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): January 13, 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)

Dere-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

Dere-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

SECTION 7 – REGULATION FD

Item 7.01 Regulation FD Disclosure.

On January 13, 2014, Galectin Therapeutics Inc. (the "Company) posted a corporate presentation on its website that contains a summary of the Company's business. The corporate presentation, which is being furnished and not filed, and is attached hereto as Exhibit 99.1.

The information in this report is being furnished pursuant to this Item 7.01 and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 (the "Exchange Act") or otherwise subject to the liabilities of that section, and it shall not be deemed incorporated by reference in any filing under the Securities Act of 1933 or under the Exchange Act, whether made before or after the date hereof, except as expressly set forth by specific reference in such filing to this report.

SECTION 9 – FINANCIAL STATEMENTS AND EXHIBITS

Item 9.01 Financial Statements and Exhibits.

(a) Financial Statements of Businesses Acquired.

Not applicable.

(b) Pro Forma Financial Information.

Not applicable.

(c) Shell Company Transactions.

Not applicable.

(d) Exhibits.

Exhibit Number Description

99.1

Corporate Presentation

SIGNATURES

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

Date: January 13, 2014

Galectin Therapeutics Inc.

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

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Corporate Presentation

January 2014

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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 and spending, 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 primary focus
- Cancer Immunotherapy
- Summary

What We Do



- Clinical stage biopharmaceutical company targeting fibrotic diseases and cancer with novel compounds that inhibit galectin proteins (galectin-3)
 - Galectin proteins are important in the development and promotion of many inflammatory, fibrotic and neoplastic diseases
- Currently in clinical trials in liver fibrosis and cancer
 - Liver fibrosis indication: NASH (Fatty Liver Disease) with advanced liver fibrosis
 - Cancer immunotherapy indication: Metastatic melanoma





Key Facts – As of January 9, 2014

Trading Symbol	Nasdaq: GALT
Corporate Headquarters	Norcross, GA (suburb of Atlanta)
Stock Price; 52 Week Range	\$13.49 \$1.99 - \$14.20
Shares Outstanding	20.7 million
Daily Volume (50 day average)	332,583 shares
Market Capitalization	\$279 million
Debt	\$0
Cash & Equivalents	\$32.3 million
Estimated Spending in 2014	\$14.5 million
Fiscal Year Ends	December 31
Accounting Firm	McGladrey LLP

Experienced Leadership Team



James Czirr, Executive Chairman • Manager and general partner of 10X Fund, L.P., Co-Founder, Pro-Pharmaceuticals, CEO, Minerva Biotechnologies Corporation Peter G, Traber, MD President, CEO, CMO • Over 28 years experience in biomedicine and pharmaceutical industries in research and development, clinical medicine and business development. GlaxoSmithKline (CMO), Un of Pennsylvania (CEO, Chief of GI, Chairman of Medicine), Baylor College of Medicine (CEO) Harold H. Shlevin, PhD COO & Corporate Secretary • Over 28 years of senior experience in the development and commercialization of pharmaceuticals and business development including mergers and acquisitions. Jack W. Callicutt CFO • Over 24 years in accounting and finance with life science and technology companies with significant experience in negotiating and closing financing transactions. Eliezer Zomer, PhD Pharmaceutical Development • Over 30 years experience in biotechnology engineering and regulatory in pharmaceuticals and diagnostics. J. Rex Horton Executive Director, Regulatory Affairs and Quality Assurance • Over 24 years of experience working in the biotech and life sciences industries, regulatory affairs and manufacturing. • Director Regulatory Affairs at Solvay Pharmaceuticals and Chelsea Therapeutics, Georgia Institute of Technology.		
Peter G. Traber, MD President, CEO, CMO Over 28 years experience in biomedicine and pharmaceutical industries in research and development, clinical medicine and business development. GlaxoSmithKline (CMO), Un of Pennsylvania (CEO, Chief of GI, Chairman of Medicine), Baylor College of Medicine (CEO) Harold H. Shlevin, PhD COS & Corporate Secretary Over 32 years of senior experience in the development and commercialization of pharmaceuticals and business development including mergers and acquisitions. Solvay Pharmaceuticals (CEO), CIBA Vision Ophthalmics (nka Novartis Vision) (SVP & corfounder), Tikvah Therapeutics (Founder, CEO), Board of Directors, Cardiome Pharma Corp. (NASDAQ: CRME) Jack W. Callicutt CFO Over 24 years in accounting and finance with life science and technology companies with significant experience in negotiating and closing financing transactions. CFO Reach Health, CFO of Vystar Corporation, CFO Corautus Genetics, Deloitte Eliezer Zomer, PhD Pharmaceutical Development Over 30 years experience in biotechnology engineering and regulatory in pharmaceuticals and diagnostics. Koor Biotechnologies, Charm Sciences, Glycogenesis , HU Medical School (Jerusalem), Harvard University J. Rex Horton Executive Director, Regulatory Affairs and Quality Assurance Over 24 years of experience working in the biotech and life sciences industries, regulatory affairs and manufacturing. Director Regulatory Affairs at Solvay Pharmaceuti	James Czirr, Executive Chairman	 Manager and general partner of 10X Fund, L.P., Co-Founder, Pro-Pharmaceuticals, CEO, Minerva Biotechnologies Corporation
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© 2014 Galectin Therapeutics	Regulatory Affairs and Quality Assurance	 Director Regulatory Affairs at Solvay Pharmaceuticals and Chelsea Therapeutics, Georgia Institute of Technology.
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Agenda



- The Company and Key Team Members
- Galectin Inhibitors
- Fibrosis Program our key focus
- Cancer Immunotherapy
- Summary



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, but highest in immune cells (macrophages)
 - 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-rhamnogalaturonate (GR) class: GR-MD-02
- Discovery pipeline
 - Derivatives of GM and GR for subcutaneous administration
 - Synthetic carbohydrates
 - Small organic molecule galectin inhibitors

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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)
 - Multiple method of use patents pending, but all uses covered by composition claims.
- GR-MD Class (current NCE is GR-MD-02)
 - Composition of matter patent pending (priority 2011)
 - Method of use in liver fibrosis patent issued (expires 2026)
 - Method of use in NASH patent issued (expires 2031)
 - Method of use for Cancer Immunotherapy pending (priority 2011)
 - Method of use in Diabetic nephropathy pending (priority 2011)
 - Method of use in lung fibrosis pending (priority 2012)

Sole ownership of compounds in development

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Fundamental Science on Target is Strong: 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

Mice treated with liver toxin to induce fibrosis

Red stain is collagen, the principal component of fibrotic tissue



Normal mice develop fibrosis whereas those without gal-3 do not

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Henderson, et al 2006

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

Company's Galectin Inhibitors Reverse Cirrhosis in Rat Model



Broad bands of

- 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



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



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





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: Galectin GR-MD-02 Reduces Fibrosis in Diabetic Mouse





Arrows show areas of interstitial fibrosis

Reduction in interstitial fibrosis

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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 (nonalcoholic steatohepatitis, or NASH).
 - Prevalence of NASH in U.S. is between 9-15 million people
 - Over 25% will develop cirrhosis; estimated prevalence of patients with advanced fibrosis is 6 million.
 - NASH cirrhosis projected to be primary reason for liver transplant

NASH with Fibrosis Development Program: Accomplishments



- New strategic focus: 2011 Annual Stockholder Meeting
- 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 concluded that we may proceed with human clinical studies.
- Fast Tract Designation received in August 2013
- Phase 1 trial: First cohort enrollment completed. Data to be reported around end of first quarter 2014.

Development Program: Targeting Therapy In The Progression of NASH



- Late disease much closer to clinical outcomes
- Because of effect on inflammation in NASH and ability to reduce existing fibrosis, our clinical program targets NASH patients with late disease

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Phase 1 Clinical Trial



- <u>Patient inclusion</u>: Biopsy proven NASH with advanced fibrosis (stage 3)
- <u>Design</u>: Each cohort has 8 patients (6 active, 2 placebo) Dose escalation combining single and multiple dose in design. Single IV dose followed by three additional weekly doses in each cohort. At least three dose escalation cohorts guided by PK. Option to add additional cohorts and extension of 10 additional patients to last cohort.
- <u>Dose:</u> Starting dose of 2 mg/kg which is within the presumptive therapeutic range; next two cohort doses 4 mg/kg and 8 mg/kg.
- Primary endpoints:
 - Patient safety
 - Pharmacokinetics
- Secondary endpoints:
 - Exploratory serum biomarkers to assess for potential treatment effect including markers for inflammation, cell death, and fibrogenesis. Considering adding FibroScan and HepQuant to next cohorts
- Timing of expected data from each cohort
 - Cohort 1: Mar-Apr 2014
 - Cohort 2: Jul-Aug 2014
 - Cohort 3: Oct–Nov 2014

Key Biomarkers for Assessing Potential Efficacy in Phase 1 Clinical Trial



- Biomarkers associated with fibrosis
 - ELF (Enhanced Liver Fibrosis) Score: Includes measurement of hyaluronic acid, tissue inhibitor of metalloproteinase-1, and PIIINP (amino terminal propeptide of type III procollagen)
 - TGF-β
 - Matrix metalloproteinase-1, -3, and -9
 - Lumican
- Biomarkers associated with NASH—ballooning degeneration of hepatocytes
 - Cytokeratin-18 (M30 and M65 antibody tests)
- Biomarkers associated with NASH inflammation
 - Cytokines: INF-γ, IL-6, IL-8, TNF-α, CD-40 ligand
 - VEGF, Endothelin-1
 - Osteopontin
 - IP-10

Phase 2 Clinical Trial Plans



- **Patient inclusion**: Biopsy proven NASH with advanced fibrosis (stage 3 and stage 4 with well compensated cirrhosis)
- **Design**: Randomized, placebo controlled, and double blind.
- Dose: Likely two dosage groups
- Treatment Duration: 6-12 months TBD
- Primary endpoint: Liver biopsy: Collagen proportional area
 - FDA-AASLD NASH endpoints workshop September 5-6, 2013
 - Galectin human NASH biopsy study done to guide design
- Timeline: Start around end of 2014; Top line data: 1H 2016.
- Secondary endpoints:
 - Liver Biopsy: NASH Activity Score and Fibrosis Stage
 - Liver function testing: HepQuant (bile acid clearance test)
 - Imaging methods—Fibroscan or MR-elastography
 - Serum biomarkers based on analysis of Phase 1 data: ELF Score key biomarker

Competition in NASH



- Most drugs in development focus on improving NASH activity score (fat, inflammation, and cell death) at a stage of the disease when there are minimal amounts of fibrosis.
 - PIVENS
 - FLINT trial (NIDDK and Intercept)
- Few companies currently have programs 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



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May 22, 2013

Cancer immunotherapy drugs will soon be a \$35 bn global industry

May 22, 2013

FIRSTPOST. BUSINESS

> "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)

Cancer Immunotherapy Named Top Scientific Breakthrough of 2013 by Science Magazine

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



Tumor cell invasion: extracellular matrix adhesion & detachment

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- Metastasis: cell invasion and migration
- Angiogenesis
 - Tumor immunity has recently been shown to be critically affected by galectins



Cancer Therapy Strategy

- Focus on cancer immunotherapy based on the hypothesis that galectin inhibitors will enhance efficacy of immunotherapies
- Metastatic melanoma is initial cancer indication
 - In US 76,000 new diagnoses and 9,100 deaths annually
 - 5% five year survival for metastatic disease
 - Even with newly approved drugs, still a substantial unmet medical need
- We have sought collaborations with institutions that have:
 - Demonstrated clinical trial expertise in melanoma
 - Tumor immunology basic science research
 - Ability to conduct clinical trials and assist in funding
- 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



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Exploratory Clinical Trial at Ludwig Institute in Brussels Belgium

- Metastatic melanoma trial, funded by Ludwig Institute, was initiated in 2011
 - Design was to prime patients for treatment with a melanoma specific peptide vaccine and then treat with GM-CT-01
- Eight patients screened, 6 patients enrolled, and 3 patients reached treatment with GM-CT-01 and completed the protocol
 - No treatment emergent AE's
 - 2 patients with mixed response and 1 with progressive disease
- Enrollment in the study has been suspended

 - The Ludwig Institute does not currently have plans for regulatory approval of its peptide vaccine

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Pre-clinical studies show galectin inhibitors enhance immune response

- Collaboration established in 2012 with Earle A. Chiles Research Institute (EACRI)
- Pre-clinical results demonstrate that treatment with GR-MD-02 enhances antigen-specific CD8+ T-cell response and augmentation of memory CD8+ T-cells in non-tumor mice
- In tumor bearing animals, the combination of checkpoint inhibitors (anti-CTLA4 and anti-PD1) with GR-MD-02 enhances CD8+ and CD4+ T-cell proliferation, reduces tumor size, and enhances survival in multiple mouse cancer models
- Important to note that GM-CT-01 did not have an effect

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 These results have led to decision to initiate a clinical trial combining Yervoy with GR-MD-02



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

Initiation of a Phase 1B study of patients with metastatic melanoma using GR-MD-02 in combination with Yervoy® (ipilimumab)

- The Providence Portland Medical Center (PPMC), associated with the EACRI submitted an IND for a clinical trial on 12/27/13
- Patients with advanced melanoma for whom ipilimumab would be considered standard of care.
- 3+3 phase 1 design with dose escalation of GR-MD-02 in conjunction with standard doses of ipilimumab. 10 patients will be treated at maximum tolerated dose of GR-MD-02
- Endpoints
 - Tumor response
 - 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.
- Initial funding of clinical trial by PPMC/EACRI. Galectin is providing GR-MD-02 study drug, reference to its IND, and PK analysis

Cancer Therapy Strategy: Summary



- Two immunotherapy agents have been approved for use to date, with many more vaccines and activators in development
- Our strategy is to leverage world class expertise in basic tumor immunology and in the conduct of melanoma clinical trials.
 - Providence Portland Medical Center and Earle A. Chiles Research Institute (EACRI): Ongoing pre-clinical studies; IND submitted for phase 1B clinical trial in patients with advanced melanoma treated with a combination of Yervoy and GR-MD-02
- 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

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Summary of Development Program

- Liver Fibrosis
 - First indication: GR-MD-02 in NASH with advanced fibrosis
 - Phase 1 clinical trial underway; interim data expected March-April 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

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