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GLMD - Q4 2019 Galmed Pharmaceuticals Ltd Earnings Call

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PRESENTATION

Operator

Good day, and welcome to Galmed's Fourth Quarter and Full Year 2019 Conference Call. Today's call 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 the heading Risk Factors described in our annual report on Form 20-F filed with the SEC and the risks and uncertainties, including 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. - Co-Founder, CEO, President & Director*

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; and our Chief Financial Officer, Yohai Stenzler, who'll provide you with an update on our clinical development program as well as report to you on our financial results for the fourth quarter and full year of 2019. As always, we will be happy to take any questions you may have at the conclusion of our prepared remarks.

As our Phase III ARMOR study progresses, I would like to provide you with insights regarding our progress as well as the assessment of, and plans for, addressing uncertainties related to the coronavirus. The ARMOR study had been approved in 9 countries today, including the U.S.A., Canada, France, Belgium, the U.K., Turkey, Spain, Chile and South Korea. We're expecting approvals in Australia and Mexico in the next quarter and Brazil and China before the year ends. The eruption of the novel coronavirus has thus far mainly affected operations of the ARMOR study in South Korea and China, where activities came to a halt. As publicly reported, hospitals in these regions are under strict public health restriction and travel in general is restricted. Unfortunately, in recent days, we started seeing an impact on some of our European sites, and we see meeting and activities cancel and key people going into quarantine following travel. There is not -- there is a general unease of conducting unnecessary activities in medical centers.

It is too early to assess the full effect of the corona crisis on the study, but left unaddressed, by Galmed, it will inevitably affect our ability to conclude recruitment in the original time frame. Our approach to mitigating the adverse effect is to accelerate the opening of additional research sites from our backup country to counter the slowdown in some countries. I want to point out from a cost perspective, other than our general and administrative costs, which are quite modest, our clinical expenses are directly correlated to patient enrollment, and therefore, delays in enrollment also reduced our cash burn until the patients are enrolled in the study. We are very focused on ensuring the quality, timelines and cost-effectiveness of the ARMOR study. I'm quite certain that we are not the only life science company witnessing this phenomenon. We will continue to closely monitor the spread of the virus and the activity level of our participating sites to collaborate our response.

In parallel, we continue on working those NDA submission during the first half of 2023, with completion of enrollment of the first part of the study now expected by the second quarter of 2021 and reporting top line results of the first part of the study by the fourth quarter of 2022.

Now moving to other activities. 2 Phase I studies have been initiated earlier this year and an additional Phase I study is expected to be initiated later this year. The first Phase I study, hepatic impairment trial, cohort 1 of the 3, was recently completed. Top line data from this study is expected to be published by the fourth quarter of this year. The second study is a mass balance study, which is running on schedule with first dosing expected in May 2020 and top line results expected by Q4 2020.

We are planning to commence a TQT study. The protocol of this study is currently under FDA review. We expect this study will be initiated by the second half of this year and completion by Q1 2021.

Simultaneously, we continue to advance our knowledge on ARMOR mechanism of action and its translation in human clinical studies. Data on the effect of Aramchol, glycemic control, i.e., diabetes, was accepted to be presented at EASL, European Liver Congress, which is still scheduled to take place in London on April 16 to 19, 2020.

We are expecting 3 manuscripts to be published during 2020: a manuscript entitled Aramchol down-regulated SCD1 hepatic stellate cells to accelerate cellular activation of fibrogenesis; a manuscript of the results of our Phase II BRAF study; and the manuscript entitled Aramchol improved liver glucose and liver homeostasis in NASH via AMPK and Aramchol regulation, which we submitted recently.

Lastly, I'm happy to inform you that we came to an agreement with the FDA on our pediatric study plan of the evaluation of Aramchol for the treatment of NASH in pediatric population.

I would like now to turn the call over to Yohai Stenzler, our CFO, to review our financial results for the fourth quarter and full year of 2019. Yohai?

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

Thank you, Allen, and good morning. And thank you for joining us today. This morning, we'll be providing you with our financial results for the fourth quarter and the full year of 2019. For more information, please refer to our annual report on Form 20-F filed earlier today with the SEC, which among other things, provide a summary of such financial results.

Our net loss for the 3 and 12 months ended December 31, 2019, totaled $8.3 million and $20.5 million, respectively compared with a net loss of $3.7 million and $9.9 million for the corresponding period in 2018. As a result, our loss per share for the 3 and 12 months ended December 31, 2019, was $0.39 per share and $0.97 per share as compared to $0.18 per share and $0.54 per share for the corresponding period in 2018. We had no revenue for the 12 months ended December 31, 2019, compared to $2 million during 2018. Last year's revenue was in connection with our license agreement with Samil Pharma.

Research and development expenses for the 3 and 12 months ended December 2019 was $7.4 million and $18.2 million. This compares with $2.7 million and $8.3 million for the corresponding period in 2018. All R&D activities have increased during the year 2019, mainly due to the preparation and the initiation of the ARMOR study.

Turning now to G&A. Our general and administrative expenses for the 3 and 12 months ended December 31, 2019, was at $1.3 million and $4.2 million, respectively, versus $1.5 million and $4.4 million for the corresponding period in 2018. The decrease primarily resulted from a decrease in salaries and benefit expenses due to lower year-end bonuses.

During the 3 and 12 months ended December 31, 2019, we had a net financial income of $0.3 million and $1.9 million, respectively, versus $0.5 million and $0.9 million during 2018. The increase is attributable to our interest income from financial instruments.

Finally, our cash balance as of December 31, 2019, which include cash, cash equivalents, short-term deposits, marketable debt securities and restricted cash totaled $75.6 million.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Yasmeen Rahimi with Roth Capital Partners.

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

And thank you for the update. And we hope you're safe and sound, most important thing. Allen, I wanted to find out, can you give a little bit more color on what are these backup countries that you're referring to for opening additional sites? How many additional sites do you think would be needed? And is there any additional costs associated to get those sites up and running?

And then the second part of the question is -- we would love to hear an update in regards to discussions that you have been having in regards to partnerships x U.S. or x Europe, to the extent that you can speak about it.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

Thank you, Yasmeen. So as to backup countries, Brazil, Australia and China were preliminary on our backup list, and we were not going to open these countries for the first part of the study, i.e., for the first 1,200 patients, enrollment of the first 1,200 patients. We've now accelerated the regulatory submission. We are engaged -- we engage with the local regulatory firm, which will work under our CRO, Covance. And in order to accelerate approval in our -- regulatory approval in Brazil, we submitted a pre-IND to the Chinese authorities, the NMPA. And Australia is also advancing, and there is a fast-track there of approvals, the regulatory approvals. So I expect that around July, we'll be able to start recruiting patients in Australia. We are looking at -- we have, still, a list of other countries, including Argentina and some in Eastern Europe, which we keep as -- that we've done the due diligence and feasibility on many sites. And we will keep going for -- mainly for the second part of the study. But if needed, we would, of course, also accelerate those countries and these sites as well.

We try to keep -- as to the number of the sites, I try to speak to the numbers that we've reported before, somewhere between 150, 160 sites. We are carefully monitoring the activity of the site. And I can tell you that we will not hesitate closing sites which are underperforming. If we see sites which have a lot of screen failures, and of course, before they randomized first patient, we will close the site. So the balance of the site is going to stay the same. It's not -- the cost of adding additional sites is negligible comparing to the damage of keeping those sites open for the duration of the study. So we will try to keep, as we've always said, very efficient number and of size and make sure that all sides are highly performing sites.

As to the second part of your question, unfortunately, the coronavirus is also delaying discussions that we were holding. And as we can understand, there's nothing to report at this stage. And when I have something to report, of course, we would report to the market and you'll see we report the market.

Operator

Our next question comes from the line of Steven Seedhouse with Raymond James.

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

I just want to clarify a few things from your filing. First of all, thanks for the clarity on the impact of the coronavirus. I think that's obviously top of mind right now for everyone. And just regards -- regarding some of the comments in your filings, so you mentioned still that the ARMOR study initiation is dependent in part on an IND that you plan to file with the FDA, and it has similar language per foreign regulators regarding commencement of the study outside the U.S. Obviously, ARMOR was initiated in September. So I was just hoping you could clarify what that IND is referring to and just the status of any requirements with the FDA to begin or continue to enroll ARMOR.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

So thank you for your question, Steven. Maybe I did not make it clear. We don't have -- the IND is only for China, where we did not have an IND in our study. So that's the only country we didn't need an IND. In all countries, in other places, we are preparing our NDA. So we are -- for the U.S.A., there is -- we want to make sure that everything that has to be finished on time, including carcinogenicity studies, other preclinical studies, Phase I studies. All of these protocols and discussion with the FDA are ongoing to ensure that once the data of the ARMOR study is published, we can submit an NDA very promptly. And this is why we try to -- we give a guideline on the date of submission of where we believe we'll get an NDA and where we believe that we will have the top line data from this category.

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

Okay. And you also mentioned in the filing, just -- you highlighted on the call the Phase I studies that are ongoing, so data from 2 of them, I believe, in 4Q '20 and from 1 of them in the first quarter of '21. In your annual filing just mentions certain regulatory agencies in Europe are requiring additional clinical studies prior to initiating ARMOR in those jurisdictions. So I just wanted to clarify if those Phase I studies are gating factors for some of those jurisdictions in Europe or if this is separate.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

Again, thank you for clarifying the question. No, we have no request, no special requests from any of the countries. And as you can see, most of the countries participating in the study already gave us the approval to initiate the study. The Phase I studies I'm referring to are studies to support the NDA.

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

Perfect. Okay. And I was interested to read -- also, it sounds like you guys have entered into a research and option agreement with an academic institution to acquire a product candidate, and preclinical research on that candidate is currently ongoing. So I was hoping you could just talk about that product and clarify if it's a NASH product.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

So this is still very early stage. It's still in preclinical stage, and we are doing a lot of preclinical work in order to make this compound as Phase I-ready, and we will communicate. Obviously, the cost for these activities are negligible, and this is why we did not report them separately, and they are part of the R&D cost of -- the general R&D cost of Galmed. Once we'll get closer to IND, we would communicate the compounds, the indications

and the plans for, clinical plan, for this compound. And most probably, this year. All of that will -- should be opened in the coming quarters this year.

Operator

Our next question comes from the line of Ed Arce with H.C. Wainwright.

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

So a few for me. First, I just wanted to clarify and confirm your time line for ARMOR. You mentioned 2Q '21, and I missed exactly what that was and the top line results of 4Q '22. Just given the ongoing and likely ongoing disruptions at various sites from COVID, wanted to also confirm that, at this point, from your perspective, given the flexibility that you have, with additional sites and so forth, that you do not expect any sort of time line delays at this point.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

This is correct. I mean as I said it before, there may be -- we made slide 1 quarter. So from Q3 that I've communicated earlier, we have changed the date to Q4 2022 for results of the study. And we're doing our utmost to keep the original time, the original schedule by opening new sites and by using some of our backup countries. So it's too early to make any clear -- to give a very clear time line, but we believe that we are able to maintain the original time frame of submitting the NDA in the first half of 2023.

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

Okay. That's helpful. And then I missed actually what you had mentioned in your prepared remarks around EASL next month.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

So we have a publication in EASL that was accepted for presentation but on the glycemic effects of Aramchol. This is data that is based both on our ARREST Study and our preclinical study and how nice the translation of -- the mechanism of action translation from animal study to human data. This data was accepted for EASL. But as we are all waiting, I mean, I hope that it's -- either it will take place, but there's high probability that it will be only virtual. So we may be able to deliver this presentation by WebEx or any other form. But this presentation will come out around that time. Nonetheless, the presentation is ready, and we'll make sure how to communicate it to the public.

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

Anyway, Aramchol is submitted already for publication. We just realized, I think, it's a very good data showing the effects of Aramchol in hemoglobin A1c in our patients in ARREST. We see a very good, I would say, diabetes modulation by Aramchol in our patients. Together with the mechanism of action that is supporting it, it's a very good paper, and we hope to get a very strong answer for assessing this paper for publication. We are waiting for the [EndoPAT] to get us back with the results. So it's the first time that we are showing translation, mechanism of action of Aramchol to the clinical value. And few more publications will follow on the translation of the -- of the mechanism of action to the clinical that we saw in ARREST, and we will see, hopefully, in ARMOR as well.

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

Okay. Great. I very -- appreciate it. Two more if I -- just two more quick ones, if I could. You mentioned some progress with the agency in terms of your design for a pediatric study. If you could share any details, that'd be great. And then lastly, with your current cash at $75.6 million, what is in your view the cash runway at this point?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

Okay. Thank you, Ed. So we have agreed -- as I've alluded before, we have agreed with the FDA on our pediatric plan. We will be starting towards the end of this year the necessary toxicology studies, and the first clinical study would start shortly after the completion of the first part of ARMOR, which is the end of 2022. And then we, of course, agreed on -- I mean the study design is for -- first for 12 to 19 and 6 to 12 and then the waiver for earlier -- for younger patients. So all of that is agreed, time lines, protocols. And I hope we'll be able to move forward for this very important indication.

The other questions, remind me what would be...

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

Cash balance.

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

The cash balance.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

The cash balance. Yes. So our -- there is no change in our view about the cash balance. Study costs remain the same, and we keep very, very closely on budget. As I said before, it is based on activities. So it should not increase. As you can see from our balance sheet, our previous year and we look also on our budget for the -- for next year, our burn rate, which is not related to the study, remains the same, about $1.5 million per quarter. And I hope that we'll still be able to generate with a very conservative investment -- financial investment that we use for the money that we have, that covers more or less the burn rate for -- the quarterly burn rate. So even if there is 1 or 2 quarters of delay, with the burn rate, I think that mostly can be offset by the financial income.

Operator

Our next question comes from the line of Kristen Kluska with Cantor Fitzgerald.

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

The first is what do you think will be the main advantages for your company if you are not the first on the market. Meaning, which criteria or items will you internally be on the lookout for that could help pave the way for Aramchol if approved.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

Okay. Thank you, Kristen. I will let Liat take this, with your permission.

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

So thank you, Kristen. I think that Aramchol is not actually competing with any of the candidates that are currently ongoing. So if you look at OCALIVA, OCALIVA is mainly targeting fibrosis, which don't have effects on liver fats. And they are targeting mainly, I would say, F3 and at the beginning, they will start with F3 that has more of a risk to deteriorate to F4. We don't really know currently what's going on with [OCALIVA], but if they will, and we hope they will, be approved they are targeting mainly liver fat. Aramchol is targeting liver fat and fibrosis. If you look at the mechanism of action, and if you look at the preclinical of OCALIVA, for example, and we just recently sought paper that they published about the effect on [hepatic] cells with the collagen production, which is comparable to Aramchol, which we were very glad because it was translated for them in the clinic, showing a lot of probability of success for us as well. And on the other hand, we have a very good effect in our clinic and from mechanism point of view on liver fat as well.

So we are -- on partly, we can actually say, and definitely shown a good effect on liver fibrosis like, OCALIVA, for example. And we are showing a very good effect on liver fats as well, which, hopefully, we would see with others. So we will, maybe, be not first one to the market. We will be the first one to show an effect on liver fat at the same time as liver fibrosis targeting both balloonings, steatosis and liver fibrosis. By targeting those, we believe that we will be the first one to show.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

Now to add to that with the very clean safety and tolerability profile of Aramchol, I think that all the drugs that are now in development, which are showing the very high effect on liver fat but have some safety concerns will be given, at the end of the day, an induction maintenance for short-term fast reduction of liver fat. Aramchol, as we see that for the time being, is the only drug which is suitable for chronic, long-life treatment for NASH resolution and fibrosis and prevention for progressional fibrosis with a benefit, a little bit, for reversing fibrosis as we've seen in our earlier study.

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

Okay. Great. And then I think EASL is making a decision today regarding the status of the conference. But outside of that, which conferences or events do you hope to attend later this year? And what might we expect there?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

We would try, and we -- my philosophy is I'm coming to any party that I'm invited to. So anywhere that -- all conferences, we will try to make as many as bank conferences, of course. And we have today 11 analysts covering Galmed. So there's quite a lot of exposure from the different financial institutions. But certainly, Liat was -- just recently came from NASH-TAG in Utah, presented in Boston in the NASH Summit in Boston and in London. And there are a number of important NASH conferences scheduled later this year. We have already registered to most of them. And I hope I believe there is a high likelihood that EASL is not going to take place. But I hope that after that, when it gets warmer, we'll get next to business.

Operator

(Operator Instructions) Our next question comes from the line of Jason McCarthy with Maxim Group.

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

It's Adheip on the line for Jason. Just a question here. So with backup countries being used and with potentially different regulations in place in these countries, I just wanted to see if you guys foresee any changes in R&D expenses as a result of these site changes. Or if you guys expect to see any differences in the ease with which patients might be recruited for the study.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

So the philosophy that -- thank you, first of all, Jason, for the question. The philosophy that we have taken from the beginning is that we have set up very clear budget that -- for all sites. And we have not deviated for any of them. There is a budget for U.S. site, and we have a budget for European sites, and we have a budget for the rest of the world sites, and these are different budgets. And we have to adhere to the keeping up the -- and when we're negotiating with the site, I have to say that they respect that, and they understand that we have a fiduciary duty to other sites. So when we say that we are not paying any other sites more than we are willing to pay you, they usually accept our budget. So I don't see that we -- any -- the budget is going to change according to the different markets and different -- and as I said before, we are actively managing our sites, i.e., sites, which are -- and we already gave a warning to certain sites which were not performing. We did a lot of screening and -- or did some screening, and we've gave them a very clear message that we will not hesitate, close the site if we don't see activities which are as planned.

And just as a reminder, our budget and our strategy plan, improvement strategy plan, is built bottom-up. It's been a lot of work based on our ARREST study, which we had more than 80 sites, together with the data that we have from the 3, also other large Phase III studies that have been completed. So we know who are the best-performing sites and we are working with sites that we are sure and be good performers and hence, make this a very efficient study.

I think that the cost, when there is cost of these studies tend to increase when you need to hold a couple of hundreds of sites like 400, 500 sites that we've seen some of the studies, and those have -- some of the sites only randomized 1 patient but it's very, very costly to hold for the duration of the study. This is something that we are trying to avoid at all costs.

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

Great. And then I just want to make sure I got the stance. So for the ARMOR study, you guys plan on completing enrollment by 2Q '21, and you guys expect top line data by 4Q '22. Is that correct?

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

That's correct.

Operator

Ladies and gentlemen, that concludes our question-and-answer session. I'll turn the floor back to Mr. Baharaff for any final comments.

Allen Baharaff - *Galmed Pharmaceuticals Ltd. - Co-Founder, CEO, President & Director*

So I would like to thank you all for joining on this. It's not an easy day on the financial markets. And I really, really appreciate all of us here in Galmed. Appreciate -- I see on your screen that there is a very high attendance of investors and analysts. So we appreciate very much your continued support in Galmed. We are planning a booth for us, we have a large booth at EASL, it's booth 512. So anyone who would come to EASL in London on 16 to 19 of April, I hope this will still take place. And if not, we will try to do our utmost to submit MDRs during the -- once the travel would be free and business will be as usual. Thank you very much for joining today.

Operator

Thank you. This concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation.
