## 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

February 5, 2013

Date of Report (Date of earliest event reported)

#### 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 Blvd., Suite 240 Norcross, GA 30071 (Address of principal executive offices) (Zip Code)

 $\begin{tabular}{ll} (678)\ 620\mbox{-}3186 \\ (Registrant's\ telephone\ number,\ including\ area\ code) \end{tabular}$ 

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):

- $\ \square$  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))
- $\square$  Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 7.01. Regulation FD Disclosure.

Executives of Galectin Therapeutics Inc. are presenting a corporate update in February contained in the slide presentation attached as Exhibit 99.1 to this Current Report on Form 8-K (this "Report").

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.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1 Corporate Update Presentation Slides dated February 5, 2013

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

#### GALECTIN THERAPEUTICS INC.

By: /s/ Peter G. Traber

Peter G. Traber, M.D. President, Chief Executive Officer & Chief Medical Officer

Date: February 5, 2013



# **Corporate Summary**

February 5, 2013

NASDAQ: GALT

# Galectin G

### **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. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others: incurrence of operating losses since our inception, uncertainty as to adequate financing of our operations, extensive and costly regulatory oversight that could restrict or prevent product commercialization, inability to achieve commercial product acceptance, inability to protect our intellectual property, dependence on strategic partnerships, product competition, and others stated in risk factors contained in our SEC filings. We cannot assure that we have identified all risks or that others may emerge which we do not anticipate. 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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## **Investment Highlights**



Proprietary Compounds	<ul> <li>First in class, proprietary compounds that inhibit galectin proteins</li> <li>Complex carbohydrate drugs with highly favorable safety profile</li> <li>GM-CT-01: Enhanced ability of immune cells to kill of cancer cells</li> <li>GR-MD-02: Potential to treat non-alcoholic steatohepatitis (NASH) and other causes of liver fibrosis</li> </ul>
Validated Science	Pre-clinical models show galectins are critical targets for intended diseases with mechanisms that would be novel in the market
Large Market Opportunities	<ul> <li>Enhancing the ability of immune system to kill cancer cells is synergistic with many current and experimental therapies</li> <li>NASH and liver fibrosis indications would be first therapies for completely unmet medical needs, representing a multi-billion dollar market</li> </ul>
Intellectual Property	<ul> <li>Sole ownership, no licenses granted</li> <li>GM-CT-01: Matter and methods granted (expire 2023)</li> <li>GR-MD-02: Use in liver fibrosis (expire 2026); Matter pending (priority of 2011)</li> </ul>
Experienced Management Team	Management team has collective experiencer in multiple biotech and Pharmaceutical companies and relevant scientific areas

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## **Experienced Management Team**



Peter G. Traber, MD President, CEO, CMO	Over 25 years experience in biomedicine and pharmaceutical industries in research and development, clinical medicine, management and leadership, and business development. Medical expertise in liver disease
	GlaxoSmithKline (CMO), Un of Pennsylvania (CEO), Baylor College of Medicine (CEO)
Harold H. Shlevin, PhD COO	<ul> <li>Over 25 years of senior management experience in the development and commercialization of pharmaceuticals, diagnostics and vaccines</li> </ul>
	<ul> <li>Solvay Pharmaceuticals (CEO), CIBA Vision Ophthalmics (co-founder), Tikvah Therapeutics (Founder, CEO), Georgia Institute of Technology's Advanced Technology Development Center, Altea Therapeutics Corporation</li> </ul>
Eliezer Zomer, PhD EVP, Product 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>
Thomas A. McGauley	Over 10 years in accounting and finance with life science and technology companies
CFO (acting)	PricewaterhouseCoopers, Pro-Pharmaceuticals, deCode Genetics
Anatole Klyosov, PhD Chief Scientist	Over 30 years' experience in business and operations management for public and private scientific, and biotech corporations and startup companies
	eHealthDirect, Signatron, ArsDigita and Thermo Fibergen
J. Rex Horton Executive Director,	<ul> <li>Over 20 years of experience working in the biotech and life sciences industries, regulatory affairs and manufacturing.</li> </ul>
Regulatory Affairs and Quality Assurance	Solvay Pharmaceuticals, Chelsea Therapeutics, Georgia Institute of Technology.

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#### Science of Galectins

- Galectin Function
- Galectin Inhibitors
- Intellectual Property

### Immune Enhancement in Cancer Therapy

- Mechanism of Action
- Regulatory and Clinical Plan
- Competitive Positioning

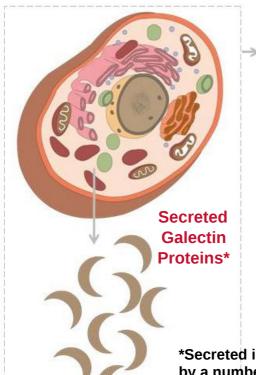
### Liver Fibrosis

- Mechanism of Action
- Regulatory and Clinical Plan
- Competitive Positioning
- Milestones

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### **Galectin Proteins Are Critical Participants In Pathogenesis of Many Fibrotic and Neoplastic Diseases**





Bind to cell surface and matrix glycoproteins (galactose residues)

- Modulate cell signaling
- interactions
- Promote cellmatrix interactions

Promote cell-cell

**Galectin-3** is most prominent galectin secreted in disease

**GALECTINS PROMOTE PATHOLOGY** 

**Markedly Increased in:** 

1. Inflammation

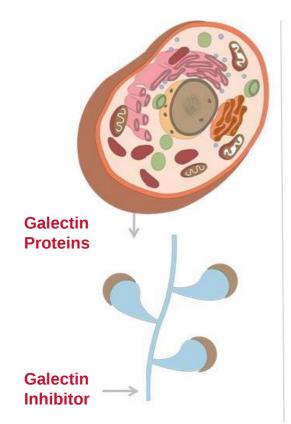
2. Fibrosis

3. Cancer

\*Secreted in small amounts normally by a number of cells, predominantly macrophages

# Galectin Inhibitors: A New Class of Pathology Modulators





- Novel complex carbohydrate drugs that target secreted and membrane-associated galectins by virtue of high molecular weight
- Strongest binding to galectin-3, most prominent galectin in disease processes
- Binding to galectins disrupts function and modulates <u>multiple</u> cellular pathways in pathology representing a potential <u>new class of</u> <u>therapeutic agents</u>
- Low toxicity potential as a carbohydrate with no toxic metabolites
- Two classes of compounds under development
  - GM-CT
  - GR-MD
- Low manufacturing costs; abundant natural plant product starting materials

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### **Intellectual Property**



- 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)
- GR-MD Class (current NCE is GR-MD-02)
  - Method of use in liver fibrosis patent issued (expires 2026)
  - Composition of matter patent pending (priority 2011)
  - Method of use in NASH patent pending (priority 2011)
- All intellectual property generated in house with no encumbrances
- No established generic pathway for such complex carbohydrate drugs

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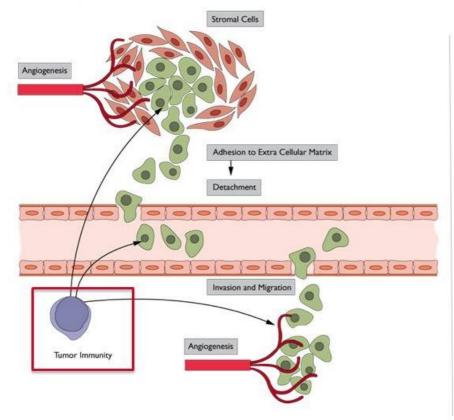


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### The Vast Majority of Cancers Secrete Large Amounts Galectin of Galectins Which Have Multiple Roles in Tumor **Pathogenesis**



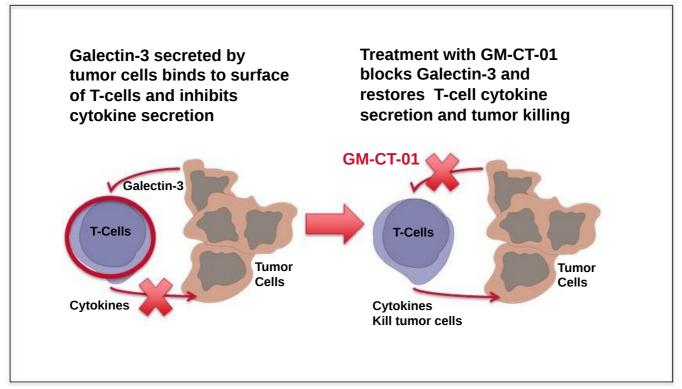


- **Tumor cell invasion:** extracellular matrix adhesion & detachment
- **Metastasis:** cell invasion and migration
- **Angiogenesis**
- **Tumor immunity has** recently been shown to be critically affected by galectins

The "Galectin Effect" protects tumors from immune system



# **Tumors Evade the Immune System Using the**"Galectin Effect" and GM-CT-01 Reverses This Effect



Experiments performed by Dr. Pierre van der Bruggen of the Ludwig Institute in Brussels, Belgium in collaboration with Galectin Therapeutics

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### GM-CT-01 Has Demonstrated Safety in over 100 Human Subjects in Phase I and Partially Completed Phase II Clinical Trials with Some Evidence of Efficacy



- Phase I trial (DAVFU-001) in 40 subjects with end stage cancer showed GM-CT-01 was safe alone and in combination with the chemotherapy 5-FU
- Three Phase II trials were conducted, but only partially completed
  - One Phase II trial (DAVFU-001) of 5-FU plus GM-CT-01 in line 3/4 therapy of metastatic colorectal cancer showed 6.7 months median survival. In similar patients, Erbitux<sup>®\*</sup> had a 6.1 month survival compared to 4.6 months with no therapy
  - When the data from the three partially completed Phase II trials were pooled, the serious adverse events associated with 5-FU were reduced when compared to historical controls
- Our preclinical efficacy and clinical safety data were strong enough to obtain an IMPD for Phase I/II trial in metastatic melanoma with a combination of a tumor vaccine and GM-CT-01 to test the efficacy of blocking the "Galectin Effect" [Study not being conducted under FDA IND, but there is open IND for GM-CT-01

\*"Erbitux® is a registered trademark of ImClone LLC, a wholly-owned subsidiary of Eli Lilly and Company."

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# Preclinical efficacy and clinical safety data sufficient to obtain an IMPD for treatment of metastatic melanoma to test the efficacy of blocking the "Galectin Effect"



**Melanoma "Proof of Concept" Trial:** 

Patients: Advanced metastatic melanoma

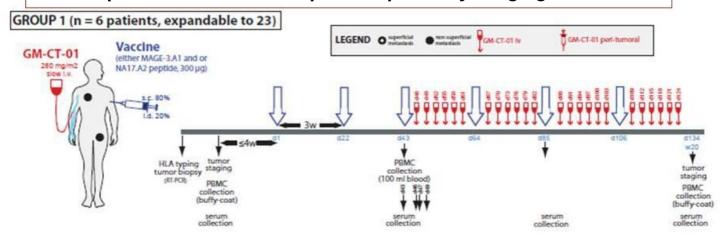
Design: Two Stage (6 X 2 cohorts in stage 1 and 23 X 2

cohorts in stage 2)

Regimen: Prime with melanoma specific peptide vaccine

Treat with GM-CT-01 to block "Galectin Effect"

**Endpoint:** Partial or complete response by imaging

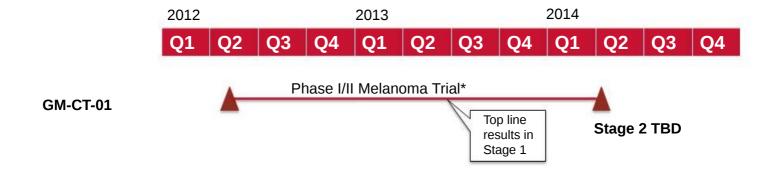


Group 2 patients have additional injection of GM-CT-01 in cutaneous tumors

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### **Tumor Immune Enhancement Development Program**





Pursue Partnering
Discussions

At conclusion of Stage 1 of study:

- Continue to Stage 2 with some efficacy
- Consider Phase IIb controlled trial with strong efficacy
- Seek partnership with company with marketed or late stage cancer immunotherapy
- · Stop for lack of efficacy

\*Conducted in Belgium under an IMPD. Not conducted under FDA IND, but there is an open IND for GM-CT-01

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# Immune Enhancement by Blocking "Galectin Effect" is Synergistic With Many Emerging Cancer Immunotherapies



- Enhancing the ability of the immune system to recognize and kill tumor cells is a very active area in the personalized approach to cancer therapy. The "Galectin Effect" inhibits the immune system
- Two agents have been approved for use to date
  - Dendritic cell vaccine: Provenge® (Dendreon)
  - T-cell activator (CTLA4 receptor mAb): Yervoy® (Ipilimumab, BMS)
  - Many more vaccines and activators in development
- Our drugs reverse the "Galectin Effect" by which tumors inhibit the immune system and may be synergistic with all tumor immunotherapies.
   May be effective with unaltered immune system
- While tumor vaccines are patient and tumor specific, reversal of the "Galectin Effect" appears to be universal. Initial Phase I/II clinical trial in Belgium in combination with a vaccine to treat metastatic melanoma
- The tumor vaccine market is forecast to be over \$7 billion by 2015

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### Best Positioned to Advance Tumor Immunotherapy with Galectin Inhibitor



- Market for tumor vaccines is expected to grow to \$7B by 2015. If ipilimumab (Yervoy ®, BMS) is included, market is even larger
- Blocking the "Galectin Effect" would be synergistic with all types of tumor vaccines or immune stimulatory approaches
- In this regard, competition will come from other galectin-inhibitors
  - Galecto Biotech AG (Sweden): Discovery phase focusing on small molecule inhibitors. Development program focused on lung fibrosis.
  - LaJolla Pharmaceuticals (CA): In Jan. 2012, they purchased GCS-100 from Solana Therapeutics (formally Prospect Therapeutics, formally Glycogenesis). GCS-100 is a natural product compound with claims for binding galectins; focused on blood cancers; significant side effects reported. Progressing in development for cancer and kidney fibrosis.
  - Mandel Med (Oakland, CA): Truncated galectin-3 protein. Not progressed into human trials and no active program currently.
- Galectin Therapeutics is best positioned with a human trial in cancer immunotherapy; GM-CT-01 has proved safe in Phase I and three partially completed Phase II trials.

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### NASH and Liver Fibrosis are Multi-Billion Dollar Markets In US Alone



- The ONLY current therapy for advanced fibrosis (cirrhosis) is liver transplantation
- No approved medical therapy for fibrosis
- While there are treatments for some underlying etiologies (Hepatitis C and B), there is no approved therapy for NASH

Transplants (6,291\*)

Wait List (17,000\*\*)

Death From Cirrhosis (44,677\*)

Cirrhosis (400,000\*\*)

NASH: 9-15 Million<sup>®</sup> Hepatitis C, Hepatitis B, Alcohol

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<sup>\*</sup> Performed in US in 2010 (UNOS) \* \* Prevalence in US 2010 (UNOS)

<sup>#</sup>Deaths in 1998 (AASLD Workshop, 2001) ##Prevalence in US 1976-1980 (NIDDK)

<sup>&</sup>amp;Prevalence in US 2011 (NIH)

# Galectin-3 Is A Critical Protein Target For Therapy of Liver Fibrosis



### **Key Evidence:**

- Galectin-3 is produced in large amounts by fibrotic liver (animal and human)
- Galectin-3 is essential in mice for the development of liver fibrosis
  - Fibrosis due to toxin exposure or fatty liver <u>does not</u> occur in mice that lack the galectin-3 gene
- Galectin inhibitors reverse experimental fibrosis in rats induced by both fibrosis and fatty liver

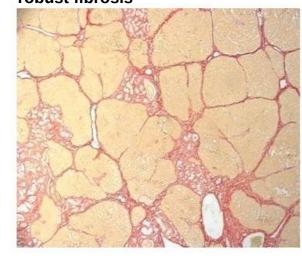
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# Galectin Inhibitor GR-MD-02 Effectively Treats Toxin-Induced Liver Fibrosis in Rats

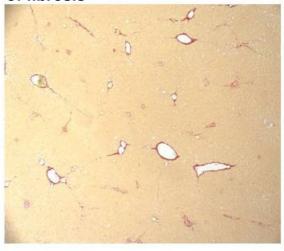


Liver fibrosis induced in all rats by injection of chemical toxin (thioacetimide) for 8 weeks

Treatment with vehicle alone for four weeks (Control) shows robust fibrosis



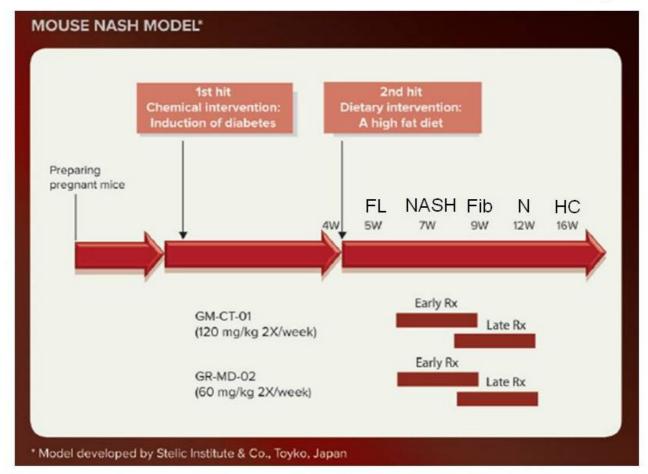
Treatment with GR-MD-02 for four weeks shows dramatic regression of fibrosis



**Galectin Therapeutics Data** 

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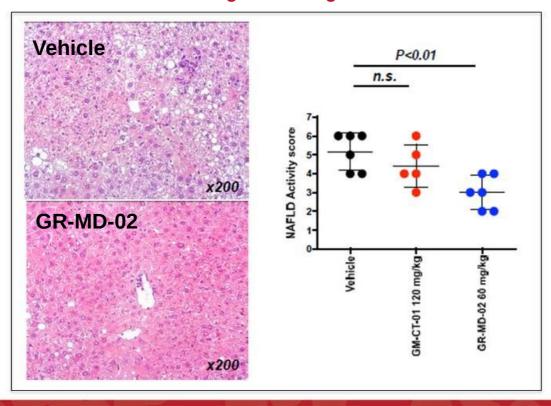




# **GR-MD-02 Markedly Improved NASH (Non-Alcoholic Steatohepatitis) in a Mouse Model**

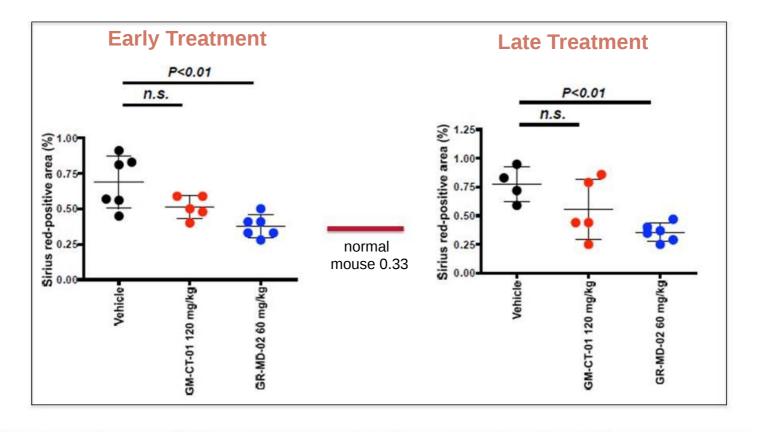


# NASH was induced in mice by rendering them diabetic and feeding them a high fat diet



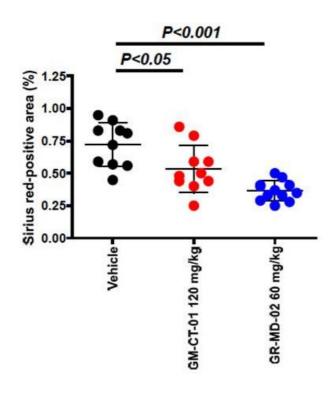
# Galectin G

# **GR-MD-02** Prevented and Completely Reversed Fibrosis in NASH Mouse Model



# Galectin G

## **Early and Late Therapy Compiled Data**

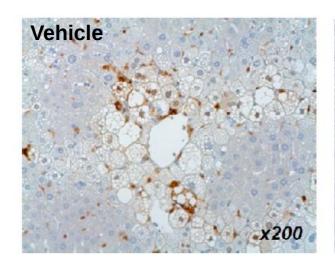


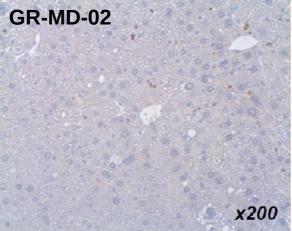
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# **Treatment with GR-MD-02 Markedly Reduces Galectin-3 in NASH Mice**



### **Immunohistochemistry for detection of Galectin-3**

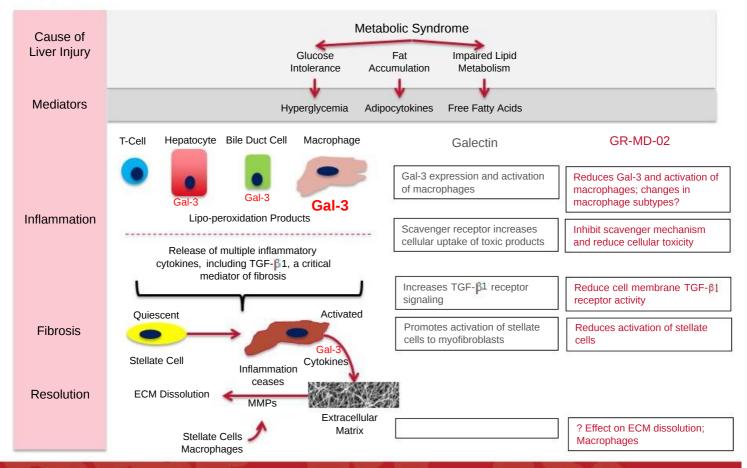




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# Inhibition of Gal-3 May Have Multiple Sites of Action in Therapy of NASH

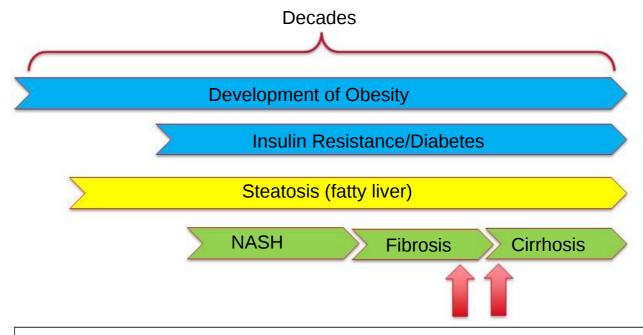




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## Targeting Anti-Galectin Therapy In The Galectin Therapeutics **Progression of NASH**

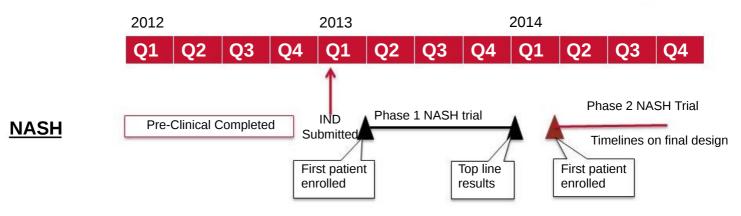




Because of effect on inflammation in NASH and ability to reduce existing fibrosis, our clinical program will target NASH patients with advanced fibrosis

### **NASH Development Program: GR-MD-02**





File Fast Track Designation to be filed; Breakthrough Designation following Phase 1

**Phase 1 Trial:** Patient Inclusion: Biopsy proven NASH with advanced fibrosis

Design: Four weekly IV doses per cohort with escalation to target dose

Primary Endpoint : Patient safety

Secondary Endpoints: Serum biomarkers to assess for pharmacodynamic effect

**Phase 2 Trial:** Patient Inclusion: Biopsy proven NASH with advanced fibrosis

Design: Randomized, controlled, double blinded study with at least six

months of therapy

Primary Endpoint: Liver biopsy evaluated for percent area collagen Secondary Endpoints: Safety; Serum biomarkers, MR-fat and elastography

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# **Examples of Therapeutic Approaches Under Investigation for Therapy of NASH**



General Mechanism	Examples	Comments
Obesity	Lifestyle, dieting	Can be beneficial; not effective in advanced NASH
Treat Diabetes and Insulin Resistance	Pioglitazone	<ul> <li>Failed to achieve significant endpoints in phase 2 and phase 3 clinical trials, but some evidence of effect</li> </ul>
Lipid Metabolism	Aramchol & others	Cholesterol inhibition, no clinical results
Modulate the Immune System	<ul><li>EGS21 (Enzo)</li><li>Pentoxifylline</li></ul>	<ul><li>Abandoned after phase 2 trial</li><li>Non significant phase 3 results</li></ul>
Protease Inhibition	• GS-9450 (Gilead)	Liver toxicity in phase 2: abandoned
Bile salt metabolism	<ul><li>Colesevelam</li><li>Obeticolic acid</li></ul>	<ul> <li>Intestinal bile salt binder, Phase 2 trial failed</li> <li>FXR agonist; Phase 2 coming to conclusion</li> </ul>
Anti-Oxidant / toxin metabolism	<ul><li>Vitamin E</li><li>MND-21 (Mochida)</li><li>Cysteamine</li></ul>	<ul> <li>Effective in NASH score in phase 3, but not fibrosis</li> <li>Omega-3 fatty acid (phase 2 trial)</li> <li>Phase 2 trial in adolescents underway</li> </ul>
Anti-collagen cross- linking	<ul> <li>Lysyl oxidase-like-2 mAb (GS-6624, Gilead)</li> </ul>	<ul> <li>Initiated Phase 2 trials in 2012 in patients with NASH and fibrosis, top line data Q3 2015.</li> </ul>

- GR-MD-02 is well positioned with respect to competition
  - · Most attractive mechanism: multiple sites of action in disease
  - · Independent of hyperglycemia or hyperlipidemia
  - May reverse established fibrosis
  - Low toxicity potential as a carbohydrate with no toxic metabolites

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#### Science of Galectins

- Galectin Function
- Galectin Inhibitors
- Intellectual Property

### Immune Enhancement in Cancer Therapy

- Mechanism of Action
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### Liver Fibrosis

- Mechanism of Action
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### **Key Company Milestones: 12 months**



- Cancer
  - Phase I/II (IIa) metastatic melanoma trial, first patient infused 5/12
  - Five patients currently enrolled; stage 1 data likely available in first half of 2013.
- NASH with Advanced Fibrosis (Fatty Liver Disease)
  - 1/30/13: IND Submitted to FDA
  - 3-4/13: Initiate Phase 1 NASH trial
  - 1/14: Phase 1 NASH trial results
  - Q1 2014: Initiate Phase 2 NASH trial
  - Top line data from Phase 2 trial TBD based on design

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### **Finances & Capitalization**

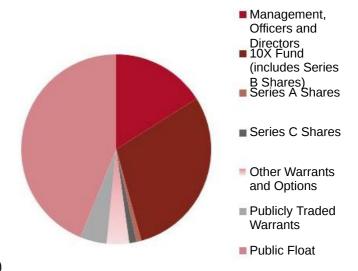


Cash on Hand: \$11.1 million (at 9/30/12) Funded to Jan 2014 (based on current planned R&D)

Common Stock	<b>Shares (9/30/12)</b>
Common Shares	15,966,437
Preferred Series A (converted)	260,430
Preferred: Series B (converted)	2,000,000
Preferred: Series C (converted)	366,680
Warrants: Series B*	5,000,000
Other Warrants**	2,424,241
Options Outstanding***	3,541,630
Total Outstanding	29,559,418

<sup>\*</sup> Exercise Price: \$3.00 (all controlled by 10X Fund)

<sup>\*\*</sup> Weighted Average Exercise Price: \$4.97 \*\*\* Weighted Average Exercise Price: \$5.88



**Total Outstanding** 

## **Investment Highlights**



Proprietary Compounds	<ul> <li>First in class, proprietary compounds that inhibit galectin proteins</li> <li>Complex carbohydrate drugs with highly favorable safety profile</li> <li>GM-CT-01: Enhanced ability of immune cells to kill of cancer cells</li> </ul>
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Large Market Opportunities	Enhancing the ability of immune system to kill cancer cells is synergistic with many current and experimental therapies
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Intellectual Property	Sole ownership, no licenses granted
	<ul> <li>GM-CT-01: Matter and methods granted (expire 2023)</li> </ul>
	<ul> <li>GR-MD-02: Use in liver fibrosis (expire 2026); Matter pending (priority of 2011)</li> </ul>
Experienced Management Team	Management team has collective experiencer in multiple biotech and Pharmaceutical companies and relevant scientific areas

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