



## Annual Stockholder Meeting Presentation

December 14, 2017

NASDAQ: GALT

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### Forward Looking Statements

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 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 the potential therapeutic benefits of our drugs and specifically the results of our NASH-CX clinical trial. Factors that could cause our actual performance to differ materially from those discussed in the forward-looking statements include, among others that:

- the data presented today represent a top line analysis, and there may be changes in the final clinical trial report due to further analysis of the full data set including additional statistical analysis;
- subsequent trials, if any, in whatever patient population chosen may fail to validate any positive results of our trial now concluded;
- future phases or future clinical studies could prove prohibitively time consuming and/or 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, personnel, and spending projections may change;
- due to the novel nature of our compounds, future phases of manufacturing scale-up and supporting chemical and physical characterizations for both trials and commercial purposes can be challenging and costly and there is no certainty this can be accomplished nor certainty it would be acceptable to regulators;
- we may be unsuccessful in developing partnerships or other business relationships with other companies or obtaining capital that would allow us to further develop and/or fund any future studies or trials or sell or license our intellectual property; and, further,
- there is the uncertainty that any drug in development could obtain regulatory approval in any patient population.

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, 2016, 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.

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## NASH-CX Clinical Trial Results: NASH<sup>1</sup> Cirrhosis

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- **Clinically meaningful positive results in subgroup of NASH cirrhosis without esophageal varices**
  - **Reduction in portal hypertension**
  - **Improvement in hepatocyte ballooning on liver biopsy**
  - **Reduced development of esophageal varices**
- **We believe this is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in portal hypertension or important aspects of liver biopsy in patients with NASH cirrhosis**

<sup>1</sup> NASH = Non-Alcoholic Steatohepatitis

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My name is Dr. Peter Traber, CEO and Chief Medical Officer of Galectin Therapeutics and I am pleased to speak with you today at the Annual Stockholder Meeting.

The big news last week was the announcement of the results of our NASH-CX Phase 2b clinical trial which evaluated the efficacy and safety of GR-MD-02, our proprietary galectin-3 inhibitor, in patients with NASH cirrhosis. This important milestone represented a culmination of 7 years of work.

It is both with a sense of pride in what this small company has accomplished, and great appreciation to our investigators and their patients who were committed to this trial that I can report to you that the results of the clinical trial were positive. Let me say that again, the results of the clinical trial were positive.

There were clinically meaningful positive results in a subgroup of NASH cirrhosis without esophageal varices. In these patients, there was a

- Reduction in portal hypertension (liver blood pressure)
- Improvement in hepatocyte ballooning on liver biopsy
- Reduced development of esophageal varices

We believe this is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in portal hypertension or important aspects of liver biopsy in patients with NASH cirrhosis

Now, you all know that in the rapid-fire comments that came out after the clinical trial announcement, there were some negative assessments, and the stock dropped before recovering later in the week. These negative comments were certainly not in the best interest of patients with NASH cirrhosis nor did they reflect an understanding of the breakthrough findings of the clinical trial.

I have said that, even though the trial did not meet the primary endpoint originally established for it when it was designed several years ago, the trial results were positive. Let me give you some validation for my statements from multiple sources that count.

Dr. Scott Friedman of Mount Sinai School of Medicine, a leading expert in liver fibrosis and hepatology and consultant to many companies in this space including us, commented to me last week that the data are “unprecedented in my view”. That’s right, unprecedented. This validates the statement that this is the first trial to show positive results in NASH cirrhosis.

One experienced biotechnology analyst who follows multiple NASH companies, Ed Arce from HC Wainwright, published a research report with the title “Landmark NASH-CX Study Shows First Ever Benefit in NASH Cirrhosis”. He stated that “this study is a landmark for the treatment of cirrhosis not only because it appears to be the first ever pharmacological benefit in NASH cirrhosis (across several parameters), but also because it defines a highly clinically significant and easily identifiable patient sub-population for treatment.”

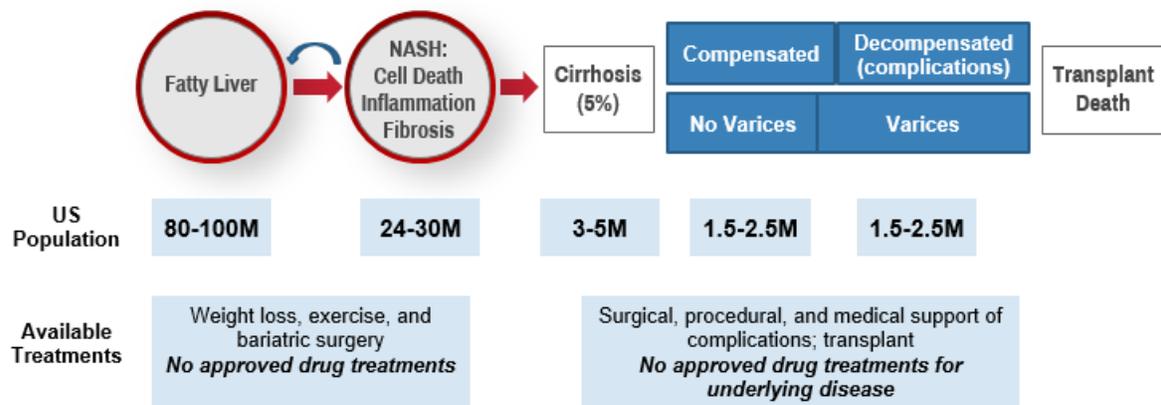
The analyst reminded us of two other situations in NASH where the market reaction was inconsistent with positive trial results. One was Genfit, where a positive post-hoc analysis on a subset of patients provided the basis for an ongoing pivotal phase 3 trial.

The other was Tobira, which missed the primary endpoint, but hit an important secondary endpoint. Allergan subsequently acquired the drug and the asset is now in a phase 3 trial. By the way, this analyst called the Tobira story correctly just after the trial data was announced.

As suggested by these two examples, one of the most important aspects of a phase 2 trial is whether it provides data to support a phase 3 program. Dr. Stephen Harrison, a leading NASH expert and lead investigator on the trial, said on the conference call last week, “I think [the results] set.. us up very nicely for a Phase 3 trial of this population. ...this is potentially a paradigm change .. with how we approach cirrhosis and potential therapeutic options for the disease...” No credible investigator would say the data sets up nicely for a phase 3 trial unless they believed the data showed encouraging results.

However, it is not what we say, nor what the analysts say, nor the what bloggers write, nor even the reaction of the stock price that is most important. The Principal Investigators of the trial, the ones taking care of the patients who were enrolled, and those patients who do not have alternatives for a serious disease, are most important to hear from. We spoke last week to many of the principal investigators on the trial and they were uniformly positive about the results. They were all positive enough about the trial that they want the company to run an extension trial to treat the patients who received placebo. And, the doctors tell us the patients are eager to be in an extension trial. I believe that this is further credible support for the positive results.

## Importance of NASH-CX Trial Findings for Patients with NASH



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I now want to speak with you about the importance for patients of our findings in NASH cirrhosis, the size of the potential market, and the state of the competition. In this discussion on the clinical care of patients with NASH, I speak not only from my 32 years of experience as a liver doctor, but also from discussions over the last week with expert physicians and investigators in NASH.

Because of the rise of obesity and diabetes in our population, many people develop fatty liver. This can progress to NASH, characterized by liver cell death, inflammation and progressive fibrosis, or scarring. In the early stages of the disease, patients can cycle back and forth between fatty liver and NASH, but as more inflammation and fibrosis develops they continue to progress. These patients are generally asymptomatic and have no liver-related clinical problems. They would not know they have liver disease unless their physician tells them because of abnormalities picked up on routine laboratory tests or imaging of their liver. Their major medical problems are associated with their obesity, diabetes, and cardiovascular disease.

In approximately 5% of all individuals with fatty liver, the fibrosis may reach the stage of severe scarring, which is called cirrhosis. NASH is a chronic disease, so the progression to cirrhosis takes over 20 years to occur. Cirrhosis is a diagnosis made by liver biopsy and represents the stage of the disease when fibrotic tissue impairs liver cell function, and most importantly, restricts blood flow through the liver.

Cirrhosis is normally classified as compensated or decompensated. Patients with compensated cirrhosis have not had any of the typical complications of cirrhosis such as bleeding from esophageal varices, and others. Decompensated patients have had at least one, and often multiple, clinical complications of cirrhosis, which can result in a liver transplant, or ultimately death.

There is another way to classify cirrhosis and that is whether patients have esophageal varices or not. Varices develop because of increased blood pressure in the liver, or portal hypertension, that causes blood to be diverted around the liver through veins in the esophagus. These dilated veins are

responsible for many of the complications of cirrhosis, the most important being catastrophic bleeding into the digestive tract.

So, how does all this relate to the results of our clinical trial? Our trial results demonstrated that GR-MD-02 had a statistically significant and clinically relevant improvement in patients with NASH cirrhosis without varices. Since our therapy may prevent patients from progressing to varices and other complications of cirrhosis, you can understand why the scientific community is so excited by the results of our trial.

When I was on a call last week with the Principal Investigators of this trial, one from a major US medical center, said, "Do you know how important a finding this is? If we can prevent patients from progressing to varices with this drug, it will not only save lives, but have an enormous impact on the cost of this disease, since the cost of treating complications or liver transplant is very large."

An indication for NASH cirrhosis without varices has substantial market potential. It is estimated that just in the United States there are between 80 and 100 million people with fatty liver and between 24 and 30 million people with NASH. Important for our purposes, it is estimated there are 3 to 5 million people with NASH cirrhosis in the US. And because 50% of patients at diagnosis of cirrhosis do not yet have varices, the total population that may have an indication for our drug would be between 1.5 and 2.5 million patients. This is just in the United States. The global potential is obviously correspondingly larger.

Let me put this in perspective. In the US, hepatitis C virus infection is the most common bloodborne infection. The best evidence shows that there are approximately 3 million people in the US with chronic hepatitis C infection. So, there are likely more people in the US with NASH cirrhosis than there are with chronic hepatitis C. Moreover, while hepatitis C is currently the number one reason for liver transplant in the US, it has been projected that NASH cirrhosis will overtake the number one spot in the next few years.

Just how big is the hepatitis C market? For the largest company in hepatitis C, Gilead, the peak annual sales of their hepatitis C franchise was nearly \$20 billion. In contrast to NASH cirrhosis which is a chronic disease that may not be cured, patients with hepatitis C are cured of their viral infection by treatment, and thus the hepatitis C market will shrink as people are treated.

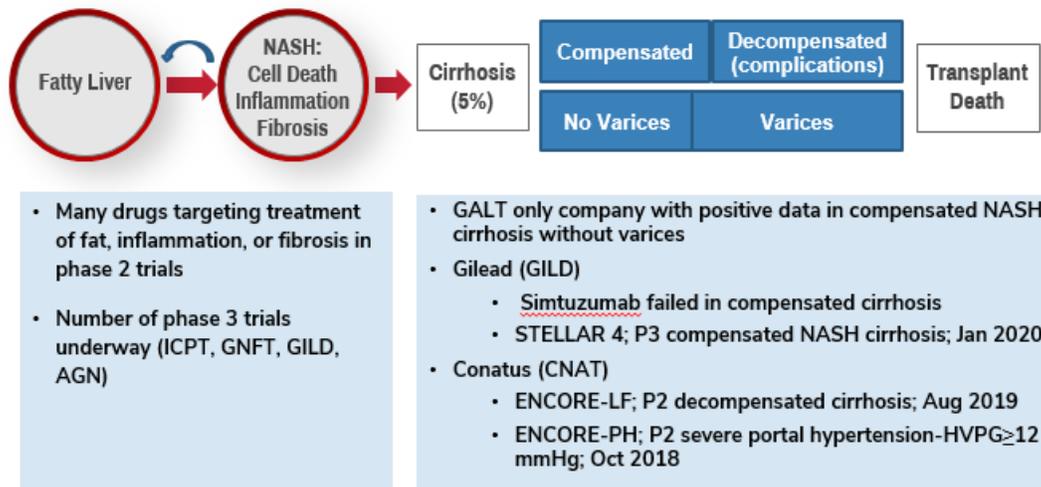
With these numbers in mind, the estimated 1.5 to 2.5 million patients in the United States who have NASH cirrhosis without varices is a large population of patients, and potentially a large market for our drug. More importantly, we can easily identify patients with NASH cirrhosis who have not developed varices. This is because practice guidelines recommend newly diagnosed patients with NASH cirrhosis have an upper endoscopy to evaluate for esophageal varices. Consequently, our study has identified a large potential patient population likely to benefit from our drug.

What are the currently available treatments for NASH or NASH cirrhosis? In patients with early NASH who do not have cirrhosis, there are some non-drug interventions that clearly have a positive effect. These include weight loss, exercise and bariatric surgery to effect rapid weight loss. In fact, in early NASH, weight reduction of 10% of body weight, can improve or reverse NASH in up to 90% of patients. However, there are currently no approved drugs for the treatment of NASH.

For patients with NASH cirrhosis, treatments are limited to those treating complications that may occur. For example, bleeding esophageal varices are injected or banded and there are interventional procedures to decrease portal pressure. For ascites, or fluid in the abdomen, the fluid may be withdrawn, or diuretics given to remove fluid from the body. When the complications cannot be controlled, liver transplant is the only option.

All of these therapies treat the complications, but none address the underlying disease.

## Experimental Treatments in NASH and NASH Cirrhosis



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What about experimental therapies that are being explored by biotech and pharma companies? NASH has been called the largest potential market opportunity in the drug industry today, so as you might imagine, there are many drugs that are being studied.

For early NASH with various degrees of fibrosis, but without cirrhosis, there are many phase 2 clinical trials ongoing. The drug mechanisms are many, affecting various aspects of NASH such as fat, inflammation, or fibrosis. The endpoints and the ultimate goal in these trials is to reverse or improve NASH or retard the progression of fibrosis to cirrhosis. This is a very different patient population and goal from what we studied in NASH cirrhosis. A number of these drug programs have moved to phase 3 clinical trials.

The more relevant area of investigation for our drug are those patients with NASH cirrhosis. Galectin Therapeutics is the only company with positive phase 2 clinical trial data in patients with compensated NASH cirrhosis without esophageal varices. As I mentioned previously, this is a large and clinically relevant patient group. Consider our results in contrast to the other NASH cirrhosis trials as currently listed on [clinicaltrials.gov](http://clinicaltrials.gov).

Gilead reported last year that their monoclonal antibody simtuzumab failed in a large phase 2 trial. They enrolled patients who were like those we studied in the NASH-CX trial. They are now conducting a phase 3 clinical trial, called STELLAR 4, with another drug in patients with compensated NASH cirrhosis. The top line data from this trial is expected in January 2020, according to [clinicaltrials.gov](http://clinicaltrials.gov).

Conatus is conducting two phase 2 clinical trials in NASH cirrhosis, but both studies examine very different patient populations than we studied in our trial. In ENCORE-LF, patients with decompensated cirrhosis are being studied with top line results expected in August of 2019. In the ENCORE-PH trial, patients with severe portal hypertension who have an HVPG greater than or equal to 12 mmHg are

being studied. The majority of these patients would be expected to have esophageal varices. Top line results from this trial are expected in October of 2018.

The important point from this analysis is that currently we are the only company with positive clinical trial data in patients with NASH cirrhosis without esophageal varices. This is why Dr. Friedman said to me that our data are “unprecedented in my view.”

Furthermore, the only competitor clinical trial for the patient population in which we saw positive results is Gilead’s STELLAR 4 study which will not have data until 2020. The Conatus clinical trials study very different patient populations of NASH cirrhosis and are, in fact, not relevant to the results of our study since they study patients with decompensated cirrhosis or very high portal pressure.

In our view, this puts us in a good competitive position. Additionally, it opens opportunities for companies with drugs that address other populations in NASH, or have other mechanisms, to consider having a second complimentary drug such as GR-MD-02.

## Next Steps

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- **Communication to scientific, industry and general audiences**
- **Design a phase 3 program**
- **Explore collaboration with biotech and pharma**

Now that we have these positive data, I want to talk about next steps.

The first step is to communicate this good news to a broad spectrum of audiences. Regarding scientific audiences, we will submit the results for presentation at the International Liver Conference to be held in Paris, France, in April 2018, and submit a manuscript to a peer reviewed journal.

We will also seek opportunities for articles in the medical and industry trade press, like the *Healio* article that was published last week entitled, “NASH cirrhosis treatment successful in patients without esophageal varices.”

In addition, the popular press is gaining an appreciation of the NASH epidemic. For example, in January 2016, *Newsweek* published a feature article entitled “NASH Is the 21st Century’s Looming Public Health Threat.” This article featured Galectin Therapeutics, the NASH-CX trial, as well as one of our investigators and a patient enrolled in the trial. We will seek additional such opportunities for broad communication to further advance awareness of the disease and our progress in developing an important therapy.

Next, we will be designing a phase 3 clinical trial program in collaboration with liver experts and in consultation with the FDA. Designing a phase 3 program is essential to define the way forward. We have already gained critical information from the phase 2 trial for designing phase 3 trials, and will continue to examine the data for additional insights. The key things we learned were the appropriate patient population to target, potential study endpoints which include some that could be surrogates for clinical outcomes and actual clinical outcomes such as the development of varices. The ultimate approval of a phase 3 program by regulatory agencies requires time, consultation with experts and discussions with the FDA to gain agreement on the appropriate clinical trial.

The next critical activity will be the exploration of collaboration with a large biotech or pharma company. The question was asked on the conference call last week whether pharma companies would be interested in an asset that had the results we did.

While Galectin does not and will not comment on potential collaborations with pharmaceutical companies, Dr. Stephen Harrison, who was speaking as a drug development scientist and not on behalf of the company, answered this question by saying, "I think everybody is scrambling for a way to treat these patients. And I think there would be significant interest in this for a couple of reasons. Number one, ...there is a handful of companies that are studying NASH cirrhosis. And compared to those that are studying milder disease, there *are* just not a lot of players in the space [NASH cirrhosis]. Having the first therapy to actually showing benefit of any kind in a cirrhotic patient, I think is positive."

Many companies have background information on our program from multiple previous discussions before the read out of this clinical trial. We will now begin discussing the results with them in earnest to identify potential partners. The companies and the discussions are confidential, and these types of transactions and partnerships can take many forms, so there will not be regular updates, and the process can take some months to meet with all the appropriate companies.

I thank you for your attention and your interest in Galectin Therapeutics. I wish everyone health and happiness in this holiday season and best wishes for the new year.