REFINITIV STREETEVENTS

EDITED TRANSCRIPT

Q1 2021 Galapagos NV Earnings Call

EVENT DATE/TIME: MAY 07, 2021 / 12:00PM GMT

CORPORATE PARTICIPANTS

Bart Filius *Galapagos NV - President, COO & Member of Management Board*
Elizabeth Goodwin *Galapagos NV - VP of IR*
Michele Manto *Galapagos NV - Chief Commercial Officer & Member of Management Board*
Onno van de Stolpe *Galapagos NV - Co-Founder, Chairman of the Management Board, CEO*
Piet Wigerinck *Galapagos NV - Chief Scientific Officer & Member of Management Board*
Walid Abi-Saab *Galapagos NV - Chief Medical Officer & Member of Management Board*

CONFERENCE CALL PARTICIPANTS

Brian Corey Abrahams *RBC Capital Markets, Research Division - Senior Biotechnology Analyst*
Connor McGuinness Meehan *Morgan Stanley, Research Division - Research Associate*
Dane Vincent Leone *Raymond James & Associates, Inc., Research Division - Research Analyst*
Graig Suvannavejh *Goldman Sachs Group, Inc., Research Division - Executive Director & Senior Equity Research Analyst*
Jason Matthew Gerberry *BofA Securities, Research Division - MD in US Equity Research*
Laerke L. Engkilde *JPMorgan Chase & Co, Research Division - Analyst*
Laura Sutcliffe *UBS Investment Bank, Research Division - Equity Research Analyst*
Lenny Van Steenhuyse *KBC Securities NV, Research Division - Financial Analyst*
Michael Okunewitch *Maxim Group LLC, Research Division - Equity Research Associate*
Peter James Welford *Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst*
Philip M. Nadeau *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*
Rosie Turner *Barclays Bank PLC, Research Division - Research Analyst*
Wimal Kapadia *Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst*

PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the Galapagos Financial Results Q1 2021 Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded. (Operator Instructions) I would now like to hand the conference over to your first speaker today, Elizabeth Goodwin. Please go ahead.

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

Thank you all, and welcome to our call today. I'm Elizabeth Goodwin, Investor Relations, and the webcast that we're recording is going to be accessible via the Galapagos website homepage and will be available for download and replay later on today.

I'd like to remind everyone that we'll be making forward-looking statements during today's webcast. These forward-looking statements include remarks concerning future developments of the pipeline and 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 speakers will be Onno van de Stolpe, CEO; and Bart Filius, President and COO. Onno will reflect on the operational highlights, and then Bart will go over the financial results and with expected news flow for the year. You'll see a PowerPoint presentation on screen. We estimate that their prepared remarks will take about 10 minutes. And then we'll open up with the Q&A with Bart and Onno joined by the rest of our Management Board.

And with that, I would now like to hand over to Onno.

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

Thank you, Elizabeth, and welcome, everybody, to this webcast. We have clearly had a tough 12 months behind us. A lot of confidence was lost. We had a dramatic drop in stock price caused by a number of events, including failures in our late-stage pipeline with GLPG1972 and ziritaxestat and of course, the CRL with regard to Jyseleca in the United States. So very disappointing. But clearly, we are ready to go forward with confidence to regain the trust of the investors and regain the excitement around the company that was with us for a very long period of time. We have done a sole searching and analyzed our R&D portfolio and our organization and see what we can do to optimize and balance the risk better than we have been doing. We have done a complete portfolio review in the research pipeline. And we have taken a number of actions that I will highlight that we believe is improving the risk balance. This gives us a better chance of

bringing new mode of actions to the patients.

On the commercial side, we are full in the launch of Jyseleca in Europe for Rheumatoid Arthritis. We have taken over many of the European countries from our partner, Gilead. And so Galapagos by the end of the year will be the only one marketing filgotinib in Europe, Jyseleca. And that is, of course, fantastic for Galapagos to be in that position after many years of development of filgotinib to now bring the drugs to patients. We have said that we are stepping up to the plate with regard to our business development. We have a lag in the pipeline between -- a gap in the pipeline between Jyseleca on the market and the earlier-stage programs with the TYK2 and Toledo that are in proof-of-concept studies. And we would like to fill that with getting a product into in-licensing or through an acquisition. So that is one of the objectives for this year. And then on the financial side, we decided to rightsize the company with a reorganization around with substantial savings that Bart will highlight later in this presentation.

If we go to the next slide, I can show you the priorities that we have in R&D. We decided to focus on the core indications. So we let go of some of the disease areas that we were having activities in. We prioritized projects, and we also put additional resources on certain candidates, product candidates where we believe has the highest chance of reaching the clinical phases and potential make the difference in certain diseases. So I think we did a very good analysis of our R&D pipeline.

If we go to the next slide. If you look at the pipeline, it's quite differentiated and quite diverse still after the reanalysis of that pipeline with filgotinib still in one late-stage Phase III study in Crohn's disease, of course, RA on the market. UC is in filing, we expect the EMA approval in the second half of this year. We have another program in the JAK class 555, which is in an exploratory study in osteoarthritis. And then, of course, we have the whole Toledo franchise that I won't go through in detail, but we have a number of molecules moving forward with '3970 our most advanced molecule in 5 different proof-of-concept studies. So a very big part of our research and early development pipeline at the moment. We have our TYK2 in psoriasis in a proof-of-concept study, then we have another -- a range of other programs in various stages that are moving forward. So a pipeline that we heavily focused on inflammation and fibrosis. So we are focused, but still have a lot of different mechanisms in the various disease areas.

If we go to the next slide, you see the discontinued programs as a consequence of the analysis where we decided to stop our molecule '1205 in fibrosis and selected actually an in-licensed molecule to move into Phase II in IPF unfortunate, but we believe it's the best decision. Also based on the information we learned from the ziritaxestat failure in Phase III. Then we have stopped all activities in metabolic disease, which is, of course, disappointing, but I think the right thing to do for Galapagos. It's a difficult disease area, and it's clearly not our core expertise. And we also decided to stop early discovery work in osteoarthritis. We had started that 2 years ago with the idea to come up with new targets. OA is a very difficult disease area to bring products to the patient, especially because the Phase III criteria, registration criteria are not clear. There's still discussion between the FDA and other authorities. So we decided to stop that part and put our resources to work in areas where we believe we have a better chance and a risk balance profile.

In the next slide, you see some exciting data in exploratory Crohn's disease studies. We had a small study in -- together with Gilead in small bowel Crohn's disease as well as in Fistulizing Crohn's disease. And you see that in both studies, the 200-milligram performed really, really well. We are very pleased with this data set. And maybe in the Q&A, you can ask questions to Walid to talk more about this data set. So it's clearly very encouraging and hopefully bodes well for the Crohn's disease data, the big study that is currently ongoing that we anticipate to be fully recruited this year. So it's taken a long time to find the patients for that big study, but at least these data give us confidence that we're on the right track. And clearly, the Fistulizing Crohn's disease data were met with incredible enthusiasm also by our partner, Gilead.

With that, I would like to hand it over to Bart to continue with the commercial part. Bart?

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Yes. Thank you, Onno, and good afternoon, everyone, in Europe. Good morning, everyone calling in from the U.S. Great to say a few words about the progress also on the commercial front. And before I dive into the financial details for the quarter and Michele Manto, our Chief Commercial Officer, is also available for the Q&A later on for any further updates on launch progress in Europe.

On this chart of Europe, you see where we are with the operational transition, transition on track. Actually, in the biggest markets, the

transition has been completed with regard to the commercial teams. So that applies to Germany, that applies to the U.K. Employees from Gilead have moved over to Galapagos. France, Italy and Spain, as you all know, were already our primary focus to begin with, especially in rheumatoid arthritis, but also -- in UC in those markets, some transitions are taking place. So roughly 80% of the market potential is now, let's say, managed directly by us. And before the end of the year, we will still also take over the Nordics, Austria, Switzerland and Ireland. And as we have also said before, we are not planning to be ourselves active in the other, let's say, dark gray markets here on the chart. The rest of Europe will work through a third party, and we'll update you as this year progresses as to how we are planning to execute on that one. So good progress here. For the avoidance of doubt, we're not yet booking the sales in Germany and in the U.K. that's connected to the actual physical supply of goods, and that will happen in the second half of this year. Hence, you will not have seen any, let's say, top line revenues yet in our financials, either for those markets as they are still covered by Gilead at least for the first 6 months of this year and probably during Q3, we'll make that transition.

A quick word on reimbursement on the next slide, some interesting updates actually here. Germany, especially fully reimbursed already since Q4 of last year as it's always the case in Germany that you can launch the product immediately after approval. But we now also have received the verdicts from the Federal Joint Committee, the G-BA, and they've given us an additional benefit qualification, which is, we think, a big plus. It's a similar qualification that RINVOQ has in this market but a better one than Xeljanz and Olumiant have in this market. So that, we think, bodes well for the Germany launch progression. In France, we anticipate to launch actually in this second quarter. There, the authorities have let us know that they want to see the MANTA data to be included before they allow us to launch in male patients. And then we will need to review that, obviously, once that's submitted, but we'll launch on a female only basis in France. And in the U.K., and this is what we communicated already before, we're proud to tell you that actually through a recommendation by NICE, we will be the first advanced therapy that is going to be recommended by NICE for the moderate and severe RA patients and the moderate patient population is the novelty here.

Spain and Italy reimbursement progressing as planned and in the course of the third quarter, we anticipate this to also go to patients in those countries in a reimbursed fashion and the same applies for the rest of Europe, reimbursement discussions on track for finalization by the end of the year. Then skipping on the commercial going to the organizational and financial parts of this presentation and Onno mentioned that already, we have refocused our clinical efforts on the programs that were described before. We've also applied and I think the current portfolio review is a good example of that, some more stringent stage gating work, making sure that we really progress the best opportunities to next stages and we also make sure that the portfolio approach is appropriate in terms of risk balance across different stages and across different therapy areas. All this leads to a very meaningful savings program, and we are planning to take out EUR 150 million of expenses on a full year basis. And that EUR 150 million represents roughly let's say between 20% and 25% of our cash burn. We had previously indicated that our cash burn for the year would be about -- around EUR 670 million. We're now guiding for a midpoint of EUR 600 million, a range between EUR 580 million and EUR 620 million. And that reflects that we anticipate that roughly half of the savings will be materialized in 2021, and then we'll have a full year savings effect in the calendar year 2022.

Then a bit on the financials for the first quarter itself. First, on cash. Cash position still at EUR 5.1 billion in a very healthy place. There's always a couple of exceptional items. As you know, in every quarter that we do not include in our operating cash burn. Those are proceeds from warrant exercises. In this quarter, specifically, worthwhile to highlight that we have divested Fidelta, our CRO in Croatia, that generates a net cash proceeds of a little less than EUR 30 million. We had a positive currency quarter. That's obviously 1 quarter is up other quarter is down. We had a positive currency quarter, and that leads to a translation effect of about EUR 40 million positive. And our cash burn operationally is a negative EUR 128 million. And for clarity, that includes first income, cash income of EUR 35 million from Gilead, that was part of the agreement that we signed in December. So then you can do the math on the quarterly to the full year cash burn as well, which we then, as I have said before, anticipate to be between EUR 580 million and EUR 620 million.

Then on the P&L, a quick word on revenues, in costs and in this case, profits. Revenues are up and driven by revenue recognition on filgotinib and the platform. These are the deferred revenue or the deferred income positions in our balance sheet that we accrue -- or that we have accrued that we recognize every quarter, a total of EUR 124 million for revenues. Costs are up a bit, and actually, revenues and costs are up by approximately the same amount to about EUR 175 million. And the drivers here are filgotinib, our Toledo program and the cost for SG&A in terms of commercial expansion as well as some items in support costs. On a net basis, we're actually in profit this quarter, 2 big drivers thereof. One is the same effect in terms of cash that I mentioned in cash, which is currency translation, working in our favor, but also the disposal of Fidelta leads to an accounting profit of EUR 22 million in the quarter. And as a result, we are EUR 9

million positive on net results.

Then last words before we go over to the Q&A on the outlook for the remainder of the year. Still quite a lot ahead of us in terms of data we have, let's say, in summertime, data to be expected for '3667, our TYK2 in psoriasis patients. And also during summer, we anticipate to give clarity and see ourselves data from the studies with our first Toledo compound in psoriasis, RA and ulcerative colitis. And then on the filgotinib front, we anticipate an approval decision in UC in the second half of the year. And our study in Crohn's disease DIVERSITY will be fully recruited in the second half of the year as well, which gives us a timeline and the perspective on when we're going to see that data, hopefully, by the end of 2022.

With that, I'll leave it with regard to the prepared comments and slides and hand it back to Elizabeth for the Q&A. Thank you.

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

Thank you, Onno and Bart. That concludes the presentation portion indeed. And now I'd like to ask our operator, Lin, to remind us how callers can post questions. Go ahead, Lin.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

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

All right. Our first question comes from Peter Welford of Jefferies.

Peter James Welford ***Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst***

I'll start with just 2, and I'll come back with one. So firstly, just with regards to the business development. You say in the statement a transformative business development. I guess curious to hear what you're thinking when you say behind the word transformative, should we be thinking that you're looking to do more than just bring in an asset or 2 here? Is there something bigger picture that you'd like to do? And is this also going to focus on the same core areas that your internal R&D is now focusing on, i.e., I think, inflammation, fibrosis and kidney disease? Or is there potentially a wider remit with regards to business development?

And then the second question is just with regards to the JAK1 '0555, I think it's '555. That's still obviously in osteoarthritis with data, I think, due. Curious how you should think about that. Is this an asset that could potentially then be, I guess, if something were to happen to while you crystallize sooner? Or is this still potentially something that you could consider moving forward further in osteoarthritis, given obviously that thesis to be a focus area?

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

Yes, Peter, I'll take the first question, and Walid can do the second. Yes, we want a transformative BD deal with the idea to fill the gap in the pipeline. And it's clear that we now with Ziri and '1972 falling away, we have a disbalance with regard to early versus commercial. So that's something we would like to fill in. And for the moment, we're thinking about one product that will come in the pipeline late Phase II would be ideal or just before starting Phase III, that's one option. The other one is that we're interested to bring more, and that would be in the therapeutic areas, most likely that we currently are in. But we're also interested in seeing if we can get certain commercial rights for Europe alone to supplement the Jyseleca franchise that we have, so that the sales organization has more in their bucket than just Jyseleca. So actually, we got 2 different objectives here.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

Piet, are you tackling '555 or should I do it?

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer & Member of Management Board***

Yes. You can do it as Onno told.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

Well, so the '555 we're actually doing this as an intra-articular injection that we are testing in Phase I. So we are doing a series of doses that we're going to be evaluating over time. But our series of endpoints that we're going to be looking at mostly fiberco dynamics, but also safety and PK. And actually, based on these data, we will then decide what would be the most appropriate next step. As you imagine, we have some questions about the regulatory path going forward and the way the risk balance of our portfolio. But at the end of the day, we will evaluate the data and see what is the most appropriate step going forward, taking into consideration our current R&D spend and our criteria for that will be fixed then. Thank you.

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

Okay. Our next question comes from Jason Gerberry from Bank of America Merrill Lynch.

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

Thanks, Elizabeth. Maybe just for me, just on your selective TYK2. Can you talk a little bit about how you see the molecule differently than in Bristol's TYK2? And any important pharmacologic attributes of the molecule you think help differentiate and when we might get some more early-stage data on that molecule. And then just on the situation with France and the female-only label, is that unique to France? I guess if something were surprising to happen that was discordant with the 13-week results. Just wondering if a female-only label is something that you view as a plausible label for the drug if something, again, discordant with the 13-week results were to pop up.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

Okay. This is Walid. I'll take the TYK2 questions. So our molecule as a domain kinase inhibitor versus the messages on allosteric modulator. How will that translate in the clinic? Really is the big question, and for us, that's really where the money is at the end of the day. Preclinically, our molecule is selective and they're highly selective actually. And based on that, that's why we advanced it in development. In the clinical data and healthy subjects, we've had very good data from PK compatible with once a day dosing. In addition, we've had some very good pharmacodynamic activity as well, which have confirmed what we have seen preclinically. And there's been no changes. As you know, we monitor these very carefully. We're quite familiar with the JAK signature in that space, changes in sort of lipid profile or changes in life of cells, so on and so forth. We have not seen anything with our compound again still within a Phase I healthy volunteer setting, but still, we can make healthy comparisons to our other molecules. We are eagerly awaiting our Phase Ib study, which is, again, a small study, about 30 patients, 2 doses versus placebo in a 1-1-1 ratio, 4 weeks. This will give us a sense of how the compound is performing. But honestly, if you ask me what is the best way to compare it to Deucravacitinib is to run a rightsized Phase IIb trial similar to what they've done in psoriasis, most likely psoriatic arthritis but I think psoriasis would the one -- the area that's more validated or we have much more data, and then we can truly compare like-for-like both drug arms. So as to sharing the data, we look forward to doing that at the earliest possibility and regarding our mechanism of action, our target would be the upcoming rheumatology conference. I cannot promise 100% because I cannot promise that they will accept but that is our target. And the -- for the psoriasis data will be the first dermatology conference that will be coming up and we'd be talking at that. Regarding the filgotinib question, Michele, do you want to take that? Or do you want me to -- yes, Michele is going to that.

Michele Manto ***Galapagos NV - Chief Commercial Officer & Member of Management Board***

Yes, I can. Yes. This is detail here, so I'll take France. So just to refocus the situation there is relative to reimbursement. So it has nothing to do with label, which is European label and male and female populations are both approved for the European label. And actually, we see that in different geographies, there is different sensitivity in the reimbursement evaluation so that we got positive NICE even for moderate patients and the G-BA in Germany also gave an additional benefit on broad indicators. So in France, there is normal a tendency to be more cautious on safety. And the authorities there then look at it that way, without considering our MANTA data because the procedure started at the moment of the approval end of 2020. So without -- before the readout of MANTA, as we communicated recently. So we are now seeking to submit the MANTA data to the French authorities for reimbursement to revise their decision as soon as possible and also considering the procedure that we have for the UC approval and with that we are confident that we will get back that female reimbursement in the next period.

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

All right. So our next question comes from Graig Suvannavejh from Goldman Sachs.

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

Thanks, Elizabeth. I've got one primarily related to filgotinib. I just wanted to get an update on kind of what the path forward has the MANTA MANTA-RAy safety data been presented yet to FDA? And if not, if there's any visibility on when that might be? And I was just also curious if Galapagos had a view on kind of the multiple PDUFA extensions that we've seen across multiple approved JAKs also next-generation JAKs. And then just a quick question on kidney disease. I know you've got '2737 in kidney disease, but is your interest in kidney disease just beyond '2737? I'm just curious if you've got other assets that might be earlier stage? And what is the opportunity in kidney disease, specifically that excites Galapagos.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

Thank you, Graig. I'll take the filgotinib and then I'll pass it on to Piet to talk about the kidney disease. So the -- as you know, we have shared with you the top line or actually limited top line on the primary endpoint at 13 weeks of the MANTA and MANTA-RAy and the reason for that was because the FDA is asking to keep the study blinded until the reversibility data up to 52 weeks can be put together. And as such, we are limited in how much we can talk about it. However, we've provided the information to the European Health Authority and to the Japanese health authorities, which are more comprehensive than we were able to share to with you publicly. With regard to the FDA, the FDA indicated that their interest to receive the data as well, but it's not as a way of formal response or submission. So as such, they received the data, but we haven't had any return from them nothing that we can share with you at this point.

Regarding your question about the FDA and the PDUFA extensions. I really it's speculation on this part, I'll give you my opinion for whatever it's worth. I think I view them personally as in 2 buckets. There's the derm division and the question about the risk benefit of JAKs in dermatology in these indications, which usually the safety bar is much higher than other places. And in the case of the rheumatology division, I wonder -- and again, I don't have that information to what would be the submission included 2 doses instead just 1 dose of upadacitinib, which was -- which were the basis for approval for rheumatology. So I wonder whether that is the area of concern that the FDA has had. And again, those are nothing more than speculation on my part and I have no more visibility on this. What I can tell you for sure is that we haven't received any request from the FDA or any other health authority regarding any safety questions or concerns about the JAKs or providing them with any data as one would expect that there's a concern about a class effect. That's all information I can share with you comfortably. On to you Piet?

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

Thank you, Walid. Thanks for the question on '2737. So '2737 is indeed the first compound we put into a kidney disease, polycystic kidney disease, and that's a 1-year study. So this is a first entry for us in the large space of kidney diseases. So the broader program behind is not limited to polycystic kidney disease only. So it's broader. But data we've made the choice to focus on those diseases where clinical trials and endpoints would be in the range from 3 to 6 months. So we will not step in at the beginning into diseases where long-term studies are needed to come to clinical endpoints. So as said early, we will not disclose the specific compounds needed diseases at this moment.

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

All right. So the next question comes from Laerke Engkilde from JPMorgan.

Laerke L. Engkilde ***JPMorgan Chase & Co, Research Division - Analyst***

Just one left from me actually, just a quick modeling question. With the potential EUR 150 million of OpEx savings on a full year basis, could you please elaborate on how we should think about the level of OpEx in 2022 versus 2021?

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Yes. Let me take that question, Laerke, it's Bart speaking. So obviously, it's way too early to give the guidance on '22. But indicatively, we are clearly planning to materialize all of the EUR 150 million on a full year basis next year. So that will give us a new starting point for our expenses in research and development and also in G&A. And normally, we should be able to leave it at that. I always keep a caveat because if there is, let's say, a scientific, very compelling reason to change that number that obviously is the key driver. It starts with the science and with the data, and there's some very important data readouts still to come in the next 6 months for us that will ultimately determine that. But the envelope would really be to take into account that full year saving of EUR 150 million. On the commercial side, there is one technicality that I need to make you aware of or I think you are aware, but I want to emphasize is that in 2022, we are shifting our agreements with Gilead from a 50-50 cost share to a 100% cost borne by Galapagos. So as a result, the investments that we're

making this year in commercial are still, if I would say, subsidized by Gilead and that will no longer be the case for that 50% next year. On the offsetting side, we will have product sales clearly. So this will not all fall to the -- to our cash burn, but there will be some variability on the commercial side and probably some increase in costs in 2022.

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

Our next question comes from Wimal Kapadia from Bernstein.

Wimal Kapadia ***Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst***

Thanks, Elizabeth. Can I just ask one question, please. Just on the R&D strategy. So clearly, you're taking a much more focused and controlled approach moving forward. But how should we think about the evolution of the Toledo assets and TYK2 if the early data suggests more questionable differentiation versus the current offering. So how will Galapagos approach these assets in a scenario where they could be considered a little bit more me-too?

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

Walid, Piet?

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer & Member of Management Board***

Well, I'll start on Toledo. For the Toledo, we are in a phase where we are doing 5 single seeking PoC studies. And the outcome of those PoC studies will determine what disease areas to focus on. So -- and this is another mechanism of action. And it's in fact the first drug we know that would play at both ends of the immune balance. We don't see really a lot of competition out there at this moment for this mechanism of action. Clearly, this means as well that we need to come with data that makes a difference for patients versus all approved drugs. With clearly, on a direct competitor of this drug, we don't see many around. Walid, for TYK2?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

Yes, I mean, I mentioned that before. I think for the TYK2, we're going to be first step will be to look at the data from the small psoriasis study, the Phase Ib that is going to read out shortly. And with that, we'll have an initial indication. I strongly doubt that this will be very informative directionally, and it will require a next study that we can truly see benchmark against Deucravacitinib going forward. Of course, before we make any subsequent investment, we will survey the space. We will be watching very carefully how the FDA and the field is actually evaluating the Deucravacitinib data and to see whether this space is actually competitive enough. And then we need to see whether our compound is competitive enough. And those are the criteria that we will be using to determine whether we will pursue going forward with it or not. But we're going to definitely be very deliberate in our assessment of this before we jump forward in subsequent development. That will be costly.

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

Okay. Our next question comes from Rosie Turner from Barclays.

Rosie Turner ***Barclays Bank PLC, Research Division - Research Analyst***

Thanks, Elizabeth. So I think just one left for me actually. So I just wondered if you could talk a little bit more about the opportunity in Japan. Obviously, cognizant of that being run by Gilead, but there's quite a nice royalty stream set to come through to Galapagos. And when do we expect that approval to come through in terms of UC now that it's been submitted? And are there any numbers that you can give us in terms of kind of peak royalty estimates or something like that?

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

Michele, are you going to take that?

Michele Manto ***Galapagos NV - Chief Commercial Officer & Member of Management Board***

Yes. I'm taking that. Yes. So on Japan, so we have, as you said, Gilead is running the launch and the information we have shared is that the launch is progressing in RA with primary uptakes and typically, Japan has a slower uptake in the country because of the need to renew prescriptions every few weeks. So -- but for that, so it seems happy with the progression of the launch there. For UC, of course, that's very important? submission is done. And well, the approval should also come later this year, but we don't have more visibility on the perspective there.

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

Our next question comes from Brian Abrahams of RBC.

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

Two pipeline questions, if I could. First off, you discussed some data for filgotinib in small bowel and Fistulizing Crohn's disease. I was wondering if you could maybe contextualize that in terms of how that compares to existing therapies and how generalizable that will be to the broader Crohn's population that you're studying? And then secondly, you announced the decision in IPF to prioritize '4617 over '1205, that you had generated some proof-of-concept signals for the latter. And I'm just wondering if you could maybe talk a little bit more about the rationale for that and how you drew upon your extensive experience in IPF development to guide your evaluation of these candidates.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

Thank you, Brian. So the data in the 2 studies that we have, Divergence 1 and Divergence 2 in small bowel Crohn and Fistulizing Crohn were actually 2 exploratory studies that we -- Gilead was conducting. And actually, both studies were stopped about 70% from full recruitment because they were taking a lot of time and to some degree, were a bit distracting from the effort to put behind Diversity to drive it to fully recruitment. So as a result, or as a consequence, the confidence with which you can make conclusions and generalizability and comparing to others is limited. Having said that, we were quite happy when we looked at the data in a very small number of patients when we talk about these respective diseases. You're talking about 25 per arm, or something like that. In a small bowel in Crohn's disease -- when you look at the CDI and how that changes after 10 weeks so that we can compare that with FITZROY, data seems to be quite consistent with what we've seen with FITZROY although in FITZROY we want to invest 200 milligram, but the 200 milligram data seem quite consistent with that. That made us feel quite comfortable. Fistulizing Crohn is a tough disease and the endpoints there are based on MRI. But the changes that we have seen over 24 weeks were quite impressive in the way the KOLs responded to it and also Onno mentioned this, the way our colleagues at Gilead have responded to it indicated that we do have activity at 200 milligrams. Again, how do you compare it to others? It's really difficult because, again, there's a lot of variability and an MRI as an endpoint is also something a bit different than what others might have used. But overall, we think that the totality of the data indicates that when added to FITZROY that these data are consistent, and that should bode well for our diversity side, which we're very excited that it's going to be fully recruited by year-end as Gilead has been guiding.

And moving on to IPF. I think for '1205, we did have a proof of concept, and we did see an effect over placebo with '1205. However, the magnitude effect was of a size that probably would be better suited for a combination therapy as opposed to stand-alone therapy. And with ziri not being in the running anymore and the combination with nintedanib, in particular, we saw a significant uptick in the adverse event profile, but also to a lower extent pirfenidone on that made the prospect or the target or profile that we're going to be going after with such a molecule, a bit more difficult. And as a result, we decided to target the investment somewhere else. On '4716, we're excited about the pharmacology, but at the same time, we're not jumping very quickly. We want to take the lessons going from ISABELA. As you said, we've generated a lot of data with ISABELA, we still don't have all the data in-house by the way. And this is -- we're still gathering all the data and closing out the study. So 1,300 patients, many of them treated more than 6 months, many of them actually at more than 1 year. So we need to get all that data and try to understand whether there are lessons learned that would lead us to maybe stratify patients distend so on and so forth. There are some assumptions that we made when we designed the ISABELA program. But when we look at the data, actually, are not 100% panning out, like those on no background therapy did not have a reduction over a year in FVC as they did in the pivotal trial for nintedanib and pirfenidone, actually, their drop was a bit less. And those who are on background treatment with nintedanib and pirfenidone would not drop like the average of the Phase III program instead of the pirfenidone they dropped more. Retrospectively, that makes sense because those who are on background therapy and enter trial tend to be those who are not doing as well. And those who are on no background therapy and choose to stay on no background therapy when you have available therapies are the ones probably who are going to be advancing over time or progressing. But those are valuable lessons that we need to look at our data and flesh them out. And based on that, come up with an informed design for our program going forward with the hardest.

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

Our next question comes from Phil Nadeau of Cowen.

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

Two from us. First, on the Toledo proof-of-concept studies in light of your more conservative pipeline structure, can you give us a sense of what you would consider proof of concept in those 5 trials? Do you need to see compelling clinical data the trials large enough to generate that? Or is it more about safety and biomarkers. And then second, just a housekeeping question on the financials. It does look like most of the filgotinib revenue was from amortization of milestones and upfront payments. The rest EUR 79,000 in your report for commercial sales. I'm curious, were those filgotinib or are those some other products?

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer & Member of Management Board***

Bart, do you want me to start on Toledo?

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Yes, Piet go ahead.

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer & Member of Management Board***

Yes. Okay. On the Toledo proof of concept. So we, first of all, very pleased with the progress we made. So 3 of those studies are fully recruited. One is completed. And so we are pleased that over summer, we can present to you all of the data. As I said before, as well these trials are designed while small to generate clinical data that should allow us to estimate the magnitude of the clinical effect we can get with this compound and with this mechanism of action in these patients. So if you would see a biomarker signal only, we would be disappointed here. So we really hope to see clinical effects in each of the studies. And then based on those determined what is the disease that is the most appropriate to take this program forward in. Bart, over to you.

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Yes, Phil, we are booking a little bit of sales on filgo in one of the small countries in Holland in our own P&L. So that's what you're seeing there. It's a short period of time and early days, small market. As I said before, the bigger markets, Germany and the U.K., we'll start booking that sales in the second half of the year, and we'll start seeing that coming up in our P&L later on in the year.

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

All right. Our next question comes from Laura Sutcliffe of UBS.

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

Firstly, a pipeline question. So do you view the internal pipeline prioritization exercise to complete for now? Or is there still more to do? And maybe related on a BD note, is the idea of maybe collaborating with Gilead, one of their pipeline assets still a possibility? And then secondly, could you discuss what you've seen that gives you confidence in '4876 given that both that '3970 hit SIK2 and 3, would you mind just highlighting for us the key differences between those two molecules.

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

Let me take the part on Gilead assets. We are clearly in discussion with Gilead, how they could potentially help us filling the gap, and we have a very good collaboration and interaction with Gilead. So that's clearly a possibility that we would work together on one of the assets. It's also -- it would be part of the current alliance that we have with Gilead, we would get ultimately European rights and Gilead will keep the rest of the world. So we think it's both for Gilead and us and a good opportunity to look into. The first question, I -- was that for me or Bart?

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

For anyone, the question was on the internal pipeline prioritization exercise, is it completed at this point? Or is there more to do?

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

No. I think we finalized that prioritization. Of course, we will continuously look at the pipeline and see based on data and on competition and opportunity if this is the right balance. But for now, we believe these were the decisions being taken. Projects have been stopped, resources have been reallocated and we take it from here.

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer & Member of Management Board***

Okay. On '4876, the backup Tol2/3. So this is a compound with the same biological profile than '3970. But as a backup as we have advanced quite a bit in our medicinal chemistry, knowledge on the target. It's a more potent compound. So we believe that we can cover the target longer and better, if needed. So it will depend on the outcome of the POCs, whether we judge at that moment if we need to give stronger inhibition on the target, then that backup could deliver that. If out of the POCs, it's clear that we have a competitive asset in hand, we can progress '3970 at that moment.

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

All right. Our next question comes from Lenny Van Steenhuyse from KBC Securities.

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

More a high-level question from my end. There is mention of a more general stringent stage gating process for R&D determination. I was wondering if you could elaborate on what that looks like in practice, what checks and balances may have changed or been implemented to determine what assets to progress and then at what point in time?

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

It's something that's undergoing in the company to see if we have the right checks and balances for the progression. Of course, progression, especially when you go from candidates to preclinical as well as from Phase I to Phase II, those are very important and from Phase II to Phase III, very important decisions where, of course, we have checks and balances, and we have a review committee and everything in place. But we are evaluating if we can increase the governance there and so that we ultimately make better decisions for programs to progress.

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

And now Jason McCarthy from the Maxim Group.

Michael Okunewitch ***Maxim Group LLC, Research Division - Equity Research Associate***

This is Michael Okunewitch on behalf of Jason. So if I heard correctly, you mentioned that one of the Toledo programs has completed its proof-of-concept study and data is coming out in the following week. So could you just provide a bit more granularity of the timing for the specific proof-of-concept readouts on the Toledo compound?

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer & Member of Management Board***

So as I think as we guided from the beginning of the year, we will gather the 3 first PoC studies together and then bring the data of those 3 PoC studies at once. And this, I believe, we say today it's in the summertime. So we will get those data over the coming 2 months and then bring them all together and present.

Michael Okunewitch ***Maxim Group LLC, Research Division - Equity Research Associate***

All right. And then as a follow-up, I just wanted to see if you could provide any color on the specific rationale for the U.K. recommending filgotinib as an advanced therapy for moderate patients as compared to the other drugs out there?

Michele Manto ***Galapagos NV - Chief Commercial Officer & Member of Management Board***

Yes, this is Michele. Thank you. So well, first is the evaluation that the HDA body NICE FDA did on the profile. So that's a resume on the combination of our efficacy and on the safety profile. That's the first part. And then, of course, we had an access strategy, which then resulted in the balanced evaluation of the economics and the value of Jyseleca for the UK. So that resulted in that decision that, of course, bode us ahead of the competition here.

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

And now we have Peter Welford back for a follow-on.

Peter James Welford ***Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst***

Yes, apologies, very short. Just on the '4876 because that's just follow-up what you mentioned with regards to '1205 curious have PK combo studies been done with the chitinase inhibitor together with the nintedanib pirfenidone, I can't say that word. And whether or not you can tell us anything about what's been done either clinically or preclinically with regards to the PK profile of those combinations?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

I think you mean the '4716the chitinase inhibitor. Yes. So those trials are planned. So these haven't been executed yet. So I -- we will be able to tell you more about them later on on when we have more data. But those are planned for later this year.

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

All right. That seems to be all the questions we have today. I just invite you to reach out to the IR team if there are any additional questions. Oh, I see we do have just one more question coming in. Matthew Harrison from Morgan Stanley.

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

This is Connor on for Matthew. So could we just get some additional comments on your biz dev plans. Do you plan to do both commercial and clinical deals? Or do you have a priority for one of those? I know you gave some guidance on late Phase II, but just wanted to hear your thoughts on commercial versus clinical.

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

It's actually the plan to do both. We would like to have a product in to bridge the gap and then a commercial one to help the commercial group in Europe to have more in a basket than just Jyseleca.

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

And we have Dane Leone from Raymond James.

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

Thanks, Elizabeth. Sorry, somehow I got kicked out of the queue. Just 2 questions for me. The first one being, when you mentioned transformative BD earlier, which could kind of range from late-stage development assets to European rights for a commercial product or a near-commercial product. Can you just remind us of if you were to embark on an acquisition that would obviously be fairly sizable from a monetary perspective, how that works with the Gilead partnership and partnership structure? I think a number of us had thought that if you bought something, Gilead would have automatic buy-in rights. And so it wouldn't necessarily make financial sense to do something more sizable. The second question is more of a strategy question, just in terms of how you're continuing to think about the development pipeline. A question we've kind of noticed when looking at the current pipeline is a lot of the indications that you're going after, which are ranging from Phase I/II right now are fairly large indications, which is good from a market opportunity perspective, but they also require multiple studies and fairly long studies. Given your breadth of your preclinical pipeline, do you think there's assets that you could bring forward that might be able to go into more targeted markets that might have a faster development strategy behind them?

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

Thank you. Thank you for the questions. Very good questions. I start with the first one. It's indeed true that Gilead whatever we do will have opt-in rights for products after Phase II for outside Europe. And that, of course, limits the amount we can spend on our own on a certain acquisition or licensing deal because it gets too big in numbers, we need to get Gilead along us at the table. And Gilead indicated that they're clearly interested to look at that and discuss that. So it's not excluded that we would actually do a deal where Gilead to finance part of the transaction for the exchange of the non-European rights. So that's an answer to that question. With regard to indications, we are clearly looking at opportunities to come with indications in the inflammatory and fibrotic field where we would get a faster path towards approval. It's -- when we had areas like osteoarthritis with also the inflammatory areas. You're talking about very long trials, large trials, which, of course, put an additional risk burden to the company. Of course, the -- the payback in the end, if you get there, is also huge, but it would be good to have somewhat of a mix there, a balance where we actually would have programs that have a potential smaller market opportunity with a faster way to the market.

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

All right. Thank you. I think that's all we've got time for. So again, if you have any additional questions, please come to the IR team. Our next financial results call will be the first half results on the 6th of August. Thanks for participating today, and goodbye.