

GALECTIN THERAPEUTICS INC

FORM 8-K (Current report filing)

Filed 05/15/17 for the Period Ending 05/15/17

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| Address | 4960 PEACHTREE INDUSTRIAL BOULEVARD SUITE 240 NORCROSS, GA 30071 |
| Telephone | 678-620-3186 |
| CIK | 0001133416 |
| Symbol | GALT |
| 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): May 15, 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))

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 May 15, 2017, Galectin Therapeutics Inc. (“Galectin Therapeutics”) issued a press release announcing its results of operations and financial condition for the three months ended May 15, 2017 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated May 15, 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 May 15, 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: May 15, 2017

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



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

NORCROSS, Ga. (May 15, 2017) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results for the three months ended March 31, 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.

Summary of Key Development Programs and Updates

- Received a *Decision to Grant* from the Japanese Patent Office for its patent application for “Composition of Novel Carbohydrate Drug for Treatment of Human Diseases,” which, when issued, will extend composition of matter patent coverage of the Company’s lead compound, GR-MD-02, to Japan through 2032.
- Presented a late-breaking abstract at The International Liver Congress™ 2017 with data demonstrating the effectiveness of the Exalenz 13C-Methacetin Breath Test (MBT) as a non-invasive test of liver function.
- As of May 9, 2017, 92 patients have completed all 52 weeks of infusions and 155 patients have completed 26 weeks of infusions in the Company’s NASH-CX Phase 2b Clinical Trial. Approximately 92% of the entire study’s total number of infusions have been administered.

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- Company remains on track to report top line data from the NASH-CX trial in December 2017.
 - Company is funded through the end of 2017, which is sufficient to report top line data of NASH-CX.

Management Commentary

“Galectin Therapeutics continues to make steady progress in the development of our lead compound, GR-MD-02, both in our NASH-CX trial for NASH liver cirrhosis, as well as in related ailments such as psoriasis and atopic dermatitis,” said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. “As was clearly demonstrated at April’s International Liver Congress, NASH has become an area of significant interest to the medical community, and Galectin is currently the only company with a fully enrolled trial in NASH cirrhosis, which is the most advanced stage of the disease. With the NASH-CX trial on target to report top line data well before the other two NASH cirrhosis trials underway, we are very pleased that we addressed this growing epidemic early and are developing a compound that is focused on a stage of NASH where an effective treatment can halt the progression of, or reverse, existing fibrosis, a breakthrough therapeutic intervention that may prevent complications, alleviate the need for liver transplant, and even save lives.”

“We are also very pleased to have continued to expand our intellectual property protection on a global basis, most recently in Japan, which was recently declared the second most attractive drug market and third largest pharmaceutical market in the world. We have 50 additional patent applications pending in 10 foreign countries.

“And, finally, in our efforts to help develop a non-invasive test for diagnosing and following treatment of fatty liver disease, NASH, and cirrhosis, we recently announced important results of a study we sponsored that found that MBT non-invasively detects clinically significant portal hypertension with high sensitivity and specificity (CSPH, defined as HVPG \geq 10 mmHg), a main predictor of decompensation in NASH cirrhosis. Since the only broadly accepted ways to currently assess a patient’s condition is via a liver biopsy or HVPG, both invasive tests with potential side effects, a simple, non-invasive test that would enable us to diagnose and track the progression of disease would significantly benefit physicians and patients alike.

“Galectin continues to remain focused on the NASH-CX trial, while also supporting and encouraging complementary trials in skin disease and cancer. As is customary in our industry, many organizations throughout the pharmaceutical industry have shown interest in our trials, all strictly informal. More recently, we have seen the increase in the number of NASH trials create new challenges for the industry, such as the difficulty in finding trial participants, which makes us feel fortunate with the timing chosen to initiate and report on the NASH-CX trial. Our team is dedicated to unlocking the value of our proprietary GR-MD-02 molecule and will continue to vigorously conduct our trials, while also examining additional potential uses that could enlarge our growth opportunity.

“Finally, we are pleased to highlight that Mr. Richard Uihlein recently filed a Form 3 indicating an approximate 10% ownership in Galectin. Mr. Uihlein is long time shareholder and supporter of the Company, and we are fortunate to have such a supportive investor with his means, interested in our programs.”

Financial Results

For the three months ended March 31, 2017, the Company reported a net loss applicable to common stockholders of \$5.2 million, or \$0.15 per share, compared with a net loss applicable to common stockholders of \$7.0 million, or \$0.24 per share, for the three months ended March 31, 2016. The decrease is largely due to lower pre-clinical research expenses and lower non-cash stock based compensation expense in the three months ended March 31, 2017, and also the three months ended March 31, 2016, included a severance accrual and non-cash stock based compensation related to the termination of the Company's former executive chairman.

Research and development expense for the three months ended March 31, 2017, was \$3.8 million, compared with \$4.4 million for first quarter of 2016. The decrease primarily relates to a reduction in preclinical research and drug manufacturing costs.

General and administrative expense for the three months ended March 31, 2017, was \$1.2 million, compared with \$2.4 million for first quarter of 2016, primarily due to the accrual for severance and non-cash stock based compensation expense related to the termination of the Company's former executive chairman in January 2016.

As of March 31, 2017, the Company had \$13.6 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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ir@galectintherapeutics.com.

Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc.

Condensed Consolidated Statements of Operations

| | Three Months Ended | |
|---|---------------------------------------|-------------|
| | March 31, | |
| | 2017 | 2016 |
| | (in thousands, except per share data) | |
| Operating expenses: | | |
| Research and development | \$ 3,772 | \$ 4,377 |
| General and administrative | 1,174 | 2,437 |
| Total operating expenses | 4,946 | 6,814 |
| Total operating loss | (4,946) | (6,814) |
| Other income: | | |
| Interest and other | 9 | 14 |
| Total other income | 9 | 14 |
| Net loss | \$ (4,937) | \$ (6,800) |
| Preferred stock dividends and accretion costs | (272) | (210) |
| Net loss applicable to common stock | \$ (5,209) | \$ (7,010) |
| Basic and diluted net loss per share | \$ (0.15) | \$ (0.24) |
| Shares used in computing basic and diluted net loss per share | 33,928 | 28,827 |

Condensed Consolidated Balance Sheet Data

| | March 31, | December 31, |
|---|------------------|---------------------|
| | 2016 | 2016 |
| | (in thousands) | |
| Cash and cash equivalents | \$ 13,644 | \$ 15,362 |
| Total assets | 13,997 | 15,795 |
| Total current liabilities | 4,362 | 3,780 |
| Total liabilities | 4,362 | 3,780 |
| Total redeemable, convertible preferred stock | 1,723 | 1,723 |
| Total stockholders' equity | \$ 7,912 | \$ 10,292 |

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