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PRESENTATION

Operator

Good day, and welcome to the Galapagos Half Year Results Call.

At this time, I'd like to turn the conference over to Ms. Elizabeth Goodwin. Please go ahead.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

Thank you all for joining us today for the audio webcast of Galapagos' first half 2020 results.

I'm Elizabeth Goodwin, investor relations, also representing a great reporting team.

This recorded webcast is accessible via the Galapagos website homepage and will be available for replay later on today. So that your questions can be included, we request that you call in to one of the telephone numbers given in last night's press release. I've got one for you here: 32, for Belgium, 2-404-0659, with code 8997710.

I'd like to remind everyone we'll be making forward-looking statements during today's webcast. These forward-looking statements include remarks concerning future developments of the pipeline in our company and possible changes in the industry and competitive environment. Because these forward-looking statements involve risks and uncertainties, Galapagos' actual results may differ materially from the results expressed or implied in these statements.

Today's speaker will be Onno van de Stolpe, CEO, as Bart Filius is away. Onno is going to go through the operational highlights and explain the financial results and expected future news flow. You will see a PowerPoint presentation on screen, and we estimate that this will take about 10 minutes. And then we're going to open up the call for questions with Onno, who will be joined by Walid Abi-Saab, our CMO; Piet Wigerinck, CSO; and Michele Manto, who's our Chief Commercial Officer.

And now I'd like to hand to Onno. Go ahead, Onno.

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Thank you, Elizabeth. And thank you all for attending this webcast. And I hope you're all enjoying the summer, a weard summer in view of of COVID-19, but we are all making the best of it. We're all dispersed in various locations today, so I hope the logistics go well.

Yes, Let's start with a very positive note on the positive CHMP opinion for filgotinib in rheumatoid arthritis, of course a hallmark moment for Galapagos, our first molecule that received positive CHMP opinion. We are very pleased with the progress we are making to get filgotinib introduced into the market. This opinion is a recommendation for marketing authorization in Europe for treatment of moderate to severe rheumatoid arthritis patients. The very good news is that we got both the 100- as well as the 200-milligram dose recommended, which will give an option to doctors to prescribe a lower as well as a higher dose, which we believe is a benefit for this molecule. The patients that will receive filgotinib are those patients who have inadequate response or intolerance to one or more DMARDs; and monotherapy or in combination with methotrexate, which was as expected in the recommendation, so we're very pleased with that recommendation. All of this is based on the FINCH and the DARWIN data, the Phase III and the Phase II data set, that in total included 4,500 patient years experience. So there's a lot of efficacy and safety data on filgotinib with the regulators. So we're now waiting the EU marketing authorization that normally should come in a 2 months period.

So if we look at how we are approaching this in the commercialization, then clearly we will start in a limited number of countries. Gilead will have the remainder of Europe to introduce filgotinib in RA, but Galapagos will do this in the Netherlands and Belgium as well in France, Italy and Spain, so quite a large geography where Galapagos is responsible for the full marketing commercialization of filgotinib. We're also expecting that later we will also get authorization to market filgotinib for IBD, inflamed bowel disease. In that case, we will be marketing that in Belgium, the Netherlands as well as the U.K. and Germany. So a different geography for rheumatoid arthritis. A big advantage for us is that we can gradually increase our marketing efforts and footage in Europe, preparing for a full European presence on the commercial side for our next product that would hit the market. And most likely, that should be our products for idiopathic pulmonary fibrosis, ziritaxestat.

So for now we are ramping up for the first product launch for filgotinib in those 5 territories, which we believe is a great challenge, but we are very well ready to take on that challenge and is very well prepared.

So with that, we go to the next slide. Let's spend a couple of minutes on the SELECTION Phase III results in ulcerative colitis with filgotinib. Clearly, we saw very good data coming out of this trial. We hit the primary end point both for the 100 and the 200 milligram on EBS remission at week 10 and 58. With the 200 milligram, we achieved both the induction as well as the maintenance end points. The 100 milligram achieved the maintenance end point but not the induction end point. It is -- it was a tough population to treat these patients, and we were very pleased with the outcome of this trial. If we looked at the safety side, the rates of serious adverse events were low and very comparable across the treatment groups and in-line what we have seen with other trials in rheumatoid arthritis and other indications. So the full data will be presented at a future medical conference in collaboration with Gilead, obviously.

So that's for the science and development part. Let's switch to the financials. Normally, Bart would have presented that, but I'll try to do it as good as I can.

So we started the year at EUR 5.8 billion. And the big cash burn this year on the operational side reduced that with EUR 230 million, completely according to plan, so we ended the first half on a cash pile of EUR 5.6 billion. So that was completely in line with expectations. If you can go to the next slide, you'll see the financial highlights and we see the revenues going up substantially compared to a year ago. We had an extra EUR 116 million, which landed the revenues of EUR 224 million. Having said that, that is, of course, the consequence of the big deal we signed with Gilead where we have revenue recognition on the technology access that they receive through the option agreement and the upfront that they pay. And that is over -- that is recognized over a 10-year period. So that brought us to the total revenue of EUR 224 million.

Operating costs went up substantial with EUR 150 million. And that's because we are expanding in all areas, being it development, research, G&A; and also, of course, the preparation of commercial launch, which starts to kick in seriously on the financial side. So all according to plan and we are very pleased with how that is all coming along. That combined led to a net result of a loss of EUR 165

million compared to a loss of EUR 70 million last year. And that, of course, is a consequence of the substantial increase that we're doing in the various aspects of our business; nothing to be concerned about, as we had previously communicated to the market that we would ramp up pretty much all the expenses in research, development and commercialization.

If we go to the next slide. We have to raise our guidance for operational cash burn of EUR 400 million to EUR 430 million. And that includes $205 million in potential milestones, subject to regulatory approvals. So those milestones have to come in to enable us to keep that cash burn. If the milestones, for whatever reason, would not come in, in this year, then clearly we'll have a higher cash burn than the EUR 400 million to EUR 430 million.

And the last slide is about the milestones that you can expect for the remainder of the year. We have the SELECTION data come in. We're now awaiting 3 Phase II readouts, 2 Phase IIa and 1 Phase IIb. The first one, PINTA study, is in idiopathic pulmonary fibrosis with 1205. That data, we're expecting shortly. Then we have the second indication for 1690, ziritaxestat. And the first indication, as you know, was in IPF; with the second indication which is in systemic sclerosis, where we're getting that data in the NOVESA trial also in the upcoming months. And then also the long-awaited and important trial of 1972, in the ROCCELLA trial, which is in osteoarthritis, which is a very large trial of over 800 patients that we're doing together with Servier. And also that data set should come in, in the remainder of the year.

And then everybody is awaiting the anticipated regulatory decisions in RA, being it in the EU, following the CHMP opinion; as well as the FDA; and Japan. All 3 of them should come in, in the coming months. And we should know how we're going to market filgotinib based on those decisions.

So with that as an introduction, I'll hand it back to Elizabeth to take the Q&A.

Elizabeth Goodwin ***Galapagos NV - VP of IR***

Okay, thanks, Onno.

That does conclude the presentation part. Questions will now be taken on a "first come, first served" basis. You know we don't manage the queue so please limit yourself to one question per caller today.(Operator Instructions) And now I'd like to ask the operator, Jennifer, to connect us to anyone with questions for the team. Go ahead.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And we'll go first to Rushee Jolly with Bernstein.

Rushee Jolly ***Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst***

Bernstein. So do you expect a warning on the filgo label for testicular toxicity? And if there is such a warning, how quickly would you be able to remove it from the label post MANTA data? And what impacts could you see on uptake as a result of that?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Maybe I'll address the regulatory question and then turn it over to Michele. This is Walid. Good morning, afternoon to those folks on the phone. The -- I'm assuming you're referring to the European label because we don't know anything about the U.S. yet. So I think the MANTA data is -- or MANTA studies are meant to evaluate whether we see any -- evidence of effect in humans based on the sperm safety or sperm toxicity and these end points that we use. And those data will be very important to inform actually on any potential risks to humans. And so as soon as we have those data, we will be submitting them to the CHMP and discuss with them the way they will be implicated in the labels. And we believe that those are the right -- this is the right study to be done. And those are the results that will truly inform about the potential risk, if any, to humans. And I'll turn it over to Michele regarding the uptake question.

Michele Manto ***Galapagos NV - Chief Commercial Officer***

Yes. So based on what Walid said, so the driving force will be the label. So of course, we have confidence that there is no point to speak with now. And we also know that the rest of the profile of the market has strength values and strength points to make us make a good launch.

Operator

We'll go next to Debjit Chattopadhyay with H.C. Wainwright.

Debjit D. Chattopadhyay ***H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst***

In the SELECTION study, male patients in the 200-milligram dose had both a TNF and vedolizumab, which lowered the placebo-adjusted rates to between 11 -- 8% and 11% range. (inaudible) clarity on how women might have fared [if dosed] and if these rates are comparable?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Yes. Thank you for the question. You broke up a little bit, but I assume you're asking whether there's any difference between males and females in the trial. And I'll be honest. We haven't yet disclosed those information. So as you know, we plan to present the details of the SELECTION trial at an upcoming scientific conference. And then we can go into the details of the breakdown based on previous treatment; vedolizumab; TNF; both -- failures on both; and how do they compare to the others; as well as male, female and age. At this point, I can tell you I don't have any unusual results. And maybe I'll leave it at that and we'll have to see it at the -- when we present the data at an upcoming conference. Suffice it to say that in the trial we had -- and I think Onno alluded to that. We had, as you can imagine, a higher number of people who have been exposed to 2 different types of biologics, TNF and vedo. And we have a significant number of patients, close to about 50%, who actually or got exposed to both, not just one or the other. And so we are looking forward to sharing those data with you at an upcoming scientific conference.

Operator

We'll go next to Evan Seigerman with Crédit Suisse.

Evan David Seigerman ***Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst***

Congrats on the progress. So as we head into the potential launch of filgotinib in the United States and Europe, can you just kind of review some of the pre-commercial activities you're engaging with, especially in Europe, given how competitive the space is? Any points of differentiation? I know it's a common question you get a lot, but it's a question I get a lot as well.

Michele Manto ***Galapagos NV - Chief Commercial Officer***

Yes. This is Michele. Thank you for the call. So well, first thing for Galapagos, of course, was to build up our presence and operations, as Onno highlighted in the slides earlier. And we are very, very happy with the progress we're doing with that. So first thing, of course, being the recruitment of the team. So we are recruiting really strong talent coming with experience in RA and, respectively, in IBD already in Germany and U.K., who really have already strong contacts with the customers, know the market; and at the same time, also experts in medical and access. And as you can imagine now, the first actions are, of course, in tracking and planning the best and most effective way to achieve reimbursement and also setting up the contracts in the compliant way that we can have before the actual approval of filgotinib. And I must say, despite also the COVID situation, we have strong contacts, strong first [efforts] connections with experts, very strong also field tech and expectation about our upcoming launch. And as you may also have observed, we had a very strong presence at EULAR in a virtual way. It was also a way to test our virtual capabilities given the uncertainty on the future scenario. We did that with -- together with Gilead, and then our presence there at EULAR was top level with the top leaders in rheumatology. Thanks for the call.

Operator

We'll go next to Brian Abrahams with RBC Capital Markets.

Brian Corey Abrahams ***RBC Capital Markets, Research Division - Senior Biotechnology Analyst***

Thanks for taking my question. Coming out of the SELECTION study, I was wondering if you could talk a little bit more about the status of regulatory engagement; and maybe your expectations for the GI division's view on MANTA, MANTA-RAy, what they might look for there;

and your confidence that this division would be amenable to a broad label, I guess, at least in ulcerative colitis, including the 200-milligram dose, just given the limited number of TNF-naive male patients that were enrolled in the U.S. at that dose. Thanks.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Yes, thanks, Brian, for this question. Yes, tough to answer. All I can tell you, that we and Gilead are preparing for submissions, not just the U.S., also Europe and Japan, for ulcerative colitis. And we cannot give any color as to where the agencies sit on this. It would be speculation at this point. So I think suffice it to say that we are quite confident with the data that we have with filgotinib, with the totality of the safety data that we've seen both from the rheumatoid arthritis but also the IBD data, but I cannot speculate on where the agency would sit and about approval on the 200 milligram. So we're going to have to wait a bit longer for that. Thanks.

Operator

We'll go next to Jason Gerberry with Bank of America.

Jason Matthew Gerberry ***BofA Merrill Lynch, Research Division - MD in US Equity Research***

So my question is just on Toledo. When you look to initiate your proof-of-concept trials in the second half, I know that the plan was to initially evaluate ulcerative colitis. I just wanted to confirm that you -- will you be conducting trials in other populations, or is that going to be strictly limited to the UC population?

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer***

Jason, Piet here. Thanks for the question on the other pipeline, no for the Toledo program, we remain as ambitious as we've been before. So 3970 is going to be explored broadly. We'll start with different -- we'll have different waves. We'll start with wave 1, which will have 3 POC studies. And then will come wave 2, which has longer studies; and then wave 3, which is on the more chronic indications. But we remain with our ambitions. And we plan to start in second half, if COVID allows, a different number of clinical studies there. Thank you.

Operator

We'll go next to Matthew Harrison with Morgan Stanley.

Connor McGuinness Meehan ***Morgan Stanley, Research Division - Research Associate***

This is Connor on for Matthew. So just 2 quick ones from us. Can you comment on the enrollment speed in the IPF studies and if they remain generally on track amid COVID and on track for the futility analysis? And you noted in your press release, pending successful start of the Toledo studies, you plan on providing more information. And so we were just wondering if you could provide more information on what kinds of impacts you're seeing and the potential for a delay on those given COVID.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

All right. So I'll take the first question. This is Walid. I will talk about the ISABELA program. As we've discussed before in the ISABELA program, just like virtually everybody, the COVID had an impact on these trials and enrollment. That impact actually has not been consistent and uniform across the world, but it comes in waves. And I think it follows to a great extent the pandemic that we are continuing to live through. We have seen a return towards normal in the studies that we have and the recruitment. And I can -- we feel confident that we should be able to finish recruitment sometime in the first half of next year. The futility is still on track to be conducted also in the first half of next year. So while the situation is fluid, as you know, we continue to -- with that caveat in place, currently we feel optimistic that we are starting to seeing -- to see a pickup. Maybe less so in certain parts of the U.S. and mostly in Latin America, but the rest of the world, I think we're seeing a return gradually towards normal, not fully there yet but on our way.

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer***

Thanks, Walid. I'll cover the question on the COVID impact on the Toledo studies. So the challenge there was a bit different in the sense that we had to start up those studies. And during the first wave, especially in the countries where we've planned to start up the studies, we simply could not get to the hospitals and they were not ready to initiate any clinical studies. So that's now over, and our current view is that we will be able, and that's out of our direct contacts with the -- involved trials[LV1] that we'll be able of starting up these studies in the second half of the year. So we are ready to kick them off. Of course, we hope that there is not a second wave that paralyzes the whole medical system again, but we don't think that's going to happen. And so we are confident today that we will start up those studies in the second half. Thank you.

Operator

We'll go next to James Gordon with JPMorgan.

James Daniel Gordon ***JPMorgan Chase & Co, Research Division - Senior Analyst***

James Gordon of JPMorgan. My question is actually a finance one, on OpEx. So OpEx was about EUR 200 million when you reported last night, annualizing at about EUR 800 million. And if we look into 2021, so presumably quite a bit of ramp-up in sales and marketing and also lots going on in the pipeline. So for next year, could OpEx significantly exceed this sort of higher annualized 2020 figure? Or is this somewhat exceptional for this quarter?

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Well, we haven't given guidance yet on '21, clearly. This is Onno. Thanks for the question. But it's clear that our costs are going to increase with regard to the ramp-up of commercial, especially as we are ramping up for IBD. Of course, also our trials continue to mature to a later stage. So we'll be doing more Phase IIs and, hopefully, more Phase IIIs. So the costs are going up. On the other hand, we will see our first commercial sales coming in. So we see revenues coming in. We have further milestones coming in with regulatory approvals. So it's pluses and minuses, but in general it's clear that 2021 is not going to be financially a year where we will be moving closer to a break-even or a profit situation.

Operator

We'll go next to Lenny Van Steenhuyse with KBC Securities.

Lenny Van Steenhuyse ***KBC Securities NV, Research Division - Financial Analyst***

A question on the commercial side from my end. We've seen AbbVie being able to ramp up RINVOQ sales quite impressively last quarter. Of course, there the main focus lies in the U.S., while you yourselves, apart from Gilead, will be commercializing in Europe, so I was wondering. How do you think about differences and competitive pressure in these 2 regions? Are there any specific dynamics that are unique between each market? Do you believe a higher or a lower market share is possible versus Europe or U.S.? Can you give a bit of color on that?

Michele Manto ***Galapagos NV - Chief Commercial Officer***

Yes. Thank you for the question. This is Michele. So of course, this is also a very unique time to look at [AbbVie course] with the COVID pandemic ongoing. That, of course, affects the number of patients being treated and being started. That said, of course, we are looking at it and looking at all the geographies. Our focus is on Europe specifically and trusts really the strength of Gilead to do a great launch in the U.S. and prepare for it. The difference, of course, that you can look at is how, for example, Olumiant and Xeljanz launched also in Europe. And we've seen there also strong uptake that we have already, 15%-plus from those 2 products; and becoming JAK the next mode of action after anti-TNFs. In the U.S. the success of RINVOQ is the one that way testifies the need for patients for new oral therapies that are there. And so that creates also a base for new JAK launches and that's very important. That's very important as well. The other element and also very reassuring for the need of JAKs is the fact that, all across the geographies, JAKs are being used also in first line, so on bio-naive patients, whereas in later years the thought was to -- only to limit the use in TNF failures. And that also creates another need -- another platform for successful vectors. Thank you for the question.

Operator

We'll go next to Emily Field with Barclays.

Emily Field ***Barclays Bank PLC, Research Division - Research Analyst***

I just had a quick follow-up on the question on OpEx. I couldn't quite hear the comment, the last comment you made on 2021. Did you say that, that will be progressing towards breakeven? I -- just if you could clarify what you said. And then my second question was -- I believe this will be for Walid. A competitor recently showed very compelling data in psoriasis with a IL-17A and IL-17F inhibitor and has expressed optimism about that mechanism of action in psoriatic arthritis and ankylosing spondylitis given the potential beneficial impacts on joint inflammation. I was just wondering if you could comment on why you think that JAKs will be a particularly compelling mechanism of action in those 2 indications.

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Okay, I'll give Walid a second to think. I'll start. Yes, my -- what I said and maybe wasn't clear to hear is that, because of the substantial increase in costs next year related to commercial as well as to our pipeline progression, we're not expecting that we will be moving towards breakeven. So you can assume that our cash burn will at least be as high as this year. So yes. Walid?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Yes. Thanks, Emily. Look, I think the data that we have currently with the JAKs based on the way we know that the mechanism of action is in RA and also our initial data in psoriatic arthritis, including also our competitors', tell us that we have very good efficacy there. Whether or not the competitor will have similar efficacy, less efficacy, a slower onset of action, those are things that will remain to be seen when we have those data. I mean theoretically one can come up with a variety of hypotheses, but at the end of the day, we just need to look at the data, speed of onset, magnitude of effect but also sustainability of effect. And those things, we have seen very nicely with our own filgotinib with the EQUATOR study and also the long-term extension that we've been publishing data on to see how nicely the efficacy has been maintained and sustained. And also we've seen some data also with other JAKs that show very good effects on psoriatic arthritis. So we're very confident that we'll be very competitive in that space. Thank you.

Operator

We'll go next to Benoit Louage with Degroof Petercam.

Benoit Louage ***Banque Degroof Petercam S.A., Research Division - Research Analyst***

Maybe just a small one from my side on the SELECTION trial just maybe to verify. So the submission for filgotinib in UC, that will still be planned for this semester. Or would it be more in 2021?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

So usually submission for another indication will need to wait for approval and the first indication. So this will be then dependent on, for the U.S., what's happening with the RA. In the -- for Europe, I think now the path seems to be clear. Usually we should expect an opinion from EU that follows the CHMP advice, but again there's always the -- they have their prerogative to change their mind. But assuming that they were going to go down that same path, we would expect that to still happen this year. And similar for Japan, we still are on track, but first, we need to hear on the primary indication before we move forward.

Operator

We'll go next to Dane Leone with Raymond James.

Dane Vincent Leone ***Raymond James & Associates, Inc., Research Division - Research Analyst***

Congratulations on the progress. I just wanted to actually focus on IPF. Could you just kind of, one, set the table for us a bit with PINTA and what you're expecting on that readout? And any color on your thoughts around what we had seen historically with Prometic asset with a similar mechanism? And then secondly, we get asked the question on the stat plan for ISABELA, a lot around the futility analysis. Could you just update us and just remind us of the particulars of the stat plan for that futility analysis?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

So let me start with the ISABELA stat, and then we will see who will take the PINTA question. So the plan for the futility is, as we mentioned, I've discussed it before, the idea is that we wanted to make sure that we will not continue in a very long and massive program if the results from the FLORA were sort of a fluke, for lack of a better word. And this is how we designed the futility analysis. We needed to have data from approximately 1/3 of patients actually in each trial. This will translate into 70% information because we take the information from those 30% who are -- who have completed 52 weeks, plus all the others. Until that point, we have our various degree of involvement there. And with that, we will estimate the difference between drug and placebo on the FVC annual rate, so 0 to 52 weeks; and the -- our objective that, if both doses in a given trial do not show separation from placebo or we have confidence that they're not going to be separating from placebo, then we will stop that trial. So it's meant to really protect us against exposing a lot of patients to an ineffective drug, and that's kind of what's driving the futility analysis. And I will ask also maybe -- Piet, do you want to tackle the PINTA question, or do you want me to do that?

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer***

I can do PINTA. But okay, PINTA is -- well, we are pleased that the study is fully recruited. We are awaiting the results. So it's a bit of a different design compared to FLORA in the sense that we have a mix of backgrounds there. So we have the patients on nintedanib, about 1/3; 1/3 on pirfenidone; and about 1/3 on a local standard of care which is different from 1 of those 2 because they are not available. So in that sense, PINTA has a design which is similar to the ISABELA, but it's Phase II POC study, so much, much more. It's a 24-week study. So in that sense, we really hope that, second half, we can come out with a positive study which will allow us to immediately start on top of each -- we will get the view how this compound behaves on top of those 3 medications. And if data are okay and not different for any of the backgrounds, that would be clear path to progress into a next phase of studies as we hoped for. There's been a competitor which did not show -- well, which shows efficacy on one of the backgrounds, on nintedanib, but did not show efficacy on pirfenidone. We don't anticipate to see such in results, but you can never exclude any of those. Thank you.

Dane Vincent Leone ***Raymond James & Associates, Inc., Research Division - Research Analyst***

Okay. Was there something specific about the mechanism of the Prometic asset that you think your team is engineered differently? Sorry. That was the last part...

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer***

Well, yes. If we look to the 2 compounds, ours is specific GPR84 antagonist. They -- their clinical compound is a dual. It's now hard to compare the compounds, where ours is a classic, very potent selective small molecule. Their compound is a weakly potent and touching a couple of targets. We've, in fact, never been able in our experiments to confirm GPR84 antagonistic activity, so I'm not going to say that it doesn't work like that, but it's a complete different type of how it moderates the target. That is clear. And so we are hopeful and confident that in PINTA we will show that the GPR84 antagonist can show and will show good activity in IPF patients.

Operator

We'll go next to Phil Nadeau with Cowen and Company.

Philip M. Nadeau ***Cowen and Company, LLC, Research Division - MD & Senior Research Analyst***

A question on 1972. clinicaltrials.gov lists the study as completed as of mid-July, so should that imply to us that we're going to see data over the next several weeks to months? And secondly, can you talk a little bit about the primary end point in the study? How is the study powered on its end point of cartilage thickness at the cMTFC and what's the -- what's a clinically meaningful difference on that end point?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Thanks, Phil. It's Walid. So indeed the study is finished. And we are in the process of doing the data cleaning and the locking of database and all -- with all the difficulties that you now face because of COVID. As you can imagine, visiting the sites and doing closing of queries and stuff like that are a bit more challenging than usual, but we're still on track to have the data in the second half of the year for the study. In terms of the -- how the study was powered and the primary end point: So this is the study is powered using MRI as a primary end point. The MRI will measure cartilage thickness and the medial portion of the knee. We follow a very rigorous algorithm that is automated. We work with the sort of the best imaging groups out there. And we've learned a lot also from a lot of studies that were conducted in the field, particularly with sprifermin, where they have a very large database. The way we powered our study is to be able to detect a reduction in cartilage loss by about 75% and over a year period. So essentially people who have a certain degree of knee osteoarthritis use on average about 100 micron over a year, and you can measure that very accurately actually with MRI. And with the variability that we expect, we powered the study to be able to detect a difference between drug and placebo when we reduce this by about 75%.

You asked a very important question. What is the clinically meaningful effect? Actually the simple answer is and honest answer is we don't know because simply nobody has demonstrated these kind of changes and linked them to clinical meaningfulness. This is one of the opportunities and also challenges of being at the forefront and treading into uncharted territory. So we look forward to get the data and see how these will match or -- and align with some of the very important end points that we measure, including pain, including function. And we will work with our experts to be able to interpret this. And also we'll work with health authorities to figure out how we can design the subsequent trials to demonstrate indeed that the changes that we see are clinically meaningful to these patients. A very

important question, but it's a question that, unfortunately, today we don't have an answer to, but we are working with the right people externally and also the regulators to better understand what that means.

Operator

We'll go next to Laura Sutcliffe with UBS.

Laura Sutcliffe ***UBS Investment Bank, Research Division - Equity Research Analyst***

On MANTA and MANTA-RAy, you've mentioned your plans today and previously to share the data from those trials with regulators, but will you ever make the data from those trials public?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

Yeah, good question. I don't think we have specifically discussed this with Gilead, but honestly, I think, judging from the way we operate and the way they operate, these are very important data. And I think the scientific community also will be very interested in it. I'm not going to go out and commit before getting that okayed from Gilead, but I -- if you ask me, I think there is no reason why we would not. Actually I think it's our obligation to the patients who took part of the trial, to the community to be able to share the data. And I think that's probably what we will do, but I don't have a fully confirmed answer. And ultimately this is their decision, so I'm going to not go beyond this and promising that we will share the data. Thank you.

Operator

We'll go next to Graig Suvannavejh with Goldman Sachs.

Graig Suvannavejh ***Goldman Sachs Group, Inc., Research Division - Executive Director & Senior Equity Research Analyst***

Great. I just wanted to talk about the PINTA study and what you're looking for in the Phase IIa results for that asset. And I'm curious if -- is the bar for success what you saw with ziritaxestat? Do you need for the data to be as good as that to be able to move forward, or could you -- is the expectation that you'll see something better? And if you don't see something that was as good as ziritaxestat, would that be something you'd consider in terms of whether you'd want to move that forward or not?

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer***

Okay, thanks for this question on PINTA. So we see IPF as an space of unmet medical need where there are early treatments approved but where patients -- where we hope to bring to patients treatments that are at least as effective, if not better, and as well can be differentiated on safety. So we think that in that space there is -- in that disease there is space for more than one safe and efficacious drug. And in the end, it's still a dream if you could combine different mechanisms of action that is assumed to be a good way to get more control and to slowing further down the progression of that disease. So in that sense, in PINTA, which is a proof of concept, we hope to see -- and the primary end point is FVC, but we've also included FRI to see a clear signal that our drug is effective within the same range as ziritaxestat. We have longer data here. It's not 12-week, but it's a 24-week study. We have a larger patient group, so this should help as well to come to better data that will allow us to take the best decisions in this program. Thank you.

Operator

We'll go next to Alex[AVN2] Cogut with Kempen.

Alex Cogut

I would just like to understand a little better the timing of the 3 readouts this year, maybe if you can share a bit how would you expect the sequence of them to be; and whether we should take later, meaning simply late in Q4.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer***

I'm sorry. I'm not sure I heard you. You were breaking up a little bit. I don't know if anybody else heard the question...

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer***

So it is about the sequence of the readouts in Phase II, how it's planned. So we have the NOVESA. We have the PINTA and the ROCCELLA. Can you comment on how you see that sequence?

Walid Abi-Saab *Galapagos NV - Chief Medical Officer*

Yes. I think I'm not sure if you have the details of it, but I think we should be expecting those data in the second half of the year. Probably the first one would be NOVESA, and then I think ROCCELLA and PINTA might be right around the same time. That's kind of where we are with this.

Alex Cogut

All right. And with later, you're meaning essentially Q4, right?

Walid Abi-Saab *Galapagos NV - Chief Medical Officer*

Yes.

Operator

And at this time, there are no further questions.

Elizabeth Goodwin *Galapagos NV - VP of IR*

All right, well, thanks, everybody. That does conclude than our call. We'll -- please just reach out to the IR team if you have any other questions. And our next scheduled financial results call will be for the Q3 results on 6th of November.

So thanks, everyone, again for all of your participation. And wish you all a great weekend, and please stay safe. Thank you.

Operator

This does conclude today's conference. We thank you for your participation.

[LV1]I think: involved sites

[AVN2]44:30