TRANSCRIPT

Galectin Therapeutics 2016 Financial Results and Business Update Conference Call

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PRESENTATION

Operator

Good morning, ladies and gentlemen. Welcome to the 2016 year end Galectin Therapeutics business update conference call. At this time, all participants are in a listen-only mode. Later we will conduct a Q&A session, and instructions will follow at that time.

(Operator Instructions)

As a reminder, this conference call is being recorded. I would now like to turn the call over to Mr. Jack Callicutt, of Galectin Therapeutics.

Jack Callicutt - *Galectin Therapeutics - CFO*

Thank you and good morning. I'm Jack Callicutt, Chief Financial Officer for Galectin Therapeutics, and I'd like to welcome you to our business update conference call for the fourth quarter and year end of 2016.

These calls are intended to provide a corporate update and to discuss company's financial results. Today we'll cover several items that were included in the press release that we issued earlier this morning.

Joining me this morning is Dr. Peter Traber, our President and Chief Executive Officer and Chief Medical Officer. Before I turn the call over to Peter, I'd like to remind you that certain comments made during this conference call, particularly those anticipating our future financial condition and results of operations, results of our clinical trials and our strategic plans constitute forward-looking statements within the meaning of the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995.

These forward-looking statements, by their very nature, are subject to certain risks and uncertainties that may cause actual results, events and performances to differ materially from those referred to in such statements. These risks and other risks are discussed in our Securities and Exchange Commission filings, including our Form 10-K, which was also filed earlier this morning.

A transcript of this presentation will be available on our website.

I would now like to turn the call over to Dr. Traber. Peter?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Thank you, Jack. Good morning and thank you to all for joining us. Today I will provide a comprehensive view of the state of the company and its drug development programs.

We achieved a number of significant milestones in 2016, in the development of our lead compound, GR-MD-02, and we anticipate reporting critical clinical data in our NASH-CX trial in December, 2017.

Now before recapping the company's progress, our plans for the upcoming year and opening this call to questions, let me first turn the call back over to Jack to cover our financial position and results. Jack?

Jack Callicutt - *Galectin Therapeutics - CFO*

Thanks, Peter. For the year ended December 31, 2016, the company reported a net loss applicable to common shareholders of $22.4 million, or $0.76 per share, compared with a net loss applicable to common shareholders of $21.1 million, or $0.88 per share, for 2015. The increased net loss is largely due to higher research and development expenses, primarily related to our Phase 2 clinical program.

Research and development expense for 2016 were $15.3 million, compared with $13.1 million for 2015. Again, the increase primarily relates to costs for the NASH-CX Phase 2 clinical trial, partially offset by lower preclinical costs.

General and administrative expense for 2016 was $6.2 million, compared with $7.0 million for 2015, primarily due to a decrease in stock-based compensation.

As of December 31, 2016, the company had $15.4 million of non-restricted cash and cash equivalents. In January and February 2017, the company raised a total of $1.5 million in net proceeds from issuance of common stock. The company believes that it has sufficient cash to fund currently planned operations and research and development activities through December 31, 2017.

Peter?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Thank you, Jack, for that recap of the finances. In setting the stage for this update, I will start with some history.

Since taking the helm at Galectin in 2011, my goal has been to build shareholder value by realizing the tremendous potential for targeting galectin proteins in many human diseases. That's because the galectin protein is associated with inflammation, scarring and many other processes that are involved in the development of multiple diseases.

There is a growing body of research demonstrating the galectin-3 is increased and involved in the development of many types of chronic human diseases, including liver, lung, kidney and heart fibrosis, most cancers, serious skin diseases, diabetes, atherosclerosis and more.

In 2011, we began testing various animal disease models that represented large, unmet, medical needs using two different carbohydrate-based drugs that bind to galectin-3. One drug was GM-CT-01 or DAVANAT which was previously in development by the company for other purposes. And a new drug candidate we named GR-MD-02.

Both of these drugs were tested in each animal model of disease. We started with models of fibrosis, because it had been shown that galectin-3 was crucial for the development of fibrosis. And, a therapy that can reduce or reverse fibrosis would address a very large group of disorders that are responsible for a major burden of disease.

One of the two compounds, GR-MD-02, was discovered to have a more profound effect on fibrosis of the liver, kidney and lung in these animal experiments. As a result of this more profound effect on fibrosis, GR-MD-02 rather than GM-CT-01 has been the focus of our efforts.

It is important to note that we have strong intellectual property claims for our lead compound and its uses, with 15 granted patents in the United States, 24 granted patents outside the U.S., six patent applications in the U.S. and 49 patent applications outside the U.S.

We decided that liver fibrosis due to fatty liver disease would be the lead indication. This has turned out to be a good decision, since it is now widely believed that fatty liver disease, or NASH, is a very large opportunity in drug development.

Cancer was chosen as a second area of focus, because galectin-3 had been shown to be important in the aggressiveness of tumors, and inhibition of galectin may be beneficial.

Finally and much later a third area of focus arose serendipitously, when a patient with cirrhosis enrolled in our Phase 1 NASH trial had a remarkable remission of her disease.

Therefore, the company has three clinical development programs for GR-MD-02:

The lead program in fatty liver disease or non-alcoholic steatohepatitis called NASH, with the most advanced form of fibrosis called cirrhosis.

Two, chronic inflammatory skin diseases, including moderate to severe plaque psoriasis and severe atopic dermatitis.

And three, combination immunotherapy for cancer.

Based upon the clinical trials conducted to this point, these programs have demonstrated a number of critical characteristics of GR-MD-02 that are very encouraging.

First, the compound seems to be safe and well-tolerated, with thousands of doses having been administered without any serious drug-related complications.

The compound also appears to demonstrate biological activity in humans, as shown by results in ameliorating severe skin diseases.

We believe these characteristics make GR-MD-02 an attractive candidate for further investigation along all the indications currently under development.

First I will discuss our program in NASH cirrhosis. Our preclinical results show that GR-MD-02 has significant anti-fibrotic effects in multiple animal models, including liver, kidney, lung, pulmonary artery and heart fibrosis. The liver disease NASH was chosen as the first target for development of GR-MD-02 for a number of reasons.

First, it is the most common liver disease, with one in four individuals in the world having fatty liver, and about 2 percent of those destined to die of complications of late-stage NASH cirrhosis.

Second, there are no currently approved drugs for NASH, and the market for NASH drugs globally in 2025 may be as high as $40 billion annually, according to some analysts. This makes NASH one of the largest potential markets for drug development today, as evidenced by a number of significant recent transactions in the industry.

NASH is a chronic disorder, with fat accumulation in the liver resulting in inflammation and progressive fibrosis, or scarring. Over years, this can ultimately lead to the end stage of scarring called cirrhosis. Because of the long duration, potentially decades, of underlying, asymptomatic disease before reaching cirrhosis, which is when complications and death may occur, the timing of intervention during the course of disease is an important issue.

We have targeted GR-MD-02 therapy to patients with NASH cirrhosis who have not yet had serious complications. With a goal of reducing the progression of or, reversing fibrosis.

Unlike the treatment of early stage NASH, where the medical benefits are uncertain, reducing the progression of fibrosis or reversing existing fibrosis in cirrhosis is likely to reduce complications, help avoid liver transplant, or may ultimately prevent death from complications of cirrhosis.

Our robust data in animal models of liver fibrosis and cirrhosis have shown the ability of GR-MD-02 to reverse fibrosis and cirrhosis. While there are many companies and different drugs targeting pre-cirrhotic NASH, we are one of only three companies with clinical trials in NASH cirrhosis. And, we anticipate being the only company to report data this year in a NASH cirrhosis clinical trial.

The NASH-CX trial is the ongoing Phase 2b clinical trial that studies the effect of GR-MD-02 in NASH cirrhosis in patients. And, it has a number of important aspects.

The study has a rigorous, FDA-agreed design that measures many parameters in patients with NASH cirrhosis, who have not had serious complications and are not yet candidates for a liver transplant.

The trial has enrolled 162 patients in three treatment arms: placebo and two doses of drugs, the treatment given every other week for 52 weeks, or essentially, one year of therapy.

The primary endpoint of the trial is the baseline adjusted reduction in portal blood pressure, as assessed by hepatic venous pressure grading, or HVPG. Increased portal pressure occurs in advancing cirrhosis, and is directly related to patient outcomes. This is potentially an acceptable regulatory endpoint for provisional approval with follow-up outcomes data.

Secondary endpoints importantly include liver biopsy, serum biomarkers, complications and several non-invasive measures of liver structure and function, including FibroScan (Echosens) and the methacetin breath test (Exalenz), respectively.

This study is powered at greater than 80 percent, to demonstrate a difference in HVPG of at least 2 millimeters of mercury, a change that is potentially clinically significant in these patients. Seventy-one patients have completed therapy in the NASH-CX trial, but the data will remain blinded until all patients have completed the trial. Again, we are on track to report topline data in December of 2017.

Data from the NASH-CX trial will represent a significant milestone in NASH therapy and for the company. Success of this trial could be a breakthrough finding for liver cirrhosis. The company cannot provide any guidance regarding the next steps in the program in NASH cirrhosis following positive NASH-CX trial data, until the data are analyzed at the end of the trial and the FDA is consulted regarding next steps.

The pharmaceutical industry is very interested in NASH. We have had discussions with multiple companies over the last couple of years. With positive data from the NASH-CX trial, it is likely that further partnership discussions will ensue.

Next I will discuss skin diseases. GR-MD-02 seems to have an important and clinically relevant effect in cirrhosis and atopic dermatitis, two serious skin diseases. An exploratory open-label Phase 2a trial was conducted in five adults with moderate to severe plaque psoriasis. One patient had over an 80 percent reduction in disease activity after 13 every-other-week infusions, while the other four patients reached 50 percent reduction in disease activity by their tenth infusion.

We also studied GR-MD-02 in the treatment of severe and refractory atopic dermatitis, in three patients in an open-label investigator-initiated study. Atopic dermatitis is also commonly known as eczema. All three patients showed clinical response after receiving six every-other-week doses, with two patients achieving an average of approximately 70 percent reduction in disease activity after receiving only three doses of GR-MD-02.

These preliminary but clinically relevant findings provide two important conclusions. First, they show that GR-MD-02 has a clinical effect in two galectin-dependent human diseases, validating activity of the drug in clinical situations.

Second, they provide a potential opportunity for additional drug registration pathways.

While there are already multiple effective drugs on the market for the treatment of moderately severe to severe plaque psoriasis, and generics are also entering the market, atopic dermatitis may present an opportunity. Atopic dermatitis is an important, unmet medical need that can cause very serious, debilitating problems for adults as well as children, and there have been no new agents approved for moderate to severe atopic dermatitis in 30 years.*

* NOTE: After the conclusion of this conference call on March 28, 2017, dupilumab was approved by the FDA for moderate to severe atopic dermatitis.

While there are several new biological drugs in late clinical development, our preliminary results in a few patients compare favorably with the other drugs in development.

Galectin is exploring partnerships and other options to finance a potential program in atopic dermatitis, or possibly psoriasis, although no decisions have been made beyond the existing clinical studies. Until the results of the NASH-CX trial are known, potential skin disease partners would have to assure us that they would not impede subsequent partnerships with GR-MD-02 for NASH cirrhosis.

I will next discuss cancer immunotherapy. Galectin-3 production has increased in most cancers with multiple effects, including reducing the ability of the immune system to kill tumor cells. This prompted studies in combination with known immunotherapies.

Investigators at Providence Cancer Center have tested GR-MD-02 as well as our other carbohydrate-based compound, GM-CT-01, in multiple sophisticated cancer animal models, in combination with known cancer immunotherapeutic drugs. GR-MD-02 showed a synergistic effect on multiple cancers in combination with different immunotherapies. GM-CT-01, on the other hand, had no effect.

The Providence Cancer Center recently reported early results of GR-MD-02 in five patients with advanced melanoma, who were treated with a combination of 2 milligrams per kilogram GR-MD-02 and pembrolizumab, brand name Keytruda.

Out of these five patients, there has been one partial response which is moving toward a complete response; and one mixed response. While we cannot conclude that the responses were related to the addition of GR-MD-02, these findings provide a clinically relevant signal to follow as GR-MD-02 are escalated. The clinical trial is ongoing, with increasing doses of GR-MD-02 and relevant data will be reported as determined by the principal investigator. There will likely be additional data reported in early 2018.

A decision to move to a controlled Phase 2 trial of combination immunotherapy will be based on the response rate of the combination of pembrolizumab with GR-MD-02 as compared to historical response rates to pembrolizumab alone. The Providence Cancer Center is funding these trials. Potential partnerships will depend on the results of additional clinical data.

So in summary, our clinical development program for GR-MD-02 progressed significantly during 2016 and we will have critical results in 2017. Paramount among those results and a value inflection point, will be reporting of topline data for the NASH-CX trial. Expected to be the next clinical trial in the treatment of NASH cirrhosis to read out, with topline data in December of 2017.

In atopic dermatitis, additional data will be reported by the end of Q3, as patients continue on their GR-MD-02 therapy. We cannot predict whether there will be additional data on cancer immunotherapy in 2017, as this trial is controlled by Providence Cancer Center.

We believe we have a very safe drug candidate, with thousands of doses given to humans with no serious adverse events related to GR-MD-02. This is an exciting year for the company, and the reporting of topline NASH-CX data will culminate the efforts of a program that was initiated in 2011.

Additionally, it is exciting for the entire field of galectin-3 inhibitors, which have multiple potential applications beyond those indications the company is currently investigating.

I thank you for your attention, and I will now take questions from individuals on the call.

QUESTIONS AND ANSWERS

Operator

(Operator Instruction) Ed Arce, H.C. Wainwright.

Ed Arce - *H.C. Wainwright - Analyst*

Thank you. Hi, Peter, it's good to talk to you again.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes, hi Ed.

Ed Arce - *H.C. Wainwright - Analyst*

So just a few questions. First, a couple on NASH-CX. I just wanted to confirm, we talked about this before, but as you report the data and get the full results, you will then, I assume, evaluate whether to pursue either a cohort that decreases HVPG to 10 millimeters of mercury or the other -- that stops the progression to that level?

And then the other question is, the last update we had on the number of dropouts was five patients. I know that that's still below the level that you assumed for your design. I was just wondering if you had an update on that.

And then I have a couple follow ups.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes. Let me answer that second question first, because it's straightforward. We have had a total of 10 dropouts out of 162, which is about a 6 percent rate. We had anticipated at the beginning of the trial that there would be a 25 percent dropout rate. So we're still well below the rate that we had anticipated for the trial.

And let me go back to your first question, which is a complicated one in a number of aspects. Let me sort this out a little bit for you and the other callers.

First of all, portal hypertension, or high blood pressure in the portal vein, is defined as a pressure above 5 millimeters of mercury. Clinically significant portal hypertension is defined as 10 millimeters of mercury, because above 10 millimeters of mercury is when complications begin to occur, such as the development of esophageal v a r i c e s .

We designed the clinical trial to enroll patients that had a mean portal pressure, or would have been expected to have a mean portal pressure, between 12 and 15 millimeters of mercury. And without telling you the exact number, which we haven't revealed, we were successful in enrolling a group of patients with a mean HVPG or portal pressure between 12 and 15 millimeters of mercury.

So the mean patients have clinically significant portal hypertension, but not so severe that they're in the end stage. Once we see the results of this trial on the mean change in portal pressure, we will also look at different groups of patients. Those that started below 10 and those that start above, which were about two-thirds of the patients, and we will be able to determine then what the next design of a clinical trial might look like based on the analysis of those results.

But we are pleased that we were able to enroll a patient population with clinically significant portal hypertension. And we know that a 10 to 20 percent reduction in portal hypertension has clinically important outcome results in patients. So that's why we're targeting, or our statistical analysis targets, 2 millimeter of mercury drop in patients that have above 12 millimeters of mercury of portal hypertension.

Ed, I'm not sure if that fully answered your question?

Ed Arce - *H.C. Wainwright - Analyst*

Yes, it does. I just wanted to confirm that you would be looking at both sets of patients, was below and above that threshold of 10 millimeters of mercury.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes.

Ed Arce - *H.C. Wainwright - Analyst*

And it sounds like you've got one-third to two-third split, so that's helpful.

You had also mentioned the other two programs that are focused on NASH cirrhosis. I was just wondering if you had any thoughts you'd care to share about how you view those programs and the approaches that they have.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes, the other two programs, one is a pan-caspase inhibitor from Conatus who have just started a clinical trial enrolling even more severe patients with portal hypertension. And the second program is a Gilead clinical trial that is using an ASK-1 inhibitor and they are enrolling a large clinical trial. Both of these clinical trials will not read out until long after ours, because they've just been i n i t i a t e d .

Ed Arce - *H.C. Wainwright - Analyst*

OK. And then a couple last follow ups. Do you expect to have any presence at EASL next month?

And also, I guess the last question for Jack is, how should we think about operating expenses for 2017? Just perhaps even just qualitatively. Thanks.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

I'll answer the EASL question. We will be attending EASL. We do have a late-breaking abstract at ISIL, which is focused on an analysis of the methacetin breath test that we're doing in conjunction with Exalenz.

The presentation will be regarding the baseline values of the C-13 methacetin breath test as it correlates with HVPG, so we will be reporting data at ISIL from that.

And Jack, do you want to?

Jack Callicutt - *Galectin Therapeutics - CFO*

Yes, as far as our research and development expenses, as well as our G&A expenses, we think those will be similar to 2016. And as we've mentioned, we've got cash currently to fund operations through the end of the year. But we think those expenses will be about the same as they were last year.

Ed Arce - *H.C. Wainwright - Analyst*

OK, great. Thank you, guys.

Jack Callicutt - *Galectin Therapeutics - CFO*

Thanks.

Operator

Thomas Yip, FBR & Company.

Thomas Yip - *FBR & Company - Analyst*

Hi, good morning, everyone. Thank you for taking our questions. Just asking a couple of quick questions for Vernon.

We see that you have a large number of other galectin inhibitor candidates. Can you outline some R&D activities that you have ongoing? And when should we expect to see some early quarter presentation or medical conferences data for those comp panels?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes, thank you, Thomas and good to talk to you, and Vern. We have a program in discovery for identifying additional galectin-3 and other galectin inhibitors. We have not announced any information regarding those additional galectin inhibitors, but that program is ongoing, and when we have some animal data or additional data regarding those, we will communicate them. But we don't have the timing of that at this point.

Thanks, Thomas.

Thomas Yip - *FBR & Company - Analyst*

OK, so I guess from, you know, from a bigger picture standpoint, if you see a similar level of activity compared to GR-MD-02, I mean obviously they are still in pre-clinic stage. What are your plans to monetize them? Have you given any thought about that so far?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes. Well, the GR-MD-02, as you know, is a parenteral IV-administered drug. The drugs that we are working on, in discovery, would have the potential for other routes of administration, including oral a d m i n i s t r a t i o n .

Additionally, we are working on higher potency and more specificity with regard to galectin-3 inhibition.

Thomas Yip - *FBR & Company - Analyst*

OK, that sounds good. We'll just have to keep our eyes out for that.

I guess I will switch gears a little bit, then. I have questions about your pipeline in (NASH). Given the IST that you have right now with Providence, what exactly do you need to file the IND and to go into Phase 2 clinical trials? Do you need to in-license it back from Providence? Or, do you have the rights to that panel?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

We have exclusive rights to GR-MD-02, and while we have pending intellectual property jointly with Providence with regard to the method of use, we have exclusive license to that as well. So there are no licensing or intellectual property issues there.

The decision to go to a Phase 2 is going to be related, as I mentioned, to the results of ascending doses of GR-MD-02 in combination with pembrolizumab as compared to historical controls. And with a significant difference in either the response or immunologic markers which we are measuring as well. That would then lead us to a decision point about going to a Phase 2 controlled trial.

Thomas Yip - *FBR & Company - Analyst*

OK, that sounds good. Thanks for the clarity. Just one final question regarding the data that you've seen so far in atopic dermatitis. So you've outlined that earlier that you plan to out-license that indication or to enter partnerships.

So can you describe, just on a very top level, what would an ideal partnership look like? What specific characteristics will you be looking for?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes. It's a good question. As I mentioned in the review, because it's the same compound as we're using in NASH cirrhosis, whatever deal we did with a partner around atopic dermatitis or skin disease would have to not impair the very large potential of the deal in NASH. So we are focusing on international companies rather than multi-national or U.S. companies, skin-specific companies, and companies where we might do a deal that would not impede a subsequent deal in NASH.

So that's kind of the focus of where we're looking at this point.

Thomas Yip - *FBR & Company - Analyst*

OK, that sounds good. Thank you again for taking my questions, and we will look forward to the progress this year, and look forward to the (inaudible) data later this year.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Thank you, Thomas.

Operator

Len Yaffe, Stoc*Doc Partners.

Len Yaffe - *Stoc*Doc Partners - Analyst*

Thank you very much. Peter, as I speak with clinicians about how they think the NASH market will evolve with therapeutics over time, they're drawing the parallel, albeit the sizes are different, to the Hep-C market where they're of the opinion that insurers will likely approve treatment for those patients with F-3/F-4 fibrosis, cirrhosis initially because they are most at risk for having complications.

A lot of the NASH targets that other companies are developing seem to be aimed at earlier stages, when the progression hasn't yet gone as far, and therefore the likelihood possibly of complications isn't as great.

And I was just wondering if you could give us your thoughts on, what's the progression in years from NAFLD to NASH to cirrhosis and beyond is, and what indications, if any, you have will along that timeline you think that the initial treatments will be authorized by insurers or doctors who will want patients treated?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes, I think that's an insightful question and also mirrors the discussions that we've had with thought leaders in NASH and liver disease.

The progression from early fatty liver disease to cirrhosis is on the order of 20 years. So it progresses relatively slowly. There are some patients that may progress faster, and so forth, but you can think of about a 20-year period.

Once you develop cirrhosis, it's still about five years to developing complications of cirrhosis, and then a year or two before death or liver transplant. So we are focused on those with well-compensated cirrhosis in that timeframe where you have about five years or so to reverse or stave off the progression of fibrosis, so that it doesn't get to cirrhosis complications.

It's very clear that that target is going to be more accepted by both physicians, insurers and governments, because you're much closer to an outcome; a serious outcome. Whereas in early stages of NASH, in long-term follow-up studies that have been done. One study that was done in Sweden where they followed patients for 33 years, those with F-1 or F-2, Stage 1 or Stage 2 fibrosis, when followed for 33 years, had no difference in mortality or morbidity with relationship to a reference group.

So an argument could be made that those patients with early disease, we can't predict who's going to progress, and they may not have any outcome problems, so that governments, insurers and physicians are going to be more reluctant to treat somebody for decades with the early form of the disease, particularly when lifestyle changes such as weight loss, exercise and so forth can make a big impact at that time.

So I do think that it's the late stage fibrosis that is the most important approach to targeting this disease. Thanks, Len.

Len Yaffe - *Stoc*Doc Partners - Analyst*

Thank you.

Operator

Sa'ar Yaniv, Roth Capital Partners, LLC.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

Hi, good morning, guys. Thank you so much for taking my call, I appreciate it.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Hi, Sa'ar.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

Hi. I had a couple of questions about the cirrhosis study, and then some other ones.

First of all, it seems like the completed enrolment of the study was in last August. So, should we expect completion of the last patient in the study around August or September of this year?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes, that's correct.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

OK, so we're looking at about two to two-and-a-half months for you to compile the data for the study?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes, just to follow up on that a bit, Sa'ar, so after the last infusion, two weeks later the patient gets their final HVPG and other testing, and their last visit is about a month after that. So there's about six weeks of additional data gathering before the database can be locked. So you can think of mid-October as being database lock with that analysis and data report in December.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

OK, sounds good. You're not planning on having any interim analysis for safety or futility in the study?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

We have three scheduled safety interim analysis that's done by an independent drug safety monitoring board. Two of those have already been completed and there's been no safety signals. The third and final DSMB before the end of the study will be in June timeframe. So there are safety monitoring analysis, but no interim efficacy analysis until the final patient and the database lock.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

OK, great. You mentioned earlier that you had expected in the design to have a 25 percent dropout rate.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

It seems a little high, and I wanted to know what the reason for such high expectations for dropout was?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

It's a historical rate. Previous companies that have done clinical trials with patients with cirrhosis doing multiple procedures such as the HVPG and liver biopsy have had rates as high as 25 percent drop out. So when we were designing this study, it was the recommendation of KOL's and our CRO, and the FDA in fact recommended that a dropout rate of 25 percent would not be unreasonable.

We had originally estimated lower than that, but it was really the FDA questioning us about the size of the dropout rate. So we planned for 25 percent, but we're pleased to see that it's running around 6 percent.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

OK. That's very helpful, thank you.

And then my last question about the study, are you looking at any pre-specified subgroup analysis in the study? So you mentioned, for example, the HVPG rate, you know, above 5 and above 10 and then the 12 to 15 millimeter HG. Are you looking at different groups there?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes. We have prespecified analysis for looking at 5 to 10, 10 to 15, and 15 and above. So we do have, as well as above and below 10, so we have prespecified subgroup analysis as well.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

OK. One quick question with the NASH fibrosis study, you announced the results in September 2016.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

What's the status of GR-MD-02 in NASH?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Well, that study, as you know, is in NASH with Stage 3 fibrosis and we, in that short evaluation, we did not see a difference in non-invasive testing. The result of that study was twofold. One, to evaluate non-invasive tests and two, to see if there was any effect in the short-term therapy.

We don't have any plans on doing additional trials in non-cirrhotic NASH at this point.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

OK. So right now, the program is focused only on NASH cirrhosis?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes, that's correc.t

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

OK. And what about the cirrhosis program? What's the plan in that program? Are you only looking to go forward with a partner, as you suggested earlier, or will consider taking that forward by yourself?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Well, we will consider taking forward by ourselves the atopic dermatitis findings, because as I mentioned, the market is much less mature, there hasn't been a drug approved in 30 years for moderate to severe atopic dermatitis*, so we see the opportunity there as greater than cirrhosis. But we would be willing to move both forward with a partner, depending on those discussions.

* NOTE: After the conclusion of this conference call on March 28, 2017, dupilumab was approved by the FDA for moderate to severe atopic dermatitis.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

And just to be clear, there are three patients in the atopic dermatitis study?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes, just three patients, investigator-initiated.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

So is there a plan to do a slightly larger study?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes. Almost any study would be slightly larger than three. We are exploring those options. At the present time, we haven't made a decision on initiating a new trial, and it would have to come with funding for supporting that.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

OK. And then the final question, if you don't mind, do you have any plans on publishing any of the data that you've announced recently from NASH, from the cirrhosis data in August? I think you, for the NASH data in September? The atopic dermatitis. Any plans on conferences or scientific publications?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

The psoriasis data was presented by the principal investigator at an academic conference, Maui Dermatology, just this past week and we're preparing a publication of that information. And we will be publishing. We're preparing a publication for the NASH-FX trial. The atopic dermatitis, we may present that at a meeting, but we don't have plans right now for publishing that.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

OK, but sorry, you said for the NASH you're looking to publish that in a scientific journal?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Yes.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

Any plans on presenting that at any of the upcoming scientific conferences or meetings?

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

No, we're not presenting the data at the upcoming EASL meeting, but we are preparing a manuscript.

Sa'ar Yaniv - *Roth Capital Partners, LLC - Analyst*

OK, great. Thank you so much for taking my questions.

Jack Callicutt - *Galectin Therapeutics - CFO*

Thanks, Sa'ar.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

Thank you, Sa'ar.

Operator

Thank you. And at this time, the question-and-answer session is completed and I will now turn the call back over to Dr. Traber for final remarks.

Peter Traber - *Galectin Therapeutics - President, CEO, CMO*

We thank you very much for your attention and for the excellent questions, and we look forward to delivering on the promise of the therapy of GR-MD-02 during the course of this year. So thank you very much for your attention.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This concludes today's conference. You may all disconnect. Everyone have a great day.

MARCH 28, 2017 / 9AM, GALT - Q4 2016 Galectin Therapeutics Inc. Earnings Call