### 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): February 24, 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

 $\label{eq:NA} N/A$  (Former name or former address, if changed since last report)

Gene	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 ral 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))

#### **SECTION 7 – REGULATION FD**

#### Item 7.01 Regulation FD Disclosure.

On February 24, 2015, Galectin Therapeutics Inc. posted a corporate presentation on its website that contains, among other information, a summary of development of GR-MD-02 for Non-Alcoholic Steatohepatitis (NASH) With Advanced Fibrosis and Cirrhosis, which presentation is attached 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 presentation

#### 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: February 24, 2015 By: \_/s/ Jack W. Ca

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



### **Corporate Presentation**

February 24, 2015

NASDAQ: GALT www.galectintherapeutics.com

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### **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 which 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, potential partnering opportunities and estimated spending for 2015. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, our trials may not lead to positive outcomes or regulatory approval. 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 further develop and/or fund any studies or trials. We are currently the subject of litigation, which may impact our human and capital resources. 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, 2013, 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.

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### **Developing Products For Major Unmet Medical Needs**



#### **Organ Fibrosis**

- 45% of U.S. deaths are associated with fibrotic disease<sup>1</sup>
- Lead indication is liver fibrosis/cirrhosis due to fatty liver disease (75% of all liver disease in U.S.)<sup>2</sup>
- Potentially applicable to other fibrotic diseases
- · Phase 1 clinical trial completed
- Phase 2 clinical trials to start Q2 2015

### Cancer Immunotherapy

- Focus on combination immunotherapy, one of the most prominent approaches to cancer therapy
- Lead indication is advanced melanoma
- Technology applicable to other cancers
- Phase 1b clinical trial in progress
- Second trial to start Q2 2015

<sup>1</sup>Wynn, TA. Nat Rev Immunol. 2004;4:583–594. doi:10.1038/nri1412

<sup>2</sup>Younossi, et al. Clin. Gasto. Hepatol. 2011;9:524-530

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### **Investment Highlights**



	100 × 100 ×
Knowledge	Expertise with complex carbohydrate drugs that promote galectin-3 inhibition, with applicability to large patient populations
Strong Intellectual Property	Multiple composition-of-matter patents and method patents
NASH with Advanced Fibrosis	<ul> <li>Initial focus on the treatment of NASH with advanced fibrosis, with encouraging data in early human trials and preclinical data showing potential for reversal of disease</li> </ul>
Large Market & Unmet Need	<ul> <li>Lead compound, GR-MD-02, directed to a potential cirrhosis and advanced fibrosis market, currently approximately 6 million people in the U.S. and growing</li> </ul>
Defined Regulatory Pathway	Multiple mid-term clinical and regulatory milestones and potential for Phase 2 program under an SPA for a registration trial
Melanoma	GR-MD-02 is also being studied in advanced melanoma in combination with two different cancer immunotherapeutic agents
Potential Partnering	A product pipeline that may be attractive to licensing agreements with large pharmaceutical companies
Experienced Team	An accomplished management team with significant large pharma and

entrepreneurial experience

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**Experienced Team** 

### **Lead Drug Candidate Targets Galectin-3 Protein**



### Galectin-3 Protein Function

- Binds to galactose residues in glycoproteins and promotes interactions
- High expression in immune cells (macrophages)
- Modulates cell signaling and immune cell function

#### **Role in Disease**

- Gal-3 is increased in inflammation and fibrogenesis
- Elimination of gal-3 in mice prevents fibrosis in liver, lung, kidney and heart
- The majority of cancers express high levels of gal-3, which promotes tumor and inhibits immune response

# Lead Drug Candidate GR-MD-02

- A complex carbohydrate with terminal galactose residues that binds to gal-3 and disrupts function, particularly immune/repair function in macrophages
- Efficacy in preclinical models of fibrotic disease and cancer immunotherapy with encouraging early human results
- Existing patent coverage through 2031 with 2 composition and 4 method patents issued

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### **Deep Product Pipeline**



Cli	nical Focus		Stage of	Develop	ment	
Drug	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
Fibrosis	(monotherapy)					
GR-MD-02	NASH cirrhosis			Q	2 2015	
	Lung fibrosis					
	Kidney fibrosis					
	Cardiovascular fibrosis					
Cancer I	mmunotherapy (co	ombination	therapy)			
GR-MD-02	Melanoma					
Galectin	-3 Inhibitors					
GR-MD-03	Subcutaneous					
GR-MD-04 GM-CT-04	Oral					
G-XXX*	Oral					

<sup>\*</sup>Galectin Sciences, LLC

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Lead Indication in Organ Fibrosis

# ADVANCED FIBROSIS AND CIRRHOSIS DUE TO NASH

(NON-ALCOHOLIC STEATOHEPATITIS)

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### **NASH: An Epidemic With No Approved Therapies**



### Estimated prevalence of NASH in U.S. adults 1, 2 > 28 million

	U.S. Prevalence in Asymptomatic, Middle-Aged Adults (% of population) <sup>2</sup>	
Obesity	45%	
Diabetes	16.5%	
Fatty Liver	46%	
NASH	12.2%	

<sup>&</sup>lt;sup>1</sup> Based on July 2013 US census data for people >20 years old (233,880,752)

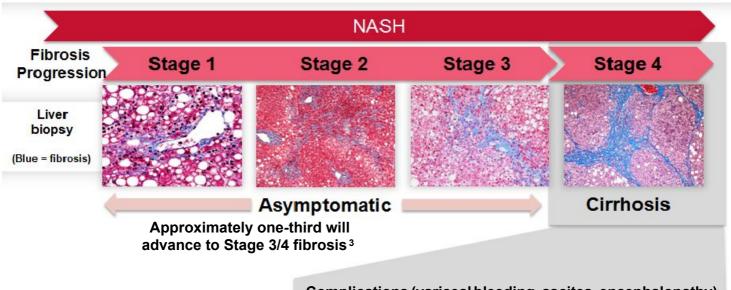
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<sup>&</sup>lt;sup>2</sup> Prospective evaluation of NAFLD and NASH prevalence (Williams, et al. Gastro. 2011;140:124-131)

# **End-Stage Fibrosis (Cirrhosis) Is When Patients With NASH Experience Symptoms And Complications**



Estimated prevalence of advanced fibrosis<sup>1,2</sup>: ~ 6 million Estimated prevalence of cirrhosis<sup>1</sup>: ~ 1-2 million



<sup>&</sup>lt;sup>1</sup> Kleiner, et al. Hepatology 2005;41:1313-1320

Complications (variceal bleeding, ascites, encephalopathy) Liver Transplantation (projected to be leading reason) Liver-Related Death

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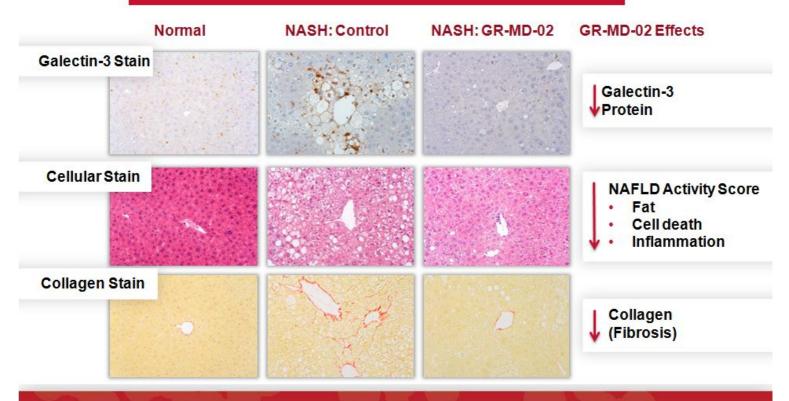
<sup>&</sup>lt;sup>2</sup> Williams, et al. Gastro. 2011;140:124-131

<sup>&</sup>lt;sup>3</sup> Caldwell, et al. Dig Dis 2010;28:162-168

## Robust Preclinical Data: GR-MD-02 Has Therapeutic Effect On NASH With Fibrosis In Mouse Model\*



### GR-MD-02 reduces Gal-3, which results in reduction in liver inflammation and fibrosis

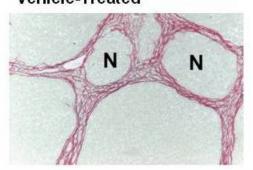


\*Traber PG and Zomer E. Therapy of Experimental NASH and Fibrosis with Galectin Inhibitors. PLOS ONE 2013;8:e83481

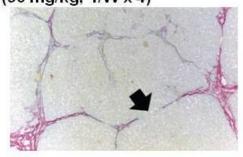
### Robust Preclinical Data: GR-MD-02 Reversed Cirrhosis Galectin And Improved Portal Hypertension In Rat Model\*

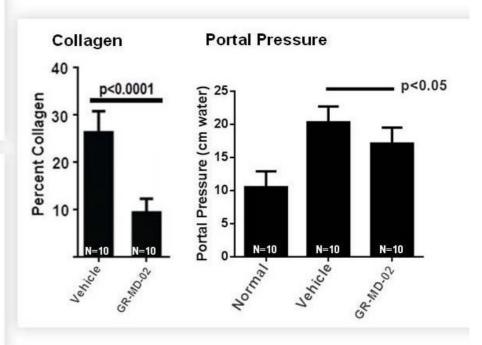






GR-MD-02-Treated (90 mg/kg, 1/W x 4)



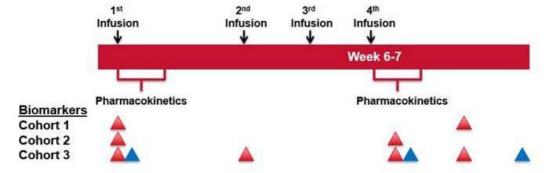


\*Traber PG, Chou H, Zomer E, Hong F, Klyosov A Fiel M-I, Friedman, SL. Therapy of Regression of fibrosis and reversal of cirrhosis in rats by galectin inhibitors in thioacetamide-induced liver disease. PLOS ONE 2013;8:e75361.

### Phase 1 Clinical Trial (GT-020): Completed December 2014



- Subjects: Biopsy proven NASH with Brunt Stage 3 fibrosis
- Design:
  - Blinded, placebo controlled, sequential dose escalation
  - Three cohorts: Four doses over 6-7 weeks of 2, 4, and 8 mg/kg lean body weight administered by IV infusion over one hour
  - https://clinicaltrials.gov/ct2/show/NCT01899859?term=GR-MD-02&rank=2
- Primary Endpoints: Safety and Pharmacokinetics
- Exploratory Endpoints: Potential serum biomarkers, FibroScan®



The red triangles indicate timing of blood draws for assessment of exploratory biomarkers and the blue triangles indicate timing of FibroScan assessment. After the last infusion, biomarkers assessed at 3 days and 14 days after infusion and FibroScan at 3 days and 28 days after infusion.

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## **Phase 1 Trial:** GR-MD-02 Was Found To Be Safe And Well Tolerated



	Cohort 1 (2 mg/kg)		Cohort 2 (4 mg/kg)		Cohort 3 (8 mg/kg)	
	Active	Placebo	Active	Placebo	Active	Placebo
Completed protocol	6	2	7	2	7	6
SUSAR (Suspected unexpected serious adverse reactions)	0	0	0	0	0	0
Serious Adverse Events	0	0	1*	0	0	0
TEAE's probably related	0	0	0	0	0	0
TEAE's possibly related **	0	2	2	0	0	2

<sup>\*</sup>The female partner of one male patient in cohort 2 had a spontaneous abortion following the study. Conception was predicted to be more than 30 days past last infusion. The Principal Investigator determined that this event was unrelated to study drug and the DSMB concurred.

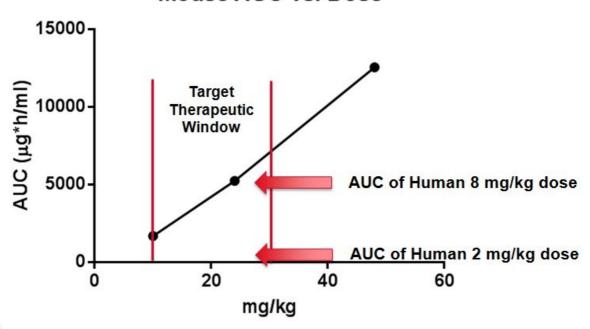
<sup>\*\*</sup>Therapy Emergent Adverse Events, possibly related to study drug were reported in 4 subjects who received placebo and 2 subjects who received GR-MD-02. All adverse events were mild (grade 1) and

# Pharmacokinetics Indicates 8 mg/kg Dose Is Within The Upper Range Of The Targeted Therapeutic Window



- The best therapeutic dose in mouse NASH was between 10 and 30 mg/kg
- Relationship between AUC and dose shows mouse and human equivalency

#### Mouse AUC vs. Dose

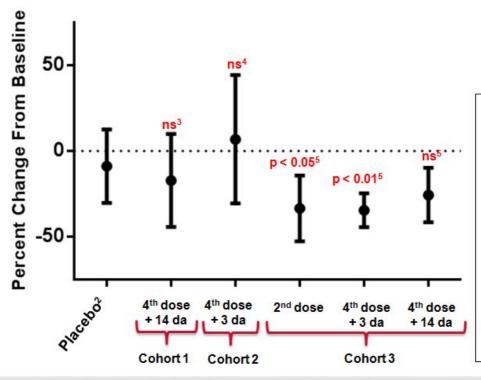


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## A Significant Reduction In FibroTest® Scores Were Seen At The 8 mg/kg Dose



FibroTest® scores are calculated from age, gender, alpha-2-macroglobulin, haptoglobin, apolipoprotein A1, gamma-glutamyl transpeptidase (GGT), and total bilirubin



#### **Legend and Notes:**

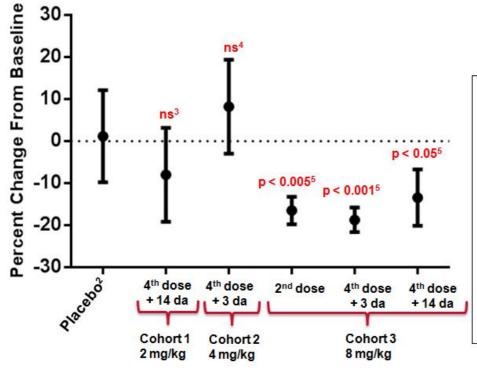
- 1. Mean ± Standard Deviation
- 2. Placebo values (change from baseline) were combined for all three cohorts because there were no differences (n=19)
- 3. Not significant versus placebo, two-sided t-test (n=6)
- 4. Not significant versus placebo, two-sided t-test (n=7)
- 5. Significant for three groups versus placebo, ANOVA with Dunnett's test for multiple comparisons (n=7)

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## Highly Significant Reduction In Alpha-2 Macroglobulin Serum Levels Seen At The 8 mg/kg Dose



A reduction in serum alpha-2-macroglobulin accounted for the reduction in FibroTest®



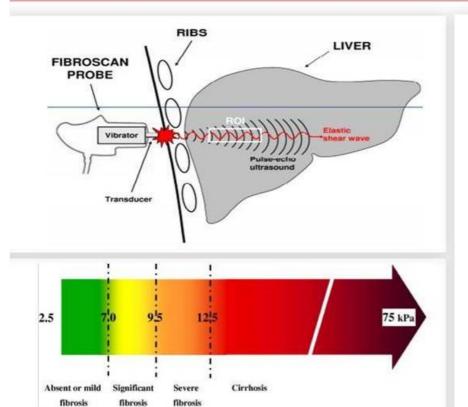
#### **Legend and Notes:**

- 1. Mean ± standard deviation
- 2. Placebo values were combined for all three cohorts because there were no differences (n=19 separate data points)
- 3. Not significant versus placebo, two-sided t-test (n=6)
- 4. Not significant versus placebo, two-sided t-test (n=7)
- Significant for three groups versus placebo, ANOVA with Dunnett's test for multiple comparisons (n=7)

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# FibroScan® Is A Non-Invasive, Ultrasound-Based Method For Assessing Liver Stiffness, Which Correlates With Liver Fibrosis





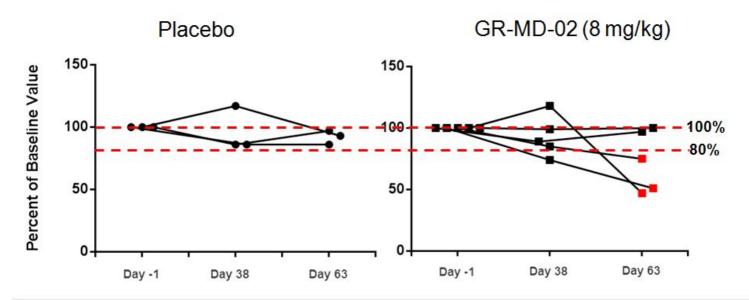
- FibroScan uses an electromechanical vibrator and pulse-echo ultrasound to evaluate the elastic shear wave in liver tissue
- The volume of liver tissue assessed is ~100-times greater than volume assessed by liver biopsy
- The stiffness of the liver is recorded as the pressure measurement of kiloPascals
- The stiffness of the liver correlates with the degree of liver fibrosis as assessed by liver biopsy
- FibroScan represents a promising non-invasive, out-patient method for measuring changes in liver fibrosis over time

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### **Evidence Of Reduced FibroScan® Scores In Cohort 3 Patients Treated With GR-MD-02**



### 3 of 5 patients treated with GR-MD-02 had reduction in liver stiffness to below 80% of baseline values (red squares)\*



\*In cohort 3 there were technically adequate scans at baseline, Day 38 and Day 63 in 5 patients administered GR-MD-02 and 3 patients administered placebo. Five patients in cohort 3 were not available for FibroScan® analysis (3 placebo and 2 active) because of unavailability of the instrument at the site (1 placebo and 1 active), unavailability of the appropriate instrument probe (1 active), a technically inadequate baseline scan (1 placebo), and the Day 63 scan not being performed (1 placebo).

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## Results Of Phase 1 Trial Provide Firm Foundation For Entry Into A Phase 2 Development Program



- GR-MD-02 at doses up to 8 mg/kg IV is safe and well tolerated in NASH patients with advanced fibrosis
- A dose of 8 mg/kg IV is in the upper range of the targeted therapeutic window for drug administration
- The combined results of a reduction in serum alpha-2 macroglobulin and a reduction in liver stiffness as assessed by FibroScan® suggests that GR-MD-02 at the highest dose tested may have an effect on liver fibrosis
- In an end-of-phase 1 meeting, the FDA provided feedback on Phase 2 program and advice on most relevant trial endpoints.
- FDA agreed to review a potentially pivotal Phase 2 trial under a Special Protocol Assessment

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### **Phase 2 NASH Clinical Development Program**



9	Patient Population		Objective	Expectation From Successful Study
NASH-CX	Cirrhosis due to NASH	1 Year of Therapy	Reduction of portal pressure as a result of reversing fibrosis	Could serve as a pivotal trial for marketing approval
NASH-FX	NASH with Advanced Fibrosis	4 Months of Therapy	Reduction of liver stiffness as a result of reversing fibrosis and comparison of non-invasive assessments	Could serve as basis for P2b and P3 trials

### The NASH-CX Trial (GT-026)



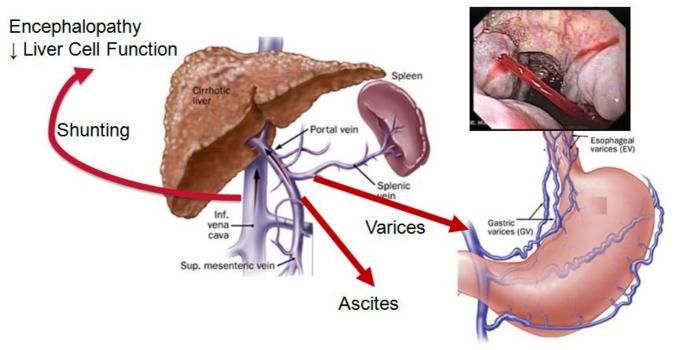
Patients	Portal hypertension with NASH cirrhosis
Design	<ul> <li>Randomized, controlled, blinded, multicenter trial</li> <li>Three groups of 52 subjects for a total of 156 subjects</li> </ul>
Dose & Duration	<ul> <li>Placebo and two doses of GR-MD-02 (2 mg/kg and 8 mg/kg)</li> <li>Randomized 1:1:1</li> <li>52 week treatment period with drug administration every other week for a total of 26 doses</li> </ul>
Primary endpoint	Evaluate the efficacy of GR-MD-02 on reducing hepatic venous pressure gradient (HVPG) as a measure of portal pressure compared to placebo at 1 year of treatment
Secondary endpoints	<ul> <li>Liver collagen on liver biopsy (digital morphometric analysis)</li> <li>Liver stiffness as determined by FibroScan® Score</li> <li>Metabolic capacity of the liver as determined by <sup>13</sup>C methacetin breath test</li> <li>Progression of cirrhosis as determined by complications</li> </ul>
Trial Sites	45-60 in US and Canada (Contract Research Organization is PPD)
Expected Milestones	First Patent Screened: May 2015 Last Patient Enrolled: July 2016 Last Patient, Last Visit: Aug 2017 Top Line Data: Q4 2017

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### **Complications of Portal Hypertension in Cirrhosis**

(Portal Hypertension = High Blood Pressure in Portal Vein)





The Goal is to:

↓ Fibrosis → ↓ Portal Pressure → ↓ Complications → ↓ Morbidity and Mortality

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## **Assessment Methods for Liver Fibrosis in NASH-CX Trial**



### Primary Endpoint: portal pressure

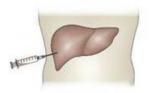
# FHVP WHVP

Hepatic venous pressure

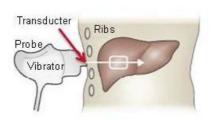
gradient (HVPG)

### **Secondary Endpoints:**

Liver biopsy



Transient Elastography (FibroScan™)



Echosense

Functional metabolic test (13C-methacetin Breath Test\*)



\*Exalenz

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### **Key Points of NASH-CX Clinical Trial**



- FDA in agreement with endpoint of HVPG
- Reduction in HVPG is reasonably likely to predict clinical benefit and therefore can be considered a surrogate marker for clinical outcome
- FDA has agreed to review protocol under Special Protocol Assessment
- Trial could serve as a pivotal trial for approval
- The endpoint of HVPG will be evaluated for correlation with liver biopsy and non-invasive measures of the liver which may be used in future studies

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### The NASH-FX Trial (GT-028)

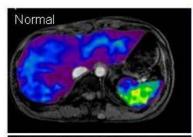


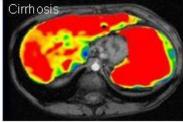
Patients	NASH with advanced fibrosis (>Brunt stage 3 fibrosis)			
Design	<ul> <li>Randomized, controlled, blinded, single center trial</li> <li>Two groups for a total of 30 subjects</li> </ul>			
Dose & Duration	<ul> <li>Placebo and 8 mg/kg GR-MD-02</li> <li>Randomized 1:2</li> <li>16 week treatment period with drug administration every other week for a total of 9 doses</li> </ul>			
Primary Endpoint	Evaluate the efficacy of GR-MD-02 on reducing liver fibrosis as assessed by MR-elastography			
Secondary Endpoints  • FibroScan® Score • Multi-parametric magnetic resonance imaging (LiverMultiScan®)				
Trial Site	Brooke Army Medical Center (Dr. Stephen Harrison)			
Expected Milestones	First Patent Enrolled: June 2015 Top Line Data: June 2016			

### Non-Invasive Assessments of Liver Fibrosis in NASH-FX trial



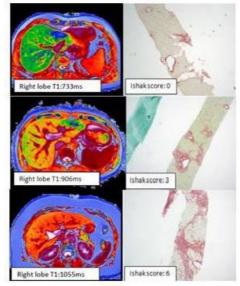
#### **MR-Elastography**





Whole liver assessment of stiffness using magnetic resonance imaging with mechanical pulse

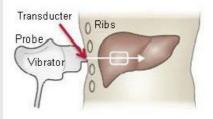
#### LiverMultiScan\*



Whole liver assessment of fibrosis using multiparametric magnetic resonance imaging

\*Perspectum Diagnostics™

### Transient Elastography (FibroScan™)



Regional assessment of liver for tissue stiffness (FDA approved)

Echosense™

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### **Key Points of NASH-FX Clinical Trial**



- Different population of patients than NASH-CX trial with advanced fibrosis, but not necessarily cirrhosis
- Shorter term treatment than NASH-CX trial
- Evaluation of three promising non-invasive tests for assessment of liver fibrosis
- A positive study might be supportive of a clinical effect which could be used in a Breakthrough Designation application to the FDA



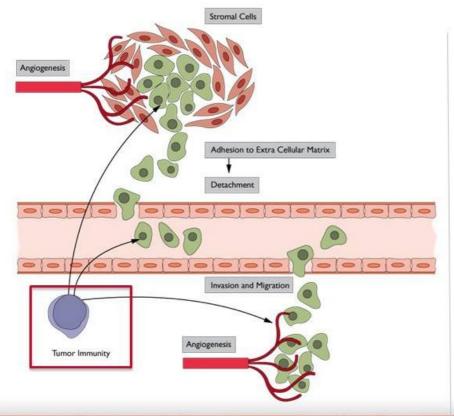
Lead Indication in Cancer Immunotherapy

### **ADVANCED MELANOMA**

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# The Vast Majority of Cancers Secrete Large Amounts of Galectins, Which Have Multiple Roles In Tumor Pathogenesis



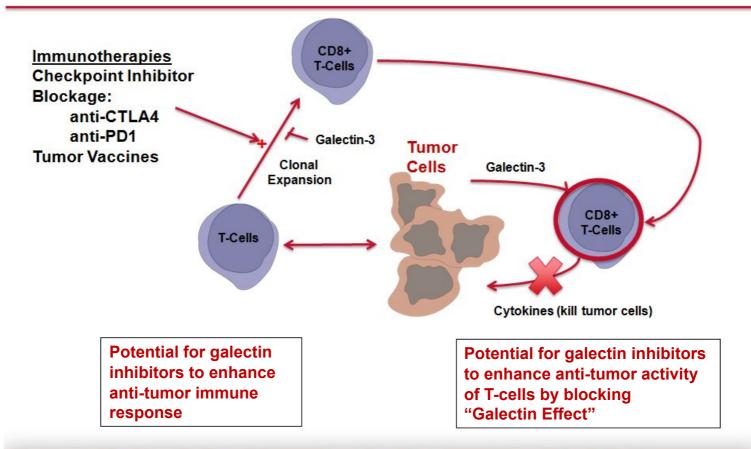


- Tumor cell invasion: extracellular matrix adhesion and detachment
- Metastasis: cell invasion and migration
- Angiogenesis
- Tumor immunity has recently been shown to be critically affected by galectins

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# Potential sites of action for galectin inhibition in tumor immunology





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### **Cancer Therapy Strategy**



Focus on Immunotherapy

Advanced Melanoma as Initial Indication

Critical
Collaboration
Established

- Immunotherapy is a major breakthrough in cancer therapeutics
- Galectin-3 has an important role in reducing the ability of immune system to fight cancer
- GR-MD-02 is efficacious on tumors in combination with other immunotherapies in animal models
- In U.S. 76,000 new diagnoses and 9,100 deaths\*
- Even with newly approved drugs, a substantial unmet medical need remains
- Robert W. Franz Cancer Research Center, Earle A.
   Chiles Research Institute (EACRI) Providence-Portland Medical Center, Portland Oregon
- Demonstrated clinical trial expertise in melanoma and tumor immunology basic science research
- · Ability to conduct clinical trials and assist in funding

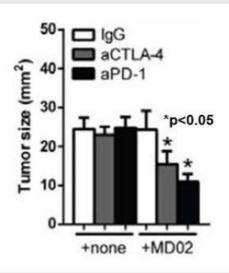
\*Siegel, et al. CA Cancer J Clin 2012;62:10

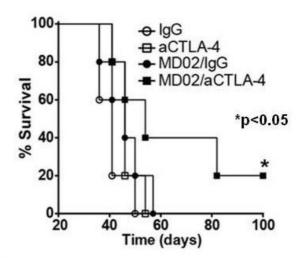
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### Checkpoint Inhibitors Plus GR-MD-02 Boosts Anti-Tumor Immunity, Reduces Tumor Size And Increases Survival In Mouse Cancer Models



These data are on TC-1 prostate cancer cells (also effective in breast cancer, melanoma, and sarcoma)





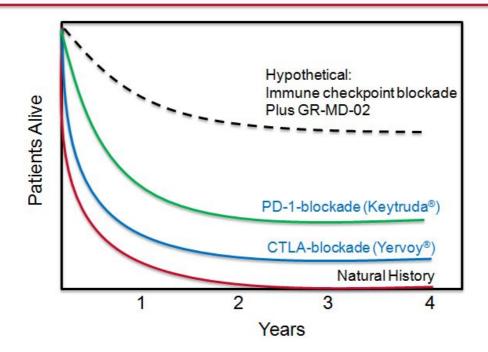
aCTLA-4 = anti-CTLA-4 mAb [ipilimumab in humans (Yervoy®, BMS)] aPD-1 = anti-PD-1 mAb [pembrolizumab in humans (Keytruda®) Merck]

Unpublished data 2013: Stefanie N. Linch, Melissa J. Kasiewicz, Peter G. Traber, and William L. Redmond, Galectin Therapeutics and Earle A. Chiles Research Institute (EACRI), Portland Oregon

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# **Hypothesis**: GR-MD-02 May Be A Complementary Therapy To Enhance Efficacy Of Immune Checkpoint Blockade Therapies





Note: these are illustrative curves not representative of actual data; redrawn from figure of the American Association for Cancer Research, 2013

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### **Phase 1b Clinical Trial In Patients With Advanced** Melanoma Using GR-MD-02 In Combination With Yervoy® Galectin



Patients	Advanced melanoma with indication for Yervoy® treatment					
Design	Three patients per cohort (+3 if serious adverse events) with 10 patients treated with maximum dose achieved					
Dose	GR-MD-02 starting at dose of 1 mg/kg and escalating following each cohort to 8 mg/kg followed by standard dose of Yervoy®					
Primary Endpoint	Determine a safe dose of GR-MD-02 used in combination with the approved dose of Yervoy®					
Secondary Endpoints	<ul> <li>Measure the response rate as assessed by ir-RECIST criteria</li> <li>Assess the biological activity by measuring:         <ul> <li>CD4+ T cells with a memory phenotype</li> <li>CD8+ T cells with effector phenotype</li> <li>Melanoma-specific T cells using autologous and/or HLA-matched tumor</li> <li>Examine composition of the tumor immune infiltrate from tumor biopsies</li> </ul> </li> <li>Assess quality of life during therapy using the FACT-M questionnaire.</li> </ul>					
Trial Site Providence-Portland Medical Center (Dr. Brendan Curti)						
Status	Cohort 1 completed—no dose limiting toxicity Cohort 2 underway					

http://clinicaltrials.gov/ct2/show/NCT02117362?term=GR-MD-02&rank=1

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# Phase 1b Clinical Trial In Patients With Advanced Melanoma Using GR-MD-02 In Combination With Keytruda®



<ul> <li>Patients</li> <li>Patients who have had melanoma progression after Yervoy® and targeted therapy in melanomas with a BRAF mutation</li> <li>Patients who have had melanoma progression after Keytruda® monotherapy</li> </ul>					
Design	Three patients per cohort (+3 if adverse events) with 10 patients treated with maximum dose achieved				
Dose	GR-MD-02 IV starting at dose of 1 mg/kg and escalating following each cohort to 8 mg/kg followed by standard dose of Keytruda®				
Primary Endpoint	Determine a safe dose of GR-MD-02 used in combination with the approved dose of Keytruda®				
Secondary Endpoints	<ul> <li>Measure the response rate as assessed by ir-RECIST criteria</li> <li>Assess the biological activity by measuring:         <ul> <li>CD4+ T cells with a memory phenotype</li> <li>CD8+ T cells with an effector phenotype</li> <li>Melanoma-specific T cells using autologous and/or HLA-matched tumor</li> <li>Examine composition of the tumor immune infiltrate from tumor biopsies</li> </ul> </li> <li>Assess quality of life during therapy using the FACT-M questionnaire</li> </ul>				
Trial Site	Providence-Portland Medical Center (Dr. Brendan Curti)				
Status Plan to initiate study Q2 2015					

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### **Expected Development Program Milestones**



### **Advanced Liver Fibrosis/Cirrhosis**

Study	Indication	Endpoints	Start	Data Reporting
GT-026 "NASH-CX"	NASH with cirrhosis	Portal pressure (HVPG)	Q2 2015	Q4 2017
GT-028 "NASH-FX"	NASH with advanced fibrosis	Liver stiffness (magnetic resonance elastography); comparisons include FibroScan® and multi- parametric MRI	Q2 2015	Q2 2016

### **Advanced Melanoma**

Study	Indication	Endpoints	Start	Data Reporting
Phase 1b: Yervoy®	Advanced melanoma	Safety ir-RECIST Immune markers	Underway	Dose Group 1: complete Dose Group 2: initiated
Phase 1b: Keytruda®	Advanced melanoma	Safety ir-RECIST Immune markers	Q2 2015	TBD

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### **Experienced Leadership Team**



James Czirr, Executive Chairman	Manager and general partner of 10X Fund, L.P., Co-Founder, Pro-Pharmaceuticals, CEO, Minerva Biotechnologies Corporation
Peter G. Traber, M.D. President, CEO, CMO	Over 28 years experience in biomedicine and pharmaceutical industries in research and development, clinical medicine and business development.
	<ul> <li>GlaxoSmithKline (CMO), Un of Pennsylvania (CEO, Chief of GI, Chairman of Medicine), Baylor College of Medicine (CEO)</li> </ul>
Harold H. Shlevin, Ph.D. COO & Corporate	<ul> <li>Over 32 years of senior experience in the development and commercialization of pharmaceuticals and business development including mergers and acquisitions.</li> </ul>
Secretary	<ul> <li>Solvay Pharmaceuticals (CEO), CIBA Vision Ophthalmics (n/k/a Novartis Vision) (SVP &amp; co-founder), Tikvah Therapeutics (Founder, CEO)</li> </ul>
Jack W. Callicutt CFO	<ul> <li>Over 24 years in accounting and finance with life science and technology companies with significant experience in negotiating and closing financing transactions.</li> </ul>
	CFO Reach Health, CFO of Vystar Corporation, CFO Corautus Genetics, Deloitte
Eliezer Zomer, Ph.D. Pharmaceutical Development	Over 30 years experience in biotechnology engineering and regulatory in pharmaceuticals and diagnostics.
	<ul> <li>Koor Biotechnologies, Charm Sciences, Glycogenesis, HU Medical School (Jerusalem), Harvard University</li> </ul>
J. Rex Horton Executive Director,	Over 24 years of experience working in the biotech and life sciences industries, regulatory affairs and manufacturing.
Regulatory Affairs and Quality Assurance	<ul> <li>Director Regulatory Affairs at Solvay Pharmaceuticals and Chelsea Therapeutics, Georgia Institute of Technology.</li> </ul>

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### Financial Key Facts – As Of December 31, 2014



Trading Symbol	Nasdaq: GALT
Corporate Headquarters	Norcross, GA (suburb of Atlanta)
Fiscal Year End	December 31
Accounting Firm	McGladrey LLP
Stock Price; 52 Week Range	\$3.47 \$3.00 - \$19.11
Shares Outstanding	22.3 million
Daily Volume (3-month average)	154,000 shares
Market Capitalization	\$89 million
Debt	\$0
Cash & Equivalents	\$29.1 million
Estimated Spending in 2015	\$20 million