
**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 10, 2015

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 August 10, 2015, 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, 2015. Galectin hereby incorporates by reference herein the information set forth in its press release dated August 10, 2015 (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, 2014, 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 August 10, 2015 |

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 10, 2015

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



Galectin Therapeutics Provides Phase 2 NASH Program Update and Reports Second Quarter 2015 Financial Results

NORCROSS, Ga. (August 10, 2015) –Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins to treat fibrosis and cancer, today reported financial results for the three and six months ended June 30, 2015. 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.

Management commentary

"The second quarter and recent weeks were very exciting for Galectin, and were highlighted by the commencement of our Phase 2 program with GR-MD-02 for the treatment of nonalcoholic steatohepatitis (NASH) with advanced fibrosis and cirrhosis," said Jim C. Czirr, executive chairman. "As anticipated, in June we began screening patients for the NASH-CX trial, which will ultimately enroll 156 patients with NASH cirrhosis and will evaluate 8 mg/kg of GR-MD-02 and 2 mg/kg of GR-MD-02 and placebo, with patients randomized 1:1:1."

Peter G. Traber, M.D., president and chief executive officer said, "Although it is very early in the study, we are pleased with our progress and continue to expect top-line data readout by the end of 2017. The primary endpoint for this trial is change in hepatic venous pressure gradient (HVPG) compared with placebo, with secondary endpoints of fibrosis stage on biopsy as well as the percent of collagen on biopsy at one year of treatment. Additionally, the HVPG and liver biopsy measurements will be correlated with non-invasive measurements of liver fibrosis and function using FibroScan and ¹³C-methacetin breath test, respectively."

Dr. Traber added, "We are also preparing to begin a second trial in NASH fibrosis, our NASH-FX study, and expect to begin enrolling patients during the third quarter. As previously discussed, that study will be a four-month treatment trial in 30 NASH patients with advanced fibrosis (stage 3), but not cirrhosis, randomized 1:1 to either 8 mg/kg of GR-MD-02 or placebo. The primary goal of this study is to evaluate the efficacy of GR-MD-02 treatment by assessing the change in inflammation/fibrosis as assessed by a proprietary magnetic resonance imaging test called LiverMultiScan; the study is powered at 80% to detect a 20% difference in this measurement. The secondary goal is to compare the primary endpoint of LiverMultiScan with two secondary endpoints which are non-invasive measures of liver stiffness that correlate with fibrosis, magnetic resonance elastography and FibroScan. We expect data readout from the NASH-FX trial by the end of 2016."

LiverMultiScan is a multi-parametric nuclear magnetic resonance imaging method developed by Perspectum Diagnostics™.

Galectin notes that during the second quarter it released positive results of a drug-drug interaction study between GR-MD-02 and midazolam, a commonly used sedative, in which there was no interaction observed. "This suggests an additional layer of safety for GR-MD-02, while broadening the potential patient population for inclusion in our Phase 2 program. We are pleased with our overall progress thus far as we work to provide a drug for up to 6 million people in the U.S. with NASH, and advanced fibrosis and cirrhosis, a leading cause of liver transplants," Dr. Traber stated.

“We also expect to begin screening patients with moderate-to-severe plaque psoriasis in a proof-of-concept open-label Phase 2a trial with GR-MD-02, treating 10 patients with a dosing regimen of 8mg/kg every 2 weeks over 90 days. This study rationale is based on the known increase in galectin-3 in the skin of psoriasis patients and a subject in the Phase 1 GR-MD-02 NASH trial with psoriasis who had an apparent remission of psoriasis while receiving 4 mg/kg of the study drug. Determination of future development in this indication will depend on the results of this exploratory study.”

Dr. Traber continued, “Last week, Galectin began an expansion of its initiative to communicate with investors and other interested parties with the commencement of a blog on our website, entitled *CEO Perspectives*. Our goal is to provide a forum through which we may help investors and members of the public understand our programs and answer questions that we routinely receive. I am enthusiastic about this opportunity to discuss the exciting activities not only at Galectin in NASH, but also in the study of other fibrotic and immunogenic diseases where our compounds might be tested. We will be posting to the blog on a regular basis.”

Financial Results

For the three months ended June 30, 2015, the Company reported a net loss applicable to common stockholders of \$4.9 million, or (\$0.21) per share, compared with a net loss applicable to common stockholders of \$3.7 million, or (\$0.17) per share, for three months ended June 30, 2014. The increase in net loss applicable to common stockholders is largely due to higher research and development expenses related to its clinical programs.

Research and development expense for the three months ended June 30, 2015 was \$2.6 million, compared with \$1.6 million for three months ended June 30, 2014. The increase is primarily due to increased costs related its recently initiated Phase 2 clinical program.

General and administrative expense for the three months ended June 30, 2015 was \$2.1 million, compared with \$1.8 million for the three months ended June 30, 2014. The primary reason for the increase related to timing of certain expenses in the three months ended June 30, 2015 verses 2014.

As of June 30, 2015, the Company had \$26.4 million of non-restricted cash and cash equivalents available to fund future operations. The Company believes that its cash on hand as of June 30, 2015 is sufficient to fund currently planned operations and research and development activities through September 30, 2016.

About Galectin Therapeutics

Galectin Therapeutics is developing promising carbohydrate-based therapies for the treatment of fibrotic liver disease and cancer based on the Company’s unique understanding of galectin proteins, which are key mediators of biologic function. Galectin seeks to leverage extensive scientific and development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. The Company is pursuing a development pathway to clinical enhancement and commercialization for its lead compounds in liver fibrosis and cancer. 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. 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, 2014, 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.

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

(Tables to follow)

Condensed Consolidated Statements of Operations

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---------------------------------------|------------|------------------------------|------------|
| | 2015 | 2014 | 2015 | 2014 |
| | (in thousands, except per share data) | | | |
| Operating expenses: | | | | |
| Research and development | \$ 2,600 | \$ 1,594 | \$ 5,736 | \$ 4,366 |
| General and administrative | 2,057 | 1,781 | 3,761 | 3,853 |
| Total operating expenses | 4,657 | 3,375 | 9,497 | 8,219 |
| Total operating loss | (4,657) | (3,375) | (9,497) | (8,219) |
| Other income (expense): | | | | |
| Interest and other | 14 | 13 | 28 | 17 |
| Loss from equity method investment | — | (67) | — | (337) |
| Total other income (expense) | 14 | (54) | 28 | (320) |
| Net loss | \$ (4,643) | \$ (3,429) | \$ (9,469) | \$ (8,539) |
| Preferred stock dividends and accretion costs | (288) | (302) | (536) | (600) |
| Net loss applicable to common stock | \$ (4,931) | \$ (3,731) | \$ (10,005) | \$ (9,139) |
| Basic and diluted net loss per share | \$ (0.21) | \$ (0.17) | \$ (0.43) | \$ (0.42) |
| Shares used in computing basic and diluted net loss per share | 23,731 | 21,983 | 23,398 | 21,570 |

Condensed Consolidated Balance Sheet Data

| | 2015 | 2014 |
|---|----------------|----------|
| | (in thousands) | |
| Cash and cash equivalents | \$26,362 | \$29,128 |
| Total assets | 26,679 | 29,677 |
| Total current liabilities | 1,908 | 1,703 |
| Total liabilities | 1,908 | 1,703 |
| Total redeemable, convertible preferred stock | 6,894 | 6,779 |
| Total stockholders' equity | \$17,877 | \$21,195 |

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