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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**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 24, 2013**

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**GALECTIN THERAPEUTICS INC.**

(Exact name of registrant as specified in its charter)

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**Nevada**  
(State or Other Jurisdiction  
of Incorporation)

**001-31791**  
(Commission  
File Number)

**04-3562325**  
(IRS Employer  
Identification No.)

**4960 PEACHTREE INDUSTRIAL BOULEVARD, Ste 240  
NORCROSS, GA 30071**

(Address of principal executive office) (zip code)

**Registrant's telephone number, including area code: (678) 620-3186**

**N/A**

(Former name or former address, if changed since last report)

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**SECTION 7 – REGULATION FD****Item 7.01 Regulation FD Disclosure.**

On September 24, 2013, Galectin Therapeutics Inc. (the “Company”) posted a slide presentation on its website that contains a corporate summary of the Company’s business. The slide 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Slide Presentation

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**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 24, 2013

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



# Corporate Presentation

September 2013

NASDAQ: GALT

[www.galectintherapeutics.com](http://www.galectintherapeutics.com)

# Forward Looking Statements

This presentation contains, in addition to historical information, statements that look forward in time or that express management's beliefs, expectations or hopes. Such statements are 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 risks and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include our plans, expectations and goals regarding drugs in development, clinical trials and regulatory approval for any of our drugs or treatments, the anticipated timeline for clinical trials and results, related market opportunities for our drugs, potential benefits of our drugs, efforts related to partnering opportunities with other companies, estimates regarding cash, liquidity and funding requirements for clinical trials, and estimates regarding those impacted by NASH, liver fibrosis and cirrhosis. The risks and uncertainties impacting these statements include that our plans, expectations and goals regarding drugs in development, clinical trials and regulatory approval are subject to factors beyond our control. Our clinical trials may not begin or produce positive results in a timely fashion, if at all, and any necessary changes during the course of such trials could prove time consuming and costly. We may have difficulty in enrolling candidates for testing and we may not be able to achieve the desired results. Upon receipt of regulatory approval for any drug or treatment, we may face competition with other drugs and treatments that are currently approved or those that are currently in development, which could have an adverse impact on our ability to achieve revenues from the approved indication. 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. Estimates regarding the potential benefits of our drugs and the potential market for any of our drugs may be inaccurate and, to the extent the estimates are correct, we may not be successful in achieving revenues from any such drugs, as the successful marketing of any approved drugs will be subject to strong competition within the health care industry and patient and physician acceptance of our drugs as safe, affordable and effective. Our ongoing discussions with other companies may not lead to partnering opportunities, and if we are unable to partner with other companies and/or raise additional capital, we will likely be unable to complete future stages of clinical trials and ultimately produce revenue from our drugs in development. Funding from potential sources of capital, including the potential exercise of warrants, may not materialize. 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 most recent Annual Report on Form 10-K 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.

# Agenda

- **The Company and Key Team Members**
- Galectin Inhibitors
- Fibrosis Program – our key focus
- Tumor Immunotherapies
- Summary

## What We Do

- Clinical stage biopharmaceutical company targeting fibrotic diseases and cancer with novel compounds that inhibit galectin proteins
  - Galectin proteins are important in the development and promotion of many fibrotic and neoplastic diseases
- Currently in clinical trials with 2 compounds
  - GR-MD-02 for the indication of NASH (Fatty Liver Disease) with advanced liver fibrosis: Phase 1
  - GM-CT-01 and GR-MD-02 in targeting cancer, enhance ability of immune system to kill cancer cells. GM-CT-01 in Phase 2a clinical trial in combination with peptide vaccine for advanced melanoma

# Key Facts - September 20, 2013

Trading Symbol	Nasdaq: GALT
Corporate Headquarters	Norcross, GA (suburb of Atlanta)
Stock Price; 52 Week Range	\$9.34     \$1.60 - \$13.21
Shares Outstanding	17.6 million
Daily Volume (50 day average)	197,930 shares
Market Capitalization	\$164.4 million
Debt	\$0
Cash & Equivalents	\$9.8 million
Estimated Cash Runway	Funded through Q2 2014
Fiscal Year Ends	December 31
Accounting Firm	McGladrey LLP



# Experienced Leadership Team

James Czirr, Executive Chairman	<ul style="list-style-type: none"> <li>• Manager and general partner of 10X Fund, L.P., Co-Founder, Pro-Pharmaceuticals, CEO, Minerva Biotechnologies Corporation</li> </ul>
Peter G. Traber, MD President, CEO, CMO	<ul style="list-style-type: none"> <li>• Over 28 years experience in biomedicine and pharmaceutical industries in research and development, clinical medicine and business development.</li> <li>• GlaxoSmithKline (CMO), Un of Pennsylvania (CEO, Chief of GI, Chairman of Medicine), Baylor College of Medicine (CEO)</li> </ul>
Harold H. Shlevin, PhD COO & Corporate Secretary	<ul style="list-style-type: none"> <li>• Over 32 years of senior experience in the development and commercialization of pharmaceuticals and business development including mergers and acquisitions.</li> <li>• Solvay Pharmaceuticals (CEO), CIBA Vision Ophthalmics (nka Novartis Vision) (SVP &amp; co-founder), Tikvah Therapeutics (Founder, CEO), Board of Directors, Cardiome Pharma Corp. (NASDAQ: CRME)</li> </ul>
Jack W. Callicutt CFO	<ul style="list-style-type: none"> <li>• Over 24 years in accounting and finance with life science and technology companies with significant experience in negotiating and closing financing transactions.</li> <li>• CFO Reach Health, CFO of Vystar Corporation, CFO Corautus Genetics, Deloitte</li> </ul>
Eliezer Zomer, PhD Pharmaceutical Development	<ul style="list-style-type: none"> <li>• Over 30 years experience in biotechnology engineering and regulatory in pharmaceuticals and diagnostics.</li> <li>• Koor Biotechnologies, Charm Sciences, Glycogenesis, HU Medical School (Jerusalem), Harvard University</li> </ul>
J. Rex Horton Executive Director, Regulatory Affairs and Quality Assurance	<ul style="list-style-type: none"> <li>• Over 24 years of experience working in the biotech and life sciences industries, regulatory affairs and manufacturing.</li> <li>• Director Regulatory Affairs at Solvay Pharmaceuticals and Chelsea Therapeutics, Georgia Institute of Technology.</li> </ul>

- The Company and Key Team Members
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# Galectins Inhibitors

- Galectin family (15 members) are classified by structure and the number of carbohydrate binding domains (CRD).
- Galectins bind via their CRD to oligosaccharides containing terminal galactose residues on macromolecules such as glycoproteins.
  - Function through binding glycoproteins on cell surface and extracellular space to modulate cellular and immune system function.
- Galectin-3 is widely expressed in mesenchymal and epithelial cells
  - Under normal physiological situations, galectin-3 is expressed at low levels
  - 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
- Our proprietary drugs are complex carbohydrates with galactose residues that bind galectin proteins (galectin-3 > galectin-1)
  - Galactomannan (GM) class: GM-CT-01
  - Galacto-rhamnogalacturonate (GR) class: GR-MD-02
- Discovery pipeline
  - Derivatives of GM and GR for subcutaneous administration
  - Synthetic carbohydrates
  - Small organic molecule galectin inhibitors

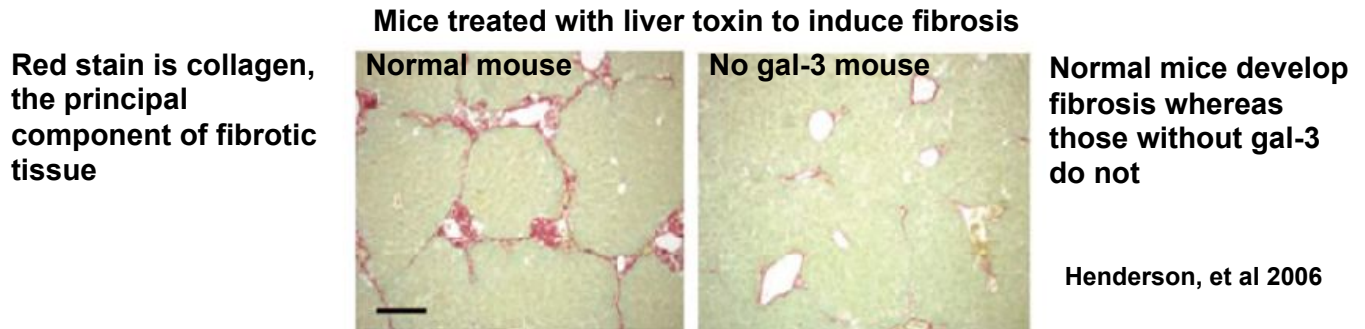
- GM-CT Class (current NCE is GM-CT-01)
  - US Composition of matter patent issued 2011 (expires 2023)
  - Five US issued method of use patents in combination with cancer therapy for increased efficacy and reduced side effects
  - International Patents: 14 granted and 5 pending
  - Method of use in liver fibrosis issued 2012 (expires 2026)
  - Method of use in NASH patent pending (priority 2011)
  - Method of use for Immune Enhancement pending (priority 2011)
- GR-MD Class (current NCE is GR-MD-02)
  - Method of use in liver fibrosis patent issued (expires 2026)
  - Method of use in NASH patent issued (expires 2031)
  - Composition of matter patent pending (priority 2011)
  - Method of use for Immune Enhancement pending (priority 2011)

**Sole ownership of compounds in development**

- The Company and Key Team Members
- Galectins and Disease
- **Fibrosis Program – our key focus**
- Tumor Immunotherapies
- Summary

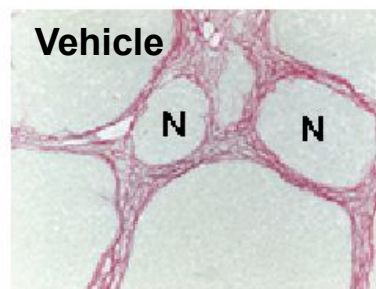
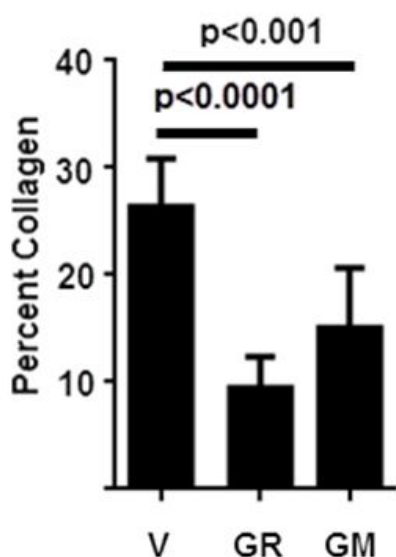
## Galectin-3 is critically important in the development of organ fibrosis

- Galectin-3 null mice (no galectin-3) are resistant to fibrosis due to toxin-induced liver toxicity

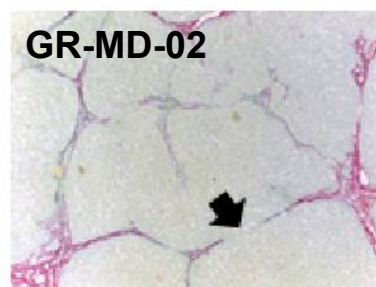


- Galectin-3 null mice are also resistant to fibrosis in:
  - **Fatty liver disease**
  - **Kidney fibrotic disease**
  - **Lung fibrotic disease**

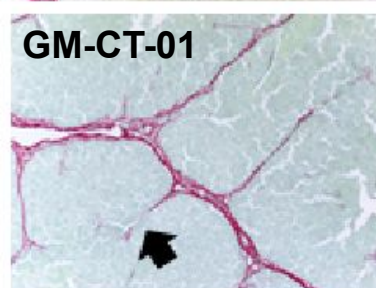
- Animal model presented a **very high hurdle** for drug treatment: Cirrhosis induced with high dose toxin and continued throughout drug treatment
- Treatment with four weekly doses



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



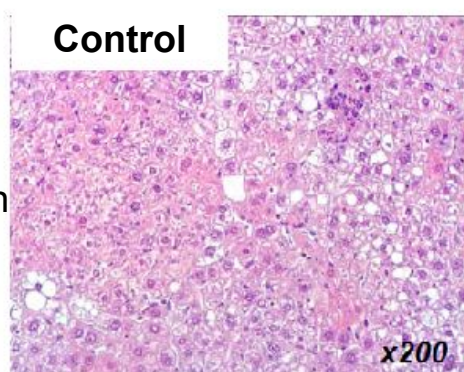
Reduction in collagen with thin and broken bands (arrow) indicates resolving fibrosis and cirrhosis



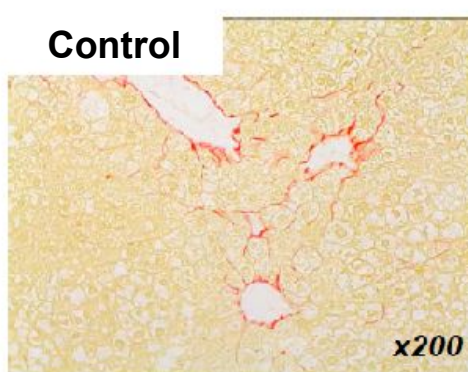


# Galectin Inhibitor GR-MD-02 Improved Fat, Liver Cell Death, Inflammation, and Fibrosis in Mouse Model of Fatty Liver Disease with Fibrosis

Fat  
Cell death  
Inflammation

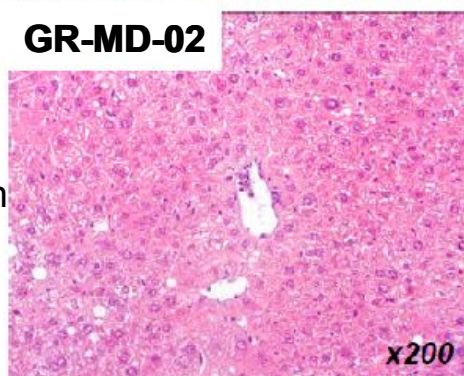


**Control**

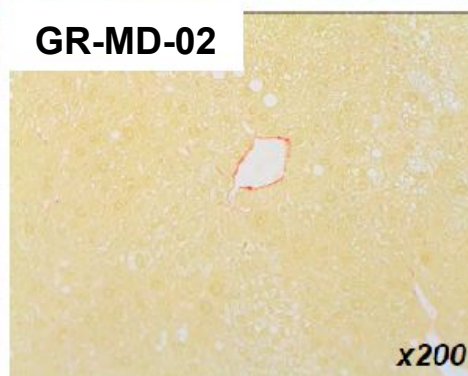


Red =  
Collagen

↓ Fat  
↓ Cell death  
↓ Inflammation



**GR-MD-02**

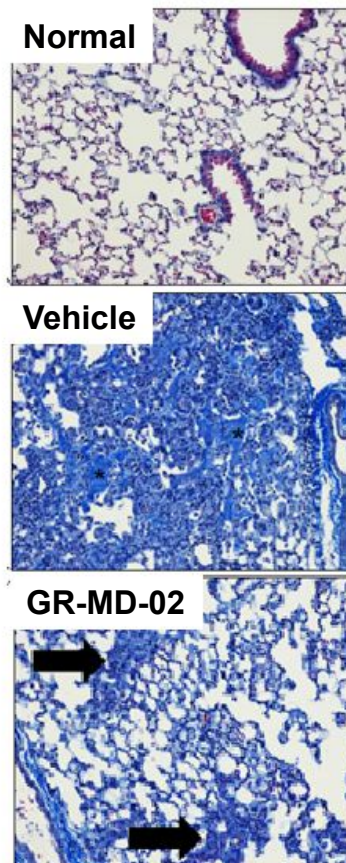
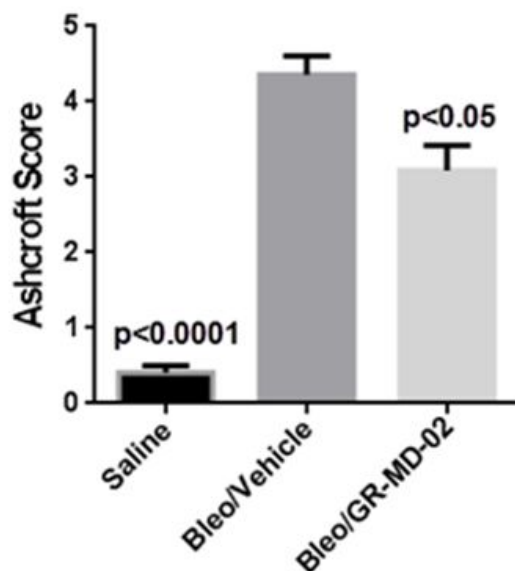


↓ Red =  
↓ Collagen



# Potential Use in Lung Fibrosis: GR-MD-02 Reduces Fibrosis in Mouse Model

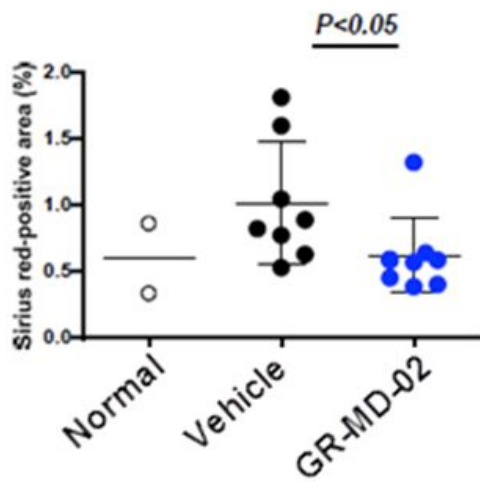
Lung fibrosis induced by tracheal instillation of bleomycin followed by four infusions of either vehicle or GR-MD-02



Large areas of confluent fibrosis.

Marked reduction in area and severity of fibrosis without aggregation into larger formations

## Potential Use in Kidney Fibrosis: GR-MD-02 Reduces Fibrosis in Diabetic Mouse



Arrows show areas of interstitial fibrosis

Reduction in interstitial fibrosis

# Liver Fibrosis Development Program

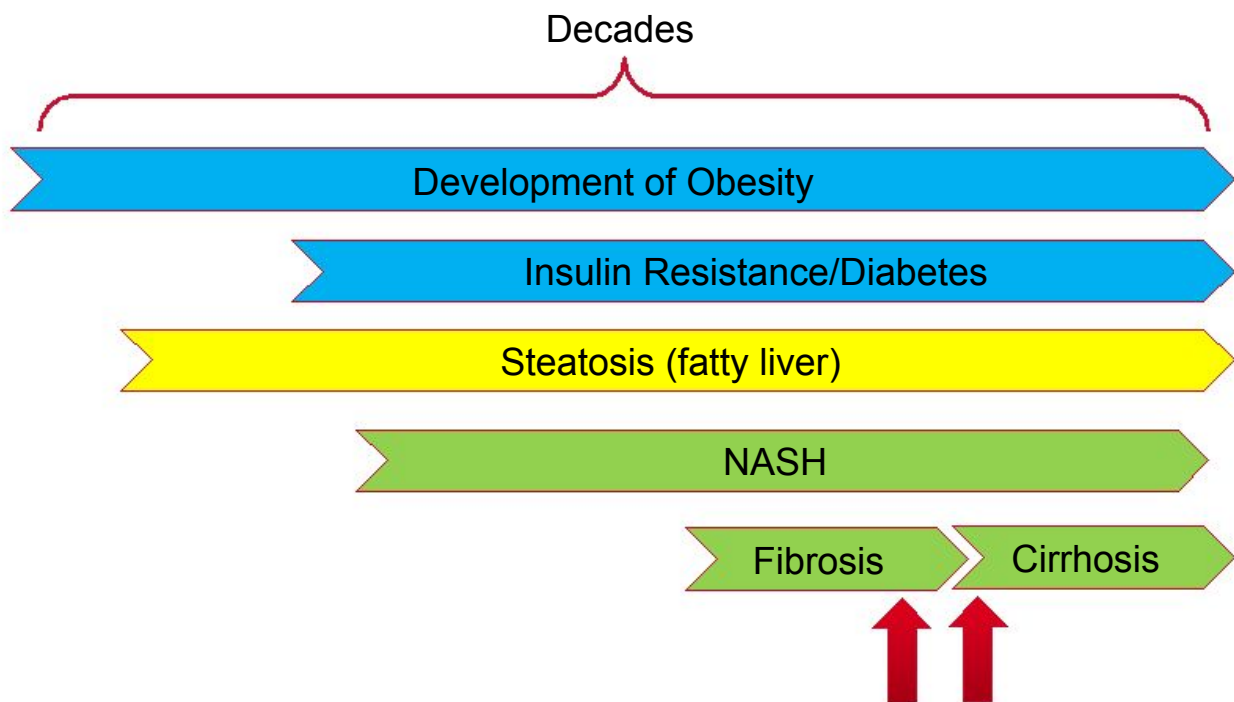
## NASH (Non-Alcoholic SteatoHepatitis)

- Multiple liver diseases lead to fibrosis
- End stage fibrosis, or cirrhosis, leads to liver failure, medical complications, and death
- Only current therapy is liver transplant
- **There is no approved medical therapy for liver fibrosis**
- **Very large unmet medical need**
- First indication is fatty liver disease with fibrosis (non-alcoholic steatohepatitis, or NASH).
  - Prevalence of NASH in U.S. is between 9-15 million people
  - Over 25% will develop cirrhosis
  - NASH cirrhosis projected to be primary reason for liver transplant

# NASH with Fibrosis Development Program: Accomplishments

- NASH indication chosen based on pre-clinical experiments
- Multiple studies in animal models confirmed robust effect on inhibition and regression of fibrosis, as well as reduction in inflammation and cell death in the liver.
  - GR-MD-02 more effective than GM-CT-01
- GMP drug substance and product produced by CMO
- Studies completed in multiple species elucidating pharmacology, pharmacokinetics, and toxicology.
- FDA review of IND for GR-MD-02 submitted Jan. 30, 2013 resulted in approval for human clinical studies.
- Phase 1 trial underway- enrolling first cohort
- **FDA Fast Track designation received August 2013**

# Development Program: Targeting Therapy In The Progression of NASH



Because of effect on inflammation in NASH and ability to reduce existing fibrosis, our clinical program will target NASH patients with advanced fibrosis



- **Patient inclusion:** Biopsy proven NASH with advanced fibrosis (stage 3 and potentially stage 4 with well compensated cirrhosis)
- **Design:** Randomized, placebo controlled, and double blind.
- **Dose:** One or two dosage groups chosen based on data from Phase 1 trial
- **Treatment Duration:** 6-12 months, TBD
- **Primary endpoint:** Liver biopsy: Collagen proportional area
  - FDA-AASLD liver fibrosis endpoints workshop, September 2013
  - Galectin human NASH biopsy study ongoing
- **Secondary endpoints:**
  - Liver Biopsy: NASH Activity Score and Fibrosis Stage
  - Imaging methods – MR-fat, MR-elastography
  - Serum biomarkers based on analysis of Phase 1 data
- **Estimated Timeline:** Start 2H 2014; Top line data: 1H 2016.

## Competition in NASH

- Most drugs in development focus on improving NASH activity score (fat, inflammation, and cell death) with minimal amounts of fibrosis.
- Few companies are focused on fibrosis which is the key cause of liver failure in patients
  - Galectin: GR-MD-02
  - Gilead: Lysyl oxidase-like-2 mAb (GS-6624): Monoclonal antibody that blocks the enzyme which cross links collagen fibers
    - Initiated Phase 2 trials in 2012 in patients with NASH and fibrosis
    - Top line data Q3 2015



## Fibrosis Strategy Summary

- NASH with Advanced Fibrosis: Evidence of efficacy of GR-MD-02 from well controlled phase 2 clinical trial
- Other Organ Fibrosis: Potential for partnering opportunities
  - Lung fibrosis – pre-clinical results suggest possible use in Idiopathic Pulmonary Fibrosis
  - Kidney fibrosis
- Ongoing discussions with large pharmaceutical companies
  - Discussions will provide foundation for partnering opportunities at the most opportune time

# Agenda

- The Company and Key Team Members
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- **Tumor Immunotherapies**
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# Cancer immunotherapy drugs will soon be a \$35 bn global industry

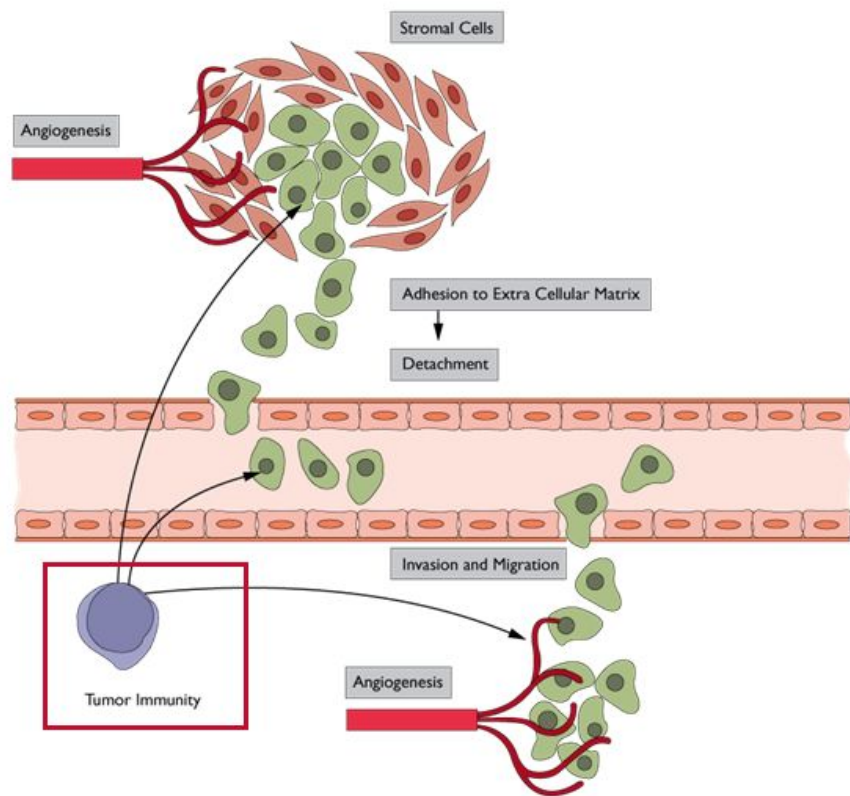
May 22, 2013

"We believe this market will generate sales of up to \$35 billion (a year) over the next 10 years and be used in some way in the management of up to 60 percent of all cancers," Citi analyst Andrew Baum said on Wednesday.

## Checkpoint Inhibitor Blockade

- **Marketed:**
  - **CTLA4 receptor mAb: Yervoy® (Ipilimumab, BMS)**
- **In Development:**
  - **Anti-PD-1 (nivolumab BMS; lambrolizumab Merck)**
  - **Anti PD-L1 (MPDL3280A , Roche)**

# 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 tumor immunotherapy
- Hypothesis: galectin inhibitors will enhance efficacy of immunotherapies
- Metastatic melanoma is initial cancer indication
- 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
- Two collaborations have been established
  - Ludwig Cancer Institute, Brussels Belgium
  - Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute (EACRI) Providence-Portland Medical Center, Portland Oregon

# Potential sites for galectin inhibition in tumor immunology

## Immunotherapies

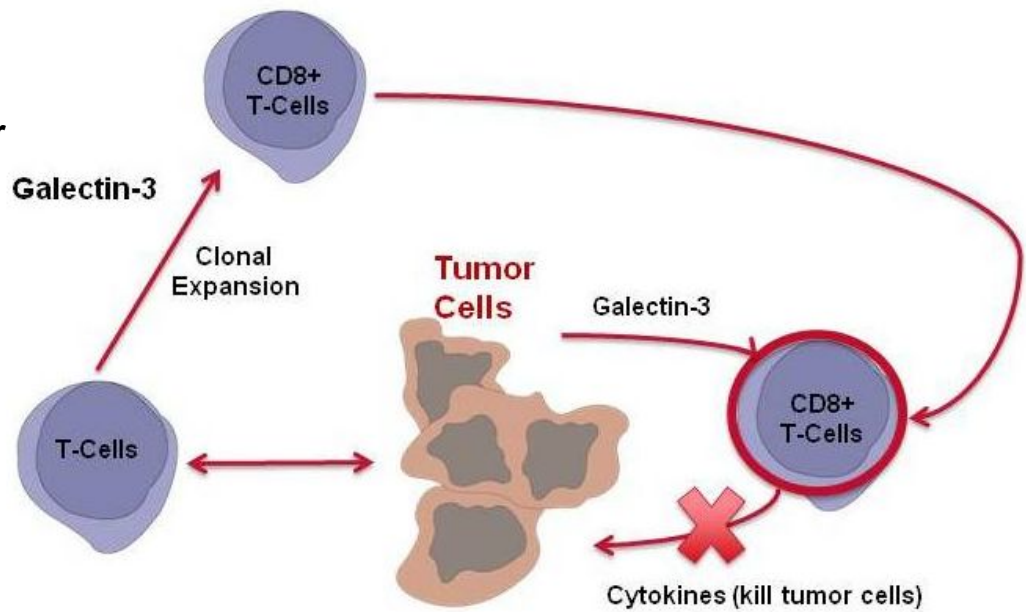
### Checkpoint Inhibitor

#### Blockade:

anti-CTLA4

anti-PD1

### Tumor Vaccines



**1. Potential for galectin inhibitors to enhance anti-tumor immune response**

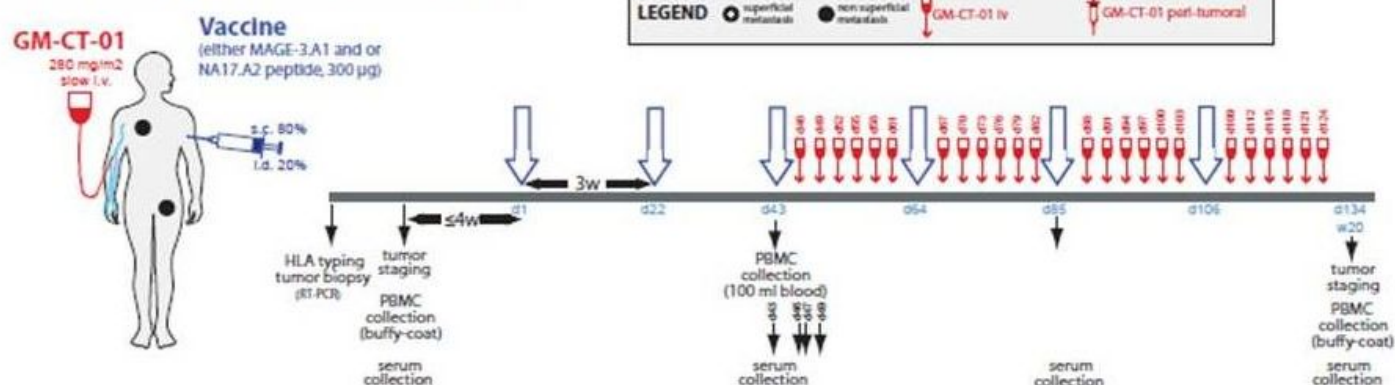
**2. Potential for galectin inhibitors to enhance anti-tumor activity of T-cells by blocking “Galectin Effect”**

# Ludwig Institute Clinical Trial to Evaluate combination of melanoma vaccine with GM-CT-01

## Melanoma "Proof of Concept" Trial:

**Patients:** Metastatic melanoma  
**Design:** Two stage Phase 2a (6x2 cohorts in stage 1 and 23x2 cohorts in stage 2)  
**Regimen:** Prime with melanoma specific peptide vaccine (overall 60% of melanoma patients express one or the other antigens) then treat with GM-CT-01  
**Endpoint:** Partial or complete response by imaging  
**Study sites:** Ludwig Institute, Brussels Belgium; second site Antwerp  
**Study funding:** Ludwig Institute (stage 1; 12 patients)

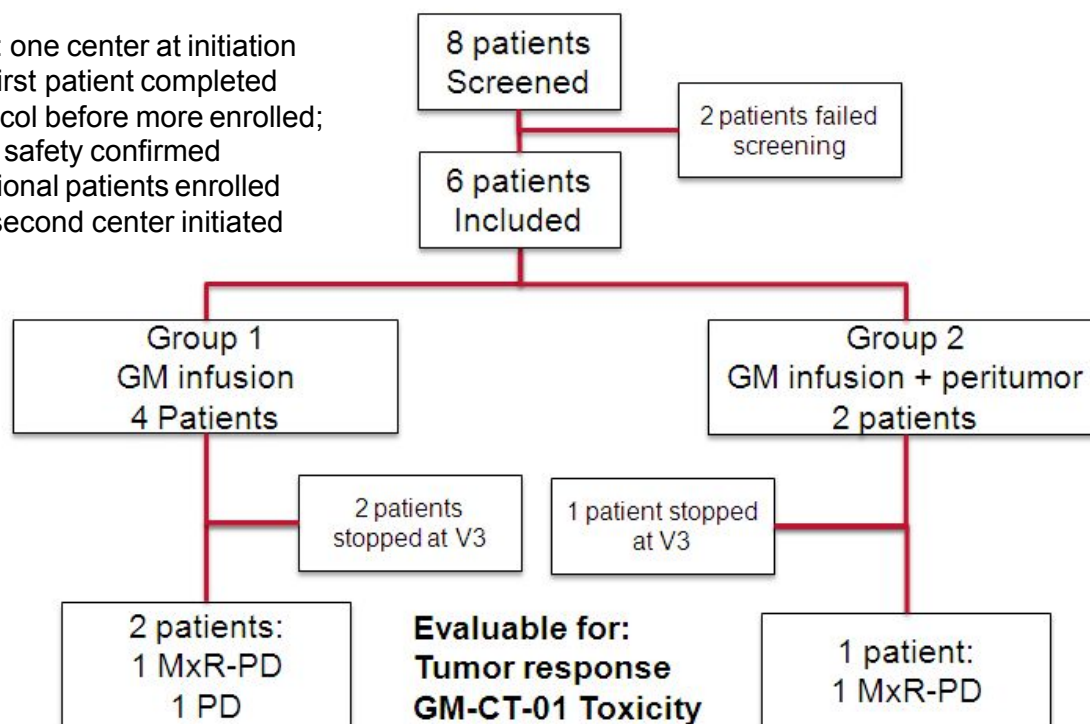
### GROUP 1 (n = 6 patients, expandable to 23)



Group 2 patients have additional injection of GM-CT-01 in cutaneous tumors

# Clinical Trial LUC10-001: Accrual

Note: one center at initiation and first patient completed protocol before more enrolled; once safety confirmed additional patients enrolled and second center initiated



- No grade 3/4 adverse events or serious adverse events
- Two out of three mixed responses encouraging, but no responses by RECIST
- Patient accrual continuing



# Potential sites for galectin inhibition in tumor immunotherapy

Collaboration established in 2012 with Earle A. Chiles Research Institute (EACRI) to evaluate the effect of galectin inhibitors on the induction of T-cell activity alone and in combination with checkpoint inhibitor blockade.

## Immunotherapies

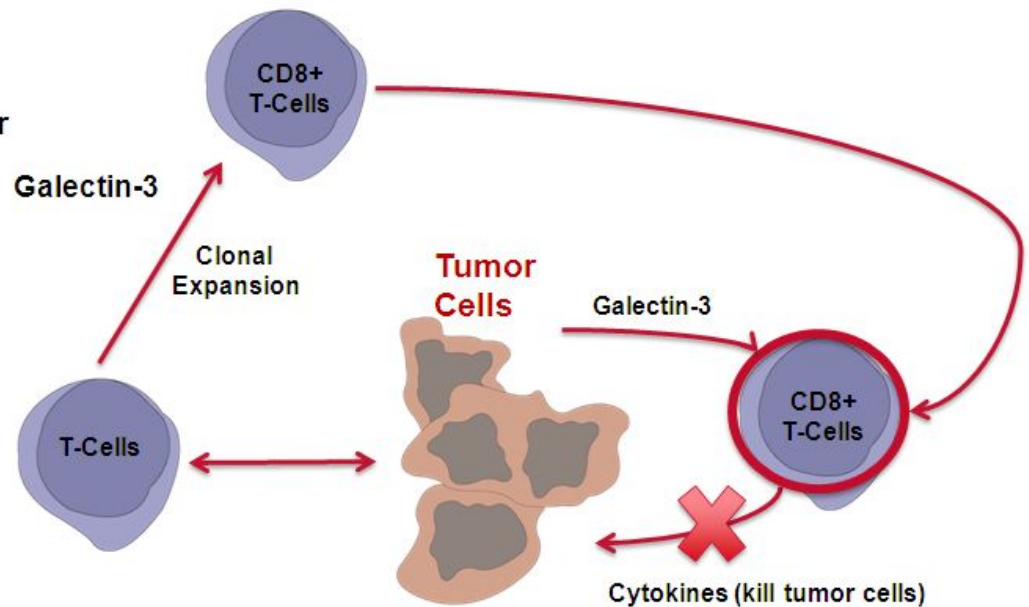
Checkpoint Inhibitor

Blockade:

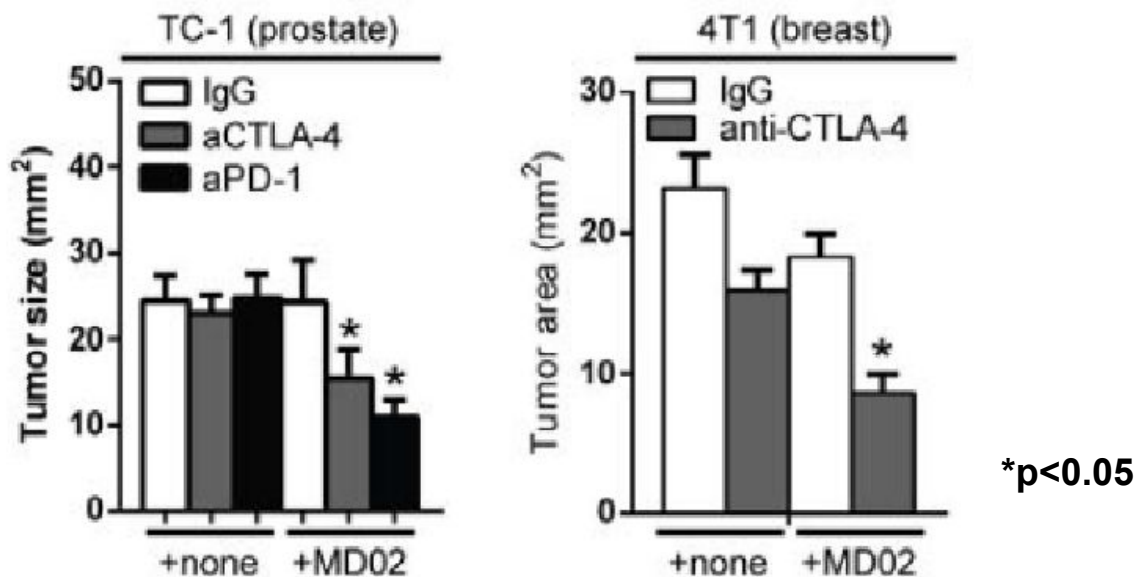
anti-CTLA4

anti-PD1

Tumor Vaccines



## Checkpoint inhibitor blockage plus GR-MD-02 boosts anti-tumor immunity in syngeneic mouse models of prostate and breast cancer



**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

- 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.
  - **Ludwig Cancer Institute:** Complete ongoing clinical trial with interim results reported at appropriate intervals
  - **Earle A. Chiles Research Institute (EACRI):** Ongoing pre-clinical studies; phase 1 clinical trial in melanoma with combination of Yervoy and GR-MD-02 in design phase
- Ongoing discussions with large pharmaceutical companies in the immunotherapy space to seek a partnering opportunity to take beyond proof of concept from initial clinical trials

# Agenda

- The Company and Key Team Members
- Galectins and Disease
- Fibrosis Program – our key focus
- Tumor Immunotherapies
- **Summary**

## Finances

- September 20, 2013 cash balance: \$9.8 million
  - Raised \$6 million from private placement and warrant exercises in July/August 2013
  - Funded through Q2 2014 and completion of Phase I clinical trial for GR-MD-02
- Additional funding required for a Phase 2 clinical trial for GR-MD-02
- Ongoing discussions with potential partners
- Actively supporting Investor Relations: Talking to new and interested fundamental investors; growing interest in funding Phase 2 program
- Fundamental investors are value investors with 3-5 year time horizon who are interested in investing at market

## Development Program

- Liver Fibrosis
  - First indication: GR-MD-02 in NASH with advanced fibrosis
  - Phase 1 clinical trial underway; interim data Jan. 2014
- Other Organ Fibrosis: Studies to demonstrate broad application of drugs in organ fibrosis; seek partner
- Cancer Therapy: Combination immunotherapy to enhance the ability of the immune system to recognize and kill tumor cells in metastatic melanoma
  - Leverage world class expertise in basic tumor immunology and in the conduct of melanoma clinical trials.
- Ongoing discussions with large pharmaceutical companies to provide foundation for partnering opportunities at the most opportune time

# Investment Highlights

Proprietary Compounds	<ul style="list-style-type: none"><li>• First in class, proprietary compounds that inhibit galectin proteins</li><li>• Complex carbohydrate drugs with favorable safety profile</li><li>• GR-MD-02: Potential to treat non-alcoholic steatohepatitis (NASH) and other causes of liver fibrosis</li><li>• GM-CT-01: Potential to enhance cancer immunotherapy</li></ul>
Validated Science	<ul style="list-style-type: none"><li>• Pre-clinical models show galectins are critical targets for intended diseases with mechanisms that would be novel in the market</li></ul>
Large Market Opportunities	<ul style="list-style-type: none"><li>• NASH and liver fibrosis indications would be first therapies for completely unmet medical needs, representing a multi-billion dollar market</li><li>• Enhancing the ability of immune system to kill cancer cells is synergistic with many current and experimental therapies</li></ul>
Intellectual Property	<ul style="list-style-type: none"><li>• Strong patent position</li><li>• Sole ownership of compounds in development</li><li>• No licenses granted</li></ul>
Experienced Management Team	<ul style="list-style-type: none"><li>• Management team has significant collective experience in multiple biotech and pharmaceutical companies and relevant scientific areas</li></ul>

# APPENDIX



# Inhibition of Gal-3 May Have Multiple Sites of Action in Therapy of NASH

