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

FORM 8-K

**CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of Report (Date of earliest event reported): September 12, 2014

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

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))
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SECTION 8 – OTHER ITEMS

Item 8.01 Other Items.

On September 12, 2014, Galectin Therapeutics Inc. posted a corporate presentation on its website that contains a summary of the summary of the Company's business, which is attached as Exhibit 99.1.

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	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: September 12, 2014

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



Corporate Presentation

September 12, 2014

NASDAQ: GALT
www.galectintherapeutics.com

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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 2014. 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.

**Drugs Target
Galectin Proteins**

- **Novel complex carbohydrate drugs that block galectin-3 protein, which is involved in multiple disease processes**
- **Robust efficacy in pre-clinical animal models of disease**
- **Lead candidate (GR-MD-02) patent protection (Dec. 2031)**

Organ Fibrosis

- **45% of US deaths associated with fibrotic disease¹**
- **Lead indication: liver fibrosis/cirrhosis due to fatty liver disease (75% of all liver disease in US)²**
- **Potentially applicable to other fibrotic diseases**
- **Phase 1 clinical trial will complete in 2014; Phase 2 clinical trial starts H1 2015**

**Cancer
Immunotherapy**

- **Focus on combination immunotherapy with GR-MD-02**
- **Lead indication is advanced melanoma**
- **Technology applicable to other cancers and immunotherapies**
- **Phase 1B clinical trial in progress**

¹Wynn, TA. Nat Rev Immunol. 2004;4:583-594. doi:10.1038/nri1412

²Younossi, et al. Clin. Gastro. Hepatol. 2011;9:524-530

Molecular Interactions

- Proteins bind to galactose residues in glycoproteins
- Promote interactions between glycoproteins
- 15 protein family; Gal-3 critical target for therapy

Expression & Function

- Gal-3 widely expressed; highest in macrophages
- Modulates cell signaling and immune cell function
- Promote cell-cell and cell-matrix interactions

Role in Disease

- Gal-3 expression increased in areas of inflammation and fibrogenesis
- Knockout of gal-3 gene in mice prevents fibrosis in liver, lung, kidney and heart
- The majority of cancers express high levels of gal-3

Drug Mechanism

- GR-MD-02 is a complex carbohydrate with terminal galactose residues
- Drug binds to gal-3 and disrupts interaction with glycoproteins

Lead Indication in Organ Fibrosis

CIRRHOSIS DUE TO NASH (NON-ALCOHOLIC STEATOHEPATITIS)

NASH Is Epidemic And There Are No Approved Therapies

Estimated prevalence of NASH in US adults^{1, 2}: > 28 million

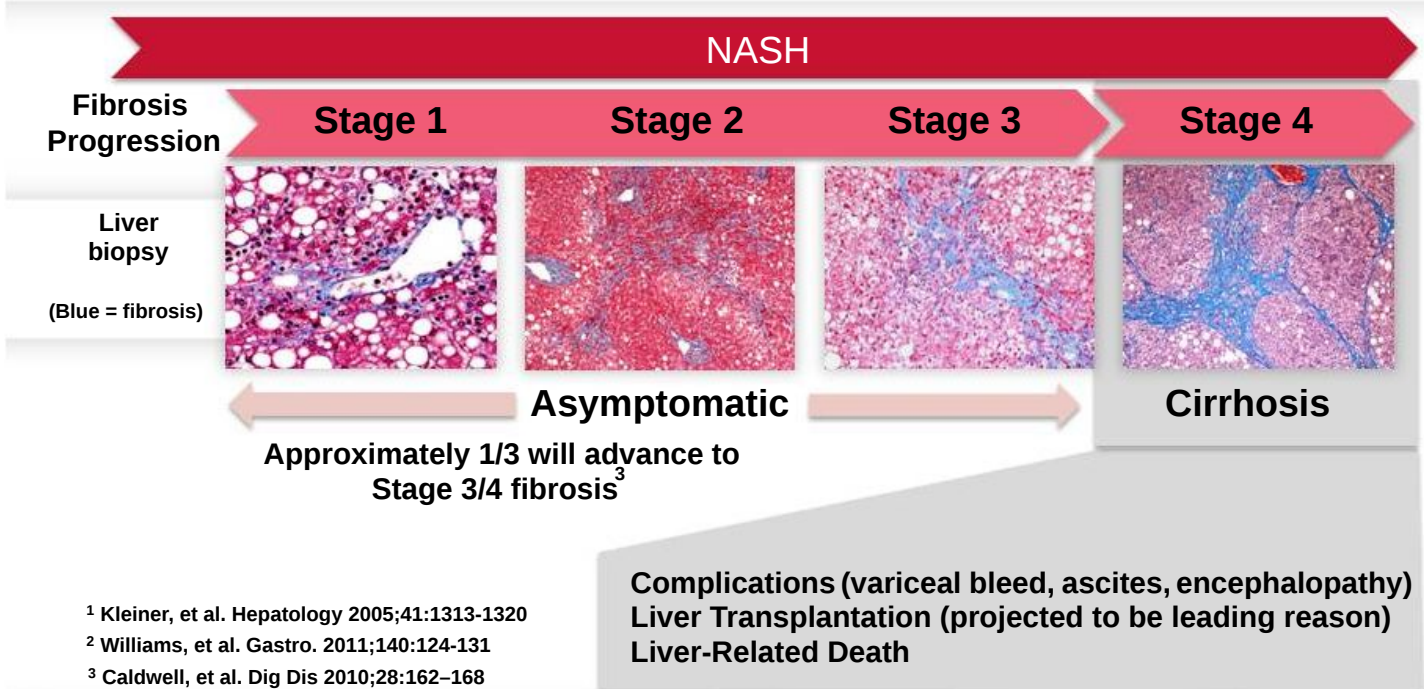


¹ Based on July 2013 US census data for people >20 years old (233,880,752)

² Prospective evaluation of NAFLD and NASH prevalence (Williams, et al. Gastro. 2011;140:124-131)

The End Stage of Fibrosis (Cirrhosis) Is When Patients With NASH Experience Symptoms And Complications

Estimated prevalence of advanced fibrosis^{1,2}: ~ 6 million
Estimated prevalence of cirrhosis¹: ~ 2 million

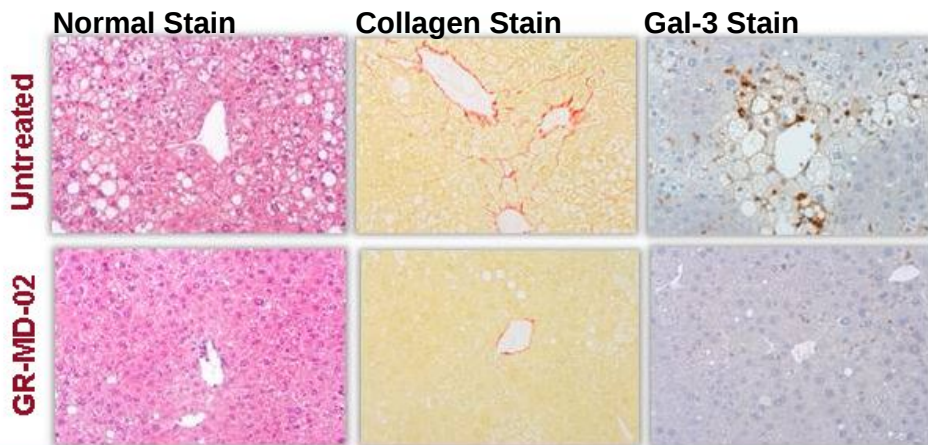


¹ Kleiner, et al. Hepatology 2005;41:1313-1320

² Williams, et al. Gastro. 2011;140:124-131

³ Caldwell, et al. Dig Dis 2010;28:162-168

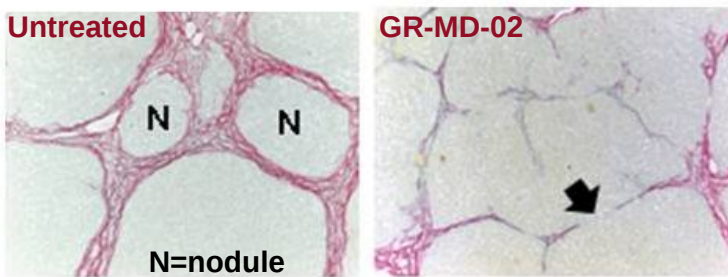
Mouse NASH Model¹



- GR-MD-02 decreases:
 - NASH Activity
 - Fat
 - Inflammation
 - Ballooning
- Collagen (fibrosis)
- Galectin-3 protein

¹Traber, et al. PLOS ONE 2013;8:e83481

Rat Cirrhosis Model²



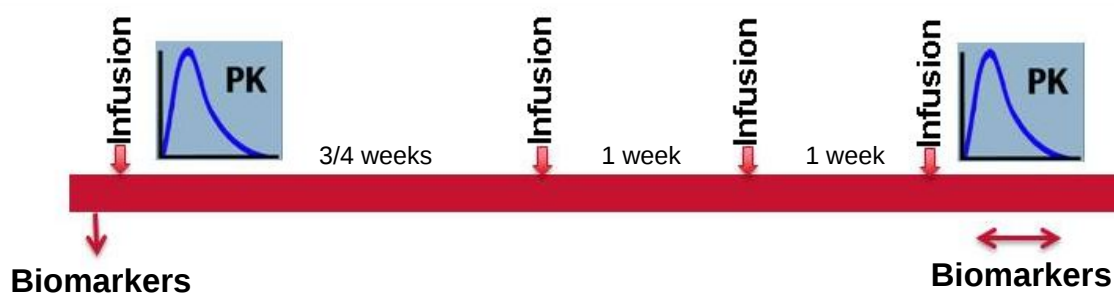
- Cirrhosis induced by toxin and continued with therapy
- Four, once weekly doses of GR-MD-02
- Marked reduction in fibrosis, thinned broken bands (arrow)
- *Cirrhosis reversed*

²Traber, et al. PLOS ONE 2013;8:e75361

- Cirrhosis is late disease that is closer to adverse clinical outcomes; cannot predict which patients with early disease will progress to cirrhosis
- Goal of therapy is to reverse fibrosis and cirrhosis, thereby reducing likelihood of adverse clinical outcomes and transplantation
- Regulatory pathway to approval better defined because potential surrogates of clinical outcomes are more developed for late disease
- This is an appropriate target population because GR-MD-02 treats NASH and reduces existing fibrosis and reverses cirrhosis in pre-clinical models
- Majority of companies developing NASH therapies are targeting early disease, including:
 - Intercept, Genfit, Galmed, Raptor, and others
 - Only company with phase 2 program in NASH cirrhosis is Gilead (anti-LOXL2 monoclonal antibody)

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

- Patient:** Biopsy proven NASH with advanced fibrosis (at least stage 3)
Design: Ascending dose cohort; single and multiple dose
First 2 cohorts enrolled, have at least 8 patients (6 active, 2 placebo);
Third cohort has up to 20 patients total
Doses: 2 mg/kg, 4 mg/kg, and 8 mg/kg in the three cohorts, respectively



- Primary endpoints:** Safety
Pharmacokinetics (PK)
- Secondary endpoints:** Disease-related serum biomarkers to assess for potential treatment effect

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

- GR-MD-02 was safe and well tolerated at doses of 2 mg/kg and 4 mg/kg
- The independent Data Safety Monitoring Board (DSMB) approved moving forward with Cohort 3.
- Pharmacokinetics revealed a proportional increase in total drug exposure with doubling of the dose of GR-MD-02 with no accumulation after four doses.
- A dose of 4 mg/kg provided drug exposure in humans that was roughly equivalent to the lowest therapeutic dose used in NASH animal model.
- The drug half-life in humans is approximately 4 times longer than in mouse at similar doses providing a more extended exposure in humans.

GR-MD-02 was safe, well tolerated, and has predictable pharmacokinetics when administered at up to 4 mg/kg, a dose that correlates with a therapeutic dose in animal model of NASH.

- While the current gold standard for the evaluation of NASH with advanced fibrosis is liver biopsy, it is not appropriate to subject individuals to serial liver biopsies over a short Phase 1 clinical trial. Biopsy assessment of liver fibrosis will be the primary endpoint in the Phase 2 clinical trial to follow this trial.
- To potentially gain some understanding of drug effect and to aid in planning of a Phase 2 clinical trial, exploratory biomarkers were evaluated before and after therapy. (note: these biomarkers are not clinically validated as an acceptable primary endpoint for efficacy in fibrosis treatment).
- While the overall impression of biomarker analysis suggested there may be an effect of the drug, there are differences in biomarker changes depending on the timing of blood sampling with respect to drug dose.
- Since biomarker results are not directly comparable between cohort 1 and cohort 2, a comparison of the effect of timing on biomarkers will be evaluated in cohort 3.

- The dose of GR-MD-02 was increased to 8 mg/kg (320 mg/m²) in the third and final cohort, a dose projected to be well within the therapeutic range as predicted in pre-clinical studies.
- The number of patients in the third cohort will be expanded up to 20 total patients (12 active drug and 8 placebo) which will allow comparison of a larger number of patients.
- Blood biomarker analysis will be conducted at four time points during the study to account for potential sample timing differences following drug infusion.
- Nine (9) patients are currently enrolled in cohort 3 and results are expected in November 2014.

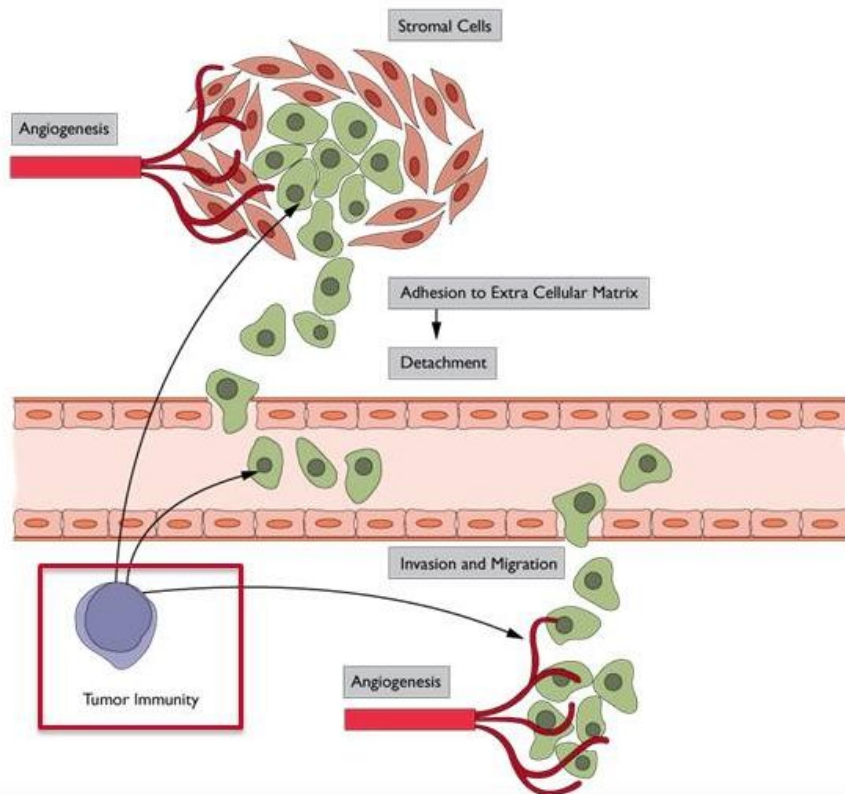
- Planning for phase 2 clinical trials is ongoing
- Phase 2 trial will be initiated in H1 2015; details of the trial(s) will be announced when planning is complete
- The results of the first and second cohort suggest that 2 mg/kg and 4 mg/kg are safe and well-tolerated doses, and we are now testing 8 mg/kg.
- The doses for evaluation in Phase 2 will be chosen using the correlation of therapeutic doses in pre-clinical animal studies and blood levels of GR-MD-02 determined in the Phase 1 trial. Biomarkers in Phase 1 study are not integral to choosing Phase 2 doses. 8 mg/kg dose is expected to be well within therapeutic dose range.
- Patient population will have cirrhosis due to NASH
- Study endpoints and other particulars of clinical trials, including duration, are under discussion with the FDA

- First liver fibrosis indication: NASH with cirrhosis, a major unmet medical need
- Current Phase 1 trial results shows safety of four doses of 2 mg/kg and 4 mg/kg.
- Controlled phase 2 clinical trial program to follow completion of phase 1 trial.
 - The current results of the Phase 1 trial this defines at least two potential dose levels for phase 2 clinical trials
- Other Organ Fibrosis
 - 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

Lead Indication in Cancer Immunotherapy

ADVANCED MELANOMA

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

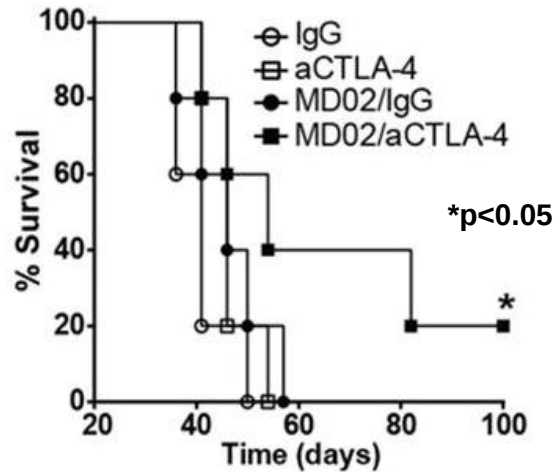
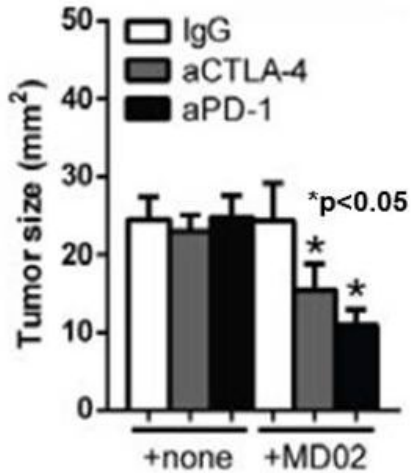


- Tumor cell invasion: extracellular matrix adhesion & detachment
- Metastasis: cell invasion and migration
- Angiogenesis
- **Tumor immunity** has recently been shown to be critically affected by galectins

- Focus on cancer immunotherapy based on the hypothesis that galectin inhibitors will enhance efficacy of immunotherapies
 - Many cancers secrete large amounts of galectins & have multiple roles in tumor pathogenesis – importantly on tumor immunity
- Metastatic melanoma is initial cancer indication
 - In US 76,000 new diagnoses and 9,100 deaths annually
 - Even with newly approved drugs, still a substantial unmet medical need
- Critical collaboration established
 - Robert W. Franz Cancer Research Center, Earle A. Chiles Research Institute (EACRI) Providence-Portland Medical Center, Portland Oregon
 - Demonstrated clinical trial expertise in melanoma
 - Tumor immunology basic science research
 - Ability to conduct clinical trials and assist in funding

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

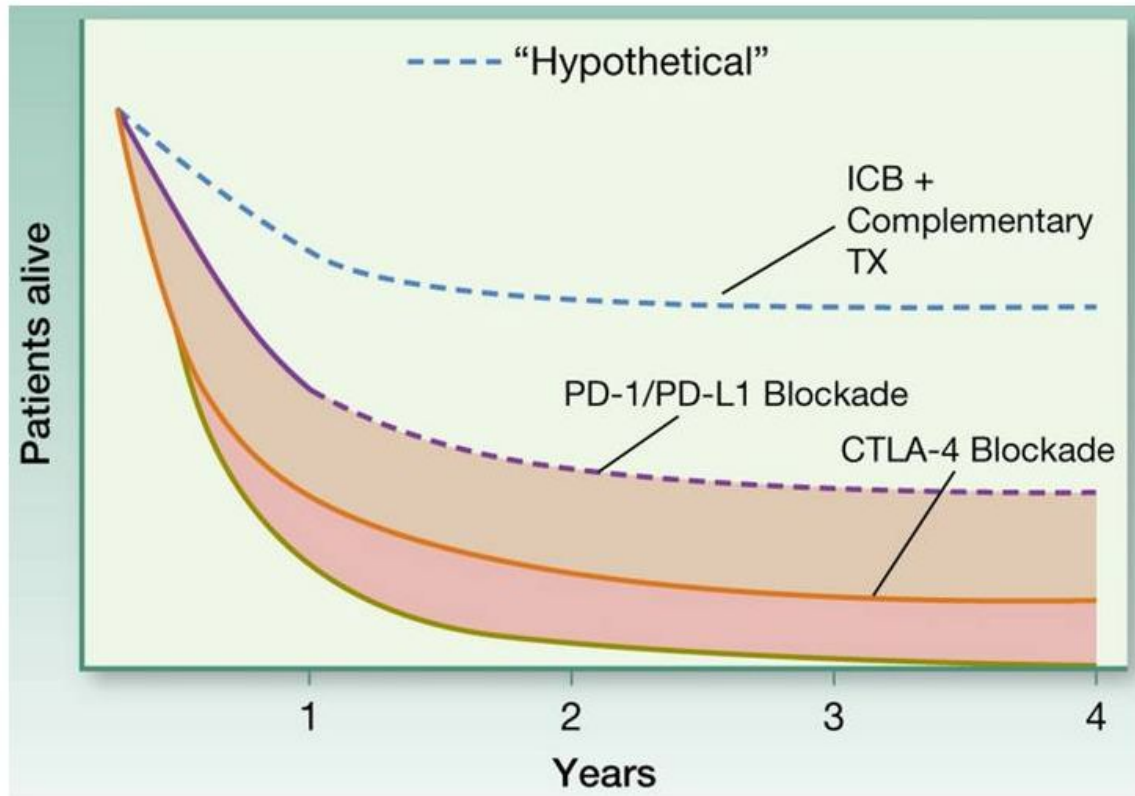
These studies on TC-1 prostate cancer cells (also effective in breast cancer, melanoma, and sarcoma)



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

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



© 2013 American Association for Cancer Research

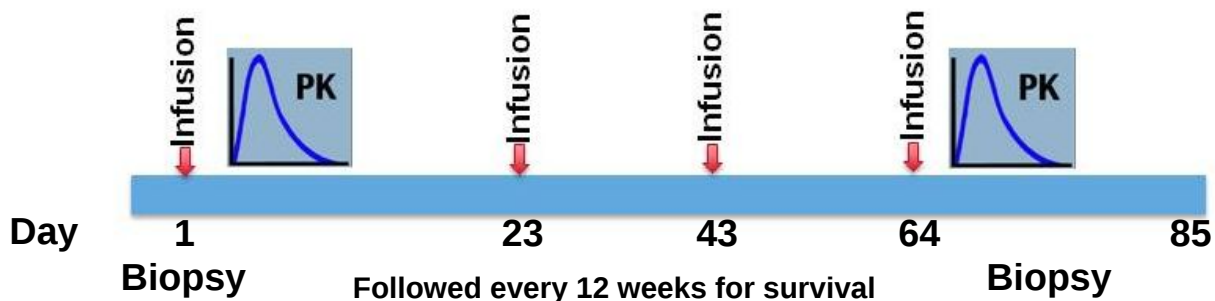
ICB = Immune Checkpoint Blockade

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



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

- 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

Compound	Program	Milestone	Timing
GR-MD-02	NASH Cirrhosis	Complete Phase 1 Trial	End 2014
		Start Phase 2 Trial	H1 2015
		Phase 2 Results	TBD
GR-MD-02	Melanoma	Complete Phase 1B Trial	End 2015

- **Peter G. Traber, MD – CEO & CMO**
 - President & CEO of Baylor College of Medicine
 - Sr. VP Clinical Development and CMO – GlaxoSmithKline plc
 - Chairman & CEO of TerraSep, LLC
 - President & CEO of University of Pennsylvania Health System,
 - Chair of Internal Medicine and Chief of Gastroenterology, University of Pennsylvania School of Medicine
- **James Czirr, Exec. Chairman**
 - Cofounder of 10X Fund and Managing Member
 - Cofounder of GalectinTherapeutics
 - CEO of Minerva Biotechnologies Corp.
- **Harold H. Shlevin, PhD – COO & Corporate Secretary**
 - Principle/Manager of Bioscience Commercialization – Georgia Institute of Technology
 - VP Operations & Commercial Development – Altea Therapeutics Inc.
 - President & CEO – Tikvah Therapeutics
 - President & CEO – Solvay Pharmaceuticals
 - Cofounder and Sr VP – Ciba Vision Ophthalmics
- **Jack W. Callicutt – CFO & Corporate Treasurer**
 - CFO of Reach Health, Inc.
 - CFO of Vystar Corporation
 - CFO of IVOX, Inc., Tikvah Therapeutics & Corautus Genetics
 - Deloitte

- **J. Rex Horton – Executive Director of Regulatory Affairs and Quality Assurance**
 - Director of Regulatory Affairs – Chelsea Therapeutics
 - Director of Regulatory Affairs – Solvay Pharmaceuticals, Inc.
- **Eliezer Zomer, PhD – Manufacturing and Product Development Head**
 - Executive VP of Manufacturing & Product Development – Galectin Therapeutics
 - Founder of Alicon Biological Control
 - VP of Product Development - Safe Sciences, Inc.
 - VP of R&D – Charm Sciences, Inc.
- **Elena Chekova, PhD – Program Manager**
 - Director of Business Development & Project Management – Pro-Pharmaceuticals
 - Founder and CEO - Biotine Consulting
 - VP of Business Development – Chiral Quest
 - Analyst – McKinsey & Bertelsmann AG

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	\$5.81 \$4.28 - \$19.11
Shares Outstanding	22 million
Daily Volume (3-month average)	733,000 shares
Market Capitalization	\$128 million
Debt	\$0
Cash & Equivalents (June 30, 2014)	\$34.4 million
Estimated Spending in 2014	\$14 million