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): September 29, 2020

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 7 – REGULATION FD

Item 7.01 Regulation FD Disclosure.

On September 29, 2020, Galectin Therapeutics Inc. (the "Company) posted to its website a presentation which is attached hereto as Exhibit 99.1.

The information in this report is being furnished pursuant to this Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933 or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this report.

SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate Overview Presentation, September 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: September 29, 2020

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

Exhibit 99.1

Galectin Therapeutics

Corporate Overview

September 2020

NASDAQ: GALT
www.galectintherapeutics.com

Forward-looking statements

This presentation contains, in addition to historical information, 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 our 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 potential therapeutic benefits of our drugs, expectations, plans and timelines related to our clinical trials, supporting activities, potential partnering opportunities and estimated spending for 2020 and beyond. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, our trials and supporting CMC information may be impacted by COVID-19.

We may experience delays in our trials, which could include enrollment delays. Future phases or future clinical studies may not begin or 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 our drugs are subject to change at any time based on the changing needs of our company as determined by management and regulatory agencies. Strategies and spending projections may change. We may be unsuccessful in developing partnerships with other companies or obtaining capital that would allow us to complete our clinical trials or further develop and/or fund any future studies or trials.

To date, we have incurred operating losses since our inception, and our future success may be impacted by our ability to manage costs and finance our continuing operations. For a discussion of additional factors impacting our business, see our Annual Report on Form 10-K for the year ended December 31, 2019, and our subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause our views to change, we disclaim any obligation to update forward-looking statements.

Contents

Introduction by Joel Lewis

Galectin Overview

- Conducting an adaptively-designed Phase 2b/3 trial of belapectin, a potent galectin-3 inhibitor, for the prevention of esophageal varices NASH cirrhosis (NASH-RX)
  - First patient enrolled June 2020, first patient randomized August 2020
- NASH market opportunity estimated to reach $35 - $40 billion/year by 2025*
- Efficacy observed in animal models and Phase 2b trial (NASH-CX)
- NASH-CX trial in patients with compensated cirrhosis and portal hypertension demonstrated that belapectin prevented the development of new esophageal varices in a population with a high degree of clinical unmet need with no available therapies and few in development
- Results of NASH-CX trial published in *Gastroenterology* (Chalasani, et. al. 2020)
- Belapectin has a robust IP portfolio (77+ granted and 27 pending patents)
  - Composition of matter for complex carbohydrates and/or methods of use in treatment of fibrosis and other indications
  - Patent applications filed for small molecule gal-3 inhibitors
- Experienced leadership

** Deutsche Bank "NASH – the next big global epidemic in 10 years?" July 14, 2014*

Strong, experienced management team

Joel Lewis, CEO and President

- Over 22 years of executive management experience: Uline, Inc.; Century America LLC; Deloitte & Touche
- Served on the Board of Directors since December 2017

Harold H. Shlevin, Ph.D., Former CEO and President, Consultant and Board Member

- Over 35 years of relevant experience
- Solvay Pharmaceuticals, CEO

Adam Allgood, Pharm D., Clinical Development

- Over 31 years experience in clinical development, medical affairs & regulatory processes.
- UCB Inc., Abbott Laboratories, Solvay Pharmaceuticals

Eli Zomer, PhD, Pharm Development

- Over 35 years of relevant experience: Koor Biotechnologies, Charm Sciences, Glycogenesis, HU Medical School (Jerusalem), and Harvard University

Pol F. Boudes, M.D.; Chief Medical Officer

- Over 25 years of experience in clinical drug development in immunology, endocrine, metabolic, orphan, and liver-related diseases, and he has contributed to the approval of multiple drugs, both in the US and globally, across a variety of therapeutic indications.
- Previous position was CMO of CymaBay Therapeutics

Jack W. Callicutt, CFO

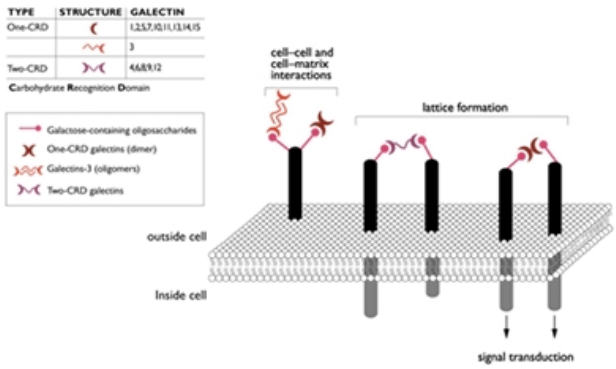
- Over 28 years of relevant experience
- Reach Health, CFO,
- Vystar Corporation, CFO,
- Corautus Genetics, Deloitte

Rex Horton, VP Regulatory

- Over 29 years of experience; Director Regulatory Affairs at Solvay Pharmaceuticals and Chelsea Therapeutics; Georgia Institute of Technology
- Head of regulation, quality assurance and manufacturing

Contents

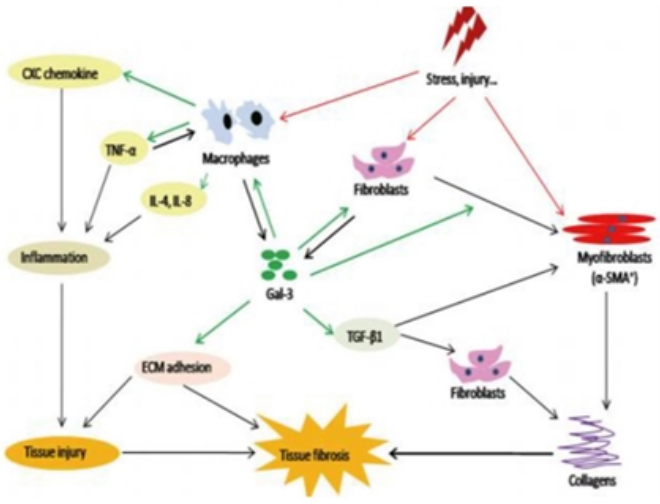
Belapectin targets and disrupts the function of galectin-3, which plays a major role in the progression of fibrotic diseases



Galectin proteins' ability to dimerize creates the opportunity for galectins to link glycoproteins and form a lattice structure on the cellular surface and to promote cell-cell and cell-matrix interactions

Galectin-3 expression is up-regulated in established human fibrotic liver disease, and disruption of Galectin-3 can markedly reduce liver fibrosis (*)

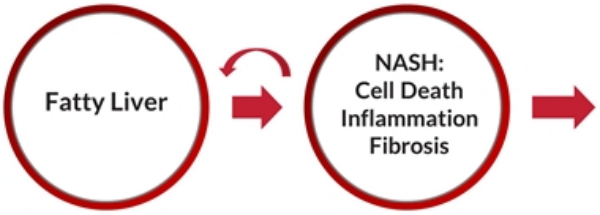
Central role of Gal-3 in multiple pathological processes



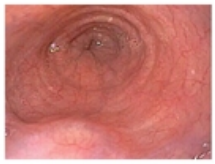
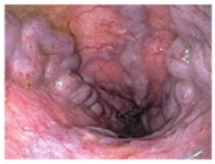
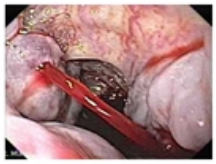
* *Source:* Henderson et al., *PNAS*, 2006.

There is currently no treatment for NASH cirrhosis, a progressive disease that may result in liver failure and increased mortality

The majority of companies are focused on pre-cirrhotic NASH



Few companies with Phase 2/3 trials in NASH cirrhosis

Compensated cirrhosis		Decompensated cirrhosis
Stage 1	Stage 2	Stage 3 and 4
No varices	*Varices develop*	*Bleeding, ascites, encephalopathy*
		
≥6	>10 Portal pressure (mmHg)	>12
Low one year mortality (1-3%)		~50% one year mortality

Unlike many companies in the NASH space, Galectin is focusing on the ***compensated cirrhotic*** patients

[1] *Garcia-Tsao, G., Friedman, S., Iredale, J., Prinzani, M. Hepatology. 2010;51:14451449*

Contents

NASH-CX was a randomized, double-blind, placebo-controlled phase 2b clinical trial that enrolled 162 NASH cirrhosis patients[1]

Phase 2b Trial design

Major inclusion criteria

- NASH cirrhosis (biopsy)
- HVPG[2] ≥ 6 mmHg
- No cirrhosis complications
- No or small varices (50:50)

Endpoints		Baseline	Week 54
Primary endpoint	Portal pressure: HVPG[2]	✓	✓
Secondary endpoints	Liver biopsy[3]	✓	✓
	Endoscopy (varices)	✓	✓
	Complications[4]	✓	✓

Dosing and administration

Every other week infusion x 26

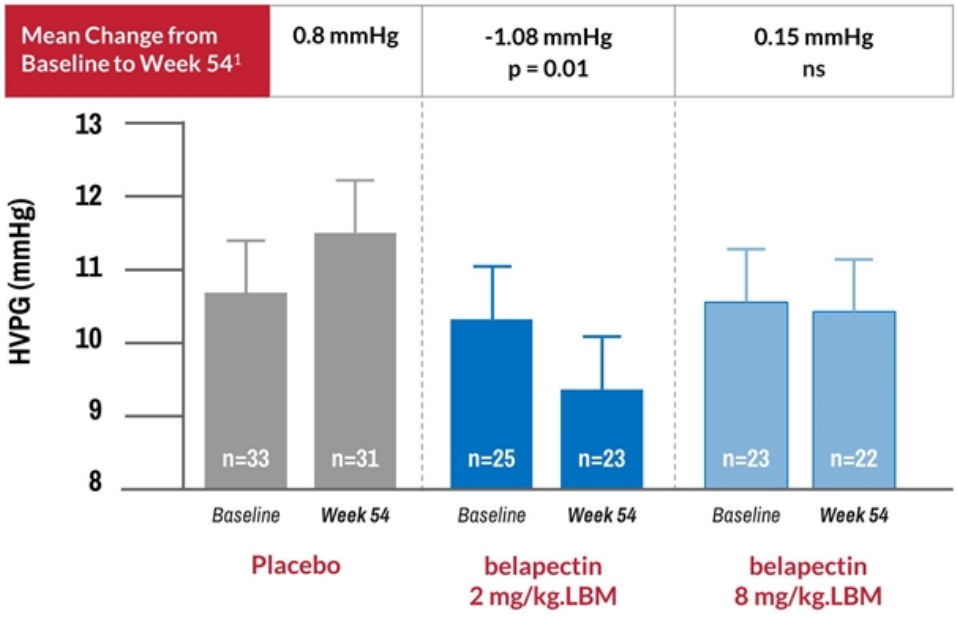
Treatment	#Patients
Placebo	54
GR-MD-02 2 mg/kg/LBM	54
GR-MD-02 8 mg/kg/LBM	54

LBM – Lean Body Mass

[1] Subjects were enrolled across 36 sites in the US
[2] HVPG = Hepatic Venous Pressure Gradient
[3] Histologic staging & quantitative morphometry for collagen
[4] Liver-related complications (varices/bleeding, ascites, hepatic encephalopathy, liver-related death, or transplant)

The belapectin 2 mg/kg.LBM group showed a statistically significant reduction in HVPG from baseline to week 54 for patients without varices

Statistically significant effect of 2 mg/kg.LBM dose on change in HVPG at baseline

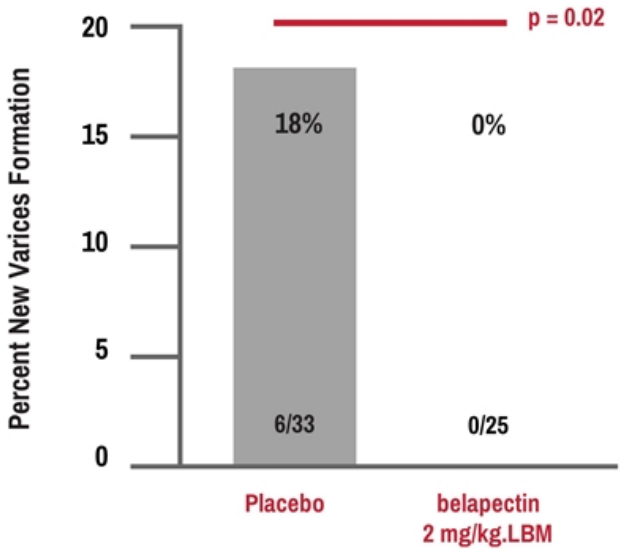


[1] ITT with LOCF, ANCOVA with LSD

Mean ± SEM

Significantly fewer new varices developed in treatment groups versus placebo, and no patients in the 2 mg/kg.LBM treatment group developed new varices

Trial hit a clinically relevant endpoint related to patient outcomes



[1] *Chi Square*

Belapectin has demonstrated efficacy in a clinically meaningful endpoint where no current therapies exist

- **Portal hypertension (PH) is a critical, clinically important consequence of cirrhosis and responsible for the majority of associated complications**
  - Portal pressures of ≥10 mmHg (HVPG) are associated with increased risk of decompensation and mortality
- **For patients with compensated cirrhosis and PH without varices, there are no specific therapies indicated for reducing PH and/or directly treating the underlying liver disease**
  - Beta-blockers may improve outcomes in patients with portal hypertension and varices, but likely do not prevent development of varices/disease progression in early stage cirrhosis patients
  - Practice guidelines do not recommend beta-blockers for the prevention of esophageal varices
- **Belapectin was safe and well tolerated in NASH-CX trial**
  - Dropout rate of 6% suggests the drug was well tolerated and patients were adherent
- **Results of NASH-CX provide strong rationale for NASH-RX trial and selection of a primary endpoint of prevention of varices**

Sources: AASLD Practice Guidelines, Garcia-Tsao et al. HEPATOLOGY, VOL. 65, NO. 1, 2017; La Mura et al. World J Hepatol 2015 April 8; 7(4): 688-695 Baveno guidelines; Ripoll et al. GASTROENTEROLOGY 2007;133:481–488; Brunt, Semin Liver Dis., 2004; 24; UpToDate; Cordon, World J Gastrointest Endosc., 2012 312-322

Summary of NASH-CX trial

- **NASH-CX is the first clinical trial to show positive results in compensated NASH cirrhosis without esophageal varices**
  - Reduction of portal pressure in a relevant subgroup of patients
  - Improvement in liver cell death, a key component of NASH
  - Prevention of new esophageal varices
  - Belapectin was safe and well-tolerated
  - FDA indicated its support for *progression to varices as a surrogate endpoint and progression to large varices (or to small varices with a weal) as a component of a composite clinical benefit endpoint*
  - The assessment of varices is part of Standard of Care and can easily be assessed with endoscopy
  - 50% of cirrhotic NASH patients do not have varices when diagnosed
  - Further awareness of NASH should increase the number of cirrhotic patients who will need varices prevention
- **These results support advancement of the development program to Phase 3**

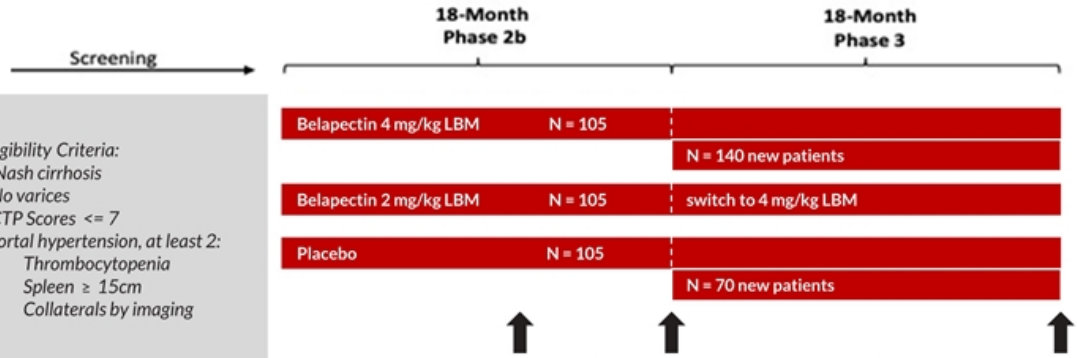
Contents

- Overview
- NASH cirrhosis and belapectin
- NASH-CX results
- **NASH-RX trial**
- Summary

Adaptively Designed Phase 2b/3 NASH-RX Trial Overview

- NASH ***cirrhosis***
  - Patients with NASH cirrhosis have the greatest immediate medical need
  - This population is not being addressed by most drug developers, who focus on the prevention of NASH cirrhosis using liver biopsies as an efficacy endpoint
  - An innovative seamless, adaptive Phase 2b/3 clinical trial developed with leading NASH experts
- Progression to varices is a potential surrogate endpoint
- Progression to large varices is a component of a composite clinical endpoint
- NASH cirrhosis patients with portal hypertension are at risk of developing esophageal varices which may bleed and are then life-threatening
- Approximately 130 sites in 12 countries and 315 patients in Phase 2b portion of the trial before a planned interim analysis

Belapectin Phase 2b/3 Adaptively Designed Trial



Key Eligibility Criteria:

1). *Nash cirrhosis*
2). *No varices*
3). *CTP Scores <= 7*
4). *Portal hypertension, at least 2:*
- *Thrombocytopenia*
- *Spleen ≥ 15cm*
- *Collaterals by imaging*

Sample size re-estimation

Interim Analysis to Inform Phase 3
1° endpoint: development of new varices

Final Analysis

1° endpoint: development of new varices

2° endpoints:
- Proportion of patients with large varices or red wales
- Varices requiring treatment
- Hepatic decompensation events
- All-cause mortality
- MELD ≥ 15
- Liver transplant
- non-invasive biomarkers

Galectin Phase 2b/3 trial – NASH-RX summary

Key clinical study milestones:

- First patient enrolled June 2020, first patient randomized August 2020
- Global study: overall ~500 patients, ~130+ sites, 12 countries in North America, Europe, Asia and Australia; First segment before Interim Analysis will be ~315 patients
- Recruitment period for phase 2b portion estimated: ~ 12 – 14 months
- Key inclusion criteria
  - NASH cirrhosis (baseline or historical liver biopsy)
  - Clinical sign of portal hypertension
  - No esophageal varices (esophago-gastro endoscopy)
- Interim analysis phase 2b expected ~Q2 2023

NASH-RX: End of Phase 2b or 3 Accelerated approval application

- **Primary Endpoint**
  - Development of new varices
- **Secondary Endpoints**
  - Proportion of patients with large varices or red wales
  - Varices requiring treatment
  - Decompensation events
  - All-cause mortality
  - MELD ≥ 15 in patients with baseline MELD<12
  - Liver transplant
  - Biomarkers
- **Informs Phase 4 features – sizing, duration**

Contents

Summary of drug development program

- **NASH Cirrhosis is a major unmet medical need with a large potential market**
  - NASH-CX trial is first positive phase 2 clinical data in a subset of patients without esophageal varices
  - Belapectin was safe and well-tolerated and improved portal pressure and reduced development of varices
  - GALT is competitively well positioned in the industry
  - Large, experienced global CRO conducting the NASH-RX trial
  - Phase 3 study: First Patient enrolled June 2020; Interim Analysis Data analysis expected Q2 2023

- **Combination cancer immunotherapy (Providence Cancer Institute)**
  - Galectin-3 important in cancer immunity with encouraging early clinical results
  - Large potential to improve results of cancer immunotherapy – trial continuing

- **Belapectin is a novel galectin-3 inhibitor that targets macrophages (a key driver in cirrhosis) and may improve multiple fibrotic diseases**

Thank you