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Q1 2019 Galapagos NV Earnings Call

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CORPORATE PARTICIPANTS

Bart Filius *Galapagos NV - CFO & COO*
Elizabeth Goodwin *Galapagos NV - VP of IR & Corporate Communications*
Onno van de Stolpe *Galapagos NV - Co-Founder, MD, CEO & Executive Director*
Piet Wigerinck *Galapagos NV - Chief Scientific Officer*
Walid Abi-Saab *Galapagos NV - Chief Medical Officer*

CONFERENCE CALL PARTICIPANTS

Adam Anderson Walsh *Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Analyst*
Christopher N. Marai *Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology*
Debjit D. Chattopadhyay *H.C. Wainwright & Co, LLC, Research Division - MD of Equity Research & Senior Healthcare Analyst*
Eliana Rachel Merle *Cantor Fitzgerald & Co., Research Division - Research Analyst*
Emily Field *Barclays Bank PLC, Research Division - Research Analyst*
Gilbert Roland Kinsey *RBC Capital Markets, LLC, Research Division - Senior Associate*
James Patrick Quigley *JP Morgan Chase & Co, Research Division - Analyst*
Patrick Ralph Trucchio *Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst*
Graig Suvannavejh *Goldman Sachs*
Vamil Kishore Divan *Crédit Suisse AG, Research Division - Senior Analyst*
Vikram Purohit *Morgan Stanley, Research Division - Research Associate*
Wimal Kapadia *Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst*

PRESENTATION

Operator

Good day, and welcome to the Galapagos Q1 Results Webcast. At this time I would like to turn the conference over to Elizabeth Goodwin. Please go ahead.

Elizabeth Goodwin ***Galapagos NV - VP of IR & Corporate Communications***

Thank you, and welcome all to our audio webcast. I'm Elizabeth Goodwin, Investor Relations at Galapagos. This recorded webcast is accessible via the Galapagos website home page and will be available for replay later on today. So that your questions could be included, we kindly request you call into one of the telephone numbers given in last night's press release. I'm going to give you the one for Belgium right now that's (322) 404-0659 and our conference code is 1452466.

I'd like to remind everyone we will 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, COO and CFO. Onno will go through the operational highlights and Bart will explain the financial results and then Bart will go into the guidance and Onno will close with the late-stage clinical news flow we expect this year. You'll see a PowerPoint presentation on screen. We expect this will take about 10 to 15 minutes and that will be followed by a Q&A session with the executive committee members joining.

And I'd like to hand over now to Onno for the presentation. Go ahead, Onno.

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

Thank you, Elizabeth. Well, we are very, very pleased with the FINCH data that we reported this quarter. We reported the FINCH 1 and the FINCH 3 data and they confirmed what we have seen previously in the other files that we have run FINCH 2 as well as the DARWIN trials that filgotinib is doing everything that we expected it to do both on the efficacy as well as on the safety.

We had excellent efficacy data on all the clinical meaningful end points being ACR50, ACR70 on a DAS remission as well as on the radiographic progression. So really this is a super moment for Galapagos that after 20 years we now have completed the week 24 Phase III program for filgotinib in RA.

But clearly in RA, the differentiator is going to be its safety profile in combination, of course, with efficacy and the safety data were absolutely excellent.

We saw very low rates of serious infections, low rates of DBTs made of death. We saw again improvement of hemoglobin and the lipid profile and we saw again a decrease in platelets. So all in all, confirming what we have seen in the previous trials and altogether making this clearly in the league of the best-in-class for the treatment of RA.

It bodes well for filgotinib going forward. Also very interesting is that we saw a nice dose response with regard to efficacy but we didn't see any dose-dependent difference on the safety side, which is really good news. So we anticipate that we'll get registration both for the 100-milligram as well as the 200-milligram doses and that bodes well for the marketing of this drug because the other JAKs are likely to only have 1 dosage approved. And doctors apparently want to see a clear differentiation with possibility to subscribe low and a high dose. So we hope to have a marketing advantage from that point of view.

So hallmark program, a landmark for Galapagos and we're very pleased that we could share that with everybody in this quarter.

We go to the next slide. This also -- the FINCH data also bring us closer to Galapagos stepping into the commercial space. We will be marketing filgotinib in our home territory being in the Benelux or Holland, Belgium and Luxembourg. And we plan to initiate that when filgotinib gets approved in Europe next year where we start booking the sales and marketing the drug in 2020.

The next step will then be to expand our commercial operations into the big countries in Europe where we will start marketing filgotinib in IBD, so Crohn's and UC, 2 of the Phase III trials that are currently underway.

And then from 2022 and onwards we anticipate to expand our geographic reach and the commercialization where we anticipate that 1690 could be launched in idiopathic lung fibrosis. And then we also are planning to enter the United States as a marketing territory.

So clearly our mission is to establish a global biopharma company. We do it step-by-step. We -- it's difficult to establish the commercial footprint but the way we have planned it we believe we can do it and be successful in bringing these products to the market.

So if we go to the next slide and let's look back on the clinical delivery in the quarter. Of course, filgotinib with FINCH 1 and 3 complementing the FINCH 2 data of last year but that was not the only news on filgotinib. We completed the recruitment for the SELECTION study, which is the Phase III in ulcerative colitis. We also finished recruiting in Sjögren's and in lupus we're actually expecting the data of these 2 Phase II studies this year so that our new indications for filgotinib in these diseases. And together with Gilead we're building the commercial organization worldwide, well for us now in the Benelux, Gilead clearly the rest of the world.

In IPF we are fully going ahead with the recruitment in the ISABELA 1690 study. We're actually -- we are ahead of planning. So the recruitment is going faster than we have anticipated which is very good news. We also started the second trial with 1690 in the systemic sclerosis, the NOVESA trial, so that's underway. And we expanded our pipeline in IPF with compounds in-licensed from Fibrocor and Evotec. So we really want to build a big franchise here, and we believe that you should look at number of different mechanisms to target this disease.

In 1972, in osteoarthritis we saw a very strong recruitment in the ROCCELLA trial, which is a Phase IIb trial together with Servier where we clearly -- substantially ahead of the original planning, which is good news because we will be fully recruited in the next quarter.

So with the cooperation with MorphoSys we are moving forward in atopic dermatitis. The program that we partnered with Novartis and we just announced yesterday the start of the GECKO Phase II trial together with MorphoSys and Novartis.

And then earlier in the inflammation space we started our first Phase I trial with 3212, which is the first generation of our Toledo program and we expect the second one to start actually this summer. So we're putting a lot of efforts on that, as I've indicated before. And we also started a Phase I trial with JAK1/TYK2 molecule 3121. So 2 Phase I trials added to the pipeline.

With that, I would like to hand it over to Bart to give us the financial highlights.

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

Thank you, Onno, and good morning, everyone, in U.S., good afternoon in Europe. Let me take you through 2 slides on the financials for the quarter, the first quarter of 2019 and then I'll finish off with saying a few words about the expected news flow for the rest of the year.

First slide on cash. So we are landing the quarter, end of the quarter at more than EUR 1.2 billion of cash, so the cash position is still very strong for the company. And in the quarter we have spent EUR 76 million on operating cash burn and we've also generated a little bit of money from award exercises EUR 3.5 million and there is always a currency translation effect in our cash balance because we keep part of our cash in dollars. And this year there's been a favorable translation effect of EUR 5 million. So the EUR 76 million, just to put that in perspective. Our full year guidance for this year is between EUR 320 million and EUR 340 million and we are retaining that guidance for the full year. We are on track to be there and EUR 76 million is representing nearly less than 1/4 of that number with some quarterly fluctuations that's perfectly in line with expectations. So good cash position and in line with guidance that's the key message on the financials.

On the next slide a couple of quick words on the P&L. Revenues have been EUR 41 million for the quarter, slightly lower than the first quarter of 2018. We had some revenue recognition for cystic fibrosis still in the first quarter of 2018 and that's a result of the transaction with AbbVie where we've handed back that rights on the CF molecules. And there's a significantly lower revenue recognition. So we're a little bit lower for the quarter but it's all accounting-wise on revenues.

On operating costs, we are higher by EUR 17 million compared to the same quarter of last year and that is mainly driven by cost for mid- and late-stage developments and within there it's clearly 1690 where we are now fully on track in our ISABELA trials and that was not yet alive and -- in the first quarter of 2018. So a bit higher in terms of operating costs and there's also a bit of an influence, which is also accounting on cost allocations for the warrants; as the share price of Galapagos has performed nicely over the quarter, we are also accruing for higher cost for warrants that are outstanding.

That leads to the net results, which is EUR 49 million negative, which is a bit worse than the first quarter of 2018 for the reason I just described on revenues and operating costs and partly offset by a EUR 5 million positive currency translation effect. So that's it for the financials. I'll stick to that. I invite everyone who's interested in further detail about by program, et cetera, to look at our quarterly report, which is an online report available on our website.

Then let me finish off the initial remarks with the expected news flow for 2019. You can see that on this slide. The first half and the orange tick marks are the news that has already reached the markets so a big chunk of the news flow [for the] for the first half that we had promised and anticipated is with you all in the public domain.

For the second half there's some very, very interesting data sets still to come, Onno mentioned it just now. We have data set around Sjögren's and lupus for filgotinib, which could be an additional 2 indications that we will be further investigating together with our partner, Gilead.

We will also be starting the psoriatic arthritis trial together with Gilead in Phase III for filgotinib. So a lot of movements around this molecule. And then a bit further down on the slide, on MOR106, there we anticipate to be able to share some data on the bridging study later this year. We have extended the time line for the news flow on the IGUANA trial as we have increased the number of patients that are included in that trial. We now anticipate that the primary analysis will be in the first half of 2020 rather than our previous guidance, second half of 2019.

And then finally on the earlier programs, so the Phase I programs, there is 3 Phase I read outs to be expected: 3312, 3121, Toledo and the JAK1/TYK1 -- JAK1/TYK2 and then 1 further compounds of which we've not yet disclosed the targets. We'll also be seeing Phase I data later on this year and will start a second Toledo compound the 3970 in Phase I. And we hope to start also a proof-of-concept with our first Toledo compounds in an IBD indication in the second half of this year.

So a lot of news flow to come still for Galapagos in the rest of the year.

With that, I'll suggest I stop the initial remarks and hand it back over to Elizabeth and the operator for further Q&A, for which we have Walid and Piet also available. Thank you all.

Elizabeth Goodwin ***Galapagos NV - VP of IR & Corporate Communications***

Okay. Thanks very much, Bart and Onno, for those prepared remarks. I'd now like to ask the operator, Savannah, to connect us to any callers with questions for the executives of Galapagos.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And we will take our first question from Wimal Kapadia with Bernstein.

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

Wimal Kapadia from Bernstein. Just a couple, please. So first, I'd like to get your thoughts on the lack of CPRT in the FINCH studies versus HUMIRA. I appreciate that you've had demonstrated superiority but that it won't be a specific claim on the label. But I guess I just wanted to get your thoughts on whether you thought this would have an impact on penetration particularly within the first-line setting. Secondly, just on MANTA, can you provide any updates post the trial expansion into the new additional indications? And then finally given the recruitment of the IPS trial is going extremely well, is it possible for us to see an interim of either PINTA or ISABELA in 1H 2020?

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

Okay. So this is Walid, I will take your questions. So first regarding the superiority in HUMIRA for FINCH 1, I think one of the things that you've seen in that trial is that once you use the lower level type of efficacy) endpoints like ACR20 or low disease activity for the DAS28, you see that the effects that we've seen with HUMIRA, particularly ACR20, for example, in that trial at 12 weeks you've seen a good 70%, which has not seen in any of the previous trials with -- when they use it as an active comparator in the UPA trial, also with the tofa and with the bari trial. So I think on that level the direct comparison on the low disease activity, which was the prespecified end point just missed superiority but once you go higher, sort of higher degree of clinical rigor, looking at clinical remission with DAS28 less than 2.6, there we do show superiority. But since it was lower in the hierarchy we have nominal superiority because it was not alpha protected.

To be clear there was no expectation that you would get a superiority claim on the label with 1 trial demonstrating superiority. The regulatory authorities are clear on that. So that was not part of the expectation sort of going forward. But again I think here you see it's another fact of having a higher response than expected but then when you increase the threshold for more meaningful end points I think you'll still see the same type of differentiation we expect from JAK1 inhibitor like filgotinib.

For the MANTA, I think that the MANTA is -- talking about expansion additional indication. It's part of our discussion with the FDA to try and essentially broaden the inclusion of inclusion criteria that you have to allow recruitment of the patient population. Often these studies are designed using sort of inclusion criteria based on WHO standards for usually healthy men. And when we look at individuals who suffered from chronic inflammatory conditions whether it's the inflammatory bowel disease or rheumatoid arthritis or other rheumatic diseases, it becomes a bit difficult to find patients who will meet the criteria set forth or defined in the healthy subject populations. So with discussions with the FDA we agreed to broaden the inclusion/exclusion criteria, one of which is essentially broadening into the rheumatic disease indications. And because obviously that the protocol and the site to conduct those studies are quite different than the ones for IBD, we created essentially an identical protocol called MANTA Ray that will expand to the rheumatic disease indications and actually the data will be pulled from both studies to have a combined total of 200 patients having completed the 13 week of treatment from primary end point. So I think it should be viewed that way. And the third point about getting results a bit earlier. I think it's a bit early to tell. I think by the end of -- by the -- probably end of the summer, around September, we'll be in a much better place for ISABELA to be able to give some guidance as to how well we're moving forward with recruitment. The early days are looking good and we're very happy with the way we're progressing and the excitement and the interest that we're seeing from various sites. But we still haven't activated the majority of our sites and we should wait until that so that we can better inform.

For the PINTA, we are recruiting on target right now and we're still expecting to have results in the second half of next year. I think I answered all the questions except for the one. Thank you.

Operator

And our next question will come from Eliana Merle with Cantor Fitzgerald.

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

Let me offer my congratulations on the truly impressive FINCH data set. So in terms of atopic dermatitis and where you're not currently studying filgotinib. Just given that there are many JAKs in development for AD that have shown activity I guess what are your thoughts around potentially studying filgotinib in AD. And I guess do you think the mechanism of JAK1 makes sense in this indication?

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

So yes. I mean I think atopic dermatitis has been on our radar screen for some time. Secondly, we look at this in the context of the big program with filgotinib. If you recall we are after a number of indications right now with RA, UC, Crohn's, but also ankylosing spondylitis and psoriatic arthritis most likely now heading towards confirmatory trials. We have also Sjögren's syndrome and cutaneaous lupus at the end of the year. As we are evaluating the totality of the data, atopic dermatitis for a variety of reasons fell below the sort of the threshold to engage further.

As you can imagine, this is always a space that is in flock. We will always reevaluate and reconsider. But for the time being we don't have any concrete plans to move forward with AD.

Whether it makes sense for the JAKs or not, I mean I think you've seen some of the data, which look interesting in terms of efficacy. To me the key question is where's the unmet medical need? And does a JAK inhibitor, which could lead to a potentially higher level of immunosuppression than you would expect from other treatments that are now available for atopic dermatitis whether it makes sense. It's kind of ironic that the most safe and efficacious so far data-wise from the JAKs is the only one that's not pursuing atopic dermatitis. But I think it's something that we will be continuing to monitor and see whether it makes sense to go in that direction or not.

Operator

And we'll move on to our next question from Emily Field with Barclays.

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

I was just wondering given the safety profile that you've seen from the FINCH trials thus far and you're running the MANTA study, do you think that there would be any potential to avoid a box warning on the U.S. label or is that -- does that remain a baseline expectation? And then just also the control arm response rates on ACR20 seem to be much higher in the FINCH trials versus the flat trials, and I was just wondering if you had any thoughts on that.

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

Field, may I ask clarification, the box warning can you say specifically on what outlet-specific box warning you're talking about?

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

No. Just I was wondering given the safety profile that you're seeing thus far across thrombosis -- thrombotic events and then also infections, if you -- if it's your baseline expectation that you will have a box lying under the U.S. label or do you think that, that could be avoided?

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

Yes. So I think again it's premature to be able to say that with any level of confidence but I would imagine that there is a general box warning around risk of infection and malignancies that probably will be -- will -- all JAKs will have to have that.

With regard to the thrombotic events I think our data so far are quite differentiating and I would expect that we should avoid having any labeling in that respect. But we will see how the agency will look at this. We'll have the glimpse as to how they think about it when they will have discussion around the UPA, which is -- which should be coming up in the next few months. But it is my expectation that

filgotinib will be positive differentiator in that space.

Talking about the placebo response rate and active control response rate in our FINCH program, I cannot give you more than speculation at this point because we haven't yet timed the additional subanalyses, which I would imagine that would be part of the -- an upcoming scientific presentation. We will have maybe more chance to discuss this. But I think at this point if we look at the FINCH 1 and 3, we tended to have a little bit more patients probably from Eastern European or may be countries like India in the trial more so that FINCH 2, for example, that could potentially explain this.

Sometimes these trials also have a condition that these patients actually worsened during the trial that will be -- they will have to exit the trial and go -- and be treated with the standard of care. And in some of those countries standard of care is not really that great so it is kind of an incentive to kind of "do better" and stay in the trial. I don't know if those actually played a factor in it but those are kind of speculation on my part without really having any of the analyses in the data to back it up. So we're going to wait and see 4 more analyses when we disclose further the data.

Operator

And our next question comes from Debjit Chattopadhyay with H.C. Wainwright.

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

So I've got a couple of questions, first one on 1690, could you walk us through the year-end go/no go decision on 1690 from a study powering perspective. And especially how much alpha spend is associated with the interim look and the final p-value assumptions assuming the trial moves forward?

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

Yes. So there's no -- it's not in the year-end. So just to be clear the time lines are not year-end. So maybe I can take a step back and can explain a little bit. So this program includes 2 identical studies each one with 750 patients, 250 per arm and it is powered -- it has 90% power to detect a difference of 1 dose versus placebo of more than 80 ml difference in FVC, and we use the sort of the rate of decline analysis in those trials.

Our plan is to conduct a futility analysis once 25% of the patients combined from both trials, so 1,500, 25%, so 375 patients would have crossed the one way line, at which point we take all the data, those for whom we have data more than 1 year, those for whom we have data less than 1 year and take the totality of the data to calculate the rate of decline in FVC. If there's a low chance that we will be able to differentiate from placebo then on both doses, no neither dose will have differentiation with placebo, at that point we will stop. I don't have more details on this right now as to what would that specifically -- what is that number specifically is because we still have to discuss it with the health authorities and come to an agreement with but that's the general framework of how we are approaching it.

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

Got it. So just to clarify, is it 1-8 ml or 8-0 ml?

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

8-0.

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

And just 1 more follow-up question. So from filgotinib, as you think about going commercial is this now a game of rapid market share gains with pricing as a key metric? Or will it play out on the safety front with the 2-dose flexibility that filgotinib offers?

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

So Bart, would you like to take this, or do you want me to take it?

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

No. I'll take it, Walid. But I think that is generally, Debjit, it's a bit early to tell because we first want to see exactly what the label is going to look like and also what the comparative situation is in the marketplace. Once we are ready for launch and then together with our

partner Gilead we'll establish what's the appropriate strategy into that market. So no further details really on our launch strategy yet, at this moment in time.

Operator

And our next question comes from James Quigley with JPMorgan.

James Patrick Quigley ***JP Morgan Chase & Co, Research Division - Analyst***

Just a couple from me. So the JAK/TYK2, which information indications do you intend to focus on? And in terms of the preclinical data how does it compare in information-disease models compared to filgotinib and also the Toledo assets? And sort of what are the additional benefits of targeting JAK1 and TYK2 as opposed to targeting one or the other on its own? And second question on MANTA RAY, currently there is only 1 center that's listed on the clinical trials record. How quickly can you add additional centers? What are the challenges in order to get those centers added? And are they going to be mainly in Europe or in the U.S.? Thirdly, a question on modeling. What should we expect in terms of a phasing of the deferred income? I mean I know it's noncash but in terms of the AbbVie upfront I think in the last year there were sort of 3 million less to amortize, only 400 million was amortized in Q1. Similarly with Gilead, what should we expect in terms of phasing?

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

Okay. Piet here. Thanks, for the questions. I'll start with the combined JAK1/TYK2. So when we decide to take that one forward it's clearly that was based on data where in a number of preclinical animal models, we've seen that the combined inhibition of 2 targets gives us really hope that for the first time in the more serious diseases like lupus we can make a difference. So it's clearly we've been evaluating our JAK1 as well there's a clinical study ongoing. We should compare their objective of combined JAK1/TYK2 the combination really performs much stronger. Next there is also good rationale to go to the IBD model they are indeed JAK1/TYK2 performance better there as well than our selective JAK1 inhibitors. But looking at a broader picture the Toledo really, clearly outperforms any other mechanism of action that we ever have seen in the IBD model. So there is a rationale to go for combined JAK1/TYK2 but our bigger hope there remains Toledo and that's as far as I want to answer on the JAK1/TYK2. Walid, over to you.

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

Yes. So for MANTA RAY, I'm not sure I haven't really looked specifically on clinical trials as of what's out there but clearly we have many more sites in being planned definitely more than 100. Those will be in mostly in Europe but also in India as well. So we're quite active moving that forward so definitely much more than 1 site if -- than 1 site is what you would be seeing. And Bart I guess the last one is for you.

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

Yes. I'll take the last one on the deferred income. James, it's indeed AbbVie's deferred income and Gilead's deferred income which was still on the balance sheet at the end of December last year. But for AbbVie this is all connected to finishing off all the transfer of activities to AbbVie and you should assume this to be fully depleted from our balance sheet fully by the first half of this year.

On the Gilead deferred income this is related to mostly the upfront that was paid in 2016, January 2016, and we anticipate this also to be fully depleted by the end of this year.

Operator

And our next question comes from Christopher Marai from Nomura.

Christopher N. Marai ***Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology***

Congratulations on the progress. First, just may be touching upon your pre-NDA meeting with the FDA. I was wondering if you could provide an update on that timing, has that occurred or is that still pending? I know it should be in the next month or 2. And then on that point, is there any updated thoughts that you could share regarding MANTA our MANTA RAY data in terms of the requirement for the submission? Do you expect that data to be required at the time of submission? Or that it may be possible to submit it just prior to approval? Then I have a follow-up.

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

Thanks, Chris. It's Walid. So I think we've already discussed this kind of strategy before and Gilead have also discussed this that once we have the FINCH data, which has occurred we will ask that as a discussion with the FDA and based on the no-risk benefit that we've seen so far in the FINCH program and discussed with them the filing strategy and that's the pre-NDA meeting that I think you're referring to. We would expect that to happen in the next few months but we don't -- we're not guiding any specific date. Although there could be more information that will be shared by Gilead, I believe next Thursday, May 2 will be their earnings call. And I direct you guys to follow up there because there might be more information at that point.

And then just whether or not the data from the MANTA program will be needed for filing or not, again that's going to be the crux of the discussion. And so at this point it really becomes an opinion that I would have on this and so I think it's better not to speculate on it. I think we have concrete data right now that we have in the FINCH program and we have clear progress that we've made within MANTA program and clear commitment that we're doing these studies those will form the basis of the discussion with the FDA and we'll see based on that what the outcome will be.

Christopher N. Marai ***Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology***

Okay. Thank you, Walid. And then just a follow up; I'm thinking about the FINCH 1, 3 patient population. I know you've noticed that versus prior trials there's a difference across geographies. And I was wondering it seems to have impacted I guess the placebo rates but do you have any expectation or reason to believe that this could also impact your PE/DVT rates cured or lack thereof in your trials? And because perhaps there were some who have less severe or have other lack of comorbidities or otherwise.

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

Yes. Good question, Chris. I don't see that. When we look at the actual patient demographics or stuff like that, I don't think we see much of the different -- again, you know there's the location or demographic changes that we talked about based on this location, geographic location, or speculation on my part but I think it has more to do with the incentive to stay in a trial as a result of the alternative being the standard of care, which probably is not as good as it would be in more Western countries like EU and the U.S. But in terms of comorbidities things like that we haven't seen anything that was different based on the evaluation of the data right now. So I don't -- I cannot imagine that, that will explain the low rate of DVTs and PEs. As a matter of fact FINCH 2 actually has no DVTs or PEs and that either.

Operator

And our next question comes from Adam Walsh with Stifel.

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

First one on filgotinib, beyond RA, could you give us an update on filgotinib and other indications, namely in Crohn's and ulcerative colitis, just how the enrollment is going there and when you feel like the next data points will be revealed? And then a second question, Walid, if MANTA turns out to be gating for the filing when would the MANTA program be complete as it's currently laid out, with the current program structure? And then I have a follow up.

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

Thanks, Adam. So beyond RA I think for UC the program has finished recruitment a couple of months ago, I think 4 months ago. This is an induction followed by maintenance studies so the in life phase of the study is 1-year long. And so I would imagine by this time next year we should have results from the UC program and that should enable us to then proceed to filing on that indication.

Crohn's disease I think our best guess at this point is about a year behind UC that's going to be our best guess at this point.

Regarding MANTA, so we've been very careful in discussion with our partner, Gilead, about what to say and how much to guide on this because until we know whether MANTA is gating information about how well it's progressing and so on so forth, is not material. And then there's also a spectrum. The FDA could agree that there's no need to have MANTA as part of the package and it will be a post approval or whatever -- or whenever the data are available, or it could be that there's a certain number that you must have by a certain time to be able to file. And again, since this has a sort of a spectrum of different date, Gilead has not been wanting to share any more

information until we have clarity. So I'd imagine after we have the meeting with the FDA and we have a clarity on the filing strategy, Gilead actually, you will hear from them first about what were the results and as a result what does that mean for filing.

And if MANTA is on the critical path or probably on the critical path they will guide about the timing for the MANTA program.

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

That's really helpful. And then just one on MOR106, the GECKO Phase II trial with the subcu formulation was just initiated and you have a Phase Ib bridging study still ongoing with the subcu formulation. Can I, can you talk about the relationship between those 2 on the subcu formulation and kind of where you are in development with that formulation? And is there any connection between those 2 studies? And then how do we think about the IV and subcu dosing regimen in terms of frequency in dosing and what have we learned so far?

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

Okay. Thanks for the MOR106 questions. So with the GECKO, we take -- or we turn a new page in the program. So one hand side is the first time we bring the program to the U.S., so that's definitely important one to validate that all we've been doing is done according to how FDA expected. But the second big step we took indeed is the first time we do a subcu study only. And to plan it up from now onwards, also, this will be subcu only. So we have the dose ranger IGUANA ongoing. That's a big study that will give us the right dose for Phase III. But when we file the GECKO, indeed, we have high hopes that the bioavailability we've observed in the IV/subcu study is good enough to allow us to do subcu dosing in the future only. So that IV/subcu bridging study is still ongoing. The multiple dose study in the patient is still ongoing. But the single-dose data we have on file and made us confident to initiate a subcu study only.

Operator

And your next question comes from Matthew Harrison with Morgan Stanley.

Vikram Purohit ***Morgan Stanley, Research Division - Research Associate***

This is Vikram on for Matthew. So we just had one quick follow-up on the Crohn's program. So the diverse...

(technical difficulty)

Operator

And Matthew, your line cut out. Can you please repeat the question?

Vikram Purohit ***Morgan Stanley, Research Division - Research Associate***

Sorry I'm not sure where I cut out. But -- so I was just saying that the Phase III Crohn's study, that started around the same time based on clinicaltrials.gov as Phase III SELECTION study. And as far as we're seeing now, the primary completion is around the same date. So -- and I know that -- it was just mentioned that Crohn's is roughly a year behind UC. So I'm just curious about what was happening with that trial, what might have caused the delay based on the dates we're seeing on ct.gov.

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

Yes. So the -- in the Crohn's disease program, I don't know if you follow, a number of different companies have been facing some significant delays because of a lot of competition. So when we look at how things are progressing, we estimate that, that is going to be probably about a year behind Crohn's disease. I think we'll have a discussion with our partner to see what kind of updates we'll need to make it to clinicaltrials.gov. But the space is highly competitive. I think if you look at a number of different companies, they've been delayed by a significant amount of time from what they originally set out to do.

Operator

And our next question will come from Patrick Trucchio with Berenberg Capital Markets.

Patrick Ralph Trucchio ***Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst***

My follow-up is on MOR106. First, can you discuss IL-17C and its role in the pathogenesis of atopic dermatitis? And then secondly, atopic derm is getting crowded with detection on the market, multiple JAKs and IL-13s in development. So I'm wondering where you see MOR106 in the treatment paradigm and the IV formulation and how this may change if or when MOR106 is approved in a subcu formulation.

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

Okay. Thanks for the MOR106 question. So let me start with IL-17C. So IL-17C is what we call an amplifier of the inflammation locally, and it's expression is restricted to epithelia only. In that sense, it's mechanism of action, if we block it, we don't expect any systemic side effects. And it's being by many companies flagged as one of the ideal targets if you want to treat skin diseases. So in that sense, IL-17C stands out as a unique target.

Second, on the competitive placement. So the plan is to do in Phase III only subcu. So we will not do IV further. So we are doing a dose ranging in IV to get a dose. But as I said on the previous question as well, we have high hopes that our subcu as it has been performing and will perform will allow us to do once every other week, once every month dosing subcu.

And then as it's a unique target with a unique safety profile, we believe it's going to be a competitive drug in this space. Thank you for the question.

Operator

And we will take our next question from Vamil Divan with Crédit Suisse.

Vamil Kishore Divan ***Crédit Suisse AG, Research Division - Senior Analyst***

I think most of mine have been asked. Just a couple of follow-ups. One, just again on MOR106. You mentioned the increase in the number of patients in IGUANA. Can you just comment on what sort of drove that decision? What have you seen that led you to increase the number?

And then a separate topic actually on your cash, and you mentioned the EUR 1.2 billion. Just curious -- obviously, a very healthy balance sheet. And along with investing in the business, are there any sort of thoughts or opportunities you see in terms of external opportunities for business development?

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

Okay. I'll start with the MOR106 question. So the decision to increase the number of patients is to allow us a very smooth transition from Phase IIb to Phase III. And so we have designed our program; we discussed with Novartis; they saw the different studies, so the IV/subcu bridging, the GECKO study and then then they said, ok if we want to be sure that we can very smoothly, as soon as we have the Phase IIb data and going to Phase III, we would like to see a bit of more data. And that's what has driven this, to be sure stepping into Phase III can be taken very smoothly. Thank you. Bart, for you the cash?

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

Yes. I'll take the question there on -- Vamil, Bart speaking. So indeed, healthy cash balance, and the primary purpose really of that cash balance is to fund the broad pipeline that we're running at Galapagos. Basically, we have at any moment in time, more than 20 programs in discovery. We have 10 molecules that are in preclinical or in Phase I stages. And then we have the 4 bigger ones that are in Phase II or Phase III. So there's an enormously broad pipeline at Galapagos that we want to fund. So that's the primary purpose.

We never rule out, and I don't think any company should, that we do something also externally. We're always on the lookout to see if there's great science in other places also beyond our company. We did actually do 2 smaller in-licensing transactions in December last year. Those will not make a dent into the cash balance because they were relatively early stage assets, both in the discovery phase. But just to highlight that we are -- that we have a very active team looking at the external role as well, and we'll put our cash to use if we see a good opportunity there.

Operator

And our next question will come from Graig Suvannavejh, with Goldman Sachs.

Graig Suvannavejh ***Goldman Sachs***

Also congrats on the FINCH data. I just want to say that again. My question -- I've got 2. My first is around filgotinib and beyond rheumatoid arthritis. Given the JAK1 selectivity and given that you're evaluating filgotinib across 11 total indications, is there anything about JAK1 or just JAK biology that gives you a sense that as you look at the other indications that there might be, at least on an indication-specific basis, a higher or lower probability of success? Meaning are there certain indications that you feel that you're more confident in versus others where, just based on the biology, it might be a little more challenging? So any sense of that would be helpful.

And then second is really more around modeling. As we look at the first quarter results, that cash burn of EUR 76 million, I think, is tracking nicely with your guidance for the year. I think it does leave about 5% to 10% or so increase to achieve that guidance over the next 3 quarters. And I'm wondering if you could help us think about how the quarterly evolution of your -- whether it's revenue or OpEx might be over the next 3 quarters. That will be helpful, too.

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

Well, I'll start with the filgotinib question. So, so far I mean I think what we have seen -- the data that we have seen so far for at least RA, the story is very clear, in our hands also continue with the rheumatic diseases for thoracic arthritis, the results that we've seen in our Phase II study were outstanding in terms of efficacy. That also tells us the story that actually JAK1 is what we need in supporting our preclinical data. That indicated that's all we need in terms of efficacy in that space. Ankylosing spondylitis gives you also the same story.

From the IBD program, I think we have a very good data with FITZROY in the Crohn's disease. Although we don't have any data yet in ulcerative colitis, we feel pretty good about those having gone through the interim analysis. And FITZROY has moved into -- officially into Phase III. Although we haven't seen the data, but I think that also bodes well.

The remaining part, I think lupus is the other disease where there's a large unmet medical need, but also this is a state that has been somehow tested to some degree in the JAK -- with JAKs. So again, our preclinical data support going forward with the (inaudible) the JAK -- with filgotinib, sorry, and support the fact that JAK1 selectivity should do the trick.

I think again, I've said this many times, when you have the selectivity for JAK1, it allows you to use doses that would maximize activity on JAK1 without having to worry about bleeding into other targets like JAK2 and JAK3 and buy you more liability than not.

So I think that the validated data so far have been supporting this hypothesis. We'll see what happens when we see data from lupus.

Sjögren in the space probably where we haven't had any clinical data as far as I know in the JAK space. Again, I think, in general, we're quite confident with the data that we have seen so far. We're awaiting the results for Sjögren and lupus, which actually should be coming in the second half of this year. So we will know quite soon where we stand. Bart, should I turn it over to you?

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

Yes, I'll take the rest of the question from Graig, which was around the modeling. Indeed, the EUR 76 million that we spent in the first quarter compares to if you linearly take our guidance, the EUR 80 million to EUR 85 million that every quarter you take. In all fairness, I think this type of deviation is what you should expect from quarter-to-quarter, a little bit more, a little bit less -- clearly there's some balance sheet positions moving at the same time.

I think, frankly, for the rest of the year, it's pretty linear. Generally, our third quarter is a little bit slower in terms of cash burn; and our fourth quarter, a little bit higher. But overall our expectation is that the cash burn during this year, 2019, is going to be rather linear from quarter-to-quarter.

Graig Suvannavejh ***Goldman Sachs***

And Bart, if I could follow up, so the revenue that was in the first quarter, is that a good run rate to annualize for 2019?

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

Yes. Revenue, in all fairness, is a bit more specific. And then you really need to look at the underlying number. There's again some further details in the report that's a bit too far to get into that for the call here. But I think on a previous question that I got from -- I think it was James around revenue recognition from the upfronts that we received previously from Gilead, that I think helps answering that. And then there's some other elements in revenue, which are quite linear from year to year. But revenues tend to fluctuate a bit more than the cash burn in 2019.

Graig Suvannavejh ***Goldman Sachs***

Okay. And congrats again on the progress.

Operator

And our next question comes from Brian Abrahams with RBC Capital Markets.

Gilbert Roland Kinsey ***RBC Capital Markets, LLC, Research Division - Senior Associate***

This is Bert on for Brian. I have one on filgotinib. Now that you have kind of the full Phase 3 data in RA, which populations of RA patients do you think would benefit most from filgotinib? And then I guess, alternatively, are there any populations where you think it might be more difficult to gain traction with?

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

Yes. Thanks, Bert. Well, I mean I think the data with filgotinib have shown across all stages of RA that we have very strong efficacy across the board and the -- what promises to be best-in-class safety profile. I think the answer that I'm going to be giving you is a general answer in the field, not pertaining specifically to filgotinib because I don't see any difference in terms of the performance of filgotinib in one group versus the other. Again, I see the data that are very solid across the board in FINCH 3, which is the early RA; FINCH 1, which is the methotrexate experience, individuals who didn't have full response; and those would pay out biological -- one or more biological in FINCH 2.

But I think in general, when you look at the field, you see clearly there's a greater interest now in thinking of the JAK in terms of the efficacy being apparently superior to the TNF alpha and the convenience of the oral administration and the lack of concern about the moving effect over time that one encounters with biologics. There's going to be a faster update. And I would imagine that as the field moves forward, it's going to become very clear that the JAKs will be used before the TNF alpha and other biologicals. That's how I -- we view them.

Whether or not they will be used early on in the disease before methotrexate or not, I think that would be a little bit more further down the line. I mean methotrexate is a compound that actually works. The rheumatologists have been using it for decades. And I think it's very well entrenched in addition to the cost, which is very low. I think it's going to be much more difficult to come ahead of methotrexate. But I think it would be used early on probably in the disease.

And as we accumulate more and more data, especially with the second-generation JAK inhibitors, like filgotinib, you gain more confidence in the efficacy but also with the safety of the compound, and you're going to start feeling more comfortable to use them early on. That's kind of my assessment of where this would go.

Elizabeth Goodwin ***Galapagos NV - VP of IR & Corporate Communications***

All right. I'm going to jump in here. This is Elizabeth. I just want to say that our time is up for today. We've had some really good questions, excellent dialogue here. And if there's any question that you still want to ask, please reach out to either me or Sofie Van Gijsel and the IR team to get that handled.

So our next scheduled call will be for the half year 2019 results on the 26th of July. We look forward to speaking with you all, and thank you very much for your support and participation today. Goodbye.