# 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): May 14, 2014**

# 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))

**SECTION 7 – REGULATION FD**

**Item 7.01 Regulation FD Disclosure.**

On May 14, 2014, Galectin Therapeutics Inc. (the "Company) posted a corporate presentation on its website that contains a summary of the Company's business. The corporate presentation, which is being furnished and not filed, and 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.**

(a) Financial Statements of Businesses Acquired.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Shell Company Transactions.

Not applicable.

(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: May 14, 2014

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

Exhibit 99.1


# 2014 Annual Stockholder Meeting

**May 14, 2014**

**NASDAQ: GALT**

**www.galectintherapeutics.com**

# Forward-Looking Statement Disclaimer

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 strategies and potential therapeutic benefits of GR-MD-02 and expectations regarding clinical trials, including the future enrollment of patients and the timing of results. These statements also include expectations regarding our pipeline, patents and spending. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, future pre-clinical and clinical results may differ materially from past results, and there is no guarantee that our trials will lead to positive outcomes or that GR-MD-02 will ever be approved by the FDA. We may experience delays in our trials and we may have difficulty enrolling patients. We may experience delays in our trials, and we may have difficulty enrolling patients and processing the resulting data. 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, and our expectations regarding patents may not be accurate. Regardless of the results of current or future studies, 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. To date, we have incurred operating losses since our inception, and our ability to successfully develop and market drugs 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..

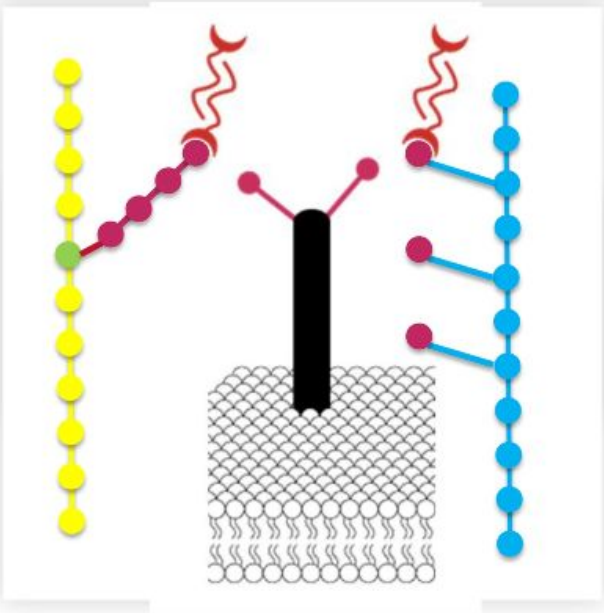
# Drugs are natural complex carbohydrates that bind to galectin-3 and block interactions with natural ligands

- **Galectin-3 is most important in pathological situations, is widely expressed, but highest in immune cells (macrophages)**
- **In areas of acute or chronic inflammation and fibrogenesis, the gal-3 expression is markedly increased. The majority of cancers express high levels of galectin-3**

## GR-MD-02

(simplified schematic)

- Produced from apple pectin



## GM-CT-01

(simplified schematic)

- Produced from guar gum

**Galactose** **Galacturonic Acid** **Rhamnose** Mannose

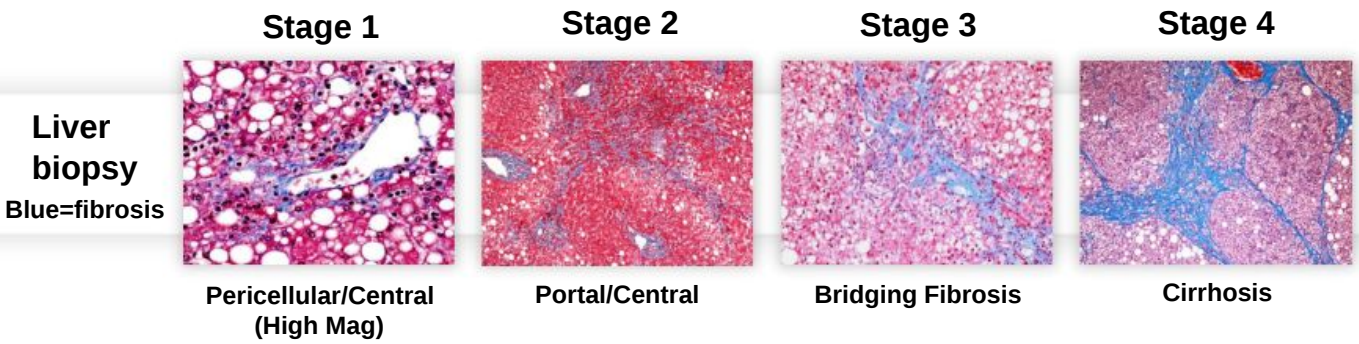
# Our Pipeline Of Galectin-3 Inhibitors

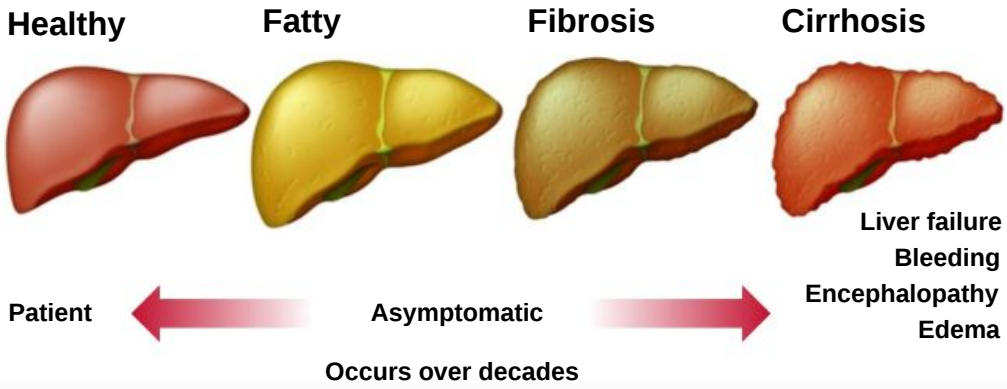
| Clinical Focus | | Stage of Development | | | | |
|---|---|---|---|---|---|---|
| **Drug** | **Indication** | **Discovery** | **Pre-clinical** | **Phase 1** | **Phase 2** | **Phase 3** |
| **Fibrosis** | | | | | | |
| GR-MD-02 | NASH (Fatty liver disease) with advanced fibrosis | | | | | |
| | Lung fibrosis | | | | | |
| | Kidney fibrosis | | | | | |
| | Cardiovascular fibrosis | | | | | |
| **Cancer Immunotherapy** | | | | | | |
| GR-MD-02 | Melanoma | | | | | |
| **Galectin-3 Inhibitors** | | | | | | |
| GR-MD-03 | Subcutaneous | | | | | |
| GR-MD-04 | Oral | | | | | |
| G-XXX* | Oral | | | | | |

*Galectin Sciences, LLC

# All Chronic Liver Diseases Lead To Fibrosis

## Example: Liver Fibrosis In Fatty Liver Disease (NASH)

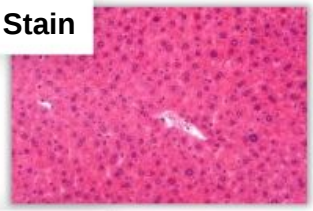
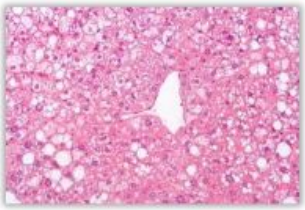
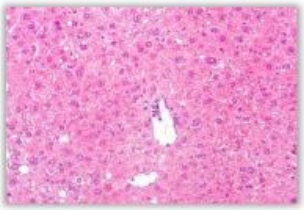
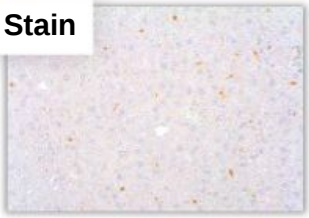
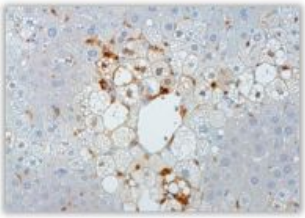
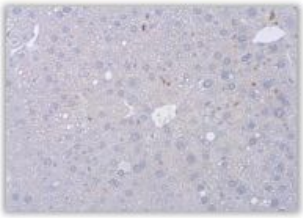



**Only therapy for patients with cirrhosis is liver transplantation**

# GR-MD-02, A Galectin-3 Inhibitor, Has Therapeutic Effect On NASH With Fibrosis In Mouse Model

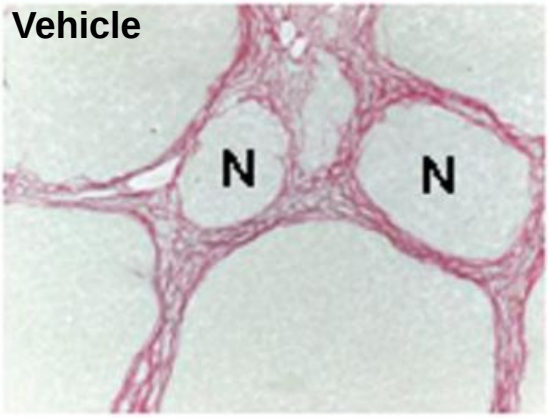
## Improvement is linked to decreased tissue Galectin-3

| | Normal | NASH:Control | NASH:GR-MD-02 | GR-MD-02 Effects |
|---|---|---|---|---|
| Normal Stain |  |  |  | ↓ Disease Activity Score<br>• Fat<br>• Cell death<br>• Inflammation |
| Collagen Stain |  |  |  | ↓ Collagen (Fibrosis) |
| Gal-3 Stain |  |  |  | ↓ Galectin-3 Protein |

# GR-MD-02 Reversed Cirrhosis in Rat Model

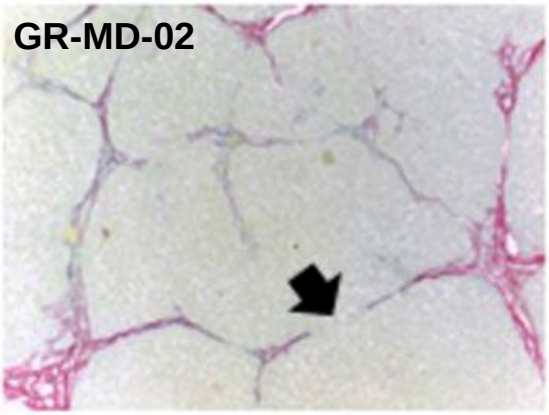
- Animal model presented a **very high hurdle** for drug treatment
- Cirrhosis induced with high dose toxin and continued throughout drug treatment
- Treatment with four, once weekly doses of GR-MD-02

**Vehicle**




**Broad bands of collagen with nodule formation (N) indicates advanced fibrosis and cirrhosis**

**GR-MD-02**



**Reduction in collagen with thin and broken bands (arrow) indicates resolving fibrosis and cirrhosis**

# GR-MD-02 Is A Galectin-3 Inhibitor That Reduces Collagen Synthesis And Increases Collagen Degradation In Pre-Clinical Models

## Liver Fibrotic Tissue Homeostasis

**In the normal liver, collagen and matrix protein synthesis matches degradation to provide appropriate amount of extracellular matrix.**

### Normal

**Collagen Synthesis = Collagen Degradation**

**Fibrosis results from increased collagen and other matrix protein synthesis with little to no change in collagen degradation.**

### Fibrosis

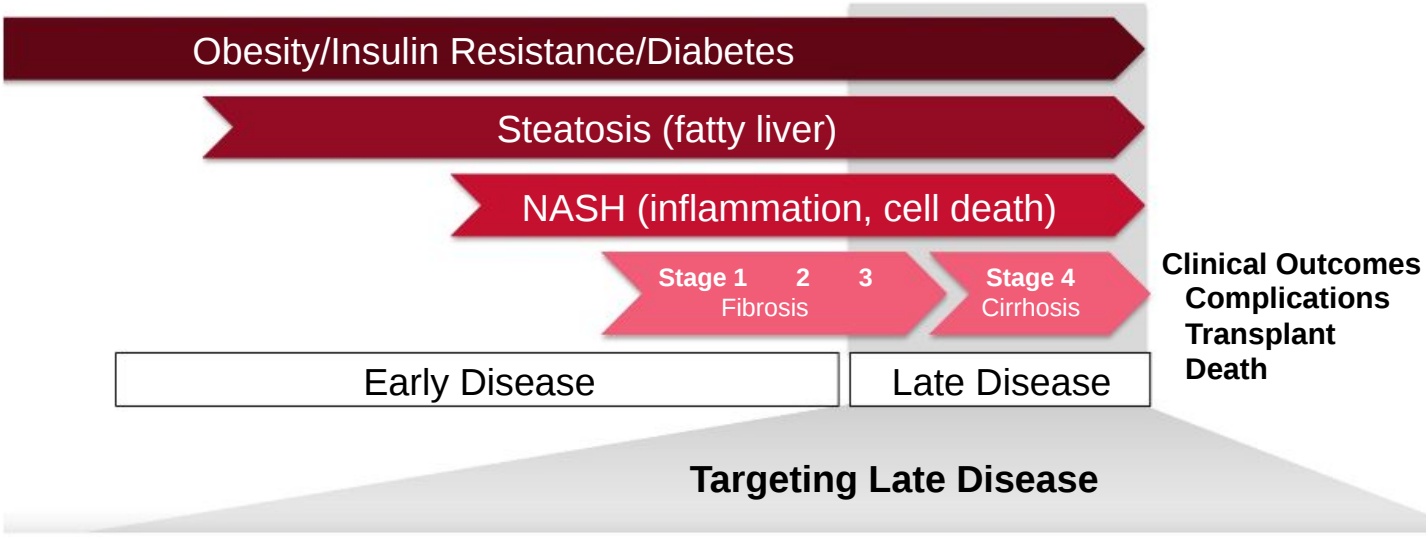
**↑ Collagen Synthesis + ↔ Collagen Degradation**

**Fibrosis can resolve either by a reduction in collagen synthesis or an increase in degradation. The combination would increase rate of resolution.**

### Restoration to Normal

**↓ Collagen Synthesis +/- ↑ Collagen Degradation**

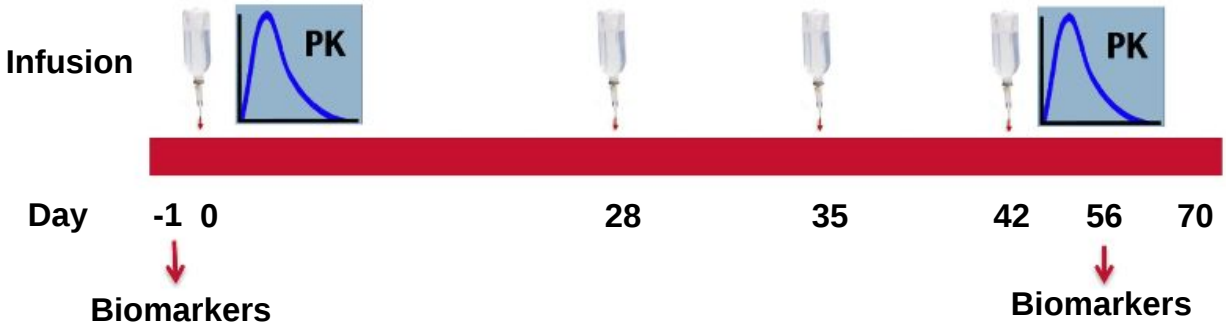
# GR-MD-02 Is Being Developed For The Indication Of NASH With Advanced Fibrosis (Stage 3 and 4)




- **No certainty of progression from early to late disease in an individual**
- **Late disease much closer to clinical outcomes**
- **Surrogates of clinical outcomes are better developed for late disease**
- **GR-MD-02 reduces inflammation, ballooning and fat in NASH and reduces existing fibrosis and reverses cirrhosis in animal models**

# Phase 1 Clinical Trial Of GR-MD-02 In NASH With Advanced Fibrosis: Fast Track FDA Designation

**Patient inclusion:** Biopsy proven NASH with advanced fibrosis (stage 3)
**Design:** Cohort has 8 patients (6 active, 2 placebo, blinded)
**Dose:** Starting dose of 2 mg/kg lean body weight (equivalent to 80 mg/m$^2$); Infusions at days 0, 28, 35 and 42.




**Primary endpoints:** Safety
Pharmacokinetics

**Secondary endpoints:** Disease-related serum biomarkers to assess for potential treatment effect

http://clinicaltrial.gov/ct2/show/NCT01899859?term=GR-MD-02&rank=2

# Patient Characteristics, Safety and Pharmacokinetics: Cohort 1

## Patient Characteristics

- 6 women and 2 men
- Ages 40-64 (mean=54)
- Mean body mass index (BMI)=39 (obese >30)
- Diabetes Mellitus in 6 patients

## Patient Safety

- There were no Serious Adverse Events
- There were no Treatment Emergent Adverse Events in patients receiving GR-MD-02 that were attributed to the drug
- There were no treatment emergent laboratory or ECG findings

## Pharmacokinetics

- GR-MD-02 blood levels were consistent between individuals with a $t_{1/2}$ of 20 hours
- Blood levels not significantly different after single or multiple infusions
- The total drug exposure in humans given 2 mg/kg was approximately 40% of the total drug exposure of the lowest dose used in the mouse NASH model which was therapeutic.

**GR-MD-02 at a dose of 2 mg/kg (80 mg/m $^2$) was safe and well tolerated**

**See presentation for full results: http://bit.ly/QAcJbz**

# Major Pathological Processes in NASH

**Steato-Hepatitis (NASH Activity)**
- Ballooning of liver cells (cell death/apoptosis) key hallmark
- Fat in liver cells (steatosis)
- Immune cell infiltration (inflammation)

**Fibrosis/Cirrhosis**
- Increase in collagen/matrix
- Disruption of architecture
- Liver cell nodules

## Do Not Always Correlate in Same Patient

- Can have high NASH activity score with minimal fibrosis
- Can have advanced fibrosis/cirrhosis with minimal NASH activity

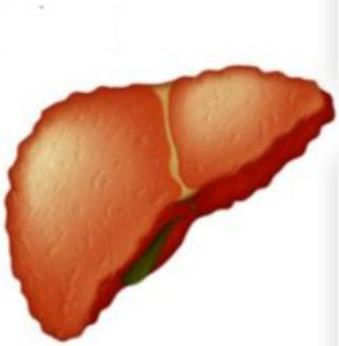
**We measured serum biomarkers of both major pathological processes**

# Serum Biomarkers Of Fibrosis In NASH

## Composite Scores

### FibroTest™ (FibroSURE™)
- Indirect biomarker of fibrosis
- Age and gender, Alpha-2-macroglobulin, Haptoglobin, Apolipoprotein A1, GGTP, Total bilirubin

### ELF (Enhanced Liver Fibrosis) Score
- Direct biomarker of fibrosis
- Hyaluronic acid
- TIMP1 (tissue inhibitor of metalloproteinase-1)
- P3NP (amino terminal propeptide of type III pro-collagen)



## Individual Markers

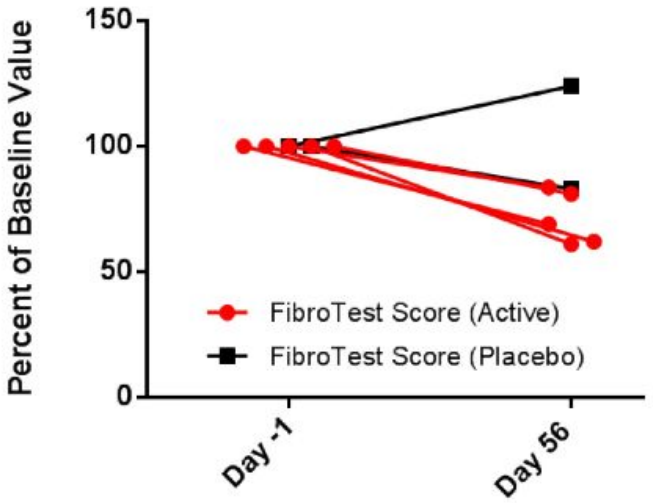
### Hyaluronic Acid
- Matrix polysaccharide
- Direct marker
- Correlates to fibrosis

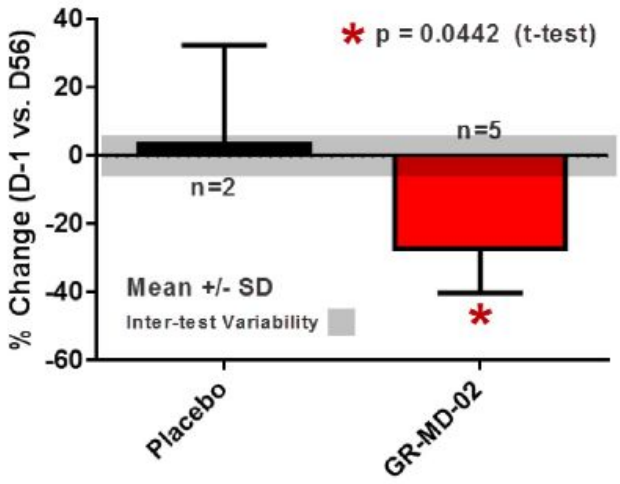
### Exploratory*
- TGF-β
- Lumican
- Osteopontin
- Matrix Metalloproteinases

* Indicates that there is some evidence that suggests they are increased in fibrosis, but not confirmed in sufficient number of patients or studies

**For more information and references on biomarkers: http://bit.ly/1jzFK50**

# FibroTest™ (FibroSURE™) Scores Significantly Decreased In GR-MD-02 Treated Patients




FibroTest™ has been shown to: 1) Correlate with stage of fibrosis; 2) Assess fibrosis regression; 3) Assess fibrosis progression; 4) Predict liver-related mortality

One patient on GR-MD-02 had scores < 0.08 which was highly discordant with biopsy (stage 3). Patient had high haptoglobin which is known for false negative test.

Note: While the numbers are small, exploratory statistics have been performed to evaluate differences using a one-sided t-test and confirmed using a non-parametric test, Mann-Whitney

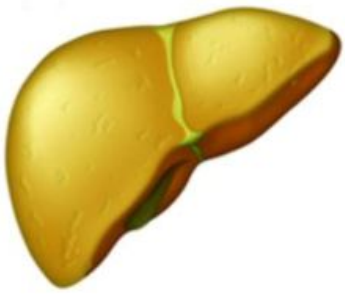
**See presentation for full results: http://bit.ly/QAcJbz**

# Serum Biomarkers of NASH Inflammation and Injury

## Inflammatory Cytokines

**Key cytokines***
- IL-6
- IL-8
- TNF-α

**Exploratory****
- INF-γ
- Endothelin-1
- IP-10
- VEGF
- CD40-ligand



* Evidence of association with human NASH and importance in pathogenesis, particularly as products of macrophages

** Some evidence of association with human and/or animal NASH in at least one publication

## Cellular Injury

**Serum Transaminases**
- ALT and AST
- Enzymes released from liver cells
- 2/3 of NASH patients have normal levels at any given time
- Entire spectrum of disease can be seen with normal levels

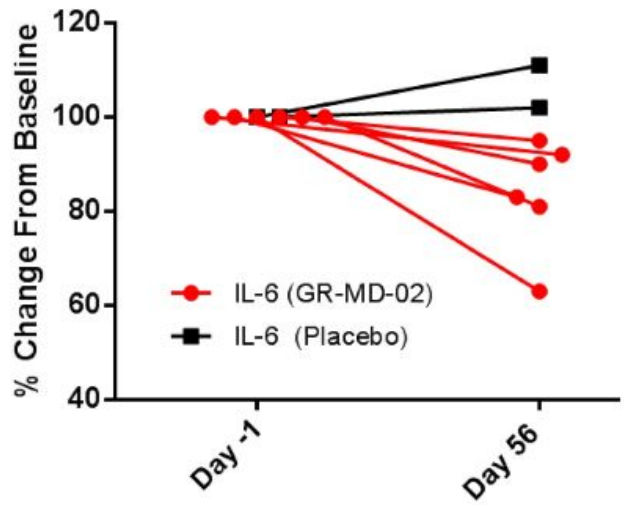
## Cell Death (Apoptosis)

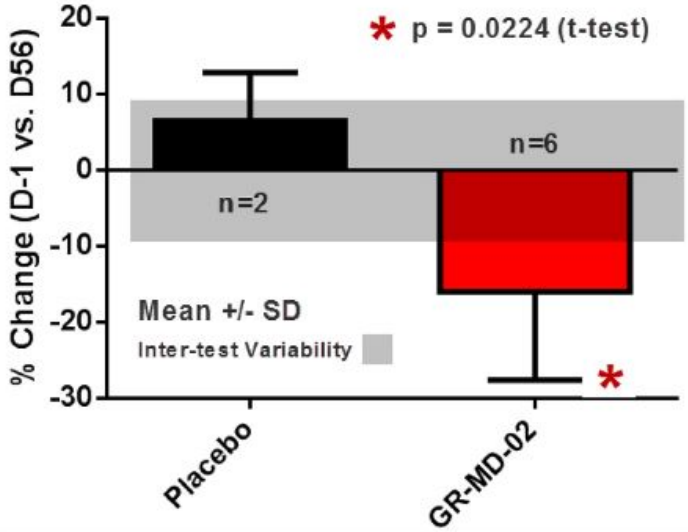
**Cytokeratin 18**
- A circulating biomarker of cell death
- Predictive of NASH severity

**For more information and references on biomarkers: http://bit.ly/1jzFK50**

# Interleukin-6 Levels Were Significantly Reduced In GR-MD-02 Treated Patients

- Pro-Inflammatory cytokine secreted by T cells and macrophages.
- GR-MD-02 treated patients had significant reduction when compared to placebo




**See presentation for full results:** http://bit.ly/QAcJbz

# GR-MD-02 Treatment Appears To Improve Both Major Pathological Processes In NASH

**Steato-Hepatitis (NASH Activity)**
- Ballooning of liver cells (cell death/apoptosis) key hallmark
- Fat in liver cells (steatosis)
- Immune cell infiltration (inflammation)

**Fibrosis/Cirrhosis**
- Increase in collagen/matrix
- Disruption of architecture
- Liver cell nodules

- Improvement in Fibrosis Biomarkers: There was a statistically significant reduction in Fibrotest™ and trends towards a reduction in ELF score and hyaluronic acid
- Improvement in Inflammation Biomarkers: There were statistically significant reductions in IL-6, IL-8 and TNF-α, all important cytokines in NASH
- Improvement in Cell Death Biomarkers: A patient subset with high ALT levels indicative of more cellular injury had improvement in CK-18

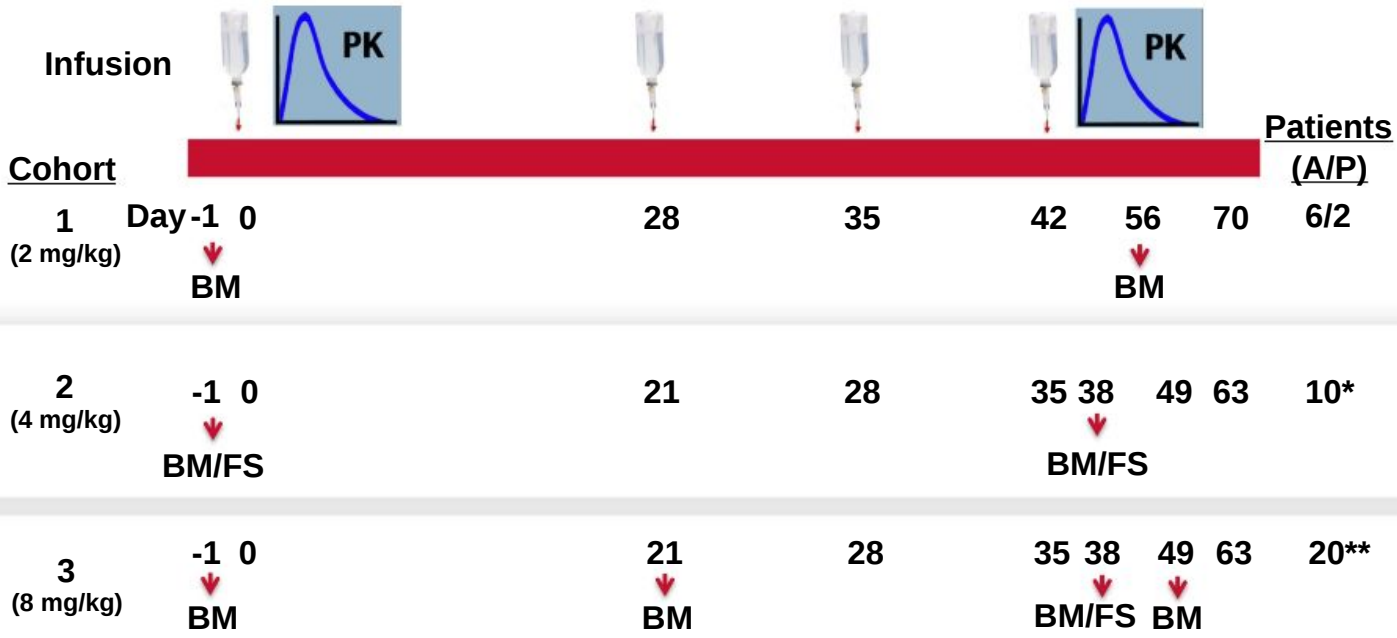
**See presentation for full results:** http://bit.ly/QAcJbz

## Summary of Findings From Cohort 1

- GR-MD-02 was safe and well tolerated at 2 mg/kg (80 mg/m$^2$) with no drug-related adverse events
- Pharmacokinetics was consistent between individuals and after single and multiple doses; exposure was 40% of lowest dose used in NASH animal model; this was a therapeutic dose
- Key composite biomarkers of fibrosis improved after four doses of GR-MD-02
- Key inflammatory cytokines were decreased after four doses of GR-MD-02
- Patients with greater cellular injury as indicated by elevated ALT levels, had a marked decrease in CK-18, a cell death biomarker
- Galectin-3 blood levels do not correlate with disease activity and are not a biomarker of drug effect in patients with NASH with advanced fibrosis

**In addition to being safe and well tolerated, GR-MD-02 improved biomarkers of fibrosis, inflammation and liver cell injury in patients with NASH with advanced fibrosis**

# Phase 1 Clinical Trial Of GR-MD-02 In NASH With Advanced Fibrosis: Second and third cohort

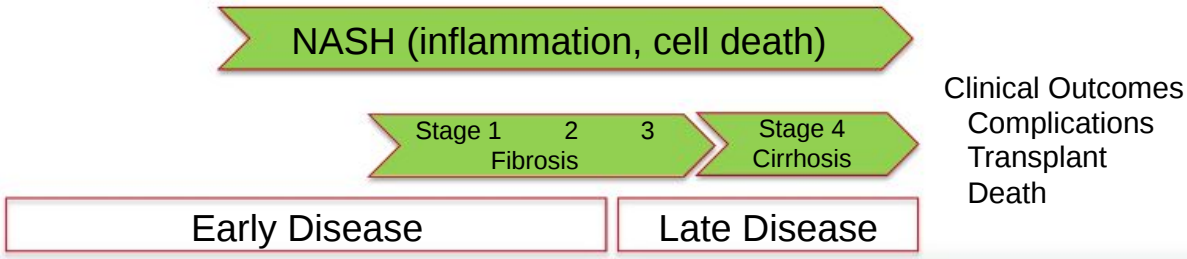



Timing of reporting results:

- Cohort 2: Around end of July
- Cohort 3: November

**BM=Biomarkers**
**FS=FibroScan®**
*** 6/10 had FibroScan®**
**** Anticipate all will have FibroScan®**

# Competition in NASH: Different Indications and Clinical Trial Endpoints




- **Focus is on improving NAFLD Activity Score (8 points total):**
  - **Fat (3 pts.), Ballooning (2 pts.), Inflammation (3 pts.)**
- **FLINT (NIDDK and Intercept)**
- **Other trials (Genfit, Galmed, Conatus)**

- **Focus is on stopping progression or reversing fibrosis**
- **Gilead Trials (stop progression)**
  - **LOL-2 (Lysyl oxidase-like-2) mAb (GS-6624): Monoclonal antibody that blocks the enzyme which cross links collagen fibers**
- **Galectin Therapeutics Trials (stop progression and reverse fibrosis)**

## Fibrosis Program Summary

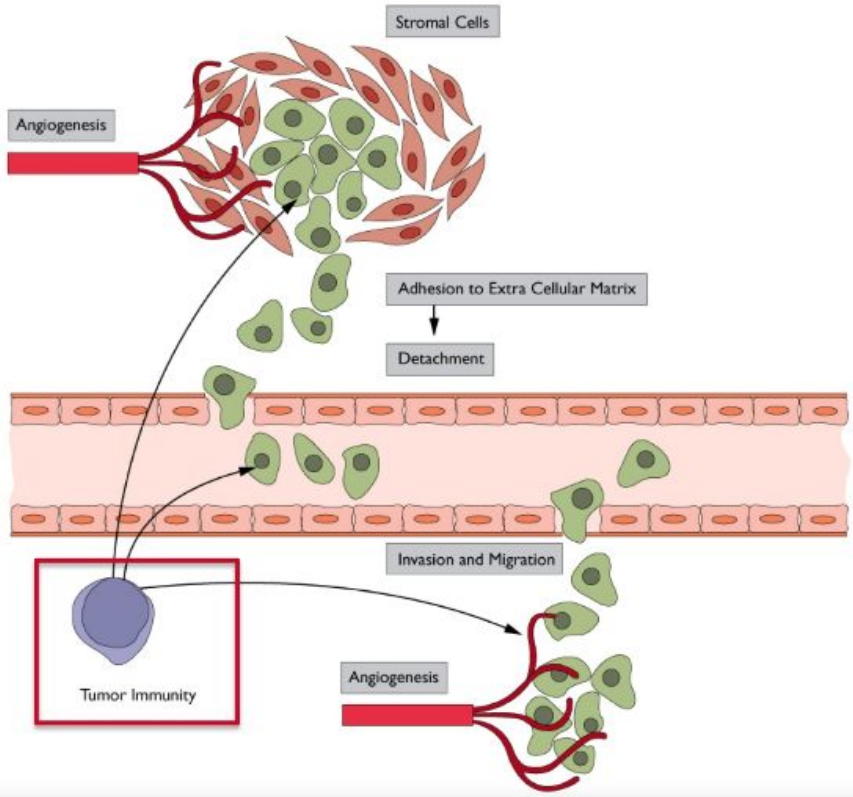
- First liver fibrosis indication: NASH with advanced fibrosis and/or cirrhosis
- Phase 1 trial indicates positive effects on fibrosis and NASH activity (inflammation and cell death)
- Controlled phase 2 clinical trial program to follow completion of phase 1 trial.
  - The results of the first cohort suggest that 2 mg/kg is a safe, well-tolerated dose that has indication of anti-fibrotic and anti-inflammatory effect. Therefore, this defines at least one potential dose level for phase 2 clinical trials
- Other Organ Fibrosis
  - Strong pre-clinical efficacy results in lung, kidney and cardiovascular fibrosis
  - Considering prospects for entering clinical development
- Ongoing discussions with large pharmaceutical companies
  - Discussions will provide foundation for partnering opportunities at the most opportune time

# Our Pipeline Of Galectin-3 Inhibitors

| Clinical Focus | | Stage of Development | | | | |
|---|---|---|---|---|---|---|
| **Drug** | **Indication** | **Discovery** | **Pre-clinical** | **Phase 1** | **Phase 2** | **Phase 3** |
| **Fibrosis** | | | | | | |
| GR-MD-02 | NASH (Fatty liver disease) with advanced fibrosis | | | | | |
| | Lung fibrosis | | | | | |
| | Kidney fibrosis | | | | | |
| | Cardiovascular fibrosis | | | | | |
| **Cancer Immunotherapy** | | | | | | |
| GR-MD-02 | Melanoma | | | | | |
| **Galectin-3 Inhibitors** | | | | | | |
| GR-MD-03 | Subcutaneous | | | | | |
| GR-MD-04 | Oral | | | | | |
| G-XXX* | Oral | | | | | |

*Galectin Sciences, LLC

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



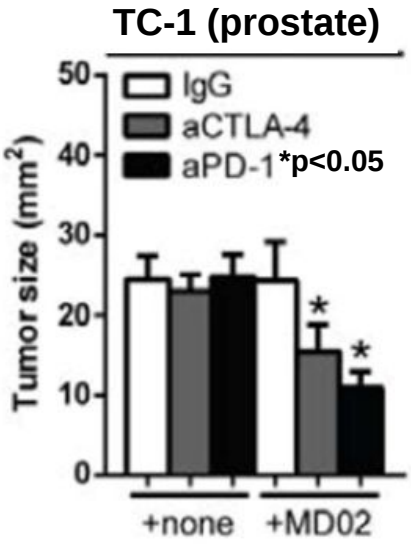

- **Tumor cell invasion: extracellular matrix adhesion & detachment**
- **Metastasis: cell invasion and migration**
- **Angiogenesis**
- **Tumor immunity has recently been shown to be critically affected by galectins**

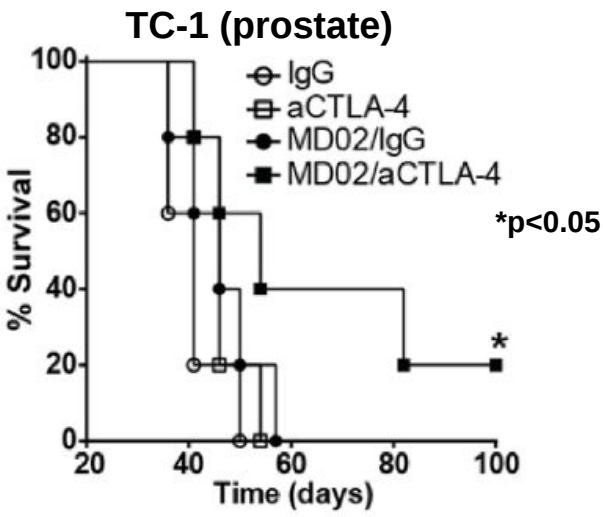
## Cancer Therapy Strategy

- Focus on cancer immunotherapy based on the hypothesis that galectin inhibitors will enhance efficacy of immunotherapies
- Metastatic melanoma is initial cancer indication
  - In US 76,000 new diagnoses and 9,100 deaths annually
  - 5% five year survival for metastatic disease
  - Even with newly approved drugs, still a substantial unmet medical need
- We have sought collaborations with institutions that have:
  - Demonstrated clinical trial expertise in melanoma
  - Tumor immunology basic science research
  - Ability to conduct clinical trials and assist in funding
- Collaboration established
  - Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute (EACRI) Providence-Portland Medical Center, Portland Oregon
  - Joint patent application with exclusive license to Galectin Therapeutics

# Checkpoint inhibitors plus GR-MD-02 boosts anti-tumor immunity, reduce tumor size and increase survival in mouse cancer models

## Also effective in breast cancer, melanoma, and sarcoma



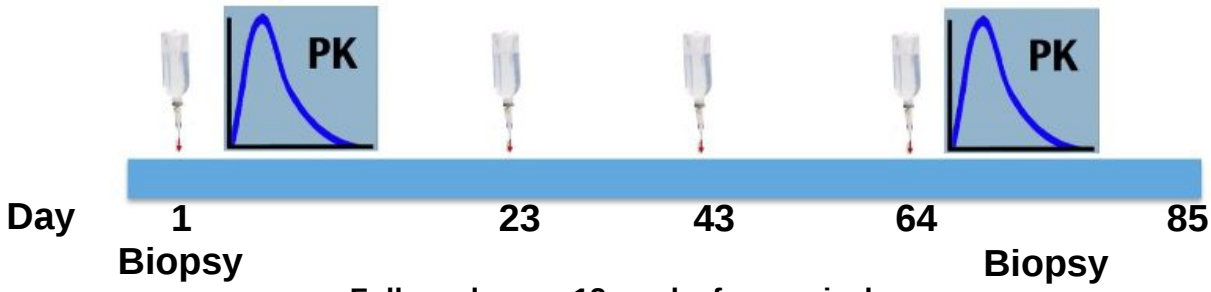

**aCTLA-4 = anti-CTLA-4 mAb [ipilimumab in humans (Yervoy, BMS)]**
**aPD-1 = anti-PD-1 mAb [positive results in clinical trials, BMS, Merck]**

**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**

# Phase 1B Clinical Trial in patients with advanced melanoma using GR-MD-02 in combination with Yervoy® (ipilimumab): Actively Enrolling

**Patient inclusion: Advanced melanoma with indication for Yervoy® treatment**
**Design: 3+3 dose escalation (3 patients if no adverse events); 10 patients treated with maximum tolerated dose Dose: Starting dose of 1 mg/kg**

**Infusion: GR-MD-02 followed by Yervoy® at standard doses**




**Followed every 12 weeks for survival**

**Endpoints:**

- **Safety; Pharmacokinetics**
- **Tumor response: immune response RECIST criteria**
- **Biological responses including memory CD4+ T-cells, memory CD8+ T-cells, melanoma specific T-cells, and composition of tumor immune infiltrate from tumor biopsies when available.**

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

## Cancer Therapy Summary

- Two immunotherapy agents have been approved for use to date, with many more vaccines and activators in development
- Our strategy is to leverage world class expertise in basic tumor immunology and in the conduct of melanoma clinical trials.
  - **Providence Portland Medical Center and Earle A. Chiles Research Institute (EACRI)**: Ongoing pre-clinical studies; IND accepted for phase 1B clinical trial in patients with advanced melanoma treated with a combination of Yervoy and GR-MD-02
  - Initial funding of clinical trial by PPMC/EACRI. Galectin is providing GR-MD-02 study drug, reference to its IND, and PK analysis
- Ongoing discussions with large pharmaceutical companies in the immunotherapy space to seek a partnering opportunity at the most opportune time

# Financial Key Facts – As of May 9, 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 | $10.23 $3.90 - $19.11 |
| Shares Outstanding | 21.9 million |
| Daily Volume (50 day average) | 527,000 shares |
| Market Capitalization | $224 million |
| Debt | $0 |
| Cash & Equivalents (March 31, 2014) | $36.6 million |
| Estimated Spending in 2014 | $14.5 million |

## Summary

- Liver fibrosis program has advanced from a concept presented three years ago at Annual Meeting to Phase 1 human results showing safety and evidence of disease effect
- Melanoma immunotherapy program has strong pre-clinical results with an active Phase 1B clinical trial underway
- Pipeline of other fibrosis indications and new anti-galectin drugs is robust
- Intellectual property strong
  - Patent attorneys are confident that GR-MD-02 and treatment indications do not infringe on other companies' patents
  - In fibrosis, Galectin has four issued patents and continues to advance additional patent submissions related to GR-MD-02
- Strong financial position to complete Phase 1 and potentially Phase 2 depending on trial design to be determined based on Phase 1 results and discussions with clinical experts and FDA.

# THANK YOU!