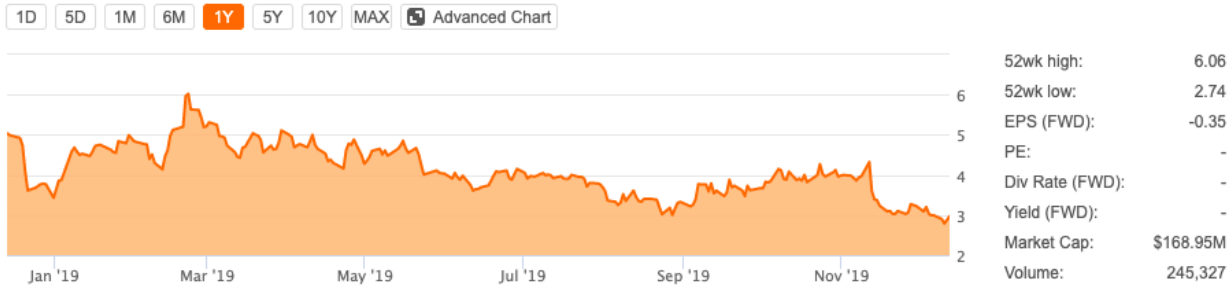
Elle Investments Research Report: GALT

Company: Galectin Therapeutics, Inc.
Symbol: **GALT**
Analysis Date: 12/10/19
Analysis Price: $2.79
Price Target (PT): $7.00
Upside: **151%**
Dividend: NA
Recommendation: **Strong Buy**

GALT: 1-Year Chart



Source: Seeking Alpha

INVESTMENT THESIS:

The NASH market is expected to be very lucrative, with estimates pegging its eventual market size at $25B-$35B, driven by increased rates of diabetes and obesity. While there are many companies running trials in this space, GALT is the only company thus far to show positive results in NASH cirrhosis patients. These results, along with the $20M investment by the Chairman during a recent financing round, make GALT a Strong Buy.

LIQUIDITY POSITION: Poor

As of 3Q19 (ended September 30), GALT had cash of $50M and access to a $10M line of credit. While its current cash burn of $2M-$3M per quarter is low, they confirmed during 3Q19 earnings that the planned phase 2/3 NASH-RX trial will cost $100M-$115M, meaning that at least another round of financing is needed. There was hope that they would find a partner to help defray the cost, but as of now it looks like they are going it alone.

On the bright side, this last round of equity financing that was completed on May 28 saw Chairman Richard E. Uihlein subscribe to $20M worth of shares. He had previously put out an open letter to shareholders concurrent with the announcement of the offering, inviting shareholders to invest alongside of him and making clear his commitment to allow current

shareholders the opportunity to buy new shares and receive warrant coverage prior to allowing in new investors. This way, the ownership percentage of existing shareholders would not be diluted. While they will need to raise more money to complete the planned phase 2/3 NASH-RX trial, at least they have shown consideration for preserving shareholder value as much as possible. And the personal investment by the Chairman is a great vote of confidence.

COMMERCIAL PROSPECTS: Excellent

GALT: Drug Development Pipeline

CLINICAL FOCUS		STAGE DEVELOPMENT				
Drug	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3
Fibrosis						
Belapectin	NASH Cirrhosis					
	NASH Advanced Fibrosis					
	Lung, Kidney					
	Arrhythmia, Pulmonary Arterial Hypertension					
Cancer Immunotherapy (combination therapy)						
Belapectin + Keytruda	Melanoma + Head/Neck Cancer					
Plaque Psoriasis						
Belapectin	Moderate-severe					
Oral Galectin-3 Inhibitors						
Discovery program to identify subcutaneous and oral forms of carbohydrates and oral small molecules						

Source: GALT website

Belapectin (GR-MD-02):

Belapectin is GALT's only candidate past the preclinical phase. It's currently in a phase 2 trial for moderate-to-severe plaque psoriasis, as well as in a combo treatment phase 1 trial (with Merck's Keytruda) for melanoma and head/neck cancer. But what we are most excited about is the NASH space.

NASH is a condition characterized by the build-up of fat in the liver. This build-up can lead to severe scarring called fibrosis. If untreated, patients may eventually develop cirrhosis, which involves the permanent loss of liver cells, and may require a liver transplant. The current estimate for the NASH population in the US is about 16M, but that number is expected to explode over the next 10 years, driven by the rise in diabetes and obesity. There are still no approved therapies for NASH. But given the expected $25B-$35B market, the NASH space has drawn attention from a lot of companies running clinical trials in the hopes of capturing a piece of the future market.

Liver damage can occur very slowly, meaning that patients can live with the condition for several years without noticing any symptoms. But once they reach the later-stages of cirrhosis, it becomes very difficult to treat.

Esophageal varices are abnormally enlarged veins in the esophagus that can cause serious complications from bleeding. They can develop when normal blood flow to the liver is disrupted by liver scarring. These varices appear in stage 2 of cirrhosis.

One of the things we really like about GALT is that they have managed to show positive results in a clinical trial involving NASH cirrhosis patients that have yet to develop esophageal varices. Their NASH-CX trial, whose results were announced on December 5, 2017, missed the overall primary endpoint (of lowering the measurement of HVPG when compared with placebo) for the total trial population. But for the 50% of trial participants that did not have varices at baseline, belapectin was able to achieve statistical significance on the primary endpoint in the GR2 group (lower dose). Additionally, among patients who did not have varices at baseline, there were more new varices in the placebo group than in the GR2 group, indicating that belapectin might also be effective at preventing the progression of varices formation.

Accordingly, the upcoming phase 2b/3 NASH-RX trial has been designed to focus on NASH cirrhosis patients that have clinical signals suggesting portal hypertension and who are at risk of developing esophageal varices. Excluding cirrhosis stages 2, 3, and 4 patients (with varices already present) increases the likelihood that we will see a repeat of the successful phase 2 NASH-CX results.

Thus far, GALT is the only company that has demonstrated positive results in a NASH cirrhosis trial. Previously, both GILD and CNAT had failed NASH cirrhosis trials. ICPT is currently in a phase 3 NASH cirrhosis trial (as it looks to expand the label of already marketed Ocaliva) but has not announced any prior results for this indication. At the moment, GALT is the clear front-runner in this difficult-to-treat population with advanced NASH complications.

In addition to the NASH cirrhosis trial, GALT is testing belapectin for NASH patients with advanced fibrosis (currently in phase 2). These patients are not as far along in terms of the progression of their liver disease, and so have proved easier to treat. There are other companies that have reported some success in treating NASH fibrosis patients, and so GALT's positioning in this space is not as compelling as with cirrhosis. But the larger patient pool means that even a smaller slice of this market could still be very lucrative, and further adds to the long thesis on GALT.

Finally, there are no safety concerns with belapectin at this time.

CONCLUSION:

GALT is not without risks: they are still at least 2-3 years away from commercialization of belapectin for NASH cirrhosis (assuming approval), and they will need at least another round of financing just to complete the phase 2b/3 NASH-RX trial. But the good results from phase 2 for NASH cirrhosis patients that do not have varices are promising. This, along with the $20M vote of confidence by the Chairman, make GALT a Strong Buy.

GLOSSARY:

HVPG: hepatic venous pressure gradient
NASH: nonalcoholic steatohepatitis

Note: Additional commentary from Elle Investments can be found at http://elle-investments.com. We welcome your feedback. Additionally, we are thinking of launching a subscription service that would offer early access to our research, along with some other features that investors might find useful (i.e. general portfolio management strategies, live blog updates highlighting our reaction to breaking news, etc.). If you would be interested in subscribing to such a service, please let us know.

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