Transcript of the videoconference, December 8, 2021 – 7.30 pm CET

MedinCell participants

Christophe Douat, *CEO*

Jaime Arango, *CFO*

Joël Richard, Chief Development Officer

David Heuzé, *Head of Communication*

David Heuzé
Hello everyone, welcome to this video conference dedicated to the presentation of our half year results meaning the period from April 1st to September 30, 2021. Today we published two documents after the close of the stock market. Firstly, the press release with a summary of our financials for this period.
Secondly, an extended report that you can download on our website. This conference would last 45 minutes maximum. You can send your question by using the chat module to the right of your screen. You can also like the questions, so that's an even higher priority.
For this meeting I'm in Paris with Christophe Douat, CEO of MedinCell. Hello Christophe.

Christophe Douat
Hello David. Hi to all.

David Heuzé
And Jaime Arango, our Chief Financial Officer. Hello Jaime.

Jaime Arango
Hello David. Hello, everyone.

David Heuzé
Joël Richard, our Chief Development Officer, is joining us live from our headquarters in Montpellier. Hello Joël.

Joël Richard
Hello everybody.

David Heuzé
So, we'll start with an update of our portfolio of products based on our long-acting injectable technology, Bepo®. The main event is obviously the progress of our most advanced product, mdc-IRM, a program developed with Teva.
We have two major announcements in the past months. First, the acceptance of the NDA, the new drug application, which is the request for marketing authorization. It was accepted for review by the FDA on August. Christophe, would you like to make a comment on why this is so significant for MedinCell?

Christophe Douat
Thank you, David. Yes, indeed, it is a fundamental event for the company. If we take into account the usual delays, since the filing was accepted by the FDA in August, the approval should happen before summer 2022. Teva confirmed that commercialization should start in 2022 as well, of course, subject to the approval from the FDA.
As a reminder, the antipsychotic long acting injectables market as today is size of 4 billion in 2021, 7 billion worldwide, 4 billion in the States sorry and 7 billion worldwide. Its growth average, growth rate, in the last three years has been 14% per year, 1, 4, 14%, and there is still a lot of needs since only 160,000 patients are treated today with antipsychotic, long acting injectables in the States. We believe we have the ideal partner, a partner with which we have a very strong relationship. A relationship that started seven years ago. Teva, our partner is showing its dynamics and its CEO, Kåre Schultz has not done a single analyst meeting in the last year without mentioning our product mdc-IRM. Beyond this, and we've communicated on them, the presentations by Teva at the psychiatry annual Congress, November 1st, were also very meaningful. Everything indicates that Teva is preparing, all he needs to do, you know, for the potential approval in 2022.

David Heuzé
Thank you, Christophe. So, as you mentioned, the second major event was a presentation by Teva of 16 posters during a Psych Congress at the end of October. Psych Congress is the largest American Psychiatric Conference. Maybe you can explain why this is so significant for MedinCell.

Christophe Douat
Yes. Well, not only Teva presented at the Congress, David, but they also presented 16 abstracts. 16. You know, this is again a testimony to the dynamics of Teva, and all the data that was presented confirms what we hoped to see at MedinCell. Our technology, as allowed us and Teva to develop a product which should be a true game changer in the field of long acting injectables antipsychotics. We have developed a product which is a subacute and not intramuscular, which is injectable with a short needle which is ready to use, easy to use, very flexible. All this, on top of all its attributes, the data shows that the product has excellent efficacy and tolerability. All these results go beyond, you know, our hopes. It is a great product. Its potential is enormous, as you can understand, and I can tell you that our teams are extremely proud.
There's a lot of excitement at MedinCell and you know, I will quote Kåre Schultz the president of Teva, this should become the preferred treatment for patients.

David Heuzé
Thank you, Christoph. We also received some information from our partners, Teva and AIC, about our partnerships programs.

Christophe Douat
Yes, as usual, we've asked them to tell us which information they could share about the programs that they are financing and which they are developing. On the Teva side, we are awaiting news on the next steps for mdc-TJK and mdc-ANG respectively at potential phase 3 and potential phase 1. It will be in 2022. We don't have any more details that our partner wishes to to share right now for regulatory, strategic and competition reasons.
On AIC and mdc-CWM, our partner, confirms that they are ready to launch phase 3. But the interactions with the FDA continue to finalize the protocol of a product, which would be a first in its category A lot is at stake, the objective is to maximize the chances, to get the approval to go to market, but also to guarantee the commercial success of mdc-CWM.

David Heuzé
Thank you, Christophe. Maybe now a few words on our TTG, Covid-19, program.
We announced a few days ago that we received 3 million euro loan from BPI France for the development of this product. Can you tell us where we stand on that?

Christophe Douat
Yes. The program is moving forward. We explained that the priority was to do an efficacy clinical trial, that is very well structured, to have a proof of efficacy that nobody can discuss in Prophylaxis, but also to optimize the development for long acting injectable. The preparation for this trial is very advanced, and we are planning that the trial will start in Europe as soon as January in several European countries where vaccination rates are lower than they are in France, and the protocol of the trial will be described when the trial starts.

David Heuzé
Thank you, Christophe. Is there anything else you want to highlight regarding our portfolio?

Christophe Douat
Yes. The other programs are moving ahead on plan, especially our project in the contraception. You know, I remind you that we received an envelope of $23 million from the Bill and Melinda Gates Foundation to move this program into clinical.
And most importantly, I really believe, you know, we are entering a period which I've been waiting for ten years. You know, we have completed a phase 3, a successful phase 3. It's a major event in our industry and it validates the technology, you know, brings a lot of credibility to the company.
And as we thought, discussions with partners are accelerating. We are prepared, news to come.

David Heuzé
Thank you. I turn to you Jaime now. Let's talk about our financial results. In few words Jaime, can you describe our situation at the end of the period on September 30?

Jaime Arango
Absolutely, David. At the end of September, we have a solid cash position of €37.4 million, composed of €34 million in cash and cash equivalents and €3 million in non-risky investments. Since September, since the end of September, we have received 3 million euros of the research tax credit from the year 2020.
And perhaps you have also read that we have received €3 million from BPI France to support the product mdc-TTG. And we have also received a partial payment of a grant that we receive from of the 1 million that we receive from the government in this scheme, called Plan Relance.

David Heuzé
Thank you, Jaime. Jaime, can you highlight what are the highlights of the period in terms of revenue and expenses?

Jaime Arango
In terms of revenue, it grew by 30% to reach €4.1 million. These €4.1 million are split between, 1.6 of the services that we provide to the Bill Gates Foundation for the program WWM, with United for the program mdc-STM. And in addition to that, we also recorded €2.5 million in the research tax credit. Regarding the operational expenses, they also grew, this time by 36% to reach €15.3 million. However, let's put this growth into context. Let's put us back, let's step back over 18 months ago, when this pandemic started and there were a lot of uncertainties then, and we had to take measures in order to maximize the cash that we have then. So we had to put in place austerity measures, prioritizing the types of expenses, there was certain teams that were on partial activity. But since the end of last year, we're going full-fledged investing in our products, advancing them into the next stages. Therefore, this high growth on the financial expenses they decreased by 79% and each had 544 K euros last year.

This expense increased because last year, we had to reevaluate the cost of the EIB loan. Regarding the variable remuneration that was due to renegotiation and an amendment that was signed with them in the middle of 2020.

David Heuzé
Thank you very much, Jaime. Can you tell us if these numbers fit with what was anticipated and can you tell us what is the expected evolution for our finances over the current semester?

Jaime Arango
Absolutely. We're in line with our expectations. By the end of March 2022, our fiscal year ends in March next year, we should receive $3 million from Teva, thanks to mdc-TJK we are anticipated that it goes in that it advances into phase 3. We continue our collaboration with The Bill and Melinda Gates Foundation and Unitaid. Therefore, our top line is expected to be more or less at the same level as we finished last year at around €12 million. In regard to expenses, we should have a more moderate growth than the first, than the initial six months to finish them at around 31 million or plus 15%.

David Heuzé
Thank you, Jaime. Jaime, can you tell us when do we anticipate receiving the first revenue from Teva, following a potential mdc-IRM commercialization?

Jaime Arango
Right, so today, with the three products that we have with Teva, we have in this contract, we have three different types of revenues.
We have milestones, that are from development. We have commercial milestones that we will receive once the products attain a certain level of sales. And third, we have the royalties, medium to high single digit, and that from the first product that is sold on the market.
Let's go back to the milestones for each product. The total amount of milestones can reach up to $122 million, and the majority of these milestones are commercial ones. So if we combine the three products, the total amount of milestones that we can receive is $366 million.
Now, to give you an idea of the split between the development and the commercial milestones, let's take the example of mdc-IRM. To date, we have received over $10 million in development milestones and the next one that we're expecting on development is on the marketing authorization that this product will get from the FDA.
We're expecting $4 million. From then, over $100 million will be dedicated to the commercial milestones that we're expecting to receive in the coming years. Now the question is do we have the confidence that we will receive the totality of these commercial milestones in the years to come?
And our feeling is that today, yes, given the very positive results of the phase 3, as Christophe mentioned, should be the preferred product for patients, for health care professionals. We're convinced of the potential of this product. Now the royalties they will start kicking in as of 2022, when the first product is commercialized.
So, from then on, each quarter, we will be recording and receiving the cash of these royalties. Again, mid to high single digit from the first sales. So, this is very exciting. We're expecting to receive these royalties again next year if there's the FDA approval, of course, but it is something that, it's a new stage for the company. Coming with regular increasing income, and we're preparing the company for that.

David Heuzé
Thank you very much Jaime. I think it was pretty clear. Christophe, last week we announced that we secured €1 million in the framework of France relance to extend our lab capacity can you provide more details about the use of this grant.

Christophe Douat
Yes, definitively David. We will soon be moving to our new building extension. This will free up room to extend our current lab, and this is absolutely necessary to help with the growth of the company. As you know, the lab is where it happens at MedinCell. So this is where the formulations are this designed, tested, you know, and determined to go into regulatory development. So, we had put the new lab on hold at the beginning of the pandemic. And this $1 million, sorry, €1 million will help us, you know, to start getting back on track.

David Heuzé
Thank you very much, Christophe. A lot of people connected today, but only one question received this evening. So, the question, Christophe, I don't know if can answer. How many sales reps will Teva have detailing your product and how does this compare to Indivior and Perseris, thanks?

Christophe Douat
Thanks. Okay. OK, two great questions. Thank you. You know, unfortunately, Teva will not disclose how many sales forces they will bring to this program. You know, I think we have enough clues to tell us that they will do as much as they can to get to a successful launch, you know, based on the data based on the comments from the CEO, it's quite rare to see the president of a company, you know, announcing a product like this, you know, at every analyst meeting. We know that Teva has a great reputation to launch products. The last launch, Austedo, has been a great success, you know, bringing in very significant additional revenue to the company.
And so, this is the same salesforce as the one that will sale our product I believe. On the second question, Indivior and Perseris. OK. So Indivior actually did, the approval for the first subcute program. When I'm asked about this question, I usually show the needle that is needed to inject a product, gauge 18.
And usually, you know, I show it to people because they can see it from the other side of the room and it's not very appealing. And there are volumes of injections are quite high as well. So, there's a lot of attributes that a product has that they don't have and certainly not the quality of data that we have obtained in our phase 3, not only in terms of quality, but also in terms of duration. You know, I believe our clinical trial was the longest trial that has been done in the long acting injectables and has shown many improvements that people don't see usually.

David Heuzé
Thank you, Christophe. Another question and I think that Joël you can answer it. Is your LAI celecoxib being explored to treat osteoarthritis?

Joël Richard
Yes, this is a good question. I'm not sure we can really comment on with the present time.
Yeah. This is a, let's say, one of the opportunities that may need to be investigated further in the next months or years. At this stage, I think we cannot really comment on this.

David Heuzé
Thank you Joël.
So no more question, I think we reached the end of this conference. Christophe, I can give you the floor for conclusion.

Christophe Douat
Yes. Thank you very much for attending our conference. I wish all of you, you know, great holidays. You know, merry Christmas, and I hope all your families and yourself will stay safe and we are looking forward for more news in the new year. 2022 should be an exciting year, should be the year of approval of our first product, and it's extremely exciting for all of us at MedinCell.

David Heuzé
Thank you Jaime, Joël.