
**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): July 29, 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 July 29, 2014, Galectin Therapeutics Inc. posted a presentation on its website that contains a summary of the results of the second cohort of patients in the Phase 1 clinical trial, which is attached as Exhibit 99.1, and issued the attached press release.

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 Presentation on Phase 1 Clinical Trial: Results of Second Cohort

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: July 29, 2014

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



GT-020 Phase 1 Clinical Trial: Results of Second Cohort

July 29, 2014

NASDAQ: GALT
www.galectintherapeutics.com

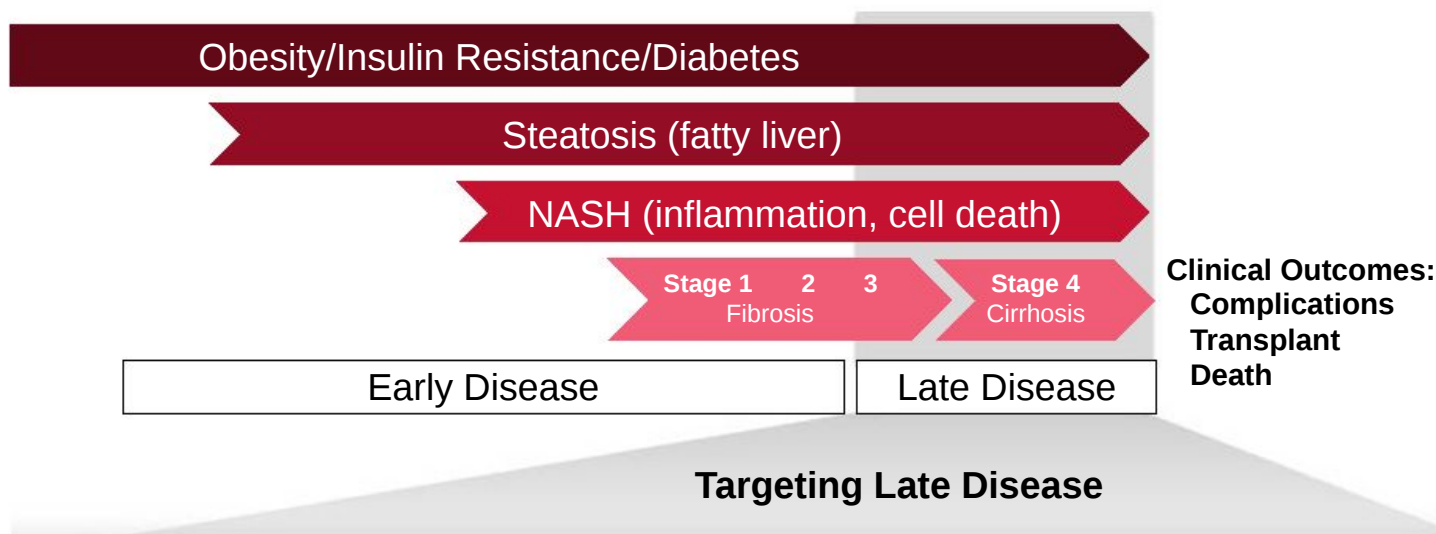
© 2014 Galectin Therapeutics inc.

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 GR-MD-02 and expectations regarding the clinical trial, including the future enrollment of patients and the timing of results from the third cohort. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others, that results from the first and second cohorts of Phase 1 may differ materially from future results, and there is no guarantee that the current clinical trial will lead to positive outcomes or that GR-MD-02 will ever be approved by the FDA. We may experience delays in the current trial, 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. 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.

Clinical Focus		Stage of Development				
Drug	Indication	Discovery	Pre-clinical	Phase 1	Phase 2	Phase 3
Fibrosis						
GR-MD-02	Fatty liver disease with advanced fibrosis	▶			Report on second cohort of Phase 1 Clinical Trial	
	Lung fibrosis	▶				
	Kidney fibrosis	▶				
	Cardiac fibrosis	▶				
Cancer Immunotherapy						
GR-MD-02	Melanoma	▶				
Galectin-3 Inhibitors						
GR-MD-03	Subcutaneous	▶				
GR-MD-04	Oral	▶				
GS compound*	Oral	▶				

*Galectin Sciences, LLC

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

Summary of Findings: **Primary Endpoints Were Met In Cohort 2**

- GR-MD-02 was safe and well tolerated at dose of 4 mg/kg (80/160 mg/m²), similar to the findings of the 2 mg/kg dose in the first cohort.
- 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 4 mg/kg, a dose that correlates with a therapeutic dose in animal model of NASH.

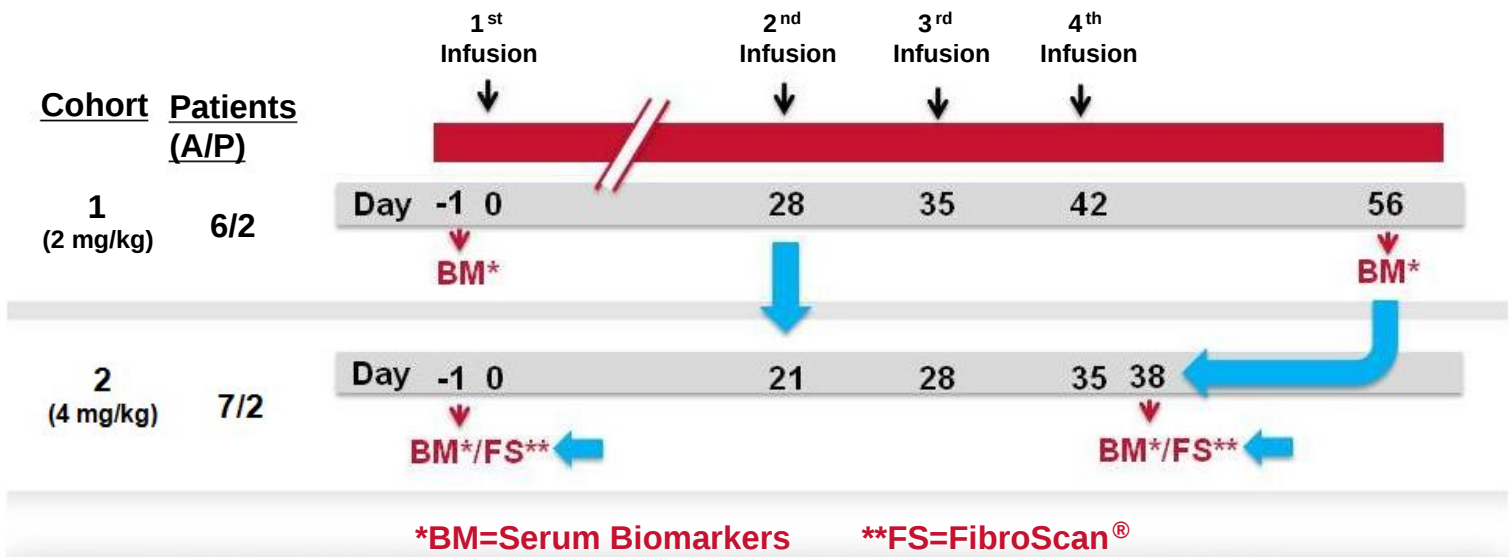
Summary of Findings: Exploratory Secondary Endpoints

- 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.
- While the overall impression of biomarker analysis suggests 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.

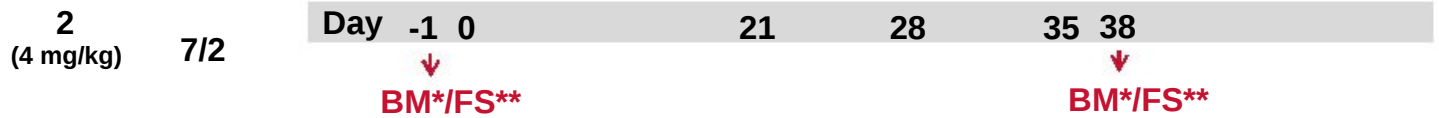
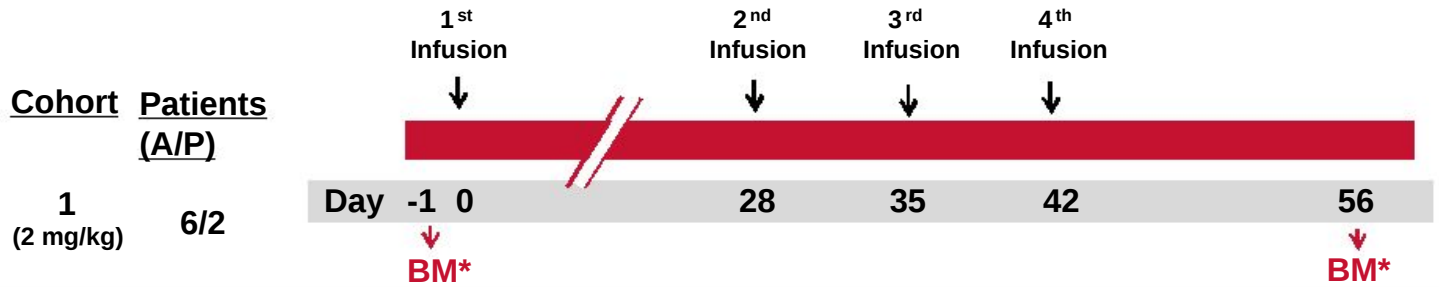
Phase 1 Clinical Trial Of GR-MD-02 In NASH With Advanced Fibrosis

Changes in Cohort 2 Protocol:

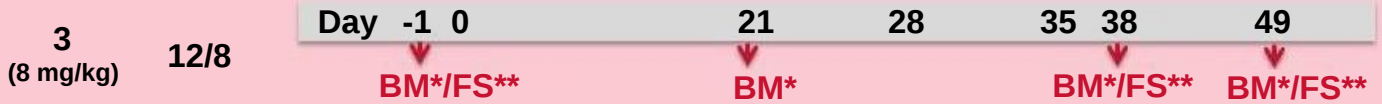
- Based on the pharmacokinetics of the drug determined from the first cohort, the protocol was shortened by 18 days:
 - The second dose was given on day 21 instead of day 28
 - The timing of serum biomarker evaluations were shortened from 14 to 3 days after the fourth and final infusion
- FibroScan evaluation was added to obtain experience with the method



Cohort 3 Plan For Phase 1 Clinical Trial Of GR-MD-02 In NASH With Advanced Fibrosis



Cohort 3 incorporates four time points for comparative evaluation



*BM=Serum Biomarkers **FS=FibroScan®

	Cohort 1 (2 mg/kg)	Cohort 2 (4 mg/kg)
Patients Enrolled	8	10
Male/Female	2/6	6/4
Age Range (Mean)	40-64 (54)	34-69 (51.5)
BMI (Mean)	39	39.6
Diabetic Patients	6	4
Fibrosis Stage	Stage 3: 7 patients Stage 4: 1 patient	Stage 3: 6 patients Stage 3/4: 4 patients

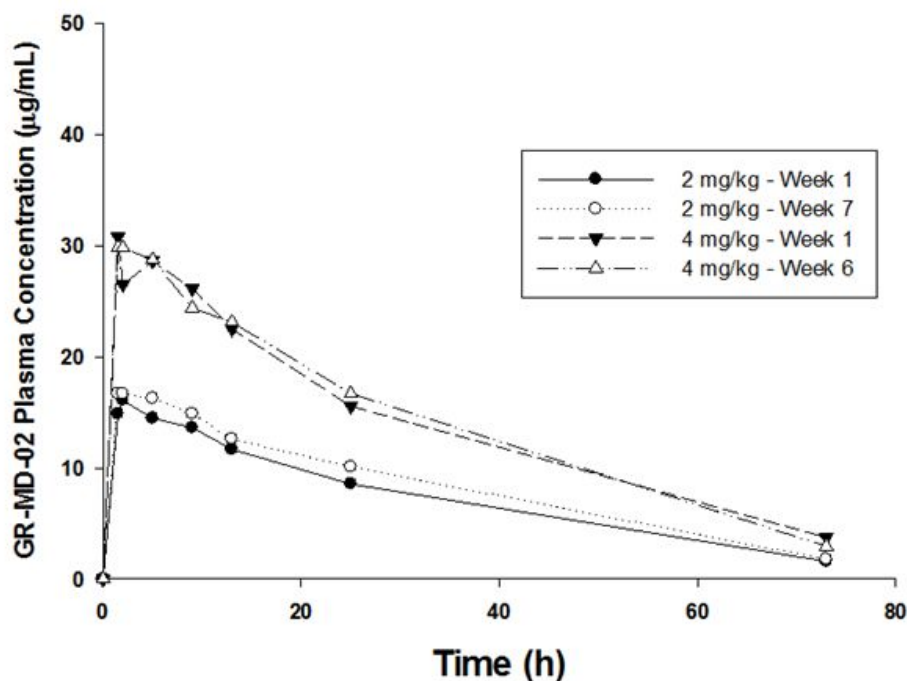
Patient Safety: GR-MD-02 At Doses Of 2 And 4 mg/kg Were Safe And Well Tolerated

	Cohort 1 (2 mg/kg)	Cohort 2 (4 mg/kg)
Completed Protocol	8	9 (One patient withdrawn because of baseline (pre-drug) borderline QTc interval prolongation)
Serious Adverse Events	0	0
Treatment Emergent AE's scored as probably related to drug	0	0
Treatment Emergent AE's scored as possibly related to drug	0	<p><u>Patient 1</u>: transient yellow toenails and left ankle edema which were mild (grade 1) and of <1 day duration. Intermittent PRI prolongation unrelated to infusion (grade 1).</p> <p><u>Patient 2</u>: right swollen wrist and painful right ankle which were mild (grade 1) and of <1 day duration.</p>

Independent Data Safety Monitoring Board Approved Proceeding to Cohort 3

Mean GR-MD-02 Plasma Concentration-Time Profiles After First And Fourth Doses In Cohorts 1 And 2

There was a proportional increase in total drug exposure with doubling of the dose of GR-MD-02 with no accumulation after four doses



2 mg/kg (1st/4th dose)

$C_{max} = 16.3/17.7 \mu\text{g/mL}$
 $T_{1/2} = 19.9/20.5 \text{ h}$
 $AUC = 573/645 \text{ h}\cdot\mu\text{g/mL}$
 $V_{ss} = 5.2/4.7 \text{ L}$
Variability $\leq 15/24\%$

4 mg/kg (1st/4th dose)

$C_{max} = 30/31 \mu\text{g/mL}$
 $T_{1/2} = 19.8/19.5 \text{ h}$
 $AUC = 1039/1075 \text{ h}\cdot\mu\text{g/mL}$
 $V_{ss} = 6.4/6.0 \text{ L}$
Variability $\leq 25/35\%$

Fibrosis 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)

Inflammatory Cytokines

Key cytokines

- TGF- β
- IL-6
- IL-8
- TNF- α

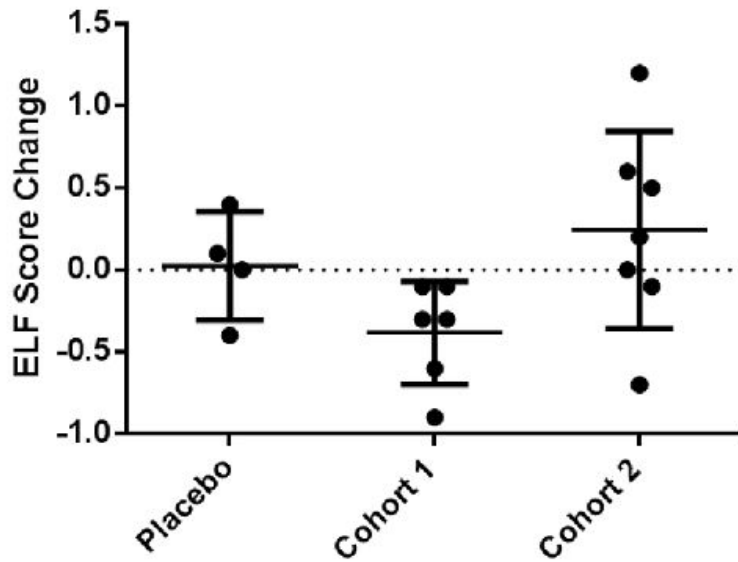
Cellular Injury

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

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

- ELF scores tended to be reduced in the patients in the first cohort
- ELF scores in the second cohort were more dispersed and tended to increase over placebo

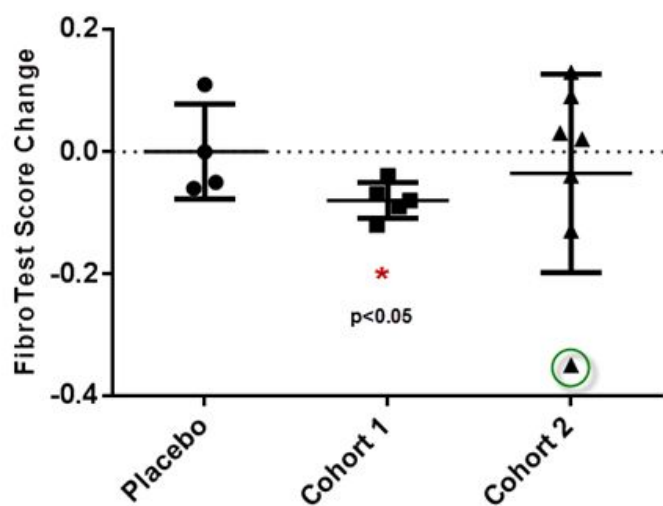


Note: Placebo patients from both cohorts were included in analysis

Interpretation:

- There is an indication of an effect in both cohorts, while not statistically significant.
- However, there are differences in the biomarker data between the cohorts, potentially due to sampling dates.
- Cohort 1 last sample was taken 14 days after the last infusion, after the drug has been eliminated.
- Cohort 2 last sample was taken 3 days after last infusion, a time when drug is still present.
- Since ELF is a marker of fibrotic tissue turnover, there may be increased turnover at 3 days which has reached a new lower state at 14 days after last infusion.

- FibroTest scores were significantly reduced in the patients in the first cohort
- Scores were more variable in the second cohort and change did not reach significance
- The patient with the greatest reduction in score (green circle) was also the patient with the highest starting score (0.83; range of test is 0 to 1.0)

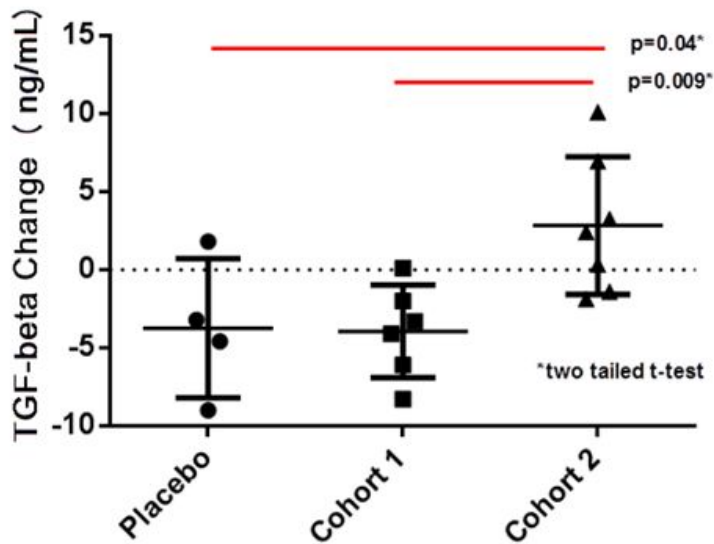


Note: Placebo patients from both cohorts were included in analysis

Interpretation:

- Similar to ELF scores, the differences in the biomarker data between the cohorts is possibly due to differences in sampling dates.
- Cohort 1 last sample was taken 14 days after the last infusion, after the drug has been eliminated.
- Cohort 2 last sample was taken 3 days after last infusion, a time when drug is still present.
- The greater dispersion of scores in cohort 2 may also indicate a fluctuation in the changes in fibrous tissue.

- TGF- β levels in the patients in the first cohort were unchanged from placebo
- TGF- β levels increased in patients in the second cohort and the change was significantly increased over placebo and first cohort patients



Note: Placebo patients from both cohorts were included in analysis

Interpretation:

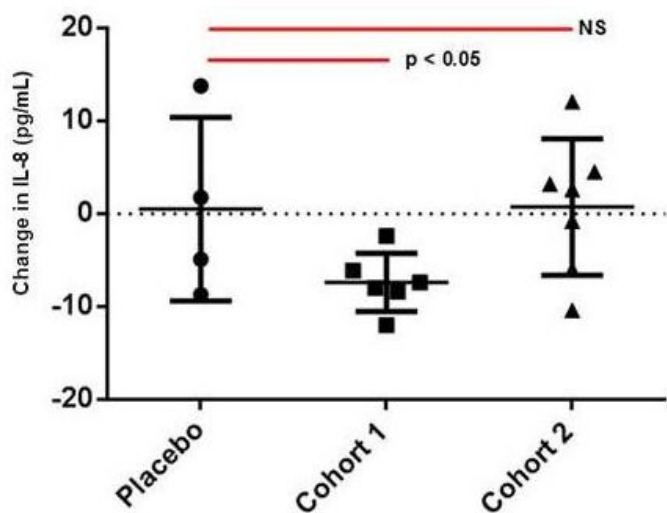
- These data provide another indication that there are differences in the biomarker data between the cohorts, potentially due to sampling dates.
- Since it is not clear whether circulating TGF- β levels are active, it is difficult to assign a biological meaning to these data.
- However, the data do indicate that there is some activity at 3 days following the infusion that is not identified at 14 days.

Interleukin-8 Levels In GR-MD-02 Treated Patients In Both Cohorts

	Cohort 1*	Cohort 2*	NAFLD**	Obese Controls**
IL-8 pg/mL	28.0 ± 8.6	22 ± 9.7	24.1 ± 38.5	7.8 ± 3.6

*Baseline levels

**Jarrar, et al. Aliment. Pharmacol. Ther. 2007



Note: Placebo patients from both cohorts were included in analysis

Interpretation:

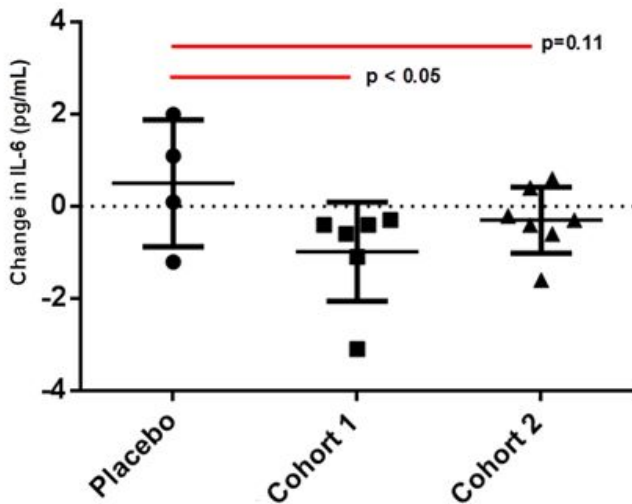
- Baseline IL-8 levels were elevated in both cohorts.
- IL-8 levels were significantly reduced in cohort 1 but not changed in cohort 2.
- These data, along with the TGF- β data suggest that the cytokine milieu is different when sampled at 3 days versus 14 days following final infusion.

Interleukin-6 Levels In GR-MD-02 Treated Patients In Both Cohorts

	Cohort 1*	Cohort 2*	NAFLD**	Obese Controls**
IL-6 pg/mL	6.1 ± 2.5	5.3 ± 1.3	23.1±72.9	7.6±6.3

*Baseline levels

**Jarrar, et al. Aliment. Pharmacol. Ther. 2007



Note: Placebo patients from both cohorts were included in analysis

Interpretation:

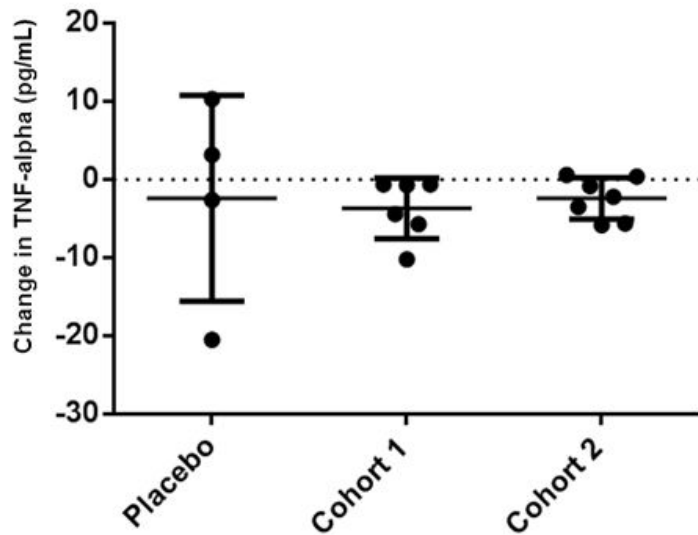
- Baseline IL-6 levels were not elevated in either cohort.
- IL-6 levels were significantly reduced in cohort 1 but not changed in cohort 2.
- These data, along with the TGF- β data suggest that the cytokine milieu is different when sampled at 3 days versus 14 days following final infusion
- Moreover, IL-6 may not be a good marker since the levels are not increased over obese controls.

TNF- α Levels In GR-MD-02 Treated Patients In Both Cohorts

	Cohort 1*	Cohort 2*	NAFLD**	Obese Controls**
TNF- α pg/mL	23 \pm 5.8	20.6 \pm 8.3	6.0 \pm 16.6	1.9 \pm 0.3

*Baseline levels

**Jarrar, et al. Aliment. Pharmacol. Ther. 2007



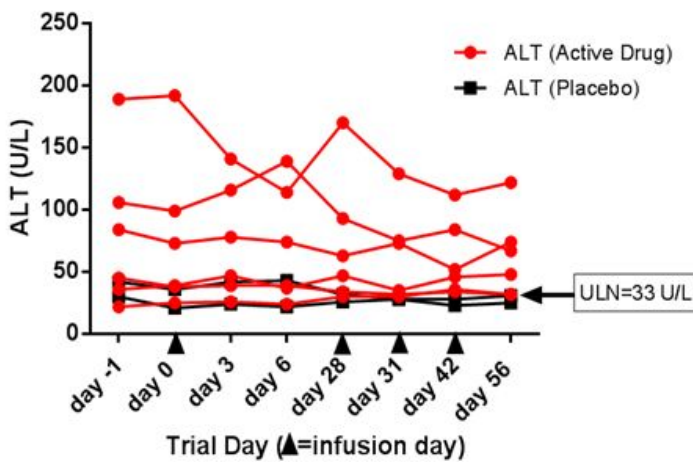
Note: Placebo patients from both cohorts were included in analysis

Interpretation:

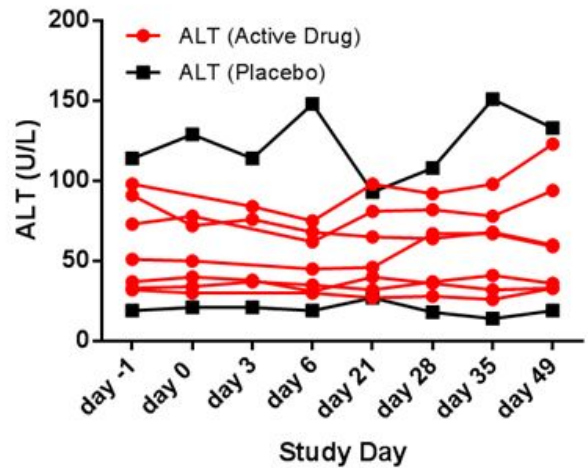
- Baseline TNF- α levels were elevated in both cohorts.
- TNF- α levels were previously reported to be significantly reduced in cohort 1, but this did not hold up with the additional two placebo patients included in the analysis.
- While the variation in placebo values is large, these data suggest that there are not changes in TNF- α levels regardless of the timing of samples after infusion.

- Both cohorts had a broad range of baseline ALT levels, which are known not to correlate with degree of fibrosis or activity of NASH.
- The first cohort had two patients with ALT over 100 which improved with therapy.
- There were no patients with ALT over 100 in second cohort and no decreases were seen with therapy.

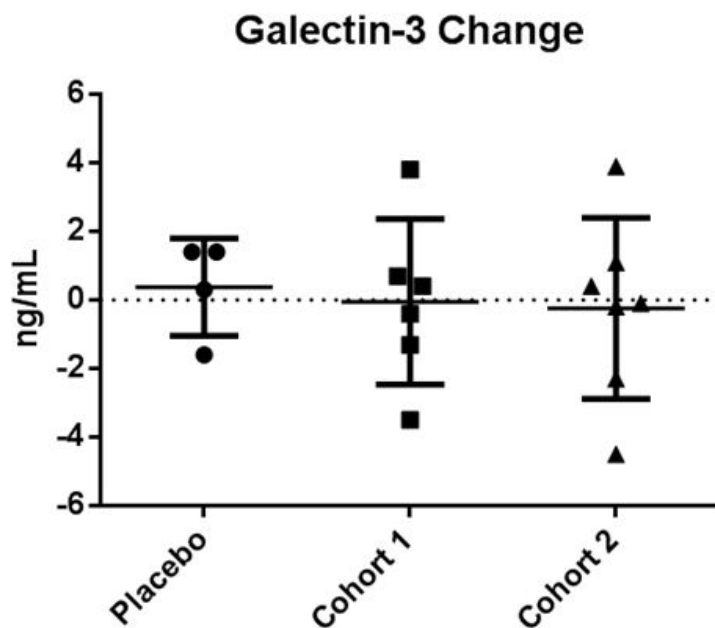
Cohort 1 ALT Levels



Cohort 2 ALT Levels



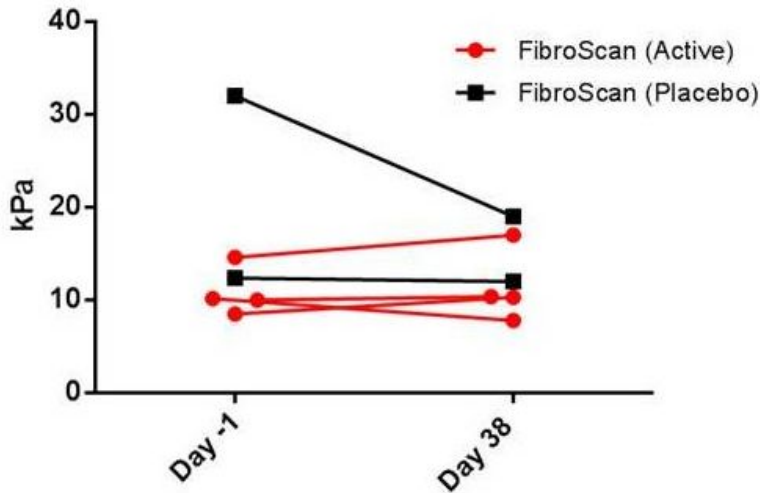
Patients Had A Normal Range Of Blood Galectin-3 Levels At Baseline And No Change With Treatment



- Blood levels of Galectin-3 do not correlate with liver levels in animal models of NASH
- Blood levels of Galectin-3 do not correlate with severity of disease in human NASH

- FibroScan® is an ultrasound-based measure of shear wave speed in the liver which correlates with liver stiffness.
- Approved by FDA as an aid to clinical management of patients with liver disease. Not approved for following changes in liver fibrosis.
- Test was done primarily to gain experience with the test prior to use in Phase 2 and was performed at sites where available (6 patients were evaluated at days -1 and 38.)

Second Cohort FibroScans



All patients had FibroScan values above the values predictive of advanced, stage 3 fibrosis (7.9 kPa).

There were no consistent changes with therapy.

The large difference in one placebo patient suggests more experience is required with this method in longitudinal studies.

Summary of Findings: Primary Endpoints Were Met In Cohort 2

- GR-MD-02 was safe and well tolerated at dose of 4 mg/kg (80/160 mg/m²), similar to the findings of the 2 mg/kg dose in the first cohort.
- 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 models.
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- 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.
- While the overall impression of biomarker analysis suggests 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 will be 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 to 20 total patients (12 active drug and 8 placebo) which will allow comparison of 12 patients in each group in analysis of the data (including 4 placebos from previous cohorts).
- Blood biomarker analysis will be conducted at four time points during the study to account for potential sample timing differences following drug infusion.
- Patient screening and enrollment for cohort 3 has begun and results are expected in November 2014.
- Planning for phase 2 clinical trials is ongoing. The results of the first and second cohort suggest that 2 and 4 mg/kg are safe and well-tolerated doses, defining a dose range for phase 2 clinical trials.