Transcript of the videoconference, December 9, 2020 – 7.30 pm CET

MedinCell participants

Christophe Douat, *CEO*

Jaime Arango, *CFO*

Joël Richard, *Chief Development Officer*

David Heuzé, *Head of Communications*

David Heuzé

Hello everybody, welcome at the videoconference for the half year results. Thank you for being with us tonight. Tonight, with us we have Christophe Douat, our CEO. Welcome Christophe. We have Joël Richard, our Chief Development Officer and Jaime Arango our CFO.
I remind you that you can ask questions by using the chat tool on the right of your screen during al the conference. As I told you we have published today the press release and the half year report, they are available on our website, invest.medincell.com. So tonight, we respect the physical distancing, so we can remove our masks. It's better for everybody, thank you.
So, I suggest that we start with you Christophe, with the last development of our portfolio of long-acting injectable products. So, first Christophe, what about the three LAI product antipsychotic that we develop with TEVA, what about what happened this semester.

Christophe Douat

Yes, thank you David. As you know we've had great news on the TEVA side with a major event this quarter with the completion of the pivotal efficacy study on November 24th, so two months ahead of schedule.

David Heuzé

Perfect and what could be the next step for this program Christophe?

Christophe Douat

So, we expect the study read out in the first quarter of 2021, as Kare Shulz the CEO of TEVA mentioned during his earning call, I encourage you to look at the transcript. The Next Steps after that should be the application for marketing authorization and then approval of course.

David Heuzé

And at the same time TEVA is completing a safety study, Christophe?

Christophe Douat

Yes. TEVA is completing a safety study, as we know.

David Heuzé

Ok, this is a product for schizophrenia, Christophe can you remind us the main metrics of this market?

Christophe Douat

Yes, schizophrenia, we mentioned it before, is the largest market for long acting injectables, it's a 5 billion dollar market worldwide, growing significantly. In the US alone it's a 3 billion dollar market, growing at 15% CAGR
David Heuzé
And this is a very important product for us, IRM?

Christophe Douat

Yes David. It's important of course as it is the first product made with the BEPO® technology that will hit the market. But also, because it is the same technology, which is underlying in all of our products, so it will automatically derisk all our pipe.

David Heuzé

Thank you, Christophe. And what about the two other antipsychotics developed by TEVA?

Christophe Douat

So, the second product is completing his phase 1, and his expected to complete this phase 1 in 2021 and the next step should be a phase 3, like mdc-IRM. And the third product is currently completing his preclinical studies and should hit the first in human trials in 2021.

David Heuzé

Thank you, Christophe. Now let's talk about the other products in clinical phase, mdc-CWM for management of post-surgery pain and inflammation. The phase 2 ended last April, our partner met the FDA this summer, where we are now?

Christophe Douat

So, indeed our partner met the FDA in an end of phase 2 meeting as it is called. It is now working; it has been working on optimizing the development plan and our partner confirms that it will initiate several large-scale safety and efficacy studies in the coming months.

David Heuzé

Thank you, Christophe. And last January, the company announced that this year, three products would be ready to enter regulatory development after the end of formulation activities, are we on track?

Christophe Douat

Yes, we are on track. And I would really like to congratulate our teams, they've done an amazing job you know on those three programs. The first one, as you know, was our contraception product with the gates Foundation. The formulation selection was announced in April and the regulatory activities are in progress. The second one, has indeed completed its formulation activities, we do have the lead formulation, that's our product in the post-surgery pain in animal health. And a third one, which is a major program for the company, also significant for patient, it's our transportation, long acting injectable, and I can confirm that the formulation is about to be selected. And we will communicate on it very soon.

David Heuzé

Thank you, Christophe. And there is even one more program that can reach that point.

Christophe Douat

Yes, so not only did we achieve finale formulation on first programs that were planned, but also the new one, mdc-TTG, our covid-19 program. The teams are finalizing the choice of a lead formulation which will be ready to go into regulatory development. We started a safety study in September to simulate the continuous administration of ivermectin through daily dozing and not just single dozing. And we will be communicating soon and give an update on this study which is going well.

David Heuzé

Thank you, Christophe, for this overview on our portfolio.

Christophe Douat

Sorry David. I probably should talk about the workshop. We have been talking to all or a last of the scientists and clinicians worldwide at that are working on ivermectin against Covid in many countries. And to encourage them to share data, share information to speed research and increase awareness we decided to initiate and organize a workshop. A professional workshop, this workshop will be held next week on the three themes, modes of action, ivermectin as a treatment and ivermectin as prophylactic.

David Heuzé

So, thank you Christophe for this overview on the portfolio and the last development. Now let's talk about financial results with you Jaime. Jaime Arango, our CFO, welcome Jaime.
Jaime can you tell us what the main takeaways of this half year in the financial point of view are?

Jaime Arango

Indeed, the three main points to keep in mind for this semester, this half year results. First is that we did a successful budgetary effort in the beginning of the semester and also with did successful transactions dilutive and non-dilutive to increase the cash visibility of the company that goes until the summer of 2022, excluding the program mdc-TTG against the Covid. Second point is on a P&L our revenues are in line with our expectations and the expenses are under control we will talk about that later. And then the third one thanks to the investments that we made, our programs continue to advance and will be ready to go into the clinical studies as mentioned by Christophe just now. So, all these programs are crucial for MedinCell's future value.

David Heuzé

Thank you, Jaime. the most important non-dilutive transaction was the PGE, which is a state guaranteed loan, can you explain what is it and what we have done?

Jaime Arango

Right, so in total we have received 13.7 million euros up until today. First, we negotiated and received the cash of 11.5 million euros between May and June of this year of this state guaranteed loans. What are this? This are loan that are very attractive for the company, this are backed by the French government at 90%, they have very low interest rates and are really long term, so the full repayment can go up until 6 years of reimbursement. The bank that participated in there were the Banque Populaire du Sud, BNP Paribas and Caisse d'Epargne. And then after the 11.9 million we received an additional 1.8 million from the BPI, back in October, of course this is after the 30th of September, so this 1.8 million are not included in our half year results.

David Heuzé

Thank you, Jaime. Another major event was the capital increase, can you give us more information about that?

Jaime Arango

Right, so back in June we did this capital increase in the form of a private placement. We raised 15.6 million euros, it was a real success with an oversubscription of 40% and a very limited discount at 8%.

David Heuzé

Thank you very much Jaime. So, our revenues for this period reached 3.1 million euros, can you give us more details?

Jaime Arango

These revenues are exclusively coming from the service that we render to the programs that we're working with the Bill and Melinda Gates Foundation, with Unitaid. The difference of almost 800.000 euros compared to the same period last year is because the previous year we received the milestone that we didn't receive during the half year results. However, as Christophe mentioned, TEVA programs are progressing well and by the end of the fiscal year, ending 31st of March of 2021, we're expecting to receive milestone payments from the advancement of the two most advanced products, IRM and TJK.

David Heuzé

Thank you, Jaime. Our operational expenses reached 11.3 million euros, can you comment?

Jaime Arango

Right, as I mentioned the expense are under control with the action that we took in the beginning of the year, they are lower by almost 700.000 or -6%. The R&D expenses, they represent almost 70% of the total spending.

David Heuzé

Ok, and what about our financial expenses, they are important during the period.

Jaime Arango

Yes, during the first 6-months they represent 2.6 million euros, we had communicated about the renegotiation of the third tranche with the European investment bank, or EIG as we call them, and this is an exceptional transaction that created exceptional expenses due to the variable remuneration linked to these EIB loan that considers the cash received and to be received from the programs that are financed by the EIB.

David Heuzé

Thank you, Jaime. Can you give us few words about our cash consumption?

Jaime Arango

During the first six month our operational cash consumption was of 6.7 million euros compared to 9.1 million euros the same period last year. However, during this semester we received a payment of 3.2 million euros that correspond to the Research tax credit, that's part of the French government instances to help innovative companies, like MedinCell. So, we received it in advance, last year during the first half we only received the 2.5 million of this research tax credit in the second half, not in the first half.

David Heuzé

Ok. And I think it's important to talk about the debt.

Jaime Arango

Right so due to the transactions that we made on this PGE loans, the 11.9 million euros, our debt increased to 43 million euros compared to the 32.7 that we had at the end of March.

David Heuzé

Thank you, Jaime. So, what can be the conclusion of our financial results this half year?

Jaime Arango

By the end of September, thanks to the reactivity and team's adaptability, MedinCell had enough cash to fulfill its strategic objectives, and cover its cash needs until the summer of 2022, excluding our mdc-TTG against the Covid.

David Heuzé

Thank you very much Jaime. Now I think it's time to make the Q/A session, we received a lot of question before this conference. Joël, one question about the program of TEVA, IRM, so we are waiting for the study readout in Q1 2021, if they are positive will the application for market be filed immediately? How long does this procedure take, and finally when will the product be on market?

Joël Richard

Thank you for the question. Actually, everything is really in the hands of TEVA as you know. They should complete the analysis of the results by Q1 as planned, and then file the product. The review should take typically 6 to 12-months, so actually we are expecting the product to be on the market end of 2021 or in the very early months of 22.

David Heuzé

Thank you Joël. As a reminder TEVA leads the program and pilot the development of the program, so it depends on what will TEVA do. We mentioned an ongoing safety study for this program, why this study, what is the goal of this study Joël, when will it be completed, and will the marketing authorization depend on the completion of this study?

Joël Richard

Thank you for the question. So, this is a very classical safety study for chronic long-acting products. Actually, this is no essential for the filing of a product and for the review of the dossier by the agency, so we are not expecting this study to delay the launch of the product, it's expected to be closed anyway by end of 21 the latest and might be even faster.

David Heuzé

Thank you very much. Jaime, can you tell us what would be the amount of the next milestones of TEVA?

Jaime Arango

So, we do not disclose the milestone amount however they will be visible by the end of the fiscal year if everything goes as we expect it to. However, let me clarify little bit about the agreement that we have with TEVA. So MedinCell will received milestone payment during the life of the different products. So, the milestone payments per project can reach an amount that can go up to 122 million dollars, split one part on development milestone and another chunk upon reaching certain level of sales. So that's up to 122 for each program, multiply by 3, for the three programs, that's 366 million dollars. And in addition to that MedinCell will receive royalty payments to high single digit depending on the sales of TEVA of the different programs and that from the sales.

David Heuzé

Thank you very much Jaime. Christophe, we also received this question, are other products development considered with TEVA.

Christophe Douat

This is an information I cannot disclose

David Heuzé

Thank you for this short answer. Christophe or maybe Joël, why would the mdc-TJK program go directly to phase 3, without going through phase 2?

Joël Richard

Right. We think that actually TJK project may have a same regulatory pathway as IRM going directly from phase 1 to phase 3. And the reason behind this is actually that this product, TJK, is based on a formulation of an already know API, already commercialized and used clinically. SO, for this reason there is no need to prove its efficacy in phase 2 study, and so most likely it should go to the phase 3 directly.

David Heuzé

That was also the pathway for IRM I think.

Joël Richard

This was this accelerated pathway that was used, taking into account that risperidone is already on the market and has been used for many years now.

David Heuzé

Another question Christophe. Do we know how much TEVA has invest in the various ongoing programs?

Christophe Douat

I am sorry, but it's not an information we can disclose as well, plus we don't even know it.

David Heuzé

Thank you for this short answer one more time. Next question for you Christophe, will the product develop with TEVA be available quickly in Europe and in the rest of the world?

Christophe Douat

So right now, TEVA is focusing on the US, because it is the largest market in the world for pharmaceutical products. And you know I can not disclose TEVA strategy for the rest of the world.

David Heuzé

And next question for you Christophe, why did you choose to make long-acting product in a field where there are already a lot of products in schizophrenia?

Christophe Douat

Well, I think TEVA picked the right strategy, it's always better to go in a field where there are existing products, which means that patients, clinicians are used to use long acting injectables, and of course to key condition is to come up with a best-in-class product and of course I think our product is best-in-class.

David Heuzé

Thank you very much Christophe. Jaime, I don't know if you can answer the next question but how much revenue do you expect from sells from TEVA products?

Jaime Arango

For the fiscal year you mean?

David Heuzé

For the coming fiscal year, this year you already answer, do you have a guidance, something like that?

Jaime Arango

No, we don't, unfortunately, provide any guidance, but as I mentioned for the fiscal year, we are expecting some milestone payments coming from the most advanced product with TEVA.

David Heuzé

Thank you, Jaime. Joël, does MedinCell manufacture the products that will be distributed by TEVA? and are you going to succeed in moving to the industrial stage?

Joël Richard

Right, so actually TEVA produces the product that will go to the market, they have the industrial equipment in Ohio, they have produced all the clinical supplies that were necessary for the clinical studies and so the drug product is in their hands for manufacturing. Now, as regards to the polymers actually we are producing the polymer at GMP scale through our joint venture with Corbion, CMB, in the US and we are at the present time at the industrial scale and able to produce all the polymers that are necessary for products coming to the market.

David Heuzé

Thank you very much. Christophe, another question, can we explain the delay on mdc-CWM? I remind you that the phase 2 ended in April.

Christophe Douat

Yes, there is a delay indeed. It should not be significative. Our partner is working on the optimization of the development plan as we speak.

David Heuzé

And Joël, do we know how long should last the next development stage? The next clinical study?

Joël Richard

We keep this information confidential for the time being, it will be published on the site of the FDA clinicaltrials.gov and so it will be available at this time.

David Heuzé

Thank you very much. Christophe, a question about TTG program, on Covid-19. Does this program still make sense with the vaccines that arrived?

Christophe Douat

So, I will describe what our vaccine experts tell us, because of course we are checking their opinion regularly. You know there's a lot of uncertainty on vaccines, on the direction of efficacy, on you know how they will protect the populations that are the most at risk like really old people, above 80. Their accessibility in emerging market and so they think that you know in all scenarios there will be room for a prophylactic treatment which can be you know using a well-known drug with little side effects.

David Heuzé

Thank you very much. Jaime, two last questions for you. Do you think that MedinCell will respect the guidance for cash consumption increase between 10 and 15% for the current fiscal year?

Jaime Arango

So, let's clarify when we talked about the guidance, we are talking about the operation expense, not about the cash consumption. However, yes, we provided this guidance of 10 to 15% given the forecast that we continuously do, we're expecting to finish the Year slightly below 10% compared to the previous year, this excluding the program mdc-TTG.

David Heuzé

Thank you and the last question for you Jaime. Are you considering new financing operations? What kind of operations, dilutive or non-dilutive?

Jaime Arango

So, I have mentioned in previous calls, we are always looking into the different options that are in front of us. That may include also limited capital raises, capital increases, but we have
to take into account the interests of MedinCell, the opportunity of doing so, and also the interest of us as, as that we are shareholders of the company.

David Heuzé

Thank you, Jaime. Before leaving the floor to Christophe to conclude. I want to remind you that there will be a general assembly next week on the 15th. Elisabeth Kogan is proposed to join the board of MedinCell. We held a videoconference who introduce Elisabeth Kogan last week, this videoconference is available on replay. So, you can still vote, you can use electronic vote or download the ballot on our website invest.medincell.com.
This general assembly will be aired live and then available on replay. The information to connect this general assembly will be released in the coming days. So, this is the end, maybe Christophe a few words to conclude?

Christophe Douat

Yes of course you know this has been a special year, this will be special year end as well and I would like to wish all of you, yourself, your friends, your family, your coworkers a great Christmas and good health as well see you soon.

David Heuzé

Thank you, Christophe, thank you Joël, thank you Jaime and thank you all and happy end of year for everybody and take care thank you bye.