
**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 9, 2016

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 9, 2016, 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, 2016. Galectin hereby incorporates by reference herein the information set forth in its press release dated August 9, 2016 (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, 2015, 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 9, 2016 |

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 9, 2016

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



Galectin Therapeutics Reports Second Quarter 2016 Financial Results and Provides Business Update

*Top-line data from NASH-FX trial in NASH patients with advanced fibrosis
expected to be reported by the end of September*

Australian patent allowance strengthens global intellectual property franchise

NORCROSS, Ga. (August 9, 2016) – 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, 2016. These results are included in the Company's 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, Updates and Anticipated Milestones

- Completed recruitment in a Phase 2 clinical trial with GR-MD-02 in patients with non-alcoholic steatohepatitis (NASH) with cirrhosis (stage 4) (the NASH-CX trial), wherein patient recruitment was completed slightly ahead of our original expectations
- Completed enrollment in Phase 2 clinical trial with GR-MD-02 in patients with non-alcoholic steatohepatitis (NASH) with advanced fibrosis (stage 3) (the NASH-FX trial)
- Positive preclinical results were presented at the American Thoracic Society (ATS) 2016 International Conference in which GR-MD-02 had shown a positive effect on vascular remodeling in an animal model of pulmonary arterial hypertension (PAH)
- Presented interim results from an exploratory, open-label, Phase 2a clinical trial with GR-MD-02 in patients with moderate-to-severe plaque psoriasis in which patients showed significant improvement in their plaque psoriasis

Management Commentary

“We are very pleased with the significant progress achieved this quarter completing enrollment in two important clinical trials, gaining further global protection of our intellectual property, and presenting further evidence of the positive effects of GR-MD-02 in new and exciting applications,” said Peter G. Traber, M.D., president, chief executive officer and chief medical officer of Galectin Therapeutics. “Most immediately, with enrollment in our NASH-FX trial in NASH patients with advanced fibrosis (stage 3) having been completed on schedule in May, we are on pace to report top-line data assessing the efficacy of GR-MD-02 by the end of September. And, with recruitment also completed for our Phase 2 NASH-CX trial, we will be able to assess the efficacy of GR-MD-02 in up to 156 patients with non-alcoholic steatohepatitis (NASH) with cirrhosis. Patient recruitment for this trial was completed slightly ahead of our original expectations and we anticipate to report top line results in December 2017, as previously planned.”

With its NASH trials investigating liver applications, Galectin is also exploring other applications of its lead compound. This quarter, the Company received encouraging results on two early stage studies. In an early stage investigation of applicability to vascular remodeling in pulmonary arterial hypertension (PAH), investigators from the Vascular Biology Center and the Department of Pharmacology and Toxicology at Augusta University presented data at the American Thoracic Society (ATS) 2016 International Conference, in which GR-MD-02 had shown a positive effect in an animal model of PAH. David Fulton, Ph.D., director of the Vascular Biology Center at Augusta University, noted that the alterations in cardiopulmonary function and vascular proliferation, as well as in fibrosis were significantly attenuated by in vivo treatment with specific gal-3 inhibitors, with our lead compound obviously being a gal-3 inhibitor.

Separately, interim results from an exploratory, open-label, Phase 2a clinical trial with GR-MD-02 in patients with moderate-to-severe plaque psoriasis, in which four patients who received 12 weeks of therapy had significant improvement in their plaque psoriasis, led to the extension of the treatment duration to 24 weeks. These interim results demonstrate a potentially important clinical effect of GR-MD-02 in clearing moderate-to-severe plaque psoriasis.

In the quarter, the Company also received Notice of Allowance from the Australian Government Patent Office for patent application for “Composition of Novel Carbohydrate Drug for Treatment of Human Diseases” that, from the date they are issued and through 2032, will extend coverage of GR-MD-02 to Australia to treat patients at risk of non-alcoholic steatohepatitis (NASH), fibrosis, inflammatory and autoimmune disorders in which galectins are at least in part involved. The allowance of these claims further strengthens the protection of the intellectual property behind GR-MD-02. This is but one of more than 50 patent applications the Company has pending in 10 foreign countries, all of which are viewed as significant markets for the active pharmaceutical ingredient (API) or the manufacture of the API. When issued, this patent will augment Galectin’s current intellectual property portfolio for treatment of liver fibrosis, kidney fibrosis, lung fibrosis or heart fibrosis.

The investigator-sponsored trials utilizing GR-MD-02 in combination with checkpoint inhibitors being conducted by Galectin’s partners at the Providence Portland Cancer Center, who are also funding the studies, continue to advance. The study of GR-MD-02 in combination with Yervoy® and Keytruda® in two separate Phase 1b trials in patients with metastatic melanoma is expected to yield data from the Yervoy combination trial by the end of the year.”

Galectin Therapeutics is exhibiting a steady pattern of progress throughout and across the organization not only with its primary investigations, but in new and evolving applications as well. As such, its addressable market increases from the still very large \$35 billion, understood to be available just from the treatment of NASH, to an even larger sum when considering psoriasis, PAH and potentially other maladies. Each of these efforts is based on a very systematic approach to advancing development whereby Galectin is moving methodically along the development path while simultaneously branching out into adjacent and complementary markets whenever the science warrants a new investigation. Allied with very strong medical professionals who are conducting these trials and investigations, Galectin’s management team is doing everything within its power to optimize the value of the organization, its intellectual property, and the other assets at its disposal.

Financial Results

For the three months ended June 30, 2016, the Company reported a net loss applicable to common stockholders of \$5.8 million, or \$0.20 per share, compared with a net loss applicable to common stockholders of \$4.9 million, or \$0.21 per share, for the three months ended June 30, 2015. The increase is largely due to higher research and development expenses primarily related to the Phase 2 clinical program in NASH.

Research and development expense for the three months ended June 30, 2016 was \$4.2 million, compared with \$2.6 million for the three months ended June 30, 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 quarter was \$1.3 million, compared with \$2.1 million for the prior year, with the decrease being to severance and non-cash stock compensation and lower legal and accounting fees.

As of June 30, 2016, the Company had \$18.0 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 June 30, 2017.

About Galectin Therapeutics

Galectin Therapeutics is developing promising 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 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 current or future 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, 2015, 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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|--------------------------------|------------|------------------------------|-------------|
| | 2016 | 2015 | 2016 | 2015 |
| (in thousands, except per share data) | | | | |
| Operating expenses: | | | | |
| Research and development | \$ 4,226 | \$ 2,600 | \$ 8,603 | \$ 5,736 |
| General and administrative | 1,305 | 2,057 | 3,742 | 3,761 |
| Total operating expenses | 5,531 | 4,657 | 12,345 | 9,497 |
| Total operating loss | (5,531) | (4,657) | (12,345) | (9,497) |
| Other income: | | | | |
| Interest and other | 12 | 14 | 26 | 28 |
| Total other income | 12 | 14 | 26 | 28 |
| Net loss | \$ (5,519) | \$ (4,643) | \$ (12,319) | \$ (9,469) |
| Preferred stock dividends and accretion costs | (308) | (288) | (518) | (536) |
| Net loss applicable to common stock | \$ (5,527) | \$ (4,931) | \$ (12,837) | \$ (10,005) |
| Basic and diluted net loss per share | \$ (0.20) | \$ (0.21) | \$ (0.44) | \$ (0.43) |
| Shares used in computing basic and diluted net loss per share | 29,023 | 23,731 | 29,001 | 23,398 |

Condensed Consolidated Balance Sheet Data

| | June 30, 2016 | | December 31, 2015 | |
|---|----------------|--------|-------------------|--------|
| | (in thousands) | | | |
| Cash and cash equivalents | \$ | 18,003 | \$ | 25,846 |
| Total assets | | 18,247 | | 26,408 |
| Total current liabilities | | 3,636 | | 1,360 |
| Total liabilities | | 3,636 | | 1,360 |
| Total redeemable, convertible preferred stock | | 7,124 | | 7,008 |
| Total stockholders' equity | \$ | 7,487 | \$ | 18,040 |

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