Transcript of the videoconference, June 16, 2021 – 7.30 pm CEST

MedinCell participants

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Jaime Arango, *CFO*

David Heuzé, *Head of Communication*

David Heuzé

Hello everybody, welcome to our videoconference dedicated to the annual results. We'll talk today about the fiscal year that ended on March 31st. I am David Heuzé, Head of Communication at MedinCell, and I am here in Jacou in our Headquarter with Christophe Douat, our CEO. hello Christophe. And with Jaime Arango our CFO. Hello Jaime. We issued today a press release with all our financial results consolidated, ok, this press release is available on our website.
Before we start, I want to remind you that you can send your question by using the chat tool on the right of your screen. We're going to try to answer the maximum of question, thank you one more time to be with us tonight and I start with you Christophe. And Christopher in a few words what should we remember for this year at MedinCell?

Christophe Douat

Good evening David, good evening everybody, thank you for being present tonight and for your interest in MedinCell.
2021 has been a very good year. Despite the very unstable environment the company continued to execute and most of our projects have moved forward. Extremely important and probably the biggest news of all was the positive results on phase 3 of our most advanced program IRM. We also ended up with very good financial situation and before we go forward, I would like to really thank, very sincerely, all the people that work at or with MedinCell, who have shown during this very unusual year resilience and adaptability. Thank you.

David Heuzé

Thank you, Christophe. So, you can see on your screen the company portfolio to date and in green you can see the program that we develope with our partner Teva pharmaceuticals in particular on the right you can see the program IRM, which reached a major milestone, as you said Christophe, this year.

Christophe Douat

Yes David. It's, as I said earlier, it's a major step for the company. We have communicated earlier in January the positive data on the phase 3 of IRM. Our partner Teva confirms of course that they are preparing you know the filing at the FDA to go commercial. They confirmed that this filing should occur very soon during the summer, and we will keep you informed. It's a major step for MedinCell for at least two reasons. I would say three. Of course you know for the patients in schizophrenia but because it's the last mile you know before commercial launch, the clock is ticking, very important step for MedinCell. And second, you know the technology on IRM is the same technology that we used throughout our programs and so this phase 3 validation you know brings a lot of credibility, additional credibility on our technology.
It's always very difficult to predict regulatory delays but Teva is telling us that they are expecting to do commercial launch in 2020 (editor's note: it's 2022), of course subject to you know a positive outcome of the regulatory process.

David Heuzé

Thank you, Christophe. And what about the second asset with Teva, mdc-TJK.

Christophe Douat

Ok, so Teva is confirming that the program is moving forward that they are analyzing the first clinical trial data and that the analysis will inform, you know, the go to phase 3, expected later.
On the third program, ANG, you know similarly they are analyzing the preclinical data to inform the next steps of development. In both cases natural steps development.

David Heuzé

Thank you, Christophe. Let's talk about the third program in clinic which is CWM, with our partner AIC, can you give an update?

Christophe Douat

Yes definitely. Thank you, David. So, we communicated in March the development plan of our partner you know large scale trials are planned, planned to start this year. The plan is as follows.
So, three clinical trials. The first one is a large-scale toxicity trial, and our partner confirms that the start of this trial is imminent, you can actually see that it is now registered on clinicaltrials.gov. In parallel, the first efficacy trial of phase 3 should start before the end of the year, and our partner is planning a second phase 3 later.
Just to clarify you know two efficacy phase 3 trials in pain is a standard regulatory requirement. Great news on top of all this you know our partner indicated in March and we communicated on this that it got a $23 million Canadian dollars financing to finance these activities, and Jaime, so that I don't make a mistake again what is it in US dollars?

Jaime Arango

It's about 19 million US dollars.

Christophe Douat

Thank you, Jaime. And then we have other programs that do you have more information on them?

David Heuzé

Yes, we have also programs that for which we selected the lead candidates this year after the formulation activities, can you give us an update?

Christophe Douat

Yes so, I should really precise again you know what we've said in past but this lead candidate stage, that's the stage when MedinCell you know thinks that the formulation, this particularly lead formulation has met its objectives, in both in vitro and in vivo and which means that MedinCell is confident enough to move into the regulatory development steps. During the 2021 year, we have reached this stage for 4 programs, WWM in contraception, with you know the program that's developed by the Gates Foundation.

David Heuzé

So, you have the portfolio on your screen, we talk about the program on the left of the portfolio. WWM is the red one.

Christophe Douat

Yes, and our three internal programs which I believe, David are in blue

David Heuzé

They are in blue

Christophe Douat

In blue, so it's, GRT, in transplantation, organ transplant, KPT in post-surgery pain for animal health and TTG in prophylactic against COVID-19. On top of that just last Monday, we announced that a lead candidate formulation was selected by MedinCell with Unitaid, the financial sponsor of this program. This program aims at breaking the transmission vector of malaria.

David Heuzé

Thank you, Christophe. We have received questions by email the recent days about the portfolio, we will address these questions later during the presentation, but now I want to ask you Jaime, Jaime Arango our CFO. I suggest to

move onto our financial results this year. Can you detail our financial situation at the end of the fiscal year so on March 31st?

Jaime Arango

Thank you, David and good evening, everybody. You know this year was a very challenging year due to the pandemic. However, despite the context we have significantly strengthened our financial resources. We now can count on a financial visibility that brings us until mid 2023, at least until the summer of 2023. As of March 31st, 2021, our cash and investments were of €51 million versus €16 million last year. Out of these €51 million, we have 47.1 in cash and cash equivalent and €3.9 million in current and non-current assets non risky.

David Heuzé

Thank you, Jaime, can you explain us how we achieve that?

Jaime Arango

Absolutely, so first we had a very significant increase in our revenues almost multiplied by 3 + 187% to reach €8.2 million versus 2.8 the previous year. This revenue consists of services that we rendered mainly to the Gates Foundation and to Unitaid for the contraceptive product for the first one and for the vector of the malaria for the later one. And also, we had $5 million in milestone payments due to the positive results of the phase 3 of the program mdc-IRM. If we add the research tax credit, then the income from the ordinary activities almost doubled compared to the previous year to reach 11.8 million euros. And second our financing strategy that we implemented last year, first we renegotiated the third tranche of the loan with European Investment Bank, and we draw the last round of €5 million at the end of last year. We had access to a total of €13.7 million in the form of state guaranteed loans. And finally, as you know, we had the success of two capital raises that we did in June 2020 and February 2021 with qualified French and international investors for a net amount of €42 million.

David Heuzé

Thank you, Jaime, thank you for this clarification. Can you give us an update on our expenses for the 2021 fiscal year?

Jaime Arango

Absolutely. The expenses reached €27.1 million an increase of 8% compared to the previous year. R&D expenses, they represent 72% of those 27 million to reach 19.6 million euros against 17.2 the previous year. These investments made it possible among other things to advance 4 programs in regulatory development during the year and a fifth one that we announced last Monday, mdc-STM. Marketing and business development activities amounted for €1.8 million a decrease of 24%, and finally G&A expenses remained almost table at 5.8 million compared to 5.6 in the previous fiscal year.

David Heuzé

Thank you, Jaime. Can you tell us how the revenues and expenses could evolve during the current fiscal year which I remind you began on April 1st?

Jaime Arango

Right. So, for this running fiscal year we can still count on revenues. First composed of the service that we will continue rendering to the Gates Foundation and to Unitaid but in addition to that we hope to receive a milestone link to the beginning face 3 for the second antipsychotic product. Regarding the expenses we anticipate an increase due to the recent passage of several programs into regulatory development.

David Heuzé

Thank you, Jaime. To finish on this financial part can you give us an update on the company debt?

Jaime Arango

As of March 31st, the gross that was of €42.3 million and the net financial debt negative at minus 8.8 million euros versus 32.7 and 16.7 the year before. What is important to know is that 49% of that debt is due after April 1st, 2024, when we are expecting to receive the regular income related to the royalties of the sales of the first products based on our technology.

David Heuzé

Thank you, Jaime. I suggest now to go straight to Q&A starting with the question that we received by email prior to this call and then we will respond to questions we received live, OK?
First, I would like to start by pointing out that we received several questions regarding an individual shareholder who is selling stocks. This is a shareholder who must officially declare his sells because he's a member of the family of a person who has responsibilities in the company. This is the reason why his sells are visible. As you can imagine the company cannot comment on what individuals do with their personal wealth. So now I jump to the next question.
We were also asked to explain why we suspended the quotation of our stock for one day in January. So I precise it was on January 7. It corresponds to the announcement of positive results with Teva. We distribute a joint PR that day. And as you know how our partner is in the US, so the press release was distributed during the opening hours of the market, of French market of Paris. That the reason why to guarantee equal information to all our shareholder we had decided the suspension of the quotation. This is what we call a best practice.
Now Jaime can you please explain, and we received the question, why we didn't give individuals the opportunity to participate in our capital raising this year, the two capital raising and I will add despite the will of the company.

Jaime Arango

Right so very important is that it was a wish to do these operations with the public, the capital raises. However, and we were preparing us to do son but as some of you might know this is a very long process. These activities of capital raise, we had to do them in a context that was very uncertain due to the pandemic crisis, and we needed to take all the chances on our side to succeed these operations. So, we had to do it quickly and it wouldn't have been possible if we were to do this with the public. So, we did that in the interests of the company and also the shareholders and we as shareholders it's also in our interest.

David Heuzé

Thank you, Jaime. The other question is for you Christophe. I read it: the CEO of Teva spoke several times about our programs and in particular risperidone in long-acting injection. A few weeks ago, he was very positive and was talking about an NDA submission soon. Do you have any details when will the product be commercialized? So, you already answer partially this question but maybe you have more details to share with us Christophe.

Christophe Douat

I'll repeat what I said, is you know that Teva is planning to file in the very near future sometime this summer. Of course, we can't predict you know regulatory delays, it's always difficult to do but Teva expects to do commercial launch in 2022. Of course, subject to a positive outcome for the regulatory process. The other information I can also give is that Teva is telling us that it plans to present data, detailed analysis of this during future scientific conferences and also in peer reviewed journals t

David Heuzé

Thank you, Christophe. Jaime, the next one is for you. Can you please give us details on the income from Teva programs?

Jaime Arango

Right so I'll remind you of the of the contractual agreements and the income that is resulting from this contract with Teva. So, for each product, we are entitled to receive up to $122 million. We have three products under development with Teva so the total maximum of milestones that we can receive for the three products combined can reach up to $366 million. To that we can add the royalty stream that will came, will start with the first sells of the products of the long-acting products. So let me clarify again, this is something that we have mentioned already in the past and is that the majority of milestones will be linked to a certain level of sales. So, a small portion of the milestones that we're entitled to correspond to development milestones. And as a reminder I mentioned that earlier in the call that this year that ended on the 31st of March 2021, we received, and we recognized $5 million in revenue due or thanks to the very positive results of the phase 3 trial for the product mdc-IRM.

David Heuzé

Thank you. Thank you, Jaime. About IRM Christophe, one more time, do you know if the product will be distributed in other countries than the US?

Christophe Douat

Yes, at this stage you know of course you know our partner is evaluating other markets.

David Heuzé

Thank you, Christophe. So, let's talk now about the program, our COVID-19 program, which is called TTG at MedinCell. Christophe, we received several questions can you give us an update?

Christophe Douat

Yeah, maybe David I'll start with the context. And I like to structure the context with three parameters. The first one is the pandemic and the virus, the second is the vaccines and the third one is ivermectin.
The situation has changed dramatically in the last year it's only been a year you know the pandemic now is here to stay. We know the viruses are muting fast. On the vaccine side you know everybody, a year ago nobody thought that the pharma would do such an extraordinary job on vaccines. Some people even though they may not be vaccines ever, but vaccines are here, and they have extremely high efficacy, higher than you know many of the vaccines of the past at least for the ARN vaccines. On the ivermectin front you know there was very little data year ago and since then over 50 trials have been done with very positive signals and you know as we speak prestigious institutes and governments have started large scale RCT trials. Like you know the NIH, the University of Minnesota, the foundation DNDi in Africa, that's for the context. Now let's remind ourselves that at MedinCell we develop a long acting injectable of ivermectin and in less than a year our team has been able to reach the lead candidate stage and we expect to start clinical trials in 2022. It's again here as well difficult you know to predict the timelines and they will depend on the context and the regulatory support that we get.

David Heuzé

Thank you, Christophe. Another question that we received is that now we have vaccines, is there still a place, a space for our product, for ivermectin?

Christophe Douat

Yes, thank you David very good question. And it will allow me to precise you know some of our strategy on this. The evolution of the pandemic and the current vaccines have allowed us to check then and confirmed that there are populations that will be non-responders to vaccines, people were vaccines do not work. And some of those populations they will be segments that are at high risk when they when they get Covid. So, there's a need and of course it's an opportunity for prophylactic long-acting. It is our primary target with great potential value proposition. For the reminder, we'll see, we cannot speculate today, and it will depend on the evolution of the pandemic, the mutants and of course the vaccine context.

David Heuzé

Thank you, Christophe. Before we address the question, we receive live, last question about ivermectin. What are the other programs developed by MedinCell with ivermectin?

Christophe Douat

So Ivermectin is a very powerful molecule with many modes of action which could be very useful in many indications. We talked about Covid, we talked about malaria. Maybe I'll zoom for a minute on malaria.
You know we're not here to treat malaria, we have you know the goal of this program is to help to break or the reduce the malaria transmission vector. We have shown in the past that by injecting cows with tiny regular amount of ivermectin the mosquitoes that bite the cows die and if you translate this to a human population, during the risky season, you can imagine that it should have impact for the malaria transmission which is done by the vector the mosquitoes. We're working on this with very well-known scientific institutes and this program is funded again by Unitaid.
For opportunities beyond Covid and malaria we are actively evaluating other indications and will talk about them when time comes.

David Heuzé

Thank you, Christophe. So now we will answer the question. We have received three questions live. So, the first one is for you Jaime. Can you please outline the debt position, repayment schedule and interest cost?

Jaime Arango

Ok. So, the debt amounts for, the gross debt, is of €42.3 million. I mentioned before the big, 49% of that debt is payable after April 2024. Prior to that date the major big installment is the payment of the first tranche to the European Investment Bank for about €9 million. We have different levels of debt, the main one today is the debt with the European Investment Bank. So, I remind you, we get a loan three years ago, in March 2018 of 20 that we could draw up to €20 million from the European Investment Bank. Three kinds of remuneration to them of low cash, capitalized interest rates and a variable remuneration for the products that are financed by them. The average cost of that debt is around 5% then the second right now the second biggest debt that we have are the state guaranteed loans that we got last year, 13.7 and the interest rates here are very low compared to the ones that I mentioned.
So, we're talking about something around 1% so these were instruments that were done by, were implemented, by the French government. It is the French banks that give those loans to the companies; however, these loans are guaranteed at 90% by the French government. So very low interest there.

David Heuzé

Thank you very much. Christophe, the next question is for you and it's a little bit provocative, so I read it. Hello question for Chrisotphe, if you have to choose between vaccine and ivermectin what will be your option and especially if you had to use them on you what choice would you make?

Christophe Douat

I can't answer this question, vaccines are available, you know a long-acting of ivermectin is not. So, the future will tell I think it will depend mostly again on the evolution of the context, the pandemic and the mutants and also on the target population.

David Heuzé

Thank you, and the last question for you Christophe, one more time about our TTG program. Very interesting question Christophe, so it won't be the last one because we have another question that arrived. But I ask you this one. Why do you need a long-acting ivermectin when you can take oral products?

Christophe Douat

There is several reasons, you know, when you have a long-acting of course it helps with compliance, and you know the more at risk you are the more you need a solution that supports compliance. Same in schizophrenia for example and it's the value is recognized by the industry and payers. When you do a long-acting you could have a more stable release which may reduce the variability you know of the ivermectin concentration, that will be you know confirmed or not you know during the next step. And also, I think on the societal point of view when you have a long-acting injection you know that the person takes its treatment, if you don't have this tool, you don't know and knowing that the person is protected is extremely valuable.

David Heuzé

Thank you very much and the last question will be for you Jaime. Is the Teva loan cleared now?

Jaime Arango

Right, so under the current agreement with Teva for this loan, reminder Teva gave MedinCell a loan of €15 million almost five years ago, in 2016 of 15 million in total. Now the interest was high of 10% there was some capitalized interest and in the current agreement there's a part of repayment that should be done to Teva with the capital raises that we've done, with the milestones that we have received with Teva, this loan has gone down to about €1 million. So

David Heuzé

So not cleared but close to. Thank you, so no more questions so I think this is the end, so Christophe I leave you the floor for last word.

Christophe Douat

Thank you, David, you know again a very good year if there was one thing I would like to remind ourselves of is the successful phase 3 data which opens the door to the last mile before commercial launch. It's exciting for us and quite also moving you know it's been many years since we've grown the company to reach this stage and so we are looking forward to the next milestone.

David Heuzé

Thank you very much, thank you Jaime, thank you Christophe. Before we leave, I remind you that this video conference and its transcript will be available on our website. So, it is the end, ciao everybody, ciao Jaime, ciao Christophe, see you soon bye.

Christophe Douat

Thank you, David, and thank you to all for again your interest in MedinCell and your continuing support and have a great day you know most of you are in the US and we are looking forward to talking to you soon.