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PRESENTATION

Operator

Good day, and welcome to the Galapagos Third Quarter 2019 Results Conference Call. At this time, I would like to turn the conference over to Elizabeth Goodwin. Please go ahead, ma'am.

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

Hi, everybody, and welcome to the audio webcast for our third quarter results. I'm Elizabeth Goodwin, Investor Relations. This recorded webcast will be accessible via the Galapagos website home page and will be available for replay later on today.

So if you have questions, and -- we request that you call into one of the telephone numbers given in last night's press release. I'll give you one for Belgium, that's 32, for Belgium, 24040659, and the access code is 665-3712.

I'd like to remind everyone we'll be making some forward-looking statements today during the 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, COO and CFO. Onno will go through the operational highlights, and Bart will explain the financial results and go over the news flow we expect. You'll see a PowerPoint presentation on-screen during this presentation. We estimate that the presentation will take about 15 minutes, and this will be followed by a Q&A session with Bart and Onno joined by Walid Abi-Saab, our CMO; and Piet Wigerinck, our Chief Scientific Officer.

I'd now like to hand over to Onno. Go ahead.

Onno van de Stolpe ***Galapagos NV - Co-Founder, MD, CEO & Executive Director***

Thank you, Elizabeth. And thank you, everybody, for joining the webcast. Pleasure to present the highlights of the third quarter to you all.

First, let's briefly recap the deal with Gilead that we signed this summer. A unique deal in life sciences, especially the way it's constructed, is very positive for Gilead and for us, and I hope, for the whole industry. It's a very long alliance that we have signed with Gilead, 10 years, where we will be collaborating on a scientific level, beneficial to Galapagos is that there will be a standstill, which basically means that the next 10 years, the independence of the company is guaranteed, which is important for Galapagos to build it out into an important player in the life sciences. We've got a very substantial upfront amount of money as a consequence of this deal of $3.95 billion. This money will be used for research and development. It's money that will be going back into innovation, into our innovative

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platform to come up with new mode of actions. There are additional financial milestones, opt-in fees that are part of this deal.

Gilead expanded its holding in Galapagos shares by buying additional new shares of -- for a total value of $1.1 billion. They also got some additional warrants to expand their shareholder ship to a maximum of 29.9%.

Gilead has an option to license all products after the conclusion of Phase II for the worldwide territory, except Europe. Europe will stay with Galapagos where we will commercialize. And for the worldwide territories, Gilead will pay an opt-in fee per product, and they will pay royalties between 20% and 24%.

A very comprehensive deal that clearly has taken the headlines in the industry because of its innovative nature.

If we can go to the next slide and talk about the highlights of the last quarter. Then a lot happened around filgotinib, our flagship product. There was a pre-NDA meeting between Gilead and the FDA, and the path was cleared towards submission with the FDA this year, and Gilead confirmed yesterday that they are on track to do the filing before the end of the year.

In the quarter, they submitted the dossier of filgotinib for RA both in Europe and Japan. So we are now on track for all these different territories to get filgotinib introduced in the market in the second half of next year.

After rheumatoid arthritis, UC and Crohn's, there's now a fourth indication that filgotinib is being explored in the Phase III, and that is in psoriatic arthritis. We have very good data in this disease. 1.5 years ago, we announced that data set. And we are now ready to start dosing the first patient in the Phase III trial, registration trial.

And Gilead is busy building up the commercial organization for filgotinib next year in RA, and Galapagos, in Europe, is building this organization in 7 different countries, which is our first commercialization effort, a major activity -- a major effort for us to get it already, but we're on track to be ready to start selling filgotinib in these countries when we get the approval and the reimbursement has been arranged for.

So very exciting next phase for Galapagos.

So in the inflammatory area, we're very pleased that the first Toledo compounds made it into the clinic. The first was the 3667 and now followed by 3970. The first one is more pan-Toledo compound, the second the more selective. Both compounds are moving through Phase I, with the intention to start Phase II trials next year in a number of different inflammatory indications. Very exciting program and we're very pleased that science is going so well, that multiple compounds are going towards the clinic here.

In MOR106, we started Japanese bridging study. We're doing that together with MorphoSys and Novartis. So a lot happened this quarter, more to come in Q4. And then we'll -- at the end of the presentation, Bart will discuss the expectations for next year, where a lot of clinical data will become available.

So an exciting period of Galapagos, we call it Galapagos 2.0, because, with all the funds available, with the collaboration with Gilead, we are, at a moment in time, that we can really accelerate the innovation, and hopefully can come up with a lot more new mode of actions in various different diseases.

Exciting to be here, and happy to hand it over to Bart for the financials.

Bart Filius ***Galapagos NV - CFO & COO***

Thank you, Onno. And good morning, everyone, in the U.S. Good afternoon in Europe. Happy to say a few words around the numbers and also the outlook for 2020. And I'll spend a little bit more time this time than usual on the numbers because there is some complexity around the accounting for the Gilead collaboration, as you can imagine. I hope that the report and press release has been relatively self-explanatory, but I'll take a few minutes to take you through the key items thereof.

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So first maybe I'll start with cash and the cash equivalents. As usual, it remains the key focal point for us as a company. Our cash balance at the end of September, EUR 5.6 billion, which is an increase of, 4.3 compared to the end of December. And you see the waterfall, that highlights the different elements that have led to this increase. There's 2 smaller elements at the beginning, that's the usual exclusions from our cash flow, which are cash proceeds from warrant exercises and currency translation effects resulting from our dollar position.

But then obviously, the 2 orange bars represent the 2 key components of the Gilead transaction. These are all euro-denominated, so EUR 960 million is connected to the share subscription agreements, and EUR 3.5 billion is the euro equivalent of the upfront that Gilead has paid us for the collaboration.

Now usually, according to our non-GAAP definition of cash flow, that means that the cash flow for the company, for the first 9 months is EUR 3.3 billion. I thought it's useful to split these into 2, the Gilead collaboration on one hand and what I would call, the recurring cash burn on the other hand, because, obviously, we've given guidance on that recurring cash burn. And that number now stands at EUR 230 million negative for the first 9 months. So a cash burn of EUR 230 million. And that's also the number that you need to compare to our overall guidance, which is between EUR 320 million and EUR 340 million. And we'll keep that unchanged. Obviously, the net cash flow will be positive for the year, but I'll spit it out when I do the annual results next February as well. And that gray piece will be landing between the EUR 320 million and EUR 340 million cash burn, excluding the Gilead collaboration.

So a very, very strong balance sheet position, in terms of cash. But there's also some other balance sheet items that I think are worthwhile highlighting. So if I go to the next slide, I'll lead you through how we have allocated the transaction price. And this is about the upfront amount that Gilead has been paying us for the transaction of, in blue, $3.95 billion or in euros, EUR $3.5 billion. There's a couple of elements to highlight. First of all, Gilead has also paid us a premium on the shares, and it's a premium if you compare the share price before the transaction was signed and the actual subscription price of EUR 140, and that premium is represented in the orange bar there of EUR 85 million. And the combined of the upfront and the premium is actually the total transaction value that we have accounted for, EUR 3.6 billion.

Then, this is split into several elements. First of all, we've also granted 2 warrants to Gilead to subscribe to first 25% and later on, 29.9% of shares. Especially the first one, which comes at a fixed strike price of EUR 140; that first one represents a financial liability. So EUR 50 million, EUR 45 million of that is the first initial 1-year warrants. It's the first element that we are accounting for separately within deferred income. Now that these warrants have been approved last Tuesday, by the exceptional General Meeting, these will be classified as a financial liability and marked-to-market every quarter, according to the evolution of the share price.

Then there's EUR 3.6 billion remaining, and we've put that into 3 different buckets. First of all, an immediate recognition of the elements connected to the license on 1690. Then, secondly, there is the cost-sharing of 50% on the filgotinib agreement, and we've allocated EUR 640 million to that portion. And then, thirdly, most importantly, obviously, the allocation to the platform, which basically includes the -- all of the rights that Gilead can subscribe to at certain moments in time here during the 10-year periods on programs that are either currently in very early stage of discovery or programs that are in later stage or in early development.

So in terms of recognition, as I said, the EUR 667 million is recognized immediately and is part of our top line in the Q3 numbers. Filgotinib will be recognized, as we have always, accounted for the filgotinib income over a period of 4 to 5 years, we estimate. And the 4 to 5 years is what we estimate the phase of development of filgotinib still to last, including several other indications beyond RA that we are investing in.

And finally, the platform we've decided for linear recognition over the 10-year period that the collaboration is signed up for. So this gives us some clarity as to what we will be accounting for in the future as well. So if you do the math on the platform, we should be recognizing EUR 230 million annually. And on filgotinib, that should be another EUR 150 million to EUR 200 million as well.

As a reminder, in the press release, I spoke of a total filgotinib deferred income of EUR 800 million, that's because there is still some deferred income left from the original 2016 transaction. So the actual total number of deferred income that is going to be recognized over the next periods is EUR 3.1 billion.

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So that's the allocation of the transaction price and the way we've accounted for. That brings us to our P&L for year-to-date third quarter 2019. As you can see here on this slide, and what I've done here is to try and highlight, what I'd call, an analytical P&L to separate out both the P&L that we would have had, excluding the Gilead collaboration, then the impact of the Gilead collaboration itself. And I'll get back to those in a bit more detail on the next slides. And then the as-reported numbers, including the Gilead collaboration.

On the first column, all I can say is it's pretty much in line with what you've seen in previous quarters. And especially noteworthy, the operating expenses of EUR 330 million, which is generally an increase of roughly 30% compared to the previous year first 9 months as well. But obviously the big impact in the quarter, and therefore also in the year-to-date figures, is coming from the Gilead collaboration.

And on the next slide, I'll see -- you'll see the same numbers coming back again, but I've given some more color to the different components thereof.

Next slide. You see here, again, the same numbers in orange, the impact of the Gilead collaboration. So the top line is including EUR 600 million from the Gilead collaboration. There was the 1690 recognition. As you've seen 2 slides back, EUR 667 million allocation there. But there's also been a, what we call, a catch-up effect on filgotinib, as we are now contributing more to the filgotinib expenses. Effectively, our, what we call, percentage of completion has gone down compared to previous estimates. And therefore, we've reassessed that and that means that there is a negative impact on the top line on filgotinib recognition, which obviously, will follow in the next 4 to 5 years back into our P&L. So net of EUR 600 million positive, and there's a bit of recognition on the platform in the first month of the collaboration as well.

Operating expenses are slightly higher. There's a couple of things happening there. First of all, the cost share for 1690 has gone up in, meaning, it's a positive impact on our P&L because we're now sharing those expenses 50-50 with our partner.

On the other hand, the filgotinib cost have clearly increased because we're there also sharing now 50-50 as opposed to the 20-80 rule we had before. There were some bonuses connected to the Gilead transaction that have an adverse impact of EUR 20 million and some fees to the transaction as well of a negative EUR 3 million. So overall, operating expenses impact negatively our P&L by EUR 29 million.

Then 2 elements that are sometimes a bit counterintuitive but are material, so I'll take a minute to go through those as well. First of all, the financial results, it is negative 160. On 2 slides back, you've seen that we have recognized a premium, the EUR 85 million, into our deferred income as a result of the share subscription and this was the difference between the price before signing and the price on the share subscription amount.

Those of you that have been tracking Galapagos, you've seen this before in 2015 and 2016. We are recognizing a financial derivative for the period between signing and closing of the transaction. And because of the increase of the share price of Galapagos, that's a premium then in the derivative becomes a liability, which flows through P&L EUR 442 million. So the big chunk of the 160 negative is coming from this derivative accounting. Obviously, this is all noncash and so much counterintuitive, but that's the way we are appropriately accounting for the impact of the share subscription agreements.

And then, finally, the income taxes, it's actually positive. So we're not -- there are no tax cashouts and -- on the Gilead collaboration. But we are recognizing a deferred tax asset of EUR 17 million, and that's in our numbers as well. So the overall impact, EUR 424 million positive on the quarter, bringing us to a net result of EUR 265 million as reported on the year-to-date Q3 figures.

So I can imagine there are some questions here and there on this. Happy to take those into Q&A or offline if some of you want to. But let's stop that for now on the numbers and let's go to the outlook for 2020.

We thought it was important to highlight this because really if you look at 2019, it's been an amazing year. The Gilead collaboration is clearly transformational. The commercial buildup, we still have up and coming the R&D update and I can invite you all to our R&D update on the 14th of November. And obviously, the application for RA in the U.S., the filing thereof, should take place in the fourth quarter as well.

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So 2019 has been a very important year, but 2020 is really going to be a major year of data also, for the company and other events. Obviously, we are anticipating the global launch of filgotinib in RA.

We also are looking forward to see the data with filgotinib in ulcerative colitis. We're going to have data from our Phase IIb osteoarthritis trial. We're going to have data in the Toledo program, both in Phase I and in Phase II. And we're going to have data with MOR106 Phase II readouts. So 2020 is going to be a very, very big year for Galapagos, and hopefully leading us to our ambition in '21 and beyond to build a commercial powerhouse in Europe, having additional product launches in additional indications for our filgotinib and for other programs and further maturing of our pipeline with all the opportunities that we're working on in discovery and early development.

So with that, I'll conclude and hand the floor back to Elizabeth and the operator. And we'll be happy to take your questions for the next 40 minutes.

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

Thank you, Bart and Onno. That does conclude the presentation part of the call. And now I'd like to ask the operator, Sergey, to connect us to any callers with questions for our executives.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from Eliana Merle of Cantor Fitzgerald.

Eliana Rachel Merle ***Cantor Fitzgerald & Co., Research Division - Research Analyst***

And congrats on all the progress. Just a question -- sorry to ask, I'm sure you get this a lot. But just on filgotinib, can you provide sort of your thoughts on class labeling for thrombosis risk and weigh in on sort of the potential to avoid this? I mean is it a real scenario? Or more of a long shot? Just sort of curious to get your thoughts.

And then my second question, in terms of Toledo. Given sort of the novel biology, can you give us sort of a little bit color on how we should think about the timing around when we could see the hypothesis play out from a clinical perspective? Like could we get signs of differentiation in the Phase II studies in 2020? Or is it, say, maybe more like a 2021 of that? And if you could just remind us the latest in terms of the timing for when you'll disclose this very anticipated target to us?

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

This is Walid, I'll take the first question. So good morning, good afternoon, everybody. So regarding the class labeling for JAKs regarding, I'm assuming thrombosis, is what you mean. I think this will, at the end, be a review issue. However, you have to look at the data that we have currently with filgotinib. The FDA will look at the totality of the data, and they judge based on the frequency of the events in your program. But also they will judge based on the background rate of these events.

We've always said that we believe in the selectivity of our JAK1 inhibition with filgotinib, and this will translate in a very favorable safety profile. And the data that we have to date, support this point.

Particularly, if you think about, not just on preclinical data, but if you look at the clinical data with filgotinib and use the changes in hemoglobin and its platelets as a way to gauge whether treating of the underlying condition with filgotinib is interfering with the natural ability of the body to recover by increasing hemoglobin and reducing platelets, you see that hemoglobin does not interfere with that. Actually, you can look at it side-by-side with medication like, maybe adalimumab that do not interfere at all with JAK signaling. And you see that we behave in the same way. So these are clearly evidence in the clinic that tells you that filgotinib actually does not affect the JAK2 pathway, does not interfere with the EPO signaling or the TPO signaling for the platelets.

And with that, we think this is why we have such a lower rate of thromboembolic event. We've been communicating on this, as you know, on a regular basis. And when we continue to update the data and show you we still see the same variable rates of these events. So we believe that when we present the totality of the data to the FDA, we have a very strong case to make to support our hypothesis, not just

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pre-clinically but we have very solid clinical data and also the rates of these thromboembolic events. But in the end, it would be a review issue that -- with the agency, and we look forward to have that scientific discussion with them around this point.

And I'll turn it on to Piet for the Toledo.

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

Thanks, Walid. Good morning for the people in U.S. Good afternoon for the people in Europe. Thanks for asking the question on the Toledo program. As you all know, we are extremely excited about this program. Up to now, we've selected 3 different molecules with different profiles for development. So 3312 was the first, as we're advancing in multiple ascending dose in Phase I healthy volunteers now, and we'll move early next year into a first patient study. And so that patient study will, for sure, give us a good indication on the level of efficacy we can attain. This will be a short study, whether this will be sufficient to completely get an idea on the differentiation profile versus other treatments that is a bit early, I think, but at least we hope to confirm in that first patient study the impressive efficacy we have seen in the animal studies.

So 390 -- 3970 started Phase I. It's in the early steps of a single ascending dose, and will move next year into multiple proof-ofconcepts that we will announce at that moment. So we don't have any plans, on the short-term, to disclose what the target is. So you're all welcome to the R&D update in New York on November 14, but don't expect that we're going to disclose the target there. I can tell you that upfront. And so there is a third and more compounds are flowing. And so they will then move one after the other into development. Thank you.

Operator

We will now move to our next question from Brian Abrahams of RBC Capital Markets.

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

Two questions on filgotinib, one on commercial elements and one on development. I guess first on the commercial side. Wondering if you have any sort of learnings or market research or anything you're hearing from the recent competitor JAK1 launch that might shape your view on the potential positioning for filgotinib? And perhaps areas of differentiation for filgotinib that could potentially resonate the most with the clinicians, patients and payers? And I have a follow-up.

Bart Filius ***Galapagos NV - CFO & COO***

Brian, it's Bart speaking. Let me answer that first one. Look, at the end of the day, what we'll be doing first is to look at the filgotinib profile, and we think that the filgotinib profile has shown great results in the clinic, both in terms of efficacy and in terms of safety. And we feel that the data that we have is differentiated from other JAKs there. So that's going to be the key angle. Then we're going to see what -- as Walid was just pointing out, what the label will eventually bring, and that will determine, obviously, overall, our commercial strategy. So it's not that much based on what the others are doing currently in the market, as more on the strength of our -- on our own molecule.

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

Got it. And then on the development side, can you talk about maybe the type of evidence of activity that you saw from the Phase II lupus and Sjögren's study? Perhaps reasons why those might not have hit their primary endpoints. And what you and Gilead will be looking at to potentially move forward in those indications? And the subpopulations for instance? And how those results might shape? How you guys think about future indications? I'll hop back in the queue.

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

Thanks, Brian, for this question. Yes. So I think you kind of answered partially some of the question yourself. But -- so the bottom line, I just need maybe to frame it a little bit. So these studies were exploratory in nature. So just if you take the lupus, we -- the way Gilead tackled this is that we went after cutaneous lupus, where we also have another ongoing study in membranous nephritis linked to lupus. And driven with this is our first foray in there.

So these studies were designed to essentially inform the next step in Phase II development. And while of the primary endpoint was not

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met, I can tell you for filgotinib, when you look at patients who have markers of more active disease or markers of inflammation or right out systemic lupus, you clearly see a signal of activity. And when I say signal of activity, I'm talking about the typical endpoint that we use for lupus, but also for Sjögren's. So this is not just the changes in certain biomarkers specifically.

So I can tell you that I'm personally excited about these results. I think these support taking the next step and further evaluating Phase II and probably, as you say, certain subpopulations. What we need to do now, which is what we're doing with Gilead is to fully analyze the data set and look at which patients will benefit most from it and design the next studies that we will be doing. And this is something that's ongoing between us and Gilead.

And then I will close by saying that we will share these results more fully in an upcoming scientific meeting coming up soon. Thanks.

Operator

We will now move to our next question from Matthew Harrison of Morgan Stanley.

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

This is Connor Meehan on for Matthew Harrison. You mentioned that psoriatic arthritis that recently --- that will be moving to Phase III. And so we were just wondering about potential. Or if you could just give us sort of recap on overall Phase II programs that filgotinib is currently engaged in? And then maybe just, you touched on this briefly just a moment ago, but next steps potentially related to lupus and Sjögren's indications as well?

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

I'm sorry, I'm going to ask you -- and I'm going to ask you to repeat the question on psoriatic arthritis. You kind of broke up for a moment there. What specifically were you asking about it?

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

Yes, sorry. So you mentioned that recently moved from Phase II, and is soon moving into Phase III. So I was just focusing more on the Phase II area. Could you just give sort of like an update to us which -- what are the primary programs ongoing in the Phase II stage for filgotinib?

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

Other than psoriatic arthritis, right?

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

Yes.

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

All right. So I think we have one more study in the membranous nephritis and lupus, as I mentioned before. And there's an ongoing study in uveitis. Those are the ongoing studies. There are still a couple of studies in adjacent areas in Crohn's, fistulizing Crohn's and related a small bowel, I believe, Crohn's. So these are the studies that are currently ongoing with filgotinib.

Regarding the studies with lupus, I think it's what we've talked about. I don't have any further details, we need to really dig into the data to see where we need to go. But again, I think what we have seen with filgotinib, would be very encouraging to be able to take the next steps. But we need to figure out in which patient population, how to best select -- particularly in lupus, if you think about it, this has been an area that's been very challenging in drug research, and we have to be very careful as we evaluate things, to chose the right population. So we make sure that we are able to detect the signal if one exist so that we can bring the drugs to patients. I mean, so that's why we're being careful. And the way we look at this and we -- way we plan our next steps that we're actively doing that.

Operator

And our next question comes from Adam Walsh of Stifel.

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Adam Anderson Walsh ***Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Analyst***

Onno, maybe you could comment on the state of drug reimbursement in Europe and your thinking about that as it relates to the upcoming filgotinib launch there? And specifically, what you can do now or what you're doing now to ensure that you optimize that reimbursement potential? And what's your longer-term strategy to maximize reimbursement access in Europe?

Onno van de Stolpe ***Galapagos NV - Co-Founder, MD, CEO & Executive Director***

I'll hand it over to Bart.

Bart Filius ***Galapagos NV - CFO & COO***

Adam, yes, happy to take that question. Look, there's no one short answer on drug reimbursement in Europe because there's different countries that have different approaches and different policies and also different time lines. And it's also different in terms of classes, how reimbursement is being put into play.

I think at the end of the day, I think we have very strong chances to get quickly a reimbursement in the key countries in Europe with filgotinib, clearly because of the clinical profile of the drug, but also because of reimbursement trajectories that Olumiant from Lily and Xeljanz from Pfizer have had over the past years.

I can also say that's actually the take-up of those 2 drugs has been encouraging over the last 18 months; encouraging for the class. So that's -- bodes well, I think, for when filgotinib gets to the market later on in the course of next year.

Adam Anderson Walsh ***Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Analyst***

Great. And then just one follow-up. Just in terms of the timing on MANTA, is there any chance that the MANTA results would not be available prior to the launch in either the U.S. or Europe?

Bart Filius ***Galapagos NV - CFO & COO***

Walid, will you take the MANTA question?

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

Yes. So the MANTA study is moving as planned. Actually we're quite happy with the progress. As you know, we don't give out details. Usually, Gilead would be the first one to answer this. But I think it's not going to have any implication as we said on the filing in the U.S. And we have previously mentioned that it will not be required also for filing in Europe, which already happened. Did I answer your question? Or did I miss anything?

Adam Anderson Walsh ***Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Analyst***

No. I think you got the gist of it.

Operator

We will now take our next question from Wimal Kapadia of Bernstein.

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

I'm Wimal Kapadia from Bernstein. Just coming back to, I know you're probably tired of it, but coming back to thrombosis and the label for filgotinib. So can I just think of a scenario where filgo does have similar comments on label for thrombosis? How should I think about your strategy to differentiate the product? Is it a case of highlighting the trial data where you are clearly the safest product? Or potentially the 2-dose approval? Or is there another approach in mind such as price? Just trying to think about the product commercially, particularly in the U.S.

And then second question is just on IPF. And just thinking about the speed at which you will begin to start combination trials if we see good data. So specifically, PINTA Phase II in the second half of '20, how should we think about potential combinations for that product? Would we need to wait to see the full data for ISABELA? Or would you want to run Phase III studies for the monotherapy, first? Or would you be comfortable in beginning to run combination trials?

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

So Bart, I'll let you answer the first question. I'm sure it's more around positioning, in case?

Bart Filius ***Galapagos NV - CFO & COO***

Yes, no. I'm happy if you - if you take it. For me the question is more around what the chances are for the label and how to get that off the label, Walid. I think at the end of the day, today, we will not be in a position to comment really on the -- on pricing or any type of discussions, especially not for the U.S., which is Gilead's territory, but maybe you can comment on the thrombo label.

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

Sure, yes. I mean, I think I've said that before. I think it's very difficult to predict what -- the position the FDA will take. All we can do is share the data that we have, which, as you guys know, continue to be very favorable. And we can articulate scientifically why we believe that we do have a differentiated profile when it comes to safety and also the low rates of the thromboembolic events.

Beyond that, I think we need to make sure that the data are adequately shared with the community, with the prescribing community as well, and then that's where we go from there. I think the data will speak for themselves. And so far, I think you have seen that the safety profile for filgotinib, including but not just limited to, thromboembolic events has been very favorable. And we think that's due to our selectivity for JAK1.

So maybe I can take on -- move on to the IPF. So yes, that's a good point. I think we are -- what we're currently doing, as you know, is we're running another program, which is the 1205 program, GPRGPR84 antagonist in -- which is currently in Phase II.

So depending on the outcome of these results, if they turn out to be good, I would imagine that we would expect to run a study that would evaluate the combination of 1205 with 1690. The shape of the program right now, I think, it's a little bit early to describe, but I think that would be, for us, the trigger to start evaluating whether there's benefit of combining the 2 compounds to treat IPF.

As you know, this is a disease with high unmet medical need. And as a result, whatever we can use to try and stop the progress of the disease towards death in these patients, this would be our goal. So combination therapy is the way to go, as you know.

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

Can I just, sorry, just a follow-up on the first question. I also wanted to get your comments on the importance of the 2 dose approval. And how important would that be to your -- the commercial aspect for filgotinib?

Bart Filius ***Galapagos NV - CFO & COO***

Look, I'll take that. Bart speaking, look. I think at the end of the day, we have a chance with -- we're getting 2 dose approval. But it's also important that we have good chance to get the high dose approved because of the high dose efficacy that we've seen and the safety profile that goes with that. So we think that definitely is an element of differentiation that we can also use in the marketplace.

Operator

We will now move to our next question from Emily Field of Barclays.

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

I just had a question about how the mechanics might work regarding a potential advisory committee meeting for filgotinib with the FDA. And I could be wrong here, but I was curious, is the company actively trying to have an AdCom in order to have a public forum in which to educate the agency in terms of the potential benefits of the JAK1 selectivity of filgotinib? And would it be a safe assumption to assume if there is not an AdCom, that perhaps the agency has decided that there will likely be a class label for thrombosis for just the JAK class overall?

And then secondarily, I was just wondering if you could talk about, how you are -- just in terms of communication going forward. I know that we will be expecting a futility analysis for 1690 at some point, potentially next year. Given the extended collaboration, is that something now that will be in Gilead's control? Or will there still be something sort of decided and probably communicated by

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Galapagos? And if there's any insights that you can give in terms of what we should be expecting in terms of when and what will be communicated as part of that for the ISABELA futility update?

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

Okay. This is Walid again. So I'll start with the 1690 because it's easier. So we will be talking -- giving more details on this on our R&D day on November 14, where we will give more color on how well things are going in terms of recruitment and when do we expect to get the futility analysis. The fact that this compound is now a joint development between us and Gilead, this will be a joint decision between us and them regarding communication. So it's not in Gilead's control or in our control, this is a joint discussion or decision and communication that will come from both of us.

Going to the AdCom, on filgotinib, I think this is nothing that would be in our control, we cannot influence. This would be -- the AdCom mechanics is that during the review process, the division will decide whether or not they have certain questions that a specialized advisory committee will help them answer. And what specific questions, advisory committees are not open ended. There are specific questions that the review division will have for the advisory committee. And based on that, they will convene it with the right composition to be able to answer those questions.

So that's what I can say. Whether or not this will mean that if there's no advisory committee, that means that the automatic class labeling, I don't think that would be the case. It depends really to what degree the agency has a question, and that's what they use the AdCom for.

If it's clear in their mind that there should be no class labeling, there will not be an AdCom. If it's clear for them there should be class labeling, there will be no AdCom, if they have questions, then they would have an AdCom. But they could also have an AdCom for other reasons as well, and that will only be apparent after they start their review. Thanks.

Operator

We'll now move to our next question from Lenny Van Steenhuyse of KBC Securities.

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

Two questions from my side. There has been some discussion on UPA pricing and health economics in the past month. With the pricing of Rinvoq now known, do you expect filgo to be priced in the same ballpark? Is that what you're aiming for? Or will pricing be an area of competitive differentiation for Galapagos? And then a short second question. Recently, we had an announcement of a smaller Chinese biotech company of -- an R&D collaboration being established with Galapagos surrounding their technology platform. Just wondering if you could elaborate on this partnership and the context and goals of that going forward?

Bart Filius ***Galapagos NV - CFO & COO***

Yes. Maybe let me take the first question on pricing. And then Piet, maybe you can say a few words about this discovery collaboration.

So Lenny, I think it's too early, to be very honest, to speak about the pricing of filgotinib and how we will approach the market there. I think, generally, what you can expect is that Gilead and Galapagos will be more, I'll say, straightforward about that, more transparent about it when we get much closer to the launch.

Today, there is clearly still the review and approval process ongoing. The label will be determining, and then we'll really come with our conclusions on pricing. So I'm sorry I can be a little bit more forthcoming, but I think we need to be a little bit more patient on pricing there.

Piet, can you say a few words on the Chinese?

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

Yes, it's Piet here. Thank you for the question on the Chinese company we work with. So over the past years, we've been working hard to expand our drug discovery platform, mainly planning but also setting the right steps to spread our wings. In New York, on the R&D

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update, we'll give you clear view of where we're going to, what elements we want to incorporate. In this context, with the Chinese company is are very small step in that much, much broader effort where we as well try to broaden our chemistry access. So we have internally compound -- a library of a couple of hundred thousand compounds. And by accessing a compound library of a couple of billions, we clearly expand our chances of finding starting points for the drug discovery efforts. So this is quite small step into much, much broader efforts for which I'm very happy to update you in New York on the 14th of November. Thank you.

Operator

Our next question comes from Peter Welford of Jefferies.

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

I have couple. So firstly on 1690, you said you'd give an update on recruitment during the second half of the year. And , you said also that there would be a timing of the futility. I think you've previously outlined that the futility would likely happen by the end of 2020. Can you still confirm that, that's the case, but obviously, give more precise guiding at the R&D day?

And could you also just talk about that futility analysis that will happen next year. Is there a plan to look at different subgroups i.e the monotherapy versus, on the other hand, the pirfenidone (inaudible) and nintedanib combinations.

I guess I'm curious here if there is potentially a positive effect but equally an adverse effect in certain subgroups, can the futility be able to tease that out such that only certain cohorts continue. Is that not possible at this interim stage? And then secondly, just on filgotinib, just a point of clarification on the accounting, thanks for running through it all in detail. But can we infer that there isn't, I presume, any milestone on starting the psoriasis -- sorry, psoriatic arthritis, sorry Phase III. And equally, there obviously hasn't been a milestone for Japanese or European filing. Can you also confirm if there isn't a milestone due from Gilead to the U.S. filing when that happens by the end of the year?

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

So I'll take the 1690 question. So yes, I will -- we'll be updating the recruitment at the November 14 meeting and we'll -- what I will do is to provide you with a bit more detail and time lines, that's why I didn't want to provide any specific date because I still am working with the team to see when we will get these data because there is so much to be done to be able to clean the data to do the interim analysis.

So it's not enough to have recruited the people and having them pass through the checkpoint that we needed them to pass-through to be able to have enough data.

We also need to make sure that the data are clean and away to be analyzed. So forgive me, I'm not going to confirm, but I don't think -- we've been telling you that we're going to be doing it around the time where we have about 25% to 30% of the patients recruited. And they would have passed a full year in the trial. In addition, we needed about 70% of the information available on the trial.

Those are 2 fundamental pieces that drive the analysis. And recruitment has been going well. We're very happy with this. The study is progressing very well, actually. And with that, I'm -- we will provide you with a bit of more detail on the time line at the November 14. Regarding subtype analysis and so on and so forth, that is not really what has been included in the futility. And frankly, we will not have enough power at that point for the futility to be able to drill into subtype analysis. The futility will be able to essentially advise us to stop the trial in the event that we don't see any meaningful effect that will translate into a significant at the end of the trial. And if that -- that chance is low, then it's really not ethical to continue the trial, and that's the purpose of the futility analysis. And that is as much as we can ask of it, with the a number subjects included in the trial. Otherwise, we would be unable to make those inferences. Thanks.

Bart Filius ***Galapagos NV - CFO & COO***

Yes, Peter. It's Bart speaking. Thanks for the question on the milestones. Let me give you a little bit of clarity here. There is actually a small milestone of $10 million connected to the first dosing in psoriatic arthritis and the trial has started. The screening has been underway. I don't think that the first dosing has taken place but it could be any moment. So there is a small milestone that we are expecting this quarter.

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This will be the last milestone that is connected to any type of trial initiation as we had in the past. From thereon, the milestones are connected to filing and approval. And most prominently, clearly, on approval, there will be a $20 million milestone connected to the filing in the U.S. for RA. And as you pointed out, there were no milestones connected to the filing in Europe or Japan.

Operator

We will now take our next question from Nick Nieland of Citi.

Nick Peter Russell Nieland ***Citigroup Inc, Research Division - VP and Analyst***

One for Bart, please. I note that your SG&A expense has taken a bit of step-up in third quarter. I wonder if you could talk about how your infrastructure in Europe is going to build out and how that might look going into 2020? And how much you plan to invest? And then secondly, on 1972, does that product still have a path to approval if the primary endpoint of cartilage thickness is not met?

Bart Filius ***Galapagos NV - CFO & COO***

Nick, yes, let me answer the first part. So SG&A has gone up indeed quite meaningfully. There's a couple of things happening there. Important to note that in SG&A, we also cover the costs that are connected to employee warrants and those are dependent on share price evolution. So the share price has gone up meaningfully over the quarter. And as result, there's an accounting expense that is connected to that, which is part of that SG&A. And indeed, we are also at this moment expanding our infrastructure in commercial. We're building the commercial teams in France, Spain, Italy, Belgium and Holland initially because those will be the countries where we are going to be leading the RA launch as opposed to Germany and U.K. where Gilead is going to be leading the RA launch. And then later on, in IBD we will be doing Germany and U.K. and Gilead will take those other 3 countries. So we've swapped those indications.

So that will -- the buildout will take place over the course of the next 12 months because clearly if we get the approval in the second half of next year in Europe, we need to be ready to launch this successfully. And to give you a taste, I think for those 3 countries plus the Benelux where we're looking at probably somewhere in the vicinity of around 150 FTEs that are in the commercial teams.

I hope that answers the question. And maybe Walid you can take the other question on 1972.

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

Okay. Thanks, Bart. So yes, I mean, the ROCCELLA study has been designed and powered to evaluate the cartilage thickness over a period of one year. But in addition, we will be looking at a number of other endpoints around pain and on function using the traditional way of looking at things like the WOMAC score in addition to other patient-reported outcomes. We will also look at x-ray and joint space narrowing. So we will have a lot of data to comb through. I certainly would hope that we will not have a problem with meeting the cartilage thickness, but I don't think -- it will be very difficult to be able to speculate what we would do. It really depends on the data if there's a clear signal on other endpoints such as functioning and pain. I think that there is a clear path forward there. So you guys have to be patient with us, and by the end of next year, we should be in a better place to give much more clarity on the next steps with the compound.

Operator

We will now take our next question from Dane Leone of Raymond James.

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

Congrats on all the work over the course of the year-to-date in the Gilead partnership. So I just have a couple of targeted questions here. Just from a high level is psoriatic arthritis the second and most near-term indication that would tack onto the rheumatology channel post-approval in RA?

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

Yes.

Bart Filius ***Galapagos NV - CFO & COO***

Yes.

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

Do we have an updated idea of how long the Phase III might take to run now that you've just kind of kicked it off? Or any kind of standard time lines that you guys generally use, as a rule of thumb for that?

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

Yes, Dane. This is Walid. So I don't think we are -- have guided to that yet. This will be a discussion that we will need to have with Gilead. But I think it's early days now to be able to estimate because we still haven't started yet. But we'll have to come back and revisit this at a later time.

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

Okay. The second kind of targeted question here. Is some of the ongoing evaluation for cutaneous lupus relate to the possibility of maybe using a topical formulation for filgotinib?

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

I don't think that it's ruled out. But I don't think that is currently in the -- the natural next step. I think, as I mentioned, the data that we've seen in these -- the study, particularly the subset of patients with more severe disease or with actually lupus itself, systemic lupus, would suggest that in certain group of patients, filgotinib orally as it's given -- as it was given in that trial would be the way to go.

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

Okay. And the last question for me. Obviously, in 2 weeks, we're going to have the American College of Rheumatology coming up, which is obviously, probably one of the biggest years for you guys ahead of filgotinib and RA. Could you just maybe give uswhat your team is focused on for the presentations that are going to be at that conference? And also, what you're trying to accomplish on the bridging into the commercial side now?

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

I think it's a question for maybe both of us, Bart. I don't know if you want to tackle it. But I think this is the -- for the commercial part, maybe I'll leave it to Bart -- and discussions with Gilead. I mean for us, it would be continuing to present data that would characterize essentially the mechanism of action of filgotinib, the data that we have in the clinic and continue to show the evidence of efficacy with this compound, and also in terms of efficacy in the subpopulation and so on and so forth. You can see that from the abstracts maybe in -- we have some abstracts in older population and so on and so forth. But it would continue to disseminate the data that is stemming from analysis of the trials that we've conducted particularly, I believe, stage II is mostly being analyzed in some additional subpopulations. And Bart, I don't know if you want to tackle the other piece regarding...

Bart Filius ***Galapagos NV - CFO & COO***

Yes, look, what I can add is that these congresses are terribly important because it's really the place where we have a chance to really display the clinical results, and we make a start with the commercial positioning even though we're not yet in an approved phase. But this is an important progress for us like the European equivalents of these congresses. And there's going to be significant presence of both the Gilead and the Galapagos team, including both CEOs that will be attending the congress. So yes, ACR is a big event for us, and we will be hoping to display the characteristics of the molecule there in full force.

Operator

Ladies and gentlemen...

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

Thanks, Dane.

Operator

Go ahead.

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

And yes, thank you. That does really wrap up our hour with you today. I want to thank everybody for participating. I'm glad that ACR and our R&D update came up many times in the call. Please reach out to the IR team, if you'll be attending ACR in Atlanta this year so we can include you in our program.

Our next scheduled call will be for the R&D update at 8 am Eastern on the 14th of November. And it's still possible to sign-up for participation in person. Just reach out to the IR team. So again, thank you very much for listening and for all your questions today. We wish everyone an excellent weekend. Goodbye.

Operator

Thank you. That will conclude today's conference call. Thank you for your participation, ladies and gentlemen. You may now disconnect.

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