GALECTIN THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	4960 PEACHTREE INDUSTRIAL BOULEVARD SUITE 240 NORCROSS, GA 30071
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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, 2017

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, 2017, Galectin Therapeutics Inc. ("Galectin Therapeutics") issued a press release announcing its results of operations and financial condition for the three and six months ended June 30, 2017 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated August 14, 2017 (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, 2016, 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, 2017

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, 2017

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

Galectin Therapeutics Reports 2017 Second Quarter Financial Results and Provides Business Update

80% of the patients enrolled have completed all 52 weeks of infusions and 99% of the doses have already been administered in the NASH Cirrhosis, NASH-CX Phase 2b Clinical Trial

NORCROSS, Ga. (August 14, 2017) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results for the three months ended June 30, 2017. 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 .

"Our major program in treating patients with NASH cirrhosis with our galectin-3 inhibitor GR-MD-02 is progressing very well," said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. "The independent Data Safety Monitoring Board (DSMB) concluded its third review of the safety and conduct of our trial and we were lauded for both the manner in which this trial is being conducted as well as its safety profile. Over 99% of the doses have already been administered. The dropout rate remains well below expectations, which may increase the power of the trial. We currently expect approximately 151 subjects will complete the trial by September 2017, which is expected to give the study a power of over 95% to detect a difference if there is one. After completion of tests to determine the study endpoints and initial analysis of data, we are on track to report top line data in early December 2017."

Summary of Key Development Programs and Updates

- As of August 11, 2017, 130 patients (80%) have completed all 52 weeks of infusions in the Company's NASH-CX Phase 2b Clinical Trial. Approximately 99% of the entire study's total number of infusions have been administered.
- Announced that in June, the DSMB concluded that, from a safety perspective, the Company's NASH-CX trial should continue. As of the time of their evaluation, therapy had been completed in 68% of subjects in the NASH-CX trial. The feedback from the committee to the Company was positive, with the panel congratulating the company for a trial that has run very smoothly.
- Company remains on track to report top line data from the NASH-CX Phase 2b Clinical Trial in December 2017.
- Company is funded through January 2018, which is sufficient to report top line data of the NASH-CX Phase 2b Clinical Trial.
- Received notice of allowance for a U.S. Patent for "Galacto-Rhamnogalacturonate compositions for the treatment of a number of diseases associated with elevated inducible nitric oxide synthase" (iNOS). The patent's principal claims cover method of use for GR-MD-02 in a broad category of diseases in which there is an inflammatory response characterized by an increase in the enzyme iNOS.
- Issued U.S. Patent 9,649,327 for "Composition of Novel Carbohydrate Drug for Treatment of Human Diseases." The patent's principal claims cover method of use for GR-MD-02 in patients with an autoimmune disease. The breadth of coverage for the patent portfolio includes; various types of organ fibrosis (liver,

lung, kidney), non-alcoholic steatohepatitis, kidney disease, and cancer, including combination cancer immunotherapy. This method of use patent protects the use of GR-MD-02 in the general category of autoimmune disease, which covers multiple types of human diseases and strengthens our other patents.

- In partnership with the Providence Cancer Center, progressed our combination cancer immunotherapy program. The Phase 1b clinical trial that combines GR-MD-02 with pembrolizumab (KEYTRUDA ®) continues to enroll patients and recently completed the second cohort, which used 4 mg/kg GR-MD-02. The third cohort, which will start 85 days following the final patient enrollment in the second cohort, will enroll 10 patients at a dose of 8 mg/kg GR-MD-02. There will likely be additional data reported in early 2018.
- As of June 2017, completed the 24-week Phase 1 study in three patients with severe atopic dermatitis, with the last 12 weeks at the increased dose of 12 mg/kg. All three patients had approximately 50% improvement in their atopic dermatitis disease scores, with no increased improvement at the higher dose.
- Launched the Liver Line , an online community and publication on liver health and liver disease, which has already had 95,000 readers.

Management Commentary

“Many NASH trials are focused on NASH Stages I, II, and III, while our NASH-CX trial is focused on NASH cirrhosis (Stage IV), the only stage of NASH where it is believed an effective treatment can halt the progression of, or reverse, existing fibrosis. This would represent a breakthrough therapeutic intervention that may prevent complications, alleviate the need for liver transplant, and even save lives. We are pleased that our Phase 2b trial in NASH cirrhosis is fully enrolled as there

are other NASH clinical trials that have reported challenges meeting their original enrollment goals. Some trials have even had to modify the veracity of their clinical endpoints, all of which makes the imminent reporting of our top line results in December that much more important. It is also reassuring to hear the independent DSMB laud our CX trial for the safe, consistent and efficient manner in which it is being conducted. This trial was designed, and is being conducted, with a primary endpoint that the U.S. Food and Drug Administration views may be a surrogate for outcomes for registration trials in this patient population."

"In this past quarter, we have received new patents that have extended the intellectual property protection of GR-MD-02 into multiple potential disease indications. For instance, we recently received a patent extending claims to a wide-range of diseases with an inflammatory response and another patent for the use of GR-MD-02 in patients with an autoimmune disease. The breadth of coverage for the patent portfolio includes; various types of organ fibrosis (liver, lung, kidney), non-alcoholic steatohepatitis, kidney disease, and cancer, including combination cancer immunotherapy. In particular, our combination cancer immunotherapy method of use patent protects the use of GR-MD-02 in the general category of autoimmune disease which covers multiple types of human diseases and strengthens our other patents. Galectin Therapeutics has additional patent applications pending, both domestically in the United States, as well as in a number of international markets."

" *Liver Line* is a central, online gathering place we have built for patients, medical professionals and researchers to learn about the latest developments in liver health and the treatment of diseases such as non-alcoholic steatohepatitis (NASH), liver fibrosis, and cirrhosis. This online community is an educational effort to ensure

important stakeholders in drug development and research in NASH have access to the most up to date information. Most people don't realize liver health is as important as heart health, and informing primary-care physicians is key, as they are on the front lines of liver health. Since its launch in May, *Liver Line* has reached over 95,000 readers and was featured as a model campaign to raise awareness of liver disease in The Wall Street Journal."

"While our main focus continues to be on the NASH-CX trial, we are also supporting parallel trials in skin disease and cancer where we have evidence that GR-MD-02 could have a therapeutic effect. Many organizations throughout the pharmaceutical industry have taken notice and informally shown interest in our trails. Our team is dedicated to demonstrating the value of our proprietary molecule, GR-MD-02, and will continue to conduct our trials, while also exploring additional uses that have the potential to enlarge our growth prospects."

Financial Results

For the three months ended June 30, 2017, the Company reported a net loss applicable to common stockholders of $4.8 million, or $0.14 per share, compared with a net loss applicable to common stockholders of $5.8 million, or $0.20 per share, for the three months ended June 30, 2016. The decrease is largely due to lower research and development expenses primarily related to pre-clinical and drug manufacturing and to lower stock compensation expenses.

Research and development expense for the three months ended June 30, 2017 was $3.4 million, compared with $4.2 million for the three months ended June 30, 2016. The decrease primarily relates lower research and development expenses primarily related to pre-clinical and drug manufacturing.

General and administrative expense for quarter was $1.0 million, compared with $1.3 million for the prior year, with the decrease being primarily related to lower investor relations and non-cash stock compensation expenses.

As of June 30, 2017, the Company had $9.1 million of non-restricted cash and cash equivalents. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through December 31, 2017.

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 that 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. 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, 2016, 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 June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 3,444	$ 4,226	$ 7,216	$ 8,603
General and administrative	1,070	1,305	2,244	3,742
Total operating expenses	4,514	5,531	9,460	12,345
Total operating loss	(4,514)	(5,531)	(9,460)	(12,345)
Other income:				
Interest and other	6	12	15	26
Total other income	6	12	15	26
Net loss	$ (4,508)	$ (5,519)	$ (9,445)	$ (12,319)
Preferred stock dividends and accretion costs	(301)	(308)	(573)	(518)
Net loss applicable to common stock	$ (4,809)	$ (5,827)	$ (10,018)	$ (12,837)
Basic and diluted net loss per share	$ (0.14)	$ (0.20)	$ (0.29)	$ (0.44)
Shares used in computing basic and diluted net loss per share	34,692	29,023	34,312	29,001

Condensed Consolidated Balance Sheet Data

	June 30, 2017	December 31, 2016
	(in thousands)	
Cash and cash equivalents	$ 9,127	$ 15,362
Total assets	9,329	15,795
Total current liabilities	3,512	3,780
Total liabilities	3,512	3,780
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 4,094	$ 10,292

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