

GALECTIN THERAPEUTICS INC

FORM 8-K (Current report filing)

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Address	4960 PEACHTREE INDUSTRIAL BOULEVARD SUITE 240 NORCROSS, GA 30071
Telephone	678-620-3186
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SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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 28, 2017

GALECTIN THERAPEUTICS INC.

(Exact name of registrant as specified in its charter)

Nevada
(State or Other Jurisdiction
of Incorporation)

001-31791
(Commission
File Number)

04-3562325
(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))
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SECTION 2 – FINANCIAL INFORMATION

Item 2.02 Results of Operations and Financial Condition.

On March 28, 2017, Galectin Therapeutics Inc. (“Galectin Therapeutics”) issued a press release announcing its results of operations and financial condition for the year ended December 31, 2016 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated March 28, 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated March 28, 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: March 28, 2017

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

Galectin Therapeutics Reports 2016 Financial Results and Provides Business Update

NORCROSS, Ga. (March 28, 2017) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results for the year ended December 31, 2016. 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.

Galectin Therapeutics management will host a conference call at 9:00 a.m. Eastern time March 28, 2017 to discuss this press release.

To access the conference call dial 844-899-6544 and provide the operator with Pin Number 89964111.

Galectin also invites all interested parties to listen to its conference call via webcast at <http://edge.media-server.com/m/p/exukm2jh>. The webcast will also be available on the investor relations portion of the Company’s website at <http://galectintherapeutics.com/>. The webcast will be archived on the Company’s website within two hours of the live call. The webcast will be available on the Company’s website at www.galectintherapeutics.com for 90 days.

Management Commentary

“Galectin Therapeutics achieved a number of significant milestones in the development of our lead compound, GR-MD-02, during 2016,” said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. “Furthermore, we’ve recently completed equity financings that have generated sufficient funding to cover currently planned expenditures through 2017.

“While non-alcoholic steatohepatitis (NASH) cirrhosis remains GR-MD-02’s primary disease target, a number of additional trials have provided encouraging early results that provide additional insight on the clinical effect of GR-MD-02. In total, what we have seen in our early trials in moderate-to-severe plaque psoriasis and severe atopic dermatitis have consistently shown that GR-MD-02 demonstrates clinically significant, biological activity in humans.

“NASH cirrhosis represents a large unmet medical need with no currently approved therapies, and we are very pleased with our progress in the NASH-CX trial. A drug that can halt progression of, or reverse existing fibrosis, in NASH cirrhosis patients would be a breakthrough therapeutic intervention that may prevent complications, alleviate the need for liver transplant, and even prevent death.

“Our Phase 2b NASH-CX clinical trial enrollment exceeded its target and, to date, 71 patients have completed all 52 weeks of infusions with GR-MD-02, and 155 patients have completed 26 weeks of infusions. More than 3,400 infusions (or 85% of the maximum infusions in the trial) have been administered, with no drug-related serious adverse reactions and a dropout rate that is below the rate included in the trial design. The top-line data readout of the NASH-CX trial remains on track for early December 2017.

“The Providence Cancer Center is continuing two investigator-initiated Phase 1 clinical trials of GR-MD-02 used in combination with approved immunotherapies, Yervoy® and Keytruda® in patients with advanced melanoma, oral/head and neck cancer (OHN) and non-small cell lung cancer (NSCLC). There have been no safety concerns in either of these studies. Of the five patients with advanced melanoma who underwent combination therapy with GR-MD-02 (2 mg/kg) and Keytruda®, one had an impressive partial response, heading towards a complete response, and one had a mixed response.

“Galectin Therapeutics also announced positive results in studies of GR-MD-02 for patients with serious skin diseases. This an encouraging new indication for GR-MD-02 and one of the previously mentioned demonstrations that the drug is biologically active in humans.

“A Phase 2, exploratory study of GR-MD-02 in patients with severe plaque psoriasis showed all five patients enrolled had significant clinical improvement (mean of 52% improvement) as measured by an objective measurement, the PASI (Psoriasis Area and Severity Index). After receiving 8 mg/kg doses of GR-MD-02 for up to 24 weeks, the fifth patient, who also had the most severe baseline disease, had an 82% PASI improvement approximately one month following the full thirteen infusions (24 weeks).

“In an investigator-initiated protocol, GR-MD-02 was also used to treat three adult patients with severe atopic dermatitis, each of whom had been recalcitrant to multiple therapies over many years. All three patients have had a marked clinical effect with near resolution of pruritus, or itching, and regression of skin lesions. Two

patients achieved a 64% and 74% reduction in Eczema Area and Severity Index (EASI), after only 6 weeks and 3 drug infusions. These findings are believed to demonstrate a clinically significant effect of this novel investigational drug in this patient population.”

“In summary, we believe that Galectin is in a solid position from clinical, financial and leadership perspectives,” Dr. Traber concluded.

Financial Results

For the year ended December 31, 2016, the Company reported a net loss applicable to common stockholders of \$22.4 million, or \$0.76 per share, compared with a net loss applicable to common stockholders of \$21.1 million, or \$0.88 per share, for 2015. The increase is largely due to higher research and development expenses primarily related to the Phase 2 clinical program.

Research and development expense for 2016 was \$15.3 million, compared with \$13.1 million for 2015. The increase primarily relates to costs for the Phase 2 clinical trials begun in 2015, partially offset by lower preclinical costs.

General and administrative expense for 2016 was \$6.2 million, compared with \$7.0 million for 2015, primarily due to a decrease in stock based compensation.

As of December 31, 2016, the Company had \$15.4 million of non-restricted cash and cash equivalents. In January and February 2017, the Company raised a total of \$1.5 million in net proceeds from issuance of common stock. 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 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. 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 connection with 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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Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc.

Yervoy® is a registered trademark of Bristol-Myers Squibb

Keytruda® is a registered trademark of Merck & Co.

Condensed Consolidated Statements of Operations

	Year Ended	
	December 31,	
	2016	2015
	<small>(in thousands, except per share data)</small>	
Operating expenses:		
Research and development	\$ 15,325	\$ 13,114
General and administrative	6,156	6,965
Total operating expenses	21,481	20,079
Total operating loss	(21,481)	(20,079)
Other income:		
Interest and other	45	52
Total other income	45	52
Net loss	<u>\$ (21,436)</u>	<u>\$ (20,027)</u>
Preferred stock dividends and accretion costs	(914)	(1,097)
Net loss applicable to common stock	<u>\$ (22,350)</u>	<u>\$ (21,124)</u>
Basic and diluted net loss per share	\$ (0.76)	\$ (0.88)
Shares used in computing basic and diluted net loss per share	29,216	24,120

Condensed Consolidated Balance Sheet Data

	December 31,	December 31,
	2016	2015
	<small>(in thousands)</small>	
Cash and cash equivalents	\$ 15,362	\$ 25,846
Total assets	15,795	26,408
Total current liabilities	3,780	1,360
Total liabilities	3,780	1,360
Total redeemable, convertible preferred stock	1,723	7,008
Total stockholders' equity	\$ 10,292	\$ 18,040

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