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GLMD - Q2 2019 Galmed Pharmaceuticals Ltd Earnings Call

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PRESENTATION

Operator

Good day, and welcome to Galmed Conference Call to discuss Financial Results for Second Quarter of 2019.

Today's conference is being recorded. Before we begin, please note that we will be making certain forward-looking statements on today's call, including those regarding financial results, statements, forecasts regarding anticipated timelines and expectations with respect to our regulatory and clinical development programs as well as other statements that relate to future events.

These statements are based on beliefs and expectations of management, as of today, and actual results, trends, timelines, projections relating to our financial position and projected development programs and pipeline could differ materially.

We urge all investors to read carefully the risks and uncertainties disclosed in our filings with the SEC, including limitation, the risks under the heading Risk Factors, described in our annual report on Form 20-F filed with the SEC, and the risks and uncertainties included in the Form 6-K filed with the SEC earlier today.

Galmed assumes no obligation to update any forward-looking statements or information, which speak as of the respective dates only. I would now like to turn the call over to Allen Baharaff, President and Chief Executive Officer. Allen, please go ahead.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

Thank you, Shelley. Good morning, and thank you for joining us on today's conference call. I'm pleased to be here today with our Chief Scientific Officer, Dr. Liat Hayardeny; our Chief Medical Officer, Dr. Tali Gorfine; and our Chief Financial Officer Yohai Stenzler to provide you with an update on our clinical development program as well as report to you on our financial results for the second quarter of 2019. As always, we will be happy to take any questions you may have at the conclusion of my prepared remarks.

During the last quarter, we continue with the preparations for the initiation of ARMOR, our Phase III/IV NASH study, and we plan to commence later this quarter. As you may recall, ARMOR would evaluate the safety and efficacy of Aramchol in approximately 2,000 patients, on a twice daily, 300 milligrams treatment, compared to placebo in a 2:1 randomization.

The study is designed to consist of 2 parts. In the first part, histology-based, 1,200 subjects will be treated with Aramchol or matching placebo for 52 weeks until the second biopsy. In the second part, clinically-based, a total of 2,000 subjects will continue with the same treatment assignment until the study completion to confirm clinical efficacy.

The study is powered to meet the 2 alternative key histology-based endpoints: first, NASH resolution and no worsening of liver fibrosis; and second, fibrosis improvement without NASH worsening.

Under current FDA guidance, meeting one of these endpoints is expected to suffice for successful achievement of approval of drugs.

Similar to our Phase-IIb ARREST study, ARMOR is designed to be a robust global study in the U.S., Europe, Latin America and Asia. Maintaining the global distribution has not only significant direct effect on the total cost of the study, but also ensure that we will adhere to the same patient population investigated during the ARREST study.

ARMOR core principal investigators are Professor Vlad Ratziu and Professor Arun Sanyal with Professor Stephen Harrison, as the U.S. lead investigator.

Based on the learnings from the other advance NASH clinical studies, we are working with industry leaders in the management of the ARMOR study, including Covance, Burke, Summit Clinical Research and others, and are looking to rapidly enroll the first 1,200 patients with a targeted timeline of 16 to 18 months from the time of commencement with the aim of reporting the top line results by Q4 2022. I would like now to turn the call over to Yohai Stenzler, our CFO. Yohai?

Yohai Stenzler - *Galmed Pharmaceuticals Ltd. - CFO & Controller*

Thank you, Allen. Good morning. This morning, I will be providing you with our financial results for the quarter ending June 30, 2019. For more information, please refer to our report on Form 6-K filed earlier today with the SEC, which, among other things, provides the summary of such financial results.

For the second quarter of 2019, our net loss totaled $4.2 million or $0.20 per share compared with a net loss of $2.7 million or $0.17 per share for the corresponding quarter in 2018. Research and development expenses totaled $3.5 million for the second quarter of 2019. This compares with $1.9 million for the second quarter in 2018. All R&D activities have increased during the second quarter, mainly to the work we are making towards the initiation of the ARMOR study later this quarter.

Turning now to G&A. Our general and administrative expenses for the quarter totaled $1.2 million compared to $1.1 million for the corresponding period in 2018. The increase primarily resulted from an increase of approximately $0.2 million in noncash stock-based compensation expenses. During the 3 months ended June 30, 2019, we had a net financial income of $0.5 million versus $0.1 million for the corresponding period in 2018. The increase is attributable to our interest income from financial instruments. Our cash balance as of June 30, 2019, which includes cash, cash equivalent, short-term deposits and marketable securities totaled $83.6 million compared to $90.2 million on December 31, 2018.

With that said, operator, please provide instructions for the Q&A portion of our call.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question is from Yasmeen Rahimi with Roth Capital Partners.

Yasmeen Rahimi - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Co-Head of Biotechnology Research*

Two questions for you. Number one is, when you talk about the [ARMOR] study you've learned in regards to enrollment [in the ARREST Phase IIb] study that will allow you to expedite enrollment into ARMOR [study] what percentage of the ARMOR sites are the same as in the ARREST Phase IIb?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

I'm sorry, Yasmeen, but you were breaking completely. I mean -- And operator, did you hear the question because we could not hear the question properly?

Yasmeen Rahimi - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Co-Head of Biotechnology Research*

I can repeat it. I can repeat it.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

Okay.

Yasmeen Rahimi - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Co-Head of Biotechnology Research*

Do you want me to repeat it?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

Thank you, Yasmeen.

Yasmeen Rahimi - *Roth Capital Partners, LLC, Research Division - MD, Senior Research Analyst & Co-Head of Biotechnology Research*

Okay. Question number 1 is, what are the key lessons that you've learned from your Phase IIb in regards to enrollment that allows you to expedite it? And then the second one is, what percentage of the sites, ARMOR sites, are the same as in the ARREST study?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

Okay. So the first, lesson obtained. We have been heavily engaged over the last year or so in understanding the NASH space and the investigators, which participated in large Phase IIb and Phase III studies. We've built, I would say, a proprietary database of global NASH physicians, and we are really looking at this bottom up because we understand that, for a successful study, it is advisable to limit the number of participating sites for 200 patients, wishing to break the paradigm of 0.2, 0.3 patients -- enrolled patients per sites per month. And it -- for doing so, we had to identify the high enrolling sites and understand the -- to build the enrollment strategy to fit ARMOR study. All of this was based -- if you remember, ARREST study was already conducted in more than 85 in the same jurisdiction. So working together with investigators, preparing the sites, discussing the need, and I hope that all these lessons will help us to limit the duration of the recruitment for the 16 to 18 months as we stated.

Operator

Our next question is from Adam Walsh with Stifel.

Adam Anderson Walsh - *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Analyst*

My first question is regarding some of the dynamics in the NASH space, we've seen datas from some other [companies' trials] it's been mixed. Just curious, as you think about a potential partnership for the drug, either geographic or in combination, has -- have the dynamics of the NASH space actually made you more or less likely to potentially sign a partnership? And then the second question is on the cash balance. Given your visibility now on the upcoming Phase III, Phase IV trial, how do you feel about your cash balance as you've kind of mapped out the logistics around the enrollment time frames and the data readout?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

Okay. Thank you, Adam, and thank you for the questions. So let's first discuss the cash. I mean our focus is not changed. We are in the same ballpark number that we've been in before, which is around $70 million for the -- $65 million, $70 million for the first part of the study. And as we advance, clearly, there's less and less risk. And we feel that our budget is indeed in place in terms of the CTAs, the contracts that are being signed as we speak with the different sites, and the cost for all the vendors that I mentioned some of them. But clearly, this is -- our focus has been accurate, and we have nothing to change on that.

As to -- sorry, the first question was...

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

The partnership.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

The partnership, Yes. So we are -- again, I don't think that -- of course, we -- unfortunately, we're seeing some negative studies from -- in the space. But our philosophy has not changed. We've always thought about -- Galmed is running a global study and in this global study, we are preparing for global licensings and global JVs or collaborations. We are not waiting for this to come. We are advancing both, for instance, China, we've effectively included China, Mainland China, not only Hong Kong, in the study. We have contracted with the leading CRO to advance the regulatory discussions with NMPA, this is the new name of the CFDA, and we are hoping that we will have an IND meeting early first quarter of 2020 or the end of this quarter -- or the end of the fourth quarter of 2019. And all of these would naturally advance the attractiveness of a potential transaction in China. I want to draw your attention to a recent transaction that was signed by GENFIT and Terns with very lucrative numbers, which are more or less what we are starting to see the kind of a licensing term that you see in other western jurisdictions. And before China was -- had much lower numbers, but now we see more and more better numbers. And the same is for Middle East, North Africa and Latin America. And so we are looking and holding discussions with a number of parties, and we -- of course, when there'll be any news, we would report as soon as there will be anything to report.

Operator

Our next question is from Joon Lee with SunTrust Robinson Humphrey.

Fang-Ke Huang - *SunTrust Robinson Humphrey, Inc., Research Division - Associate*

This is Fang-Ke, on for Joon. First one is, on the last earnings call, I remember, you guys mentioned that you're able to power the study for both histologic endpoints. Could you discuss some of your powering assumptions for each endpoint, such as placebo response rate, effect size, dropout rate, study powering and (inaudible) trending levels?

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

Okay. This is Tali, the CMO. We have very, as you know, specific assumptions when powering the study. These are based on the current knowledge in the field in terms of placebo response in terms of where it ranges. And you know the range is different for NASH resolution and for fibrosis improvement, the range is lower for NASH resolution, more stretched for fibrosis improvement. They are based on the ARREST data. They are based on what would be clinically meaningful [results], and they are based, of course, on our understanding with the FDA with regards to the multiplicity adjustment that is required in this Phase III/IV study. That means we have also the clinical endpoints and the 2 endpoints that each could be sufficient for the powering of the study. Taking all this together, brought up the number of 1,200 patients to be very well-powered for both endpoints. We always have to remember that we are increasing exposure at this time. So we did all of the preliminary assumptions based on the data that already was received in ARREST, that we know, at this time, we have a higher exposure of Aramchol being given 300 milligrams twice daily.

Fang-Ke Huang - *SunTrust Robinson Humphrey, Inc., Research Division - Associate*

Okay. That's helpful. And our second question. So we recently has a -- on a KOL call and at one that doctors mentioned that if you can have a run-in phase, potentially that can minimize the lifestyle changes that you have enrolled in the trial, which may secure the placebo response. So I'm just wondering in your Phase III or Phase IV trial, did you have a run-in Phase to kind of minimize that potential lifestyle changes. So that you have a robust dataset.

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

No. We do not have, in a study, a run-in period. But we have inclusion and exclusion criteria that will be sending in very much details describing the -- how the weight should be stable before the baseline biopsy. And we're tracking lifestyle diet and exercise in the study. This is obviously important in the field. We -- all of our inclusions and exclusions are based on the knowledge of the physician and the patient in the, at least, 6 and sometimes 12 months prior to the biopsy. Don't forget, in the baseline biopsy, the patient has an F2, F3, regardless of his lifestyle and activities and diet. So altogether, as the -- in the F baseline, the patient has evidence for advanced fibrosis on the liver biopsy regardless of the changes in lifestyle before that. And by the way, the FDA is very specific with the guidelines related to the amount of weight loss reduction that is allowable in this time period, et cetera.

Fang-Ke Huang - *SunTrust Robinson Humphrey, Inc., Research Division - Associate*

Great. And lastly, I remember, Allen, you previously mentioned that you guys are considering doing a pediatrics trial -- doing a trial for pediatric patients. And I think -- what's your plan there? And where -- I'm thinking -- when that start -- that trial can be started?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

Okay. So we've decided that at this stage, since all we could do with a pediatric study, we could only do a PK study. And it will be more prudent to wait and see the results of the first conditional approval before we advance into a large Phase IIb study. So we decided that there is no hurry and there is no need to rush the initiation of that. And we would reinvestigate this idea, as we come closer to the completion of ARMOR and then discuss with the principal investigator of the study, which, of course, we -- from a single center, will now be a multicenter study and not only a U.S. study. But all of that will have sufficient plan to discuss, as we come to the data of ARMOR, which, as I said, is planned to be by Q4 2022.

Operator

Our next question is from Steve Seedhouse with Raymond James.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

I have a few clarification questions on ARMOR. Just first, looking at the presentation that you gave at the NASH Summit in Boston, in April. One of the inclusion criteria is known type 2 diabetes or prediabetes. So can you just clarify, is that for both F2 and F3 patients? And does that mean that patients must have the diagnosis of type 2 diabetes or prediabetes stand for the study? Or are they just allowed to have it, but it's not necessary to have it?

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

It's mandatory. Thank you for the question. So all our patients in the ARMOR study will have prediabetes or diabetes. This is the same as was the inclusion in the ARREST study. We do this for several reasons. On top of not wanting to change the population between one study to the next study, we also believe that in terms of homogeneity in the population, in terms of these patients have the same risk factors that have brought them to the stage of liver disease, this makes the study more uniform. In addition, as you know, this has a potential effect on spleen failure rates and needs to reduce spleen failure rates.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Okay. And another question on the design. The Phase IV cohort. So the enrollment of up to 2,000 patients. Will that include exploratory F1 patients? Or is the entire study restricted to F2, F3?

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

The entire study is restricted to F2/F3. We know that other people do have small exploratory arm with F1, which have currently not completed regulatory population for approval. At this stage of the development, we're focusing on enrolling F2/F3 patients that will be included in the endpoint analysis for approval.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Okay. And in the clinical outcomes portion, is histologic progression to cirrhosis one of the components of the composite outcome to endpoint? And I guess, just generally, is your clinical outcomes endpoint basically what is recommended in the FDA's draft guidance?

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

Yes. Thank you. It's exactly as the FDA recommends and histologic progression to cirrhosis is included in these endpoints.

Steven James Seedhouse - *Raymond James & Associates, Inc., Research Division - Research Analyst*

Okay. And one last question for me unrelated to the study design. Any presentations Galmed submitted for AASLD this year?

Liat Hayardeny - *Galmed Pharmaceuticals Ltd. - Chief Scientific Officer*

Steve, this is Liat. Thank you very much. Yes, we did. We have 2 abstracts sent to the AASLD and hopefully, they will be accepted and we will report it.

Operator

Our next question is from Ed Arce with H.C. Wainwright.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Congrats on continued progress towards initiating ARMOR. A few questions from me. First is, on the 1,200 subjects that you've determined necessary for the 52-week histologic Phase III endpoint, I believe that number had been talked about as being 1,000 just a few months ago. And so I'm just wondering, perhaps you could discuss what changes perhaps with powering or something else led to that decision, especially given that you've known now for a good 8 or 9 months about the increased exposure in using b.i.d. dosing?

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

Okay. In terms of 1,200 patients, this number was calculated to make sure that we have robust powering of this study for the 2 endpoints with all the multiplicity adjustments. And I would remind you that in this specific design with Phase III/IV study, the patients continued to be enrolled after -- as we reach to 1,000 or 1,200 patients, so the gap in time pointed for these 200 patients, make this increase negligible when we're considering the success of the study.

The others -- and as -- we did all the assumptions per the effect that we have in ARREST. We know that this time we have higher exposures, and we hope to get much better results. Nevertheless, all the calculations were on -- based on the effect size that we have in ARREST.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

I see. All right. That's helpful. The other question I had is just to walk through the timeline given you stated now results are expected in the fourth quarter of 2022 and you obviously have a 12-month treatment period here. What are your thoughts around enrollment? How long that could take? And then once you've dosed your final patient for that endpoint, how much time do you think it would take to go through the data analysis, preparation and then finally, read out the results?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

Okay. So I'm sure with 1,200 patients, we won't be able to have the same success that we had with ARREST. But last patient backlog was on the 31st of May, and we reported the data on June 6. This is not feasible, of course, with 1,200 patients. What we are -- our guidance is that we would initiate the study at the end of this quarter, as we previously stated, assuming that the first few months, because of Thanksgiving and Christmas, are going to be slower. But even if we allow for more than the 18 months, because [that's a few week start, the 18 months only on January and] forget the patients, which are going to be randomized on the earlier months, so the last patient, the patient 1,200 is going to be randomized on June 2021, and a year later, on June 2022, he would complete -- he or she would complete 52 weeks of treatment. And then we allow for additional 3 months for data analysis and completion and backlog, et cetera, which will allow us the analysis to report the data at AASLD on November 2022.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Great. That's very helpful, Allen. One last question for me and I'll jump back in the queue. Are there going to be -- do you expect there to be any sort of interim announcements through the conduct of the trial, perhaps DSMB or any sort of other announcements before the readout?

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

Of course, we will have routine DSMBs in the study, and that's routine safety. I don't consider these interim analysis of any kind -- we will not have an interim analysis in the study.

Operator

Our next question is from Mayank Mamtani with B. Riley FBR.

Mayank Mamtani - *B. Riley FBR, Inc., Research Division - Research Analyst*

Congrats on the progress. Two, just clarifications from me and then I have 2 follow-ups. Number one, could you just confirm that you're working on the -- continue to work on the twice-daily and there is no once-daily version? Because I think the press release initially had the once-daily. So I was -- I just wanted to be clear, there is no once-daily arm in the ARMOR study?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

This is correct. There's no -- there's only -- we've got only twice-daily and randomized 2:1 placebo.

Mayank Mamtani - *B. Riley FBR, Inc., Research Division - Research Analyst*

Great. And then on that, I remember in the last update, I think the coadministration -- statin coadministration Phase I was still work-in-progress. Is there any data you could talk to from that? And if that was still needed as part of the safety filing for the -- in follow-up to the End-of-Phase II meeting, the FDA?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

We would need -- I mean, can you -- I'm not sure I followed completely the question. Can you repeat the question, please?

Mayank Mamtani - *B. Riley FBR, Inc., Research Division - Research Analyst*

Sorry. Yes, sure. There was a statin coadministration study with the twice-weekly dose and you had another study, the dose-split study, the PK. So I was just curious if there was anything from that understanding the safety package of Aramchol?

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

Yes. Thank you. It's clear now. So the question was related to Phase I drug-drug interaction with statin and that study showed no potential interaction between Aramchol and statin as well as (inaudible) isopropyl citrate or CVC.

Mayank Mamtani - *B. Riley FBR, Inc., Research Division - Research Analyst*

Okay, great. And then on the Phase II ARREST, could you just remind us what was the ALT reduction that was observed over 52 weeks? And then on the same [theme] , how are you defining NASH resolution as part of your Phase III endpoint? As you know there are 2 definitions now to look at it. So if you could give some clarity on that?

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

I think the second question is related to the definition of NASH resolution. And we'd want to define it exactly as FDA recommends. Reaching ballooning of 0 and inflammation of 0 or 1 with no worsening of fibrosis, which is defined by a 1 stage increase. And this was also the definition -- the exact definition that was used in the ARREST study predefined and reported.

The other question related to the ALT decrease in the ARREST, which was highly sophistically significant. And as we reported the reduction with 600 milligrams dose was minus 17.3 with the P value versus placebo, which was lower than 0.30:1. In placebo, there was an increase from baseline in ALT.

Mayank Mamtani - *B. Riley FBR, Inc., Research Division - Research Analyst*

Great. And just last question. I understand you're not prioritizing the pediatric study or the adolescent study, but could you maybe talk to the combination studies that you may be thinking about and before you kind of conclude the ARMOR study?

Liat Hayardeny - *Galmed Pharmaceuticals Ltd. - Chief Scientific Officer*

So thank you for the question. We keep on due diligencing all the potential combination. I won't have to say 1 by 1 during all the preclinical analysis, say, and the mechanism of action, which should be complementary. But last, but not least, very important to us is to have a substantial combination with the safe compound in order to keep the safety, which is so clean with Aramchol. That being said, we are screening 1 by 1 all the potential candidates. Once we will have the right candidate, we will report and forwarding and going to the clinic with the potential combination.

Operator

Our next question is from François Brisebois with Laidlaw.

François Daniel Brisebois - *Laidlaw & Company (UK) Ltd., Research Division - Healthcare Equity Analyst*

Just a couple here, last's been touched on, but when you talk about the combination mindset, just because you guys are so multi-targeted kind of mechanism, is there one in particular that makes sense in terms of combo? And is this something that would have to go on the preclinical side to try the combination? Or would you feel comfortable -- is there a way that you can go right into clinical studies with potentially compounds that are quite known out there?

Liat Hayardeny - *Galmed Pharmaceuticals Ltd. - Chief Scientific Officer*

Thanks for this question. So the mechanism of action of Aramchol is very distinct and well-described and published. So the down-regulation of SCD1 in the hepatocytes and hepatic steatosis is very, very distinct. And all the biochemical pathways are described, very well-researched and published. So when we are actually talking about combination therapy, we always look for complementary mechanism to Aramchol mechanism of action, which is, as I said, down-regulation of SCD1. So most probably, we will not choose anything [to those in the past of] SCD1 and SXR that is upstreamed to SCD1. So we will look towards some others. From fibrosis point of view, for example, Aramchol is preventing collagen production. We will look for any compound that has to do, for example, with MMPs, that dissolve already existing collagen, for example, or if we are looking for, in hepatocytes, anything that will have reduction in liver stress on a different mechanism. So this is where we are going in terms of complementary mechanism. I hate to say that we -- that -- I mean, in the field, there are limited potential candidates, but we are looking for them one by one. As I said, our primary goal is complementary mechanism with good Phase III, so that we will not, I would say, jeopardize this. We're very pleased with the potential of Aramchol, as a standalone, as you see in clinical trials.

François Daniel Brisebois - *Laidlaw & Company (UK) Ltd., Research Division - Healthcare Equity Analyst*

Excellent. That's very helpful. And then just lastly, Allen you mentioned potential global partnerships with, you mentioned, China and the Middle East. I was just wondering, from your perspective, is this as -- is NASH as known or I guess understood or are people as aware of NASH in those parts of the world?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

So in vitro, we've -- interestingly, we've commissioned the L.E.K. and did very interesting work on the NASH space in China, and interviewing KOL, as you know, recently China joined the ICH guidelines. So under ICH guideline 17, they're -- now they can be included in the -- in clinical -- in global clinical studies and have the drug approved based on these global clinical studies. We now have a very -- we -- I mean based on the interviews of multiple -- L.E.K. interviews with multiple KOLs, Chinese KOLs, which obviously, we are forging relationships with these KOLs because we would like to collaborate and have them participate in the ARREST -- in the ARMOR study. So we now have a very good understanding of the NASH space in China, and interestedly, I can tell you that the numbers are not different from the numbers that we see in the U.S. It's about the same market, same prevalence. If we start from -- 15% to 20% have enough evidence, which is about 200 million patients and then 15% of them, probably a lower number, are diagnosed with -- for NASH. So we're looking at numbers, which are pretty much the same as the one that you see in the U.S. and the 5EU. And obviously, the market potential, in dollar terms, is very much the same.

Operator

Our next question is from Jason McCarthy with Maxim Group.

Adheip Mally - *Maxim Group LLC, Research Division - Equity Research Associate*

It's Adheip, on the line for Jason. I was just wondering if you could shed some color on how much you see this trial costing. Or you may have mentioned this previously, I didn't -- I may have not caught that. But if you could just shed some color on what you see or what, in fact, the cost would be for the ARMOR trial, please?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

So it's still the same number that we've anticipated before, which is somewhere in between $65 million to $70 million. We are working, as I said before, with the leading industry NASH leaders in -- that participated in Phase III and large Phase IIb studies before. So we're still now much more confident with these numbers and doing a lot of the work in-house by spreading the different function of data -- of monitoring -- managing and monitoring study, data management, laboratories and et cetera. I think that we've managed to -- also to save a lot of dollars by simply allocating the different parts to different vendors. All of them -- as now we are working successfully, now when all systems are integrated, they're all working, I can say, successfully together, and we look forward for a very efficient, and I hope that is, a quick study.

Adheip Mally - *Maxim Group LLC, Research Division - Equity Research Associate*

Great. And then just 1 quick timeline-related question here. So you planned on having a 52-week read out for your -- for the initial top 100 patients, but now for that you plan on completing enrollment to the full 2,000. Correct?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

Correct.

Adheip Mally - *Maxim Group LLC, Research Division - Equity Research Associate*

Okay. Great. And then just another quick question here. So given how interconnected NASH is with cardiovascular diseases, I was just curious, if you've seen Aramchol provide any therapeutic benefit with respect to cardiovascular issues such as portal hypertension or esophageal varices in patients?

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

Can you repeat the question?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

Jason (sic) [Adheip], can you elaborate on that? I'm not sure we followed that.

Adheip Mally - *Maxim Group LLC, Research Division - Equity Research Associate*

No. Just that if you've seen any benefit that was conferred by Aramchol to patients in terms of cardiovascular issues given how the interconnected nature of NASH was with cardiovascular issues?

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

Okay. So in the ARREST Study, as we reported, we have a significant effect, not only on the liver enzymes, which talk to the well-being of the liver, but also on the glycemic control, which could potentially also be related to well-being of the liver and less stress on the liver cells. You know the connection between cardiovascular and NASH is a complex and difficult one and not possible to correlate in a one-year study specifically that, as you know, we didn't have any major cardiovascular events in the ARREST Study. So if we're talking only about biochemistry, I think we show an effect on a liver well-being and that this -- and we're also showing effect on NASH. And you know that the NASH is an independent risk factor for cardiovascular risk. The -- even the pivotal studies in the NASH space are not powers or targeting cardiovascular as endpoints and actually this field is, the more we learn, the more educated we are. And it's indeed very interesting and a very good question.

Operator

We have a follow-up question from Ed Arce with H.C. Wainwright.

Antonio Eduardo Arce - *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*

Just a quick follow-up for me. Just wondering if you could explain perhaps the rationale in adding AST over 20 international units per liter as an inclusion criteria in ARMOR, which you didn't have in ARREST.

Tali Gorfine - *Galmed Pharmaceuticals Ltd. - Chief Medical Officer*

So the -- this inclusion was added for potential 2 reasons: one was to resist spleen failure rate; and the other was to reduce possible residual response rates. And this is based on literature and advice that we have from our KOLs.

Operator

We have reached the end of our question-and-answer session. I would like to turn the conference back over to Allen Baharaff, for closing comments.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Chairman, CEO & President*

So thank you all for joining the call today. We are all here, I mean, working, and if you have any questions, any follow-up questions, as always, please do not hesitate to contact us. And we are happy to hold calls with investors or together with KOLs. And wish you all restful summer holidays. Thank you.

Operator

Thank you. This concludes today's conference. You may disconnect your lines at this time, and thank you for your participation.