalenz Bioscience's ^{13}C-Methacetin Breath Test's (MBT) ability to predict decompensation in compensated NASH cirrhotics.

Other Activities

- Management participated with a number of other companies pursuing a NASH therapy in the ROTH Capital Battle of the NASH Thrones Investor Conference on October 17.
- Dr. Harold H. Shlevin participated in the H.C. Wainwright 20th Global Investment Conference on September 6, 2018.

Dr. Shlevin concluded, "Galectin Therapeutics has developed a novel compound, GR-MD-02, a galectin-3 inhibitor, which we believe has the potential to be effective in treating a wide range of diseases wherein elevated levels of galectin protein and inflammation play key roles in the pathophysiology of the diseases. Most immediately, we are focused on advancing our Phase 3 trial in NASH Cirrhosis. However, we continue to investigate a variety of other preclinical applications where research shows that GR-MD-02's antifibrotic capabilities may help provide more effective treatment in a variety of conditions. We believe this is the best path to build value in our overall galectin franchise and maximize potential of this platform technology to treat other diseases."

Financial Results

For the three months ended September 30, 2018, the Company reported a net loss applicable to common stockholders of $3.0 million, or $0.07 per share, compared with a net loss applicable to common stockholders of $4.7 million, or $0.13 per share, for the three months ended September 30, 2017. The decrease is largely due to lower research and development expenses primarily related to the winding down of the Phase 2 NASH clinical program somewhat offset by higher non-cash stock compensation expenses.

Research and development expense for the three months ended September 30, 2018, was $1.5 million, compared with $3.5 million for the three months ended September 30, 2017. The decrease primarily reflects lower research and development expenses primarily related to the winding down of the Phase 2 NASH clinical program somewhat offset by higher non-cash stock compensation expenses.

General and administrative expense for quarter was $1.2 million, compared with $0.9 million for the prior year, with the increase being primarily related to higher investor relations, business development and non-cash stock compensation expenses.

As of September 30, 2018, the Company had $10.1 million of non-restricted cash and cash equivalents. The Company believes current cash on hand and access to a $10 million line of credit (unused at September 30, 2018) are sufficient to fund currently planned operations and research and development activities through at least September 30, 2019.

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

Condensed Consolidated Statements of Operations

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 1,505	$ 3,503	$ 5,279	$ 10,719
General and administrative	1,175	911	5,338	3,155
Total operating expenses	2,680	4,414	10,617	13,874
Total operating loss	(2,680)	(4,414)	(10,617)	(13,874)
Other income:				
Interest and other	(72)	6	(233)	21
Total other income	(72)	6	(233)	21
Net loss	$ (2,752)	$ (4,408)	$ (10,850)	$ (13,853)
Preferred stock dividends and accretion costs	(294)	(254)	(848)	(827)
Net loss applicable to common stock	$ (3,046)	$ (4,662)	$ (11,698)	$ (14,680)
Basic and diluted net loss per share	$ (0.07)	$ (0.13)	$ (0.30)	$ (0.42)
Shares used in computing basic and diluted net loss per share	40,921	35,165	38,822	34,600

Condensed Consolidated Balance Sheet Data

	September 30, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	$ 10,136	$ 3,053
Total assets	10,616	4,161
Total current liabilities	1,646	2,968
Total liabilities	1,646	2,968
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 7,247	$ (530)

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