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, 2019

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock $0.001 par value per share	**GALT**	**The Nasdaq Capital Market**

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 9, 2019, Galectin Therapeutics Inc. ("Galectin Therapeutics") issued a press release announcing its results of operations and financial condition as of and for the three and six months ended June 30, 2019 and provided a business update. Galectin hereby incorporates by reference herein the information set forth in its press release dated August 9, 2019 (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, 2018, 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 9, 2019

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, 2019

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

Galectin Therapeutics Reports Q2 2019 Financial Results and Provides Business Update

NORCROSS, Ga. (August 9, 2019) – Galectin Therapeutics Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results and provided a business update for the three months ended June 30, 2019. 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**.

Harold H. Shlevin, Ph.D., President and Chief Executive Officer of Galectin Therapeutics, said, "Over the past several months we have made significant progress advancing our proprietary compound, belapectin (GR-MD-02) for a Phase 3 trial. After having raised approximately $44.9 million in our Rights Offering and selecting a leading global CRO with deep experience in our therapeutic area and operations in over 60 countries as our clinical research organization (CRO), we recently submitted our Phase 3 clinical trial protocols to the FDA for comment along with a draft Phase 4 synopsis and statistical analysis plan. In addition, we announced that Dr. Naga Chalasani and Dr. Stephen Harrison, key NASH opinion leaders, who dedicated considerable effort in the design of the study, have been designated as co-primary investigators in the Phase 3 NASH-RX clinical trial. Consequently, we believe all of the elements to commence this important study are solidly in place. Belapectin is the first drug to show positive results in a clinical trial in patients with compensated NASH cirrhosis without esophageal varices, and it is with great optimism that we anticipate a fourth quarter launch of this very important trial."

The NASH-RX trial is designed as an international, multicenter, randomized, placebo-controlled, double-blind, parallel-group, Phase 3 study with approximately 500 patients at up to 128 sites in 11 countries in North America, Europe, Asia, and Australia. The study is designed to evaluate the safety and efficacy of two doses of belapectin for the treatment of compensated non-alcoholic steatohepatitis (NASH) cirrhosis with clinical evidence of clinically significant portal hypertension without esophageal varices. Enrollment is expected to commence in the fourth quarter of 2019 with an estimated 12-14 months to achieve full enrollment. The treatment period for Phase 3 is two years, and topline data readout is expected around the end of 2022.

"With the continued support of the medical, patient, and investment communities we are excited to be advancing this new drug toward treating the millions of people globally with NASH cirrhosis."

Richard E. Uihlein, Chairman of the Board, added, "The success of the Rights Offering, the support of Drs. Chalasani and Harrison, execution of a start-up agreement with our CRO to accelerate time to patient enrollment, and the commitment and dedication of our employees provide Galectin with a world-class team that can ensure the upcoming clinical trials are rigorously administered. We are all looking forward to the launch of this trial in the fourth quarter and the data it will provide about the important role belapectin may play in helping those suffering from NASH cirrhosis."

Summary of Key Development Programs and Updates

- Submitted our Phase 3 clinical trial protocol for using belapectin (GR-MD-02) for the treatment of compensated NASH cirrhosis in patients without esophageal varices for assessment by the FDA. Also, submitted to the FDA our complete clinical development plan, a draft Phase 4 synopsis, and statistical analysis plan among other documents in response to FDA's questions from our February 2019 meeting.
- Selected a leading global CRO with deep experience in NASH cirrhosis as our partner in the planned Phase 3 NASH-RX clinical trial and executed a start-up agreement.
- Welcomed Drs. Harrison and Chalasani as Co-Principal Investigators, both of whom have been actively involved in the design of these upcoming trials and believe that this study could further the understanding of NASH and the role Galectin-3 inhibition may play in the treatment of this growing epidemic.
- Raised $44.9 million in the Rights Offering and $2.5 million from a common stock warrant exercise by our chairman, Richard E. Uihlein. The Rights Offering, priced at $4.28 per share, resulted in the issuance of approximately 10.5 million shares of the Company's common stock and stock purchase warrants for approximately 2.6 million shares at $7.00 per share which expire seven years after issuance. As a result, the Company now has approximately 56.6 million shares of common stock issued and outstanding.

Scientific Presentations and Conferences

- Eliezer Zomer, Vice President, will present at the 3rd Annual Anti-Fibrotic Drug Development Summit (AFDD) on November 19, 2019, in Cambridge, Massachusetts. Dr. Zomer's presentation titled "Therapeutic Integrin Inhibition," will discuss the next generation of Galectin-3 inhibitors, as well as the discovery of functional allosteric inhibitors as part of efforts of Galectin Sciences LLC, our majority owned subsidiary.

Financial Results

For the three months ended June 30, 2019, the Company reported a net loss applicable to common stockholders of $3.1 million, or $0.06 per share, compared to a net loss applicable to common stockholders of $4.1 million, or $0.11 per share, for the three months ended June 30, 2018. The decrease was primarily due to lower preclinical, clinical and non-cash stock-based compensation expenses in the current period compared to the prior year period.

Research and development expense for the three months ended June 30, 2019, was $1.5 million compared with $1.5 million for the three months ended June 30, 2018. There was an increase of about $0.6 million in clinical development expenses which was offset by a similar amount of decrease in non-cash stock-based compensation expense. General and administrative expense for the three months ended June 30, 2019, were $1.5 million, compared to $2.3 million for the three months ended June 30, 2018, primarily due to a decrease in non-cash stock-based compensation expenses.

As of June 30, 2019, the Company had $52.0 million of cash and cash equivalents. The Company also has a $10 million unsecured line of credit, under which no borrowings have been made to date, and potential additional capital under its At the Market common stock issuance agreement. The Company believes there is sufficient cash, including availability of the line of credit, to fund currently planned operations at least through December 31, 2020. The Company expects that it will require more cash to fund operations after December 31, 2020 and believes it will be able to obtain additional financing as needed. The currently planned operations include estimated costs related to a planned Phase 3 clinical trial through December 31, 2020. While the costs of the trial and general overhead during the Phase 3 trial are expected to be approximately $100 million, the costs and timing of such trial is not yet completely finalized.

About Galectin Therapeutics

Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver disease and cancer. Galectin's lead drug belapectin (formerly known as 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 for which it has Fast Track designation by the U.S. Food and Drug Administration. 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. Advancement of these additional clinical programs is largely dependent on finding a suitable partner. 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 belapectin 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 and in other therapeutic indications. 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 belapectin or any of its other drugs in development; the

Company may not be successful in scaling up manufacturing and meeting requirements related to chemistry, manufacturing and control matters; the Company's currently planned 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, 2018, 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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Condensed Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 1,522	$ 1,476	$ 2,168	$ 3,774
General and administrative	1,498	2,283	3,219	4,163
Total operating expenses	3,020	3,759	5,387	7,937
Total operating loss	(3,020)	(3,759)	(5,387)	(7,937)
Other income (expense):				
Interest income	43	4	57	8
Interest expense	(21)	(85)	(43)	(169)
Total other income	22	(81)	14	(161)
Net loss	$ (2,998)	$ (3,840)	$ (5,373)	$ (8,098)
Preferred stock dividends	(67)	(268)	(163)	(553)
Warrant modification			(6,622)	
Net loss applicable to common stock	$ (3,065)	$ (4,108)	$(12,158)	$ (8,651)
Basic and diluted net loss per share	$ (0.06)	$ (0.11)	$ (0.26)	$ (0.23)
Shares used in computing basic and diluted net loss per share	50,301	38,227	47,653	37,755

Condensed Consolidated Balance Sheet Data

	June 30, 2019	December 31, 2018
	(in thousands)	
Cash and cash equivalents	$ 52,043	$ 8,253
Total assets	53,012	9,006
Total current liabilities	1,391	2,108
Total liabilities.	1,391	2,108
Total redeemable, convertible preferred stock	1,723	1,723
Total stockholders' equity	$ 49,898	$ 5,175

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