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GLMD - Q3 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 third 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 and 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 the beliefs and expectations of management as of today, and actual results, trends, timelines and 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, without limitation, the risks under heading Risk Factors described in our Annual Report on Form 20-F filed with 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 speaks 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, Steve. 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 our financial results for the third quarter of 2019. As always, we will be happy to take any questions you may have at the conclusion of our prepared remarks.

During the last quarter, we announced initiation of our Phase 3/4 ARMOR registrational study. ARMOR is a global study that will be conducted in 50 countries, including the U.S., Europe, Latin America and Asia in approximately 185 sites. A total of 2,000 subjects will be randomized to receive

Aramchol 300 milligram twice daily or matching placebo in a 2:1 ratio. Based on our recent PK dosing study, this dosing regimen is expected to result in higher exposure and has the potential for greater efficacy.

All subjects enrolled are overweight or obese and have pre-diabetes or type II diabetes. This targeted homogeneous population was selected taking into consideration that type II diabetes is an important risk factor for NASH and is therefore considered a population with an urgent unmet need.

The study consists of 2 parts. The first part, histology based, includes 1,200 subjects treated for 52 weeks and is powered to meet both key endpoints: NASH resolution and no worsening of liver fibrosis; and fibrosis improvement without NASH worsening. Meeting either of these endpoints is expected to suffice for the study to succeed at the end of part 1.

These data will serve as the basis for the submission of a marketing authorization application under regulatory provisions of accelerated/conditional approval. We look forward to rapidly completing enrollment by Q2 of 2021 with the aim of reporting top line results by the fourth quarter 2022.

In the second part, clinically based, all subjects will continue with the same treatment assignment until study completion to confirm clinical efficacy.

Specifically, I would like to reiterate the 3 reasons why we believe that ARMOR has high potential to succeed. First, dose regimen with the potential for even better efficacy as compared to ARREST. Secondly, selection of an enriched targeted population that previously showed good response to Aramchol. And last but not least, the study's powered to meet both primary endpoints, NASH resolution and fibrosis improvement at 52 weeks, and provides a robust and persuasive data required for registration.

Moving now to some of the other ongoing activities. Later this week we will present at the Liver Meeting, the annual meeting of the American Association of the Study of Liver Diseases, AASLD, in Boston. New preclinical data, which elucidates the mechanism by which Aramchol affects glucose metabolism in the liver, which resulted in the reduction of hemoglobin A1C in patients in our Phase 2b study, ARREST. The data suggest that Aramchol improves liver glucose homeostasis in patients. These new data are particularly important for the patients participating in our ongoing ARMOR study.

Additionally, we will present clinical results on the Phase 1 PK study comparing once daily Aramchol 600 milligram to twice daily 300 milligram, which demonstrated an average increase of 53% in exposure. These data, together with the data -- with the dose dependency observed thus far, is the basis for our ARMOR dose selection.

Aramchol has a unique mode of action, which has been translated to clinical efficacy in our trials to date, targeting directly both steatosis and fibrosis with an excellent safety profile. Aramchol has the potential to become a leading therapy for NASH. I'm delighted that the ARMOR study is underway, on time, placing it as one of the most advanced therapeutic candidates for NASH.

I would like to turn the call now to Yohai Stenzler, our CFO. Yohai?

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

Thank you, Allen, and good morning to everyone. This morning I will be providing you with our financial results for the quarter ended September 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 a summary of such financial results.

For the third quarter of 2019, our net loss totaled $4.5 million, or $0.21 per share, compared with a net loss of $1.0 million, or $0.05 per share, for the corresponding quarter in 2018.

Research and development expenses totaled $4.1 million for the third quarter 2019. This compares with $1.7 million for the third quarter in 2018. All R&D activities are increased during the third quarter mainly due to the R&D work we undertook in preparation for the initiation of the ARMOR study which we simply began.

Turning now to G&A. Our general and administrative expenses for the quarter totaled $1.0 million, the same as in the corresponding period in 2018.

During the 3 months ended September 30, 2019, we had a net financial income of $0.5 million versus $0.3 million for the corresponding period in 2018. The increase is attributable to our interest income from financial instruments.

Finally, our cash balance as of September 30, 2019, which includes cash, cash equivalents, short term deposits and marketable securities totaled $79.7 million compared with $90.2 million at December 31, 2018.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) The first question comes from Steven Seedhouse with Raymond James.

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

Could you just provide an update on site activation? Is that happening in all of the various regions for the Phase 3 study? And then the operating expenses are still really lean. Just wondering if you expect that to meaningfully increase as enrollment site activation, et cetera, ramps up here.

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

Okay. Thank you, Steve. So yes, we initiated study first as planned in the U.S., and most of the U.S. sites have been activated. Some under -- most enroll under central IRB. There are others which are under local IRB and we're looking forward to activate them later this year or beginning of next year. According to our recruitment strategy plan, all sites at Mexico and Chile are going to be activated by first quarter of 2020. So the study, we will start seeing full recruitment power as from the second quarter of 2020. Now but of course, yes, you are right in your assumption. The fact that the study was only recently initiated, we see a very small increase in cost, which is expected to increase as the study progresses.

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

Okay -- excuse me. Thanks, Allen. The other thing I wanted to ask about is just the agreement with Samil that's in place in Korea, I'm just wondering what, if they're involved in the development program here in Phase 3 and if there are Korean sites involved in the Phase 3, and if so, to what extent. And then also just curious if you could just comment on in general the NASH opportunity in Korea. Less familiar with that. I was wondering if you had any high-level thoughts.

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

Okay. Thank you for the question, Steve. In fact, yes, Samil is an important partner for our part of our recruitment strategy. We are going to have about 12 Korean sites, and we expect to see about 150 patients coming from Korea. Samil is very much involved in the site selection, in the regulatory affairs, in activating the sites and is a very valuable partner for us to work in this geography. We don't have specific dates as to Korea, but in Asia in total, we recently completed work with L.E.K.in China and other Asian countries including Korea, but not specifically Korea. We see more or less the same prevalence of NASH and NAFLD as we see in the western world. So it's an important market. Asia is going to be a very important market for us, and we are looking forward to advance the activation of sites. We cannot -- I cannot report any news on discussions we are holding with the NMPA in China, but once we will have these -- so we are also expecting to recruit patients from China, but from our experience, the numbers would

be much, much smaller than the ones which we expect from Korea or Hong Kong. And this is what we would see from other NASH studies, local NASH studies in China. Just as a reminder, we have a PK data in Chinese population, so we are very safe. We feel that we are working on very safe grounds when we recruit Asian population, which is no different in their PK profile from Caucasian.

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

All right, terrific. Appreciate all that info. Thanks, and thank you for taking my questions.

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

Thank you, Steven. Looking forward to see you at AASLD.

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

Likewise. See you soon.

Operator

The next question comes from Ed Arce with H.C. Wainwright & Co.

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

Congrats on the continued progress of ARMOR. So couple questions. First one just, Allen, given your broad global experience with ARREST, could you discuss both the advantages or lessons learned, as well as any expected challenges that you might face in enrolling ARMOR?

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

Okay. I will start, but I would like Tali to talk a little bit about her experience from medical point of view on that population. Just as a reminder for all of us, ARREST, our Phase 2b, was already a global study recruiting about 1/3 of the population from the U.S., 1/3 of the population from Europe and 1/3 from LatAm and the rest of the world. So what we are trying to achieve in ARMOR is to get more or less the technique a little bit maybe tilted to the U.S. We probably have about 40% of patients coming from the U.S., but the other jurisdictions are very, very important. It is important not only for the success of the study, because we want to keep the same population that was successful in the Phase 2b, but also in terms of cost, in terms of recruitment time, there are less competing due to less NASH studies as the less -- so less competition in other countries. And I think that also the patients and the data that we get is a very clean data, which I think would be very good for the homogenous way that of population that we look at ARMOR. But maybe, Tali, you want to add a few words?

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

Thank you, Allen. I think you said most of what I would say. I do want to remind everyone that NASH is a pandemic. So it is -- the epidemiology clearly shows NASH on the global scale. We started relatively early to enroll patients from different countries. So I believe we were the first to enroll in LatAm, for example. And we have very good experience with these sites and these population. Don't forget that our population is selected for pre-diabetes, diabetes and overweight or obesity. So, risk factors across the different countries is similar, and this gives us both confidence in the population. And on the other hand we have confidence in the sites that we have experience with many of the sites in the ARMOR, we have already worked closely and know from the ARREST study. When we -- I said this before. When we looked at the data from ARREST, we did not see any differences between the populations. We're fortunate to have this data because it relates not only to the disease, but also to our drug, which makes us confident in terms of the endpoints of the study to be similar in the ARMOR study.

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

One thing to add, Ed, is that all of this is also should be translated to advancing business development opportunities, global business development opportunities. The fact that we have sufficient number of patients that will enable potential partners to register the drug simultaneously at the time which it's registered in the U.S. by the FDA and other jurisdictions, should allow accelerated discussions with potential partners, whether it is distribution agreement or license agreement or any other form of joint venture in order to commercialize the Aramchol in all those jurisdictions. Whether it's the Middle East, we expect to have about 150 patients coming from the Middle East, LatAm, Asia and of course U.S. and Europe, which is the cherry of the ice cream.

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

That's great. Thanks for that detail. Perhaps one related more sort of specific question just around enrollment as that will be primary focus of the company for the next 18 months or so. What is the screen failure rate that you're assuming in your projections? And what, if anything, have you been able to do to try to minimize that?

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

Okay. Thanks for the question. I will take that. To be realistic, we expect to see up to 60% screen failure rate in the study. That of course depends on specific sites and the specific site's experience. We have carefully selected the sites that are participating in the ARMOR, and that should be one way of mitigating a higher screen failure rate. And of course the risk factors that I've mentioned in the previous question of diabetes and overweight are also, can also reduce the screen failure rate. And we're working closely with the sites to make sure that if we discover that there are higher than expected screen failure rates, then we can educate the sites. And vice versa, if we see that sites are producing better screen failure rates, then to use them as the guidance to other studies. So I think it's close follow up and work on site-by-site level, but eventually we'll be productive in terms of reducing screen failure rates. I want to add that we're not the only players in this field. Everybody is attempting to reduce screen failure rates, to have better diagnostics for NASH for now and for the future. You can browse through the AASLD abstracts and you see quite a few related to these topics. And I think it's that the field is advancing fairly decently in that respect and that we should see low screen failure rates in the near future.

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

We are also very privileged and grateful for there are 2 other large Phase 3 NASH studies that have been completed and with many lessons that have been learned by site and experience. So we are grateful for the other sponsors that advance those large Phase 3 studies, which allows us to benefit from these learnings. And hopefully Tali a little bit reduce the textbook 60% screen failure rate.

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

Okay. That's great. And then perhaps one last question, if I may. This is just a more longer term, big picture question. Given that Aramchol has long had established broad lipid effects on steatosis, as well as its direct and anti-direct effects on fibrosis via its SCD1 pathway, and that those sort of represent the 2 ends of the spectrum in terms of the pathogenesis of the disease, how do you think about the right or perhaps the optimal types of therapies that you could consider for potential combination regimens?

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

Okay. Thanks, Ed. I will -- it's Liat. And see you soon at the AASLD as well. I think that the obvious, since we are targeting very nicely the steatosis and the downregulation of the [CCDSs], and we are directly targeting the fibrosis by downregulation of collagen production, which is a really direct effect not being seen before, I think the inflammatory part is still to be add-on. And for a possible combination in anti-inflammatory with either a

simple non-steroidal anti-inflammatory, or a more sophisticated innovative one, would be a good target for that. We are still looking around, looking for the best of all of them, and we'll keep you updated when we are moving forward.

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

That's great. Thanks, Liat. And I look forward to seeing you in Boston later this week.

Operator

The next question comes from Adam Walsh with Stifel.

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

I look forward to seeing you at AASLD as well, and congrats on getting ARMOR up and running. Just a couple of questions. Not to beat a dead horse on the enrollment, but just I noticed that you've said again today that you expect the enrollment to complete around the second quarter of 2021. In the context of your balance sheet you have $80 million in cash, and you said that it would be about $65 million to $70 million to run the trial. How confident are you in that kind of enrollment timeline, and what are the variables that you're seeing as maybe most consequential to meeting that timeline just in the context of the balance sheet? Thanks.

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

Thank you, Adam. So we are, as I previously said, as we move forward and as we advance, we are more and more confident on our estimations and our budget. This is something, again just as a reminder, our Phase 2b study was already conducted in 15 countries in 80 centers. So the jump to 160 centers in 18 countries is not a very big one. We know what the cost base. We negotiate very carefully, I would say, with price. And it's managed, I'm personally involved in its micromanagement. We know that the budget is very tight, but we are very confident that indeed this would cover the first part, the Phase 3 part of the study. And we are a very lean operation. So our burn rate outside of the study is very, very minimal. And this is one of the benefits. There are a lot of detriments of working from Israel, but one of the benefits of working with Israel is the cost base. So at least give us the benefit of the doubt to enjoy the cost base of our operation. And the timelines I'm seeing are very realistic. If I look at the competition, when they talk 15 to 18 months recruitment time and ours is a little bit longer, I think that we've cushioned the numbers and it's a very realistic time. On top of that, we are trying to use the new innovative recruitment tool that we are going to present some of them in our booth at the AASLD. Again, the learning from other NASH studies, including of the use of this new tool to try and do referrals and allocate -- our population is not the typical hepatologist population. The fact that they're obese and overweight and diabetic or pre-diabetic, you can find many of the potential patients in diabetic centers as long as it's early in the what we call the usual suspect sites. So we've broadened our base. We are using a very wide net. And trying to with all these tools, new tools and learnings from the early phase or the other Phase 3 studies how to best identify those patients which have advanced fibrosis and some NASH, of course, 4 and above.

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

That's helpful. And just another question on partnership. Allen, how do you think about potentially engaging partners either geographically or for a combination or some other trial structure? How do you think about the timing of that in the context of having started the Phase 3 trial now and with data coming in the fourth quarter of 2022? Is the beginning of the trial some kind of dividing point, in your mind, in terms of value creation, or is there -- are you still actively entertaining potential geographic or other types of partnerships? Thanks.

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

Okay, thank you, Adam. So I can start from the end is that we have no intention to commercialize the drug ourselves. And as such, we understand that we have to forge alliances as early as possible. And the fact that we are a global -- we have global data attracts many players to the table. Whether it's, at the risk of repeating myself, but highly reputable pharma companies in the Middle East, in LatAm, in Europe, in Asia and all of these, and of course U.S. and Europe. We will try and keep the latter 2 as late as possible once the data would be approached. But we'll certainly, and this is something which is ongoing because we are not waiting for any event to happen. This is something that we've been working on. I can tell you that I've been already 4 times this year in China. So these are discussions, ongoing discussions. And I'm sure you follow the few very interesting NASH field in China, including the GENFIT license. So the market is already prepared, and same is for other places, other geographical places that could start any day from tomorrow until readout, at the readout.

Operator

The next question comes from Yasmeen Rahimi with Roth Capital.

Paul O'Brien

This is Paul on for Yasmeen. Just to piggy back on the partnership question, I was just wondering if you'd give a little more color about specific geographies more likely to be licensed out. And does that correlate with certain kind of larger, more concentrated parts of the ARMOR data set? Thanks.

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

So, I don't think this is related to ARMOR data set because those local players understand that once ARMOR data set would be available, there'll be limited space around the table for large pharma only. And if they would like to take part for local geographical agreement of some sort, like similar to the one we have in Korea with Samil, they have to come early and they cannot wait for the ARMOR data. We more or less divided the work according to the main geographies where we are going to have sufficient number of patients which would allow registration in the study, registration of the drug, as long as -- immediately when the study results are out. So again, at the risk of repeating myself, China is a very high priority for us. China has a very big market. And Aramchol, with its very unique mechanism of action and clean safety profile and its direct effect on fibrosis attract a lot of attention from China. I'm looking at a transaction similar to the Kite [Tucson] transaction that was done which was later on. So these are kind of local transactions, but with a way out once an M&A transaction comes in, same as happened in Kite with Gilead. So this is the type of transactions that we'll be looking at for LatAm, for China and Middle East. Maybe I'll be more specific in Turkey. Turkey is the hub for many Middle East countries that we have no direct access. And since we are also expecting to have sufficient number of patients coming from Turkey and Middle East to support registration in these countries, I think that this is also a country of high priority for us. As always, Europe and U.S. remain open, but it has to be the right deal with the right numbers.

Operator

The next question comes from Mayank Mamtani with B. Riley FBR.

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

Thanks for taking my question and congrats on the progress. Very quickly on just switching to twice daily dosing. Could you maybe comment a little bit on what further incremental work there is needed to be able to think about other populations that I think you said before, (inaudible) is set, NASH or even combination. And I know there's obviously the drug-drug integration work that you also did which is not part of the AASLD presentation. But I'm just curious of what learnings you've had for the NASH Phase 3 study. For other indications, would you have to do more work on the twice daily dosing?

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

With the twice daily, as you know, this is the single dose that we are using for ARMOR. So we -- there is no need of other work, so this is already based on the data that we have presented at AASLD on the increase in exposure. We are not working on any other combinations, new indications or any sort of stuff which are related to this twice daily.

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

The need for the twice daily changed from the dose responses we saw in ARREST and actually in previous studies as well. And we saw that you go higher the dose, better the efficacy. So we were looking for other ways of giving the compound or the Aramchol. And since it's a Class IV compound, you could not actually just simply raise the dose. So we did a PK study and we found out that we can raise not really the dose, the exposure of the Aramchol in the blood. We can have a higher concentration of Aramchol in the blood if we do those splits, which is a known method to raise the exposure in patients in a Class IV compound. And we are presenting in the AASLD the PK study that we did in the healthy volunteers as it shows that if we dose 300 milligrams twice daily instead of 600 milligrams once daily, we have elevation of 53% in blood levels in patients. And just looking simply at the PK that we have in ARREST, and looking at the dose dependency that we have in response and efficacy, we -- I can't say sure because no one is sure with anything, but I think we can be convinced that the higher exposure will reveal in higher efficacy.

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

That's great. Very helpful color. And then if you could extend that thought a little bit on the effect size that you both for covering for success, but also recognizing that the bottom fibrosis and also a NASH resolution would incrementally continue to grow with comparative readouts through the next 2, 3 quarters. Could you maybe comment on both what do you need to be -- for the study to be successful and then also remain competitive against what you may see externally.

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

I hope I understood the question. In terms of powering of the study, the ARMOR study was powered based on the ARREST results. The 600 milligram once daily is the conservative approach. We hope to see higher efficacy. We have grounds to believe that we will see higher efficacy. But in order to make sure that the ARMOR study is successful and the data is robust and persuasive, we powered it based on the ARREST data, which is something [as can]. I cannot talk more on the specifics of this, the statistical analysis. I assure you that we do all the relevant statistical methods to -- because we have 2 histology primary endpoints, NASH resolution and fibrosis improvement, and because we have 2 endpoints, histology and clinical, so there are a few multiplicity adjustments that are inherent in the study design, which I cannot comment more on.

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

Great. And just one last clarification maybe for you, Allen. You commented a lot on China, but could you maybe be more specific? I think you filed IND and you said something about the PK. What is the registration partners, and then maybe an inflection point that could draw a partner specifically in China.

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

Okay. So just to correct, we have not filed an IND yet. We are preparing the IND and we expect to have the meeting with the NMPA in the first quarter of 2020. And then we can discuss with them the program and understand what data would be the required. We have the PK data that we'll bring along, but we will only be able to know for sure what are their requirements to have the drug approved in China once we meet with the NMPA. Clearly, the fact that we already have data from some, very few, but some Chinese patients in the ARREST study, and the fact that we have PK is a very big advantage when we come to discuss the -- and also that we are enrolling other Asian/Korean populations to the study should also

support a very, I hope, fast approval so we can initiate the study in China. All of that is – puts us as one of the most advanced clinical aspects in China for NASH.

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

Excellent. Good luck for the Liver Meeting. I look forward to seeing you there in Boston. Thanks for taking my question.

Operator

The next question comes from Kristen Kluska with Cantor Fitzgerald.

Kristen Brianne Kluska - *Cantor Fitzgerald & Co., Research Division - Analyst*

Of the 1,200 subjects you plan to treat in the study, could you talk about the enrollment trends and calculations you've put together across these different geographies that lead you to your predicted timeline of completed enrollment in the second quarter of 2021?

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

Okay. So the ballpark numbers is about 40% will come from the U.S., about 30% would come from Europe, and then about 10%, a little more than 10%, 11%, 12% from other jurisdictions like LatAm, Middle East, Korea and the rest of the world. So we are going to open sites also in Australia and at least some patients that can be randomized in China, but these are going to be very few. Now in most of those places, we don't see any other competing NASH study. The next question?

Kristen Brianne Kluska - *Cantor Fitzgerald & Co., Research Division - Analyst*

Okay. And then so how do you come up with the timeline of the second quarter of 2021? Do you have some internal calculations, average number per site to get to this timeline?

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

Absolutely. We work both the math. We have a very precise dance and charts of which is taking into account the regulatory submission and interaction with the different countries, when are the sites are going to be open, and negotiation time and et cetera. And this is how, where I can in a very clear way tell you that Italy, Spain, Florence, UK, Belgium, Germany are all going to be open in the first quarter of 2020. Korea probably would be close to the end of that quarter. Turkey and the U.S. are going to be open, some are already open, but are going to start recruiting already in this year. Other countries, Australia and Canada are going to be a bit later.

Operator

The next question comes from Jason McCarthy with Maxim Group.

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

It's Adheip on the line for Jason. Thanks for taking my question. I believe you mentioned previously that the estimated cost of the first part of the study was around $65 million to $70 million. Just wanted to see if given that the trial's initiated that the estimated cost is still accurate, or if there

were any additional unforeseen expenses that were not previously accounted for. And if you could perhaps shed some color on what the total cost of the study, like inclusive of both parts, would be please. Thank you.

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

Okay. So the main cost of the study, of course, is the pass-through, which is the payments which we pay to every single site. And these are based on agreements, specific agreements with the grant, investigator grants for the different investigators. Until we know for sure, but as we advance, as we sign more and more contracts with more and more sites, this uncertainty is reduced. I left some room for leverage. Of course we are working with a very defined budget, and we are trying the minimum, maximum and the mid estimates. And we are negotiating specifically with every single site and trying to get the best results not exceeding the maximum. And the number that I'm giving you is based on maximum in those sites. I'm hoping that it will be -- we'll be able to come with a positive surprise of a cost which would be less than one that we've publicly communicated, but we are giving ourselves the leverage or the leeway or the freedom to get to the upper number.

Operator

This concludes the question-and-answer session. I'd like to turn the conference back over to Allen Baharaff for any closing remarks.

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

Thank you, Steve, and thank you everyone for joining the call today. We are coming in a very big delegation to AASLD. This is a very important venue for us both to -- as you know, we are presenting. We have few poster presentations at AASLD, as well as meting investigators that are coming from the different geographies. And we have a booth, which is booth 602, and I invite all of you, the ones which are attending AASLD, to come and visit us and very happy to continue the dialogue.

Operator

This concludes -- sorry.

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

-- good afternoon.

Operator

This concludes today's conference call. You may disconnect your lines. Thank you for participating and have a pleasant day.

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

Thank you, Steve. Bye.

Operator

Thank you.
