Transcript of the videoconference, June 14, 2022 – 7.30 pm CET

MedinCell participants

Christophe Douat, *CEO*

Jaime Arango, *CFO*

Joël Richard, *Chief Scientific Officer*

Richard Malamut, *Chief Medical Officer*

David Heuzé, *Head of Communication*

David Heuzé
Hello. I am David Heuzé, head of communication at MedinCell. So welcome to this video conference which follows the publication of the financial results for our 21-22 fiscal year ending on March 31st. The press release is available on our website. And so today I am with Christopher Douat CEO of MedinCell. Hello Christophe. With us Jaime Arango. Hello Jaime. Joël Richard, hello Joël. And Richard Malamut our new chief medical officer who joined us two months ago.
So as usual, if you have question, you can share it with us by using the chat module on the right of your screen. This conference will last 45 minutes, maximum. And to start I turn to you Christophe, with one single question. So what were the main events for the past fiscal year?

Christophe Douat
Thank you, David. We are getting closer to a very important milestone for the company the approval of our first product done and developed by Teva. I remind you that Teva filed for an application for approval and market authorization last summer. In November, Teva showed the data of mdc-IRM at the Psychiatry Congress in Texas, in the States. The data is spectacular. The CEO of Teva even describes it as phenomenal. And Rick, Richard Will. I was told not to call you Rick. Sorry, Richard.

Richard Malamut
it's Rick to my friend, so you can call me Rick.

Christophe Douat
Thank you. And you know, this data gave us a direction to show that this product, you know, could have a very, very significant commercial potential. However, as you know, the regulatory process was extended by eight to ten months. The FDA requested some additional information. Teva has to resubmit the filing and anticipates an approval in the first half of 2023.
All the lights are green with Teva, something you don't know yet, but you may have seen on its website is that Teva as made public the fact that they would develop a new indication for mdc-IRM, in neurosciences.
Teva also authorized us to mention that we were actively discussing new collaborations outside of schizophrenia in new indications. In the last few months there have been preparing for the phase thre3e of the second program we have with them mdc-TJK and we expect to go to phase 3 in the next few months.
Last but not least. Our Canadian partner AiC is ready to launch its next clinical trial of mdc-CWM and Richard will tell us about this and the other clinical stage programs in a few minutes.

David Heuzé
Thank you. Thank you, Christophe. As you said, we will discuss this program with Richard a little later, but maybe you have something has to say about what happened last year.

Christophe Douat
Yes. Everything else as moved very nicely. Of course, you know, a lot of our teams were busy supporting our partnered programs, Teva, AiC, especially on the polymer side.
Three programs that are in preclinical should reach a clinical stage in 2023: mdc-GRT, mdc-WWM and mdc-STM. The team is also preparing the pivotal trial of mdc-KPT in animal health. Our Phase 2 with oral ivermectine as part of the mdc-TTG program is going well and we expect to finale data in in Q4.
Last fall, you know, as we always do, we looked at different scenarios and you know, in the case where mdc-IRM would experience a delay, we have decided, you know, to look for, you know, complementary non-dilutive financing. Jaime will give us some information. It's a great thing that we did, you know, because as, as we all know the biotech and tech sectors have really suffered since January with you know an average of minus -30%. So it's a great thing that we started to work on these non-dilutive options which will bring you know fruit in the next few weeks.
Last, we kept working on our ESG initiatives and one of the biggest initiatives is that we created a ESG committee that depends for our conseil de surveillance, our board of directors and that committee is now fully active.

David Heuzé
Thank you. Thank you. Christophe. I take this opportunity to point out that there our 2022 ESG report will be available in French and English in July. I suggest now to move on to financial results with your Jaime. Details of the figures are available on the press release we issued today.
But Jaime, can you tell us more about the financial situation of MedinCell?

Jaime Arango
Absolutely. David. Hello, everyone. Well, let me start, like most companies, we had to adapt to the pandemic so that we could resume normally all our activities. This resulted, of course, in an increase in our expenses they reached €32.2 million versus 27.1 in the year before. Three quarters of those expenses correspond to research and development activities. They made possible for us to advance our programs in preclinical with ambitious objectives for the next year, as Christophe just mentioned. We also launched during the past year the clinical study to demonstrate the concept of our product mdc-TTG. As a reminder in our portfolio we have two programs that are supported by major foundations which are mdc-WWM in contraception with the Bill and Melinda Gates Foundation. They gave us a grant that can reach up to $19 million. What is interesting about this program is that MedinCell keeps all commercial rights. The second program is mdc-STM for Malaria, financed by UNITAID for an envelope of maximum $6.4 million. But this is exclusively a program for global health.

David Heuzé
Thank you, Jaime. So we get some of our revenues from this program supported by the Gates Foundation and UNITAID.

Jaime Arango
Right. Our income from our ordinary activities reached €8.3 million during the year versus 11.8 last year. Half of those revenues come from our collaborations and the service that we render to the Gates Foundation and Unitaid. The other half corresponds to the research tax credit that we can benefit in France, that reached €4.2 million. For the past financial year we did not receive any development milestone from a partner Teva.
However, let me remind you that at the closing of the 31st of March 2021 we had receive a milestone payment of $5 million for the positive results of the Phase 3 of mdc-IRM. As a reminder, we had anticipated a payment of milestone for the program, the second program with Teva mdc-TJK going into phase 3 that we were expecting in the beginning of the year.
Now we're expecting that in the second half of this year.
Our operating cash burn was of €21.4 million at the end of March 2022. This is slightly higher than what we were expecting, and this is normal giving the facing that the new facing that we have with mdc-TJK. I take also this opportunity to specify that for the current financial year we anticipate a significant drop in our cash burn while maintaining strong momentum in our activities.
In the next 28 (editor's note: 18 months) months we're expecting to reach several value creating milestones for the products that are today in our portfolio.

David Heuzé
Thank you. Thank you, Jaime. Let's talk now about our cash position. Can you tell us what, what it was at the end of the last fiscal year?

Jaime Arango
Right. So on March 31st, 2022, we had €27.2 million composed of 24.6 in cash and cash equivalent and 2.6 in non-risky financial assets. As of today, we have a very good financial visibility that takes us until September 2023. But the efforts that we have put in the past three months, since last autumn are bearing fruit. We're working on two main levers.
The first one is to restructure the current debt that we have with the European Investment Bank or the EIB, as I will call it in the future. I remind you that in 2018 we obtained the loan of €20 million. Now on June 1st we reached a significant and an important first step in order to restructure this debt. What it means is that we did an amendment to the current loan and part of that amendment includes postponing by six months the payment of the first tranche to the EIB from June 2023 to December 2023 and also changing the variable remuneration that is due to the EIB.
This change in the variable remuneration will generate financial expenses during the current fiscal year. But what is important with this amendment is that this first step is essential and paves the way for further discussions with the EIB, and I hope I can tell you more about that sooner, very, very soon.
The second lever is to access additional non-dilutive financing, and we're very actively working on it.
So I believe that you have understood that a capital increase is not being considered today. I should also point out that in our hypotheses for the cash visibility, we are not including revenues that could be obtained from new collaborations with new partners or new programs that could be added to the pipeline with our existing partners.

David Heuzé
Thank you, Jaime. So where does it bring us in terms of cash visibility.

Jaime Arango
My objective is quite simple, David, and that means that with these two levers we are targeting to have a visibility until the end of 2024.

David Heuzé
Thank you, Jaime. So the commercialization of our first product by Teva should be delayed by a few months following the CRL received by our partner. So what impact on the company finances?

Jaime Arango
Right so first of all, we like to work on a scenario basis. We evaluate the different scenarios, but more important is that we act upon the different scenarios that reach upon us. So receiving the CRL was a considered scenario. However, of course not the preferred

one, but in any case, I was being we were being cautious or conservative about the numbers we're expecting mdc-IRM to be launched in the second half of this year.
So with the information that we have from a partner, we're expecting then the product to be approved in the first half of 2023. Which means a delay of those revenues of a few months. Now the commercial impact of this product remains very important. And let me remind you the terms of this collaboration with Teva. So each product can receive milestone payments in development and commercial milestones that can reach up to $122 million.
Now we have three products with them, so that makes a total of maximum $366 million. The next milestone that we are expecting from mdc-IRM is of $4 million for the approval. And in addition to these milestones, we will be receiving royalties from the first product that is sold. So regular revenues, we're expecting that to start kicking in as of the first semester of 2023.

David Heuzé
Thank you. Thank you, Jaime. So I suggest now we get a regulatory point of view with you Richard. Before that I just want to say that Richard, you, you are a former member of our medical advisory board and an observer of our supervisory board. And for two months now you have joined the company as chief medical officer. You are based in the United States where we conduct most of our regulatory and clinical activities and I just want to remind everybody that, you know, perfectly our programs with Teva, because you oversaw the early clinical strategy of mdc-IRM as you were senior V.P. of global clinical development for pain, psychiatry, oncology and new therapeutic entities, which means innovative product, at Teva. So, Richard, can you help us to understand clearly where we are with the ongoing regulatory review of mdc-IRM?

Richard Malamut
Dure happy to do so, David. So just a quick reminder and to highlight some of the things Christophe mentioned about the long-acting injectable Risperidone product. Teva filed the NDA in June of 2021 and made public the results of the Phase 3 efficacy study in November of 2021. And perhaps not surprising that statistical significance was reached on the primary endpoint of relapse rate. But was what was unexpected were some of the additional findings seen in the study that provide strong differentiation for the long-acting injectable risperidone product versus other long-acting injectable antipsychotics on the market. So the data was supposed to run for six months. That was the primary endpoint, but the study was to continue until a minimum number of relapses were recorded.
And as the number of relapses was less than anticipated, the study went longer in duration, but the benefit was more patients ended up being treated for the full two years that was available to them. And so this study for the first time demonstrated efficacy on relapses and other endpoints over a two-year period in a double blind placebo controlled fashion compared to a much shorter time for marketed products.
The other thing the study showed was a statistically significant difference on quality-of-life measurements. Very difficult to show in studies in all indications, but even more so in psychiatry and other CNS indications. Further the study showed that after the running of risperidone, oral risperidone to control all the patients entering the study, the patients who were randomized to placebo had the expected worsening of relapse.
But what was surprising was that the patients who received the long-acting injectable risperidone continue to improve on their scores and measures of schizophrenia. So as this product moves through the regulatory process and hopefully is approved, we see quite a bit of value for patients and for physicians who prescribe it. Now, what was not desirable was the complete response letter that Teva received in April of 2022.
And I think it's important to understand that a complete response letter is not the end, it's not the end of the program, it's part of the regulatory process in which the FDA identified issues that they had with the submission and the program and provides suggestions on how to address them. And so Teva has been working since they received the complete response letter to try to address the FDA concerns and are planning to meet with the FDA very soon to discuss their suggestions as to how to address the FDA concerns.
This will be followed by a resubmission of the NDA. When that happens, it's six months from the resubmission date until the FDA renders their decision hopefully in approval. I should also mention that through communication with Teva and our own understanding that there were no concerns with MedinCell product, the formulation, the polymers or the manufacturing sites. We also know that through Teva that there are no plans to repeat any clinical studies, which certainly would provide a longer delay than what Teva is providing publicly. So Teva is enthusiastic about the MedinCell formulation, and this is evidenced by the fact that they're moving to an FDA meeting to discuss another antipsychotic, olanzapine.
Again, in a long-acting injectable formulation, Teva has completed a Phase 1 study with a long-acting injectable formulation of olanzapine, which showed no safety concerns and acceptable pharmacokinetics. They will be meeting with the FDA sometime during the third quarter of this year to discuss their proposed protocol and discuss the development requirements to move that product towards an NDA submission.
And in a, you know, with risperidone, hopefully on the market a long-acting risperidone, the question might be why do we need another antipsychotic like olanzapine? And the answer is that while risperidone is the most prescribed antipsychotic for schizophrenia, olanzapine is often reserved for more severe symptoms and more severe cases of schizophrenia. So there will be quite complementary.
And then the third thing that Christophe has mentioned is the new indication for long-acting injectable risperidone. What we can disclose is that it will be in the neuroscience area. We're not able to disclose additional information about a specific indication but again, this displays Teva, confidence in the MedinCell formulation.

David Heuzé
Thank you, Richard. What about the other program with our partner AiC who will reach the next clinical stage soon?

Richard Malamut
So AIC is a company based in Toronto, Canada, who in collaboration with us is working to develop a formulation of celecoxib to be injected intraarticularly in the setting of knee replacement surgery. And the value there is that we know that pain relief is important in the first days after surgery and that if pain relief can continue for a minimum of three days, there's an impact on the need for opioids beyond that.

And we all know the impact and the problems with opioids when taken for longer than the few days after surgery. So further, AIC has conducted a Phase 2 study in which they demonstrated that a long, that an intra articular formulation of celecoxib demonstrated separation from standard of care, not only at three days, but also at seven days and at two weeks.
So a product that can demonstrate analgesic efficacy for more than a few days after surgery and as much as two weeks would be quite valuable to clinicians and lessen risk to patients. So study design for the next studies is quite critical to the success of any program. And AIC has had extensive discussions with the FDA and external experts in the field to discuss the design of the next protocol.
And so AIC is planning to initiate a 150-patient safety and efficacy study in the third quarter of 2022. Results from that study will dictate next steps and additional studies on the path to submission of an NDA and hopefully ultimate approval.

David Heuzé
Thank you, Richard. So now I turn to you Joël. You're the chief scientific officer at MedinCell. We won't describe all activities of your team in the last past year, but maybe you can give us an update on the portfolio of programs at a regulatory stage, preclinical stage, but also at formulation stage.

Joël Richard
Sure. David, so actually our teams are working at the present time to develop and advance our portfolio of products. And, you know, our goal is to be able to launch the clinical activities of three human health programs in 2023 as well as for pivotal studies of our first animal health program. At the same time, I would like to remind you that actually for an animal health product, pivotal studies are the last development step before filing a new drug application.
So we are progressing very well on this program.
We have also launched during the past financial year, the Phase 2 study aimed at demonstrating the prophylactic efficacy of ivermectin against COVID19 and its variants. And in addition, a three month formulation of our product is now ready to go to regulatory development. And we will wait for final analysis of this clinical study probably in the fall to decide on the next steps of a program.
And then I would also like to mention that we have worked a lot on extending the capabilities of our technology to broaden the range of possibilities for new formulations and the work carried out by the research teams is really outstanding. And in the coming months, we should see the concrete applications of this research come into development, which is really fundamental for the future of a company.

David Heuzé
Thank you. Thank you Joël. So, gentlemen, you stay with us because we received a few questions. The first one is about the program with AiC. And it's for you Richard. So, the question is, is the next clinical trial part of a phase 3? If the results are good, what will be the goal of the additional trial?
And when can we expect this product to be on the market? Thanks a lot.

Richard Malamut
Well, so a lot a lot to talk about there. So, again, the FDA has moved away from calling studies phase 2 or phase 3 and prefer instead to look at the statistical plan of the study, the number of patients in the study and so even a study that's called a phase 2 can contribute to a submission. And a study that's called a phase 3 may not. So, what's more important is what's in the study.
And so, this is a larger study than the phase 2 study that was completed. It will include robust safety and efficacy endpoints. And then results from the study will really dictate what the next studies are, you know, whether they're an additional efficacy study into submission, whether additional work will need to be done. Development is a stepwise progress, and we use data and build on data from each successive study to determine next steps.
And so, to answer, you know, the final part of the question in trying to determine when this would be approved. Well, a lot depends on the study that will start very soon. And I think once we have results from that study, we will be able to be a little more certain about what the next steps would be and then give you a little more definite in the way of timelines.

David Heuzé
Thank you, Richard. Next question is for you Jaime, can you please outline your anticipated R&D spend this year? How much will be spent on clinical development versus other R&D spent?

Jaime Arango
Right. We do not disclose all this detail about the clinical and the other R&D spend. However, what I can tell you is that we are anticipating our expenses to go up between 10 and 15% this year. As I mentioned earlier, however, our cash burn for this year will be lower than the 21 that we reached at the end of March 2022, as we're expecting also further revenues, high increase in revenues coming in this in this fiscal year. And the growth will be driven by the different activities in development mainly.

David Heuzé
Thank you, Jaime, next question for you. What does a non-dilutive financing options separated at the moment?

Jaime Arango
Yeah, I'm terribly sorry, but I cannot disclose the different discussions that we are having today. Things are moving forward and yeah; we keep on moving very actively on that and we remain positive about - the outcomes. But I'm sorry, I cannot tell you more for confidentiality reasons. We will have to wait.

David Heuzé
OK, thank you, Richard. Next question for you, why has Teva delayed the start of the phase 3 for the second program, considering you had anticipated it early this year?

Richard Malamut
Well, some of that has to do with a little bit of a delay in the regulatory interactions and obtaining a meeting with the FDA. We

know that the FDA like many parts of the world, are under resourced. And so that leads to delays in reviewing documents, granting meetings, and so on. I don't think it reflects a lessening of Teva's enthusiasm about the program.
Know that once a decision is made to assess whether a phase 3 study should be conducted and an FDA meeting is decided to be requested, there will be a disincentive to delay on Teva's part to move that forward. So, I believe that the reason for the delay is simply based on regulatory timelines.

David Heuzé
Thank you, Richard, so next question is still for you. What is the new timeline for the filing and expected approval of mdc-IRM? TV-46000 after receiving CRL in April 2022? You already say that, but maybe we can.

Richard Malamut
Yeah. No, I'm happy to say again. So again, the fixed timeline that we know about is a six-month approval time from the day the FDA receives the resubmission to the day that they render their opinion. The variability is going to start with the meeting that Teva will have with the FDA shortly, in which the FDA will confirm the Teva's proposals to address the concerns in the CRL can be met. Once that confirmed Teva will perform the work needed to address those concerns.
The variability as to how long that will take, will depend on the discussions with the FDA, and then that's followed by writing the relevant parts of the NDA and submitting. So, I apologize I can't give you an exact date or even month when it'll be approved. I think once we know that the NDA has been resubmitted, we'll have a little more certainty around six months from there.

David Heuzé
Thank you, Richard. And the last question today, I don't know, maybe Christophe, you will answer it. Back in 2017 MedinCell started a collaboration with Sandoz to evaluate the use of BEPO® technology in oncology. What happened since 2017 is this research still ongoing?

Christophe Douat
No, it's not. At the time we were working on a drug and active principle, which was extremely difficult to handle, and we had underestimated the complexity of finding that drug and one promise actually I made to, at the time the CEO of Sandoz US, Peter Goldsmith, was that it would never happen again. And we actually, and he analyzed the fact that it was also Sandoz responsibility for actual, you know, to have chosen such a difficult API.
But what we've done now is that every time we start and work on a new program, we evaluate, you know, all the risks, what we call technical assessment in the specific unit of, you know, Joël's department. And within six months, we understand the risks and what needs to be done, can we reach a formulation and what needs to be done.
And so, every single program that we do today goes through that technical assessment. Actually, we just recently signed you know, several feasibility studies that are going as we speak in technical assessment. And every future program that we are discussing today whether, you know, with Teva or a new partner will go through that step as well.

David Heuzé
Thank you. Thank you, Christophe.
I think we reached the end, but Christophe, I leave you the floor for the conclusion.

Christophe Douat
Well, it's too bad we cannot celebrate yet, the approval. In Montpellier we do that we call Paillote on the beach, but we will have to wait a few more months. And I don't know if it's going to be a good idea in the winter. If it happens in the winter. But anyway, you know, there is delay. It's a delay. And as Richard, Jaime and Joel described very well, the company keeps moving forward. The next 12 months you know should be instrumental will bring, should bring the company within a new dimension. You know with the approval of mdc-IRM and the phase 3 of mdc-TJK and the new clinical trial of mdc-CWM. So, lots of things going on.
I would really like to thank all our employees for really working hard, you know, to bring the company where it is. I would like to really thank all of you know, individual shareholders, institutional shareholders, employees, former employees for your support. And we will be talking to you soon. Thank you. Thank you, Christophe.

David Heuzé
Thank you, gentlemen. Thank you, everybody, for joining us today. See you soon.