

AMP Quick Facts

Biotechnology

Galectin Therapeutics (Nasdaq: GALT)



NASDAQ: GALT

Last Price: \$15.15

06/23/14

Fiscal Yr: 12/31

Sector: Life Sciences

Industry: Biotechnology

Market Cap: \$325M

Potential Market: \$83B

52 W. High: \$19.11

52 W. Low: \$3.90

Insider Holdings: 19.48%

Instit Holdings: 2.5%

Shares Out. 21.9M

Float: 14.8M

Avg. Daily Vol. (3 M) 453,056

For More Information

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Galectin is a clinical development-stage biopharmaceutical company based in Norcross, Georgia, that is targeting fibrotic diseases and cancer with novel galectin inhibitor compounds.

Galectins are a class of proteins made by many cells in the body and are important therapeutic targets because they are the mediators of fundamental biologic mechanisms in pathological processes. Galectin Therapeutics leverages its extensive scientific knowledge of galectins to advance their discovery program including research and discovery of new compounds. Through a relationship with a world-class research program at the University of Georgia, the Company focuses on the discovery of new carbohydrate molecules that can be used in the therapy of diseases where galectin proteins play a major role including cancer and inflammatory and fibrotic disorders.

Galectin Therapeutics (Nasdaq: GALT) is advancing proprietary galectin inhibitor called GR-MD-02, which has potential to reverse fibrosis and cirrhosis and transform the fatty liver disease landscape.

GALT has two primary drug candidates, **GR-MD-02** and **GM-CT-01**, both the mechanism of action for these are based upon interaction with inhibition of galectin proteins, which are expressed at high levels in certain pathological states including inflammation, fibrosis, and cancer.

1. First candidate GR-MD-02 targets an Untapped \$83B Fatty Liver Disease/ Fibrosis Market

- GR-MD-02, which has FDA Fast Track designation, could face limited competition upon its anticipated approval in 2021
- GR-MD-02 has at least \$1B blockbuster potential
- There are no therapies approved to treat fibrosis in fatty liver diseases, which are prognostic for cirrhosis and liver failure.

2. GR-MD-02 Synergy with Cancer Immunotherapy

- The company's strategy in cancer therapy involves investigating galectin modulation of the immune system in response to cancerous cells. Galectin-3 in particular is thought to play a key role in diminishing the ability of tumor infiltrating lymphocytes (TIL) to kill tumors.
- A preclinical study found that **GR-MD-02** increased tumor shrinkage and enhanced survival in immune competent mice with prostate and breast cancers when combined with one of the immune checkpoint inhibitors, anti-CTLA-4 or anti-PD-1. These findings suggest a role for GR-MD-02 in cancer immunotherapy.
- Providence Portland Medical Center filed an IND to study GR-MD-02 in combination with Yervoy (ipilimumab) in a Phase 1B study of patients with metastatic melanoma

Catalysts and Milestone Announcements - Projected Event

Fibrosis

Topline results from Cohort 1 in GR-MD-02 Phase I trial in NASH patients with advanced fibrosis	1Q14
Topline results - Cohort 2 in GR-MD-02 Phase I trial in NASH patients with advanced liver fibrosis	2Q14
Topline results - Cohort 3 in GR-MD-02 Phase I trial in NASH patients with advanced liver fibrosis	3Q14
Meeting with FDA to discuss Phase II evaluation of GR-MD-02 in patients with NASH	2H14
<i>Initiate Phase II trial to evaluate GR-MD-02 in NASH patients with advanced liver fibrosis</i>	2H14
Potential partnership collaboration for GR-MD-02 development in 1 or more fibrosis indications	2015
Advancement GR-MD-02 - Phase II trials in other organ fibrosis indications (anticipate kidney / lung)	2015
Announce topline results from GR-MD-02 Phase II trial in NASH patients with advanced fibrosis	2016
FDA EOP2 meeting for further evaluation of GR-MD-02 in NASH patients with advanced fibrosis	2016
Initiate pivotal trial to evaluate GR-MD-02 in NASH patients with advanced liver fibrosis	2017

Cancer Immunotherapy

Initiate Phase I trial to evaluate combination of GR-MD-02 and ipilimumab in melanoma	1Q14
Potential announcement of partnership for GM or GR series compound development in oncology	2015

Source: Company reports and MLV & Co. research. Note: Bolded items represent potential stock catalysts.

Galectin Therapeutics Inc. (GALT) 4960 Peachtree Industrial Boulevard Suite 240 Norcross, Georgia 30071

The key investment points are:

- **Lead product GR-MD-02 targets a wide open est. \$83BN liver disease market.** There are no therapies approved to treat fibrosis in the estimated \$83BN market for liver diseases, which is prognostic for cirrhosis and liver failure. With its potential to reverse cirrhosis, GR-MD-02 has blockbuster potential.
- **Galectin's focus on biopsy-proven fibrosis is key to demonstrating whether GR-MD-02 can reverse NASH.** The thought is that Galectin Therapeutics' should enroll only NASH patients with biopsy-confirmed advanced fibrosis for its GR-MD-02 Phase II study strongly positions it to demonstrate positive results at each readout and confirm its potential to reverse NASH.
- **Collaborations could drive further GR-MD-02 value creation.** Galectin Therapeutics' near-term seeks collaborations with institutions to fund advancement of GR-MD-02 for oncology indications. These studies, in particular combinations with a marketed anti-CTLA-4 or emerging anti-PD-1 therapy, are expected to provide data demonstrating GR-MD-02's potential to enhance cancer immunotherapy and thus provide data points that can be used to seek partners for its further development.
- **Possible Commercialization rights from GM-CT-01, Galectin Therapeutics** could receive payments of \$10MM-\$40MM (\$10MM upfront in 2016) totaling \$202MM (*Source: MLV & Co. research.*)
- **Possible Worldwide commercialization rights to GR-MD-02 in 2014.** Galectin Therapeutics could receive payments of \$10MM-\$35MM (\$20MM upfront in 2014) totaling \$315MM upon achievement of clinical and regulatory milestones through 2021, plus a \$75MM milestone payment in 2022. (*Source: MLV & Co. research.*)

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