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 14, 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 August 14, 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 six months ended June 30, 2018 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated August 14, 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 August 14, 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: August 14, 2018

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

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

NORCROSS, Ga. (August 14, 2018) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results for its second fiscal quarter, which ended June 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.

Key Highlights

- Company has initiated Phase 3 preparation of GR-MD-02 for NASH cirrhosis
- Reported a net operating loss of $4.1M and has sufficient cash resources to fund operations at least through June 2019
- Has received notice of issuance of additional patents surrounding GR-MD-02
- Board of Directors elected Richard E. Uihlein as Chairman and Kevin D. Freeman as Vice Chairman
- Engaged Back Bay Life Science Advisors to pursue strategic alternatives

"The second quarter was another active quarter with significant progress advancing our proprietary compound GR-MD-02 to a pivotal Phase 3 trial and preparing for the opportunities it represents to our business," said Dr. Harold H. Shlevin, Ph.D., President and Chief Executive Officer of Galectin Therapeutics. "Most importantly, we announced that we are proceeding with plans for a Phase 3 clinical trial program with GR-MD-02 in NASH cirrhosis, incorporating advice and guidance obtained in a meeting with the US Food and Drug Administration (FDA), and based on the positive effects of GR-MD-02 on HVPG and the possible prevention or postponement of development of esophageal varices in the Phase 2 NASH-CX trial, which we believe is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in these patients."

Richard Uihlein, Chairman of the Board, added, "Galectin's new leadership is focused on planning and conducting additional supportive work to prepare for a Phase 3 trial for GR-MD-02 in NASH cirrhosis based on the positive effects of GR-MD-02 on HVPG. However, we believe our galectin-3 inhibitor GR-MD-02 has widespread applicability for a range of diseases. Consequently, we are simultaneously pursuing other opportunities and, most immediately, anticipate results on our combination immunotherapy clinical trial. We also now have a potential pathway forward in pulmonary fibrosis, where GR-MD-02 was recently granted a patent. Finally, on behalf of the Board, we are extremely pleased that Dr. Harold Shlevin has agreed to take on the broader role of CEO, and we are all confident in his ability to drive Galectin Therapeutics forward across all our multiple programs."

Expected Upcoming Milestones Enrollment in cohort 3 (GR-MD-02 8 mg/kg) of the pembrolizumab combination immunotherapy Phase 1 clinical trial has completed and will likely include up to 10 evaluable patients with melanoma and head & neck cancer, to provide a larger group of and different type of cancer patients in this initial evaluation. It is hoped that these additional data can be reported in the near term when we anticipate a decision on progressing this program to the next phase.

Summary of Key Development Programs and Updates

- Announced that we are proceeding with 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. 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 submitted a final clinical trial protocol with the FDA.
- At the Company's Annual Meeting of Shareholders on May 22, 2018, it was announced that the Board of Directors had elected Richard E. Uihlein, who has been a member of the Board since 2017, as Chairman and Kevin D. Freeman, who has been a member of the Board since 2011, as Vice Chairman.
- The Company received notice of issuance of U.S. Patent Number 9,968,631 titled "Method and Treatment of Pulmonary Fibrosis," covering method of use of GR-MD-02 as a means to treat pulmonary fibrosis. Pharmaceutical companies may have an interest in this molecule as there is a sizeable section of the population in need of treatment and well defined regulatory pathways for approval of agents to treat pulmonary fibrosis.
- The Company received notice of issuance on May 22, 2018 of U.S. Patent Number *9,974,802* titled "Composition of Novel Carbohydrate Drug for Treatment of Human Diseases" covering a composition comprising its galectin inhibitor, GR-MD-02, and an immunotherapeutic agent or a vaccine directed against CTLA4, OX40, PD-1, PD-L1 or combinations thereof (and the composition for use in cancer disorders). This patent complements USP ***9,872,909*** issued on January 23, 2018 which covers method of treating cancer by administering GR-MD-02 and an immunomodulatory agent wherein the cancer is one of gastrointestinal cancer, pancreatic cancer, bile duct cancer, sarcoma, myosarcoma, breast cancer, lung cancer, head and neck cancer, mouth cancer, skin cancer, melanoma, kidney cancer, urinary tract cancer, prostate cancer, testicular cancer, ovarian cancer, endometrial cancer, neurological cancer, endocrine gland cancer, bone cancer, hematological cancers, multiple myeloma, and myelofibrosis.
- The Company has engaged Back Bay Life Science Advisors, a Boston-based, internationally focused integrated strategy and transaction advisory organization, to support the Company's exploration of strategic alternatives.

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."

Financial Results

For the three months ended June 30, 2018, the Company reported a net loss applicable to common stockholders of $4.1 million, or $0.11 per share, compared with a net loss applicable to common stockholders of $4.8 million, or $0.14 per share, for the three months ended June 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 June 30, 2018 was $1.5 million, compared with $3.4 million for the three months ended June 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 $2.3 million, compared with $1.1 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 June 30, 2018, the Company had $10.5 million of non-restricted cash and cash equivalents. The Company believes it has sufficient cash on hand in addition to its $10 million line of credit (untapped at June 30, 2018) to fund currently planned operations and research and development activities through at least June 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:
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(678) 620-3186
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Condensed Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 1,476	$ 3,444	$ 3,774	$ 7,216
General and administrative	2,283	1,070	4,163	2,244
Total operating expenses	3,759	4,514	7,937	9,460
Total operating loss	(3,759)	(4,514)	(7,937)	(9,460)
Other income:				
Interest and other	(81)	6	(161)	15
Total other income	(81)	6	(161)	15
Net loss	$ (3,840)	$ (4,508)	$ (8,098)	$ (9,445)
Preferred stock dividends and accretion costs	(268)	(301)	(553)	(573)
Net loss applicable to common stock	$ (4,108)	$ (4,809)	$ (8,651)	$ (10,018)
Basic and diluted net loss per share	$ (0.11)	$ (0.14)	$ (0.23)	$ (0.29)
Shares used in computing basic and diluted net loss per share	38,227	34,692	37,755	34,312

Condensed Consolidated Balance Sheet Data

	June 30, 2018	December 31, 2017
	(in thousands)	
Cash and cash equivalents	$ 10,497	$ 3,053
Total assets	11,210	4,161
Total current liabilities	1,435	2,968
Total liabilities	1,435	2,968
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 8,052	$ (530)

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