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+++ presentation

Operator^ Good day, and welcome to the Galapagos financial year 2018 results webcast and conference call. Today's conference is being recorded. At this time, I would like to turn the conference over to Elizabeth Goodwin. Please go ahead, ma'am.

Elizabeth Goodwin^ Thank you very much, and welcome all to our audio webcast today. I'm Elizabeth Goodwin, Investor Relations, and I'll be hosting the event. This recorded webcast is accessible via the Galapagos home page and will be available for replay later on today. So that your questions could be included, we request that you call in to one of the telephone numbers given in last night's press release. I've got one right here. For Belgium, (32) 24040659 and the code is 5739601.

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

Today's speakers will be Onno van de Stolpe, CEO; Walid Abi-Saab, CMO; Piet Wigerinck, CSO; and Bart Filius, COO and CFO. Onno will go through

the operational highlights, Bart will explain the financial results and give guidance for 2019. Onno will then close at the late-stage clinical news flow we expect this year. And you will see a complex presentation on screen during our talk. We estimate that this will take about 15 minutes and will be followed by a Q&A session, including Pete and Walid. I would now like to hand over to Onno at this point. Onno?

Onno van de Stolpe^ Thank you, Elizabeth. Pleasure to be here. Everybody, welcome on the webcast. I'll start with the slide, which we call: Think big. Think big is the slide that shows what Galapagos stands for. It's an important year for Galapagos because we're having our 20th-year anniversary. 20 years in which a lot has happened since we started as a small biology outfit looking for novel targets towards the move to become a fully integrated company by introducing filgotinib in the marketplace.

If we go back and look at some of the highlights and I want to point to 2003 when we actually discovered in our platform the JAK1 target as the right one to go for if you want to target rheumatoid arthritis. So a long time, 16 years until we are waiting for the Phase III results with filgotinib.

Some other highlights. The IPO in 2005 and the first pharma alliance for those who have followed us a long time that actually was with GSK in 2006. And then the first proof-of-concept in 2012 when filgotinib showed excellent results in the famous Moldova trial. And then we went public on the DARWIN results in -- on the NASDAQ in 2015 shortly after followed with a deal with Gilead on filgotinib.

And then last year, the highlight of the year clearly the first Phase III data of filgotinib with FINCH 2. Excellent data set and now eagerly awaiting as everybody else the Phase III -- the other Phase III FINCH 2 data -- FINCH data that are coming this quarter. Last year also a highlight, of course, the start of the ISABELA trial in IPF. So we're looking forward to an excellent year this year, but before that, let's look at some of the highlights that we delivered in 2018 and especially the clinical ones. So a lot of filgotinib news with the FINCH 2 results as I mentioned, but also other indications in psoriatic arthritis and ankylosing spondylitis that we showed fantastic proof-of-concept data in the TORTUGA and EQUATOR trials. And then, of course, we initiated the start of the commercial organization. We're building that internally. And, of course, Gilead is preparing for the introduction of filgotinib in the various markets worldwide.

In IPF, we started the Phase III program, a daring move based on a very small Phase II trial. We got agreements with EMA and FDA to launch a regulatory program there, and we are currently in recruitment phase. That's not the only thing. We also started on another target, another mode of action, the Phase II trial, the PINTA trial in IPF. So we're really building out in IPF franchise.

In osteoarthritis, a very important disease area. We started the ROCCELLA trial, Phase IIb trial, together with Servier, where Galapagos is responsible for the U.S. market, Servier is doing the rest of the market. Recruitment there is going quite a bit faster than anticipated, so that's

looking good. Also last year, a lot of news on MOR106 in atopic dermatitis where we made a deal with Novartis that they took over the program from MorphoSys and us, whereby, we continue to execute some of the trials, after which, Novartis will take over also the operational side of the business. So we started the IGUANA Phase II trial and then Phase I bridging study. So last but not least is clearly the progress we've made in Toledo where we saw very, very exciting preclinical results in IBD but also now with lupus.

We have moved the first molecule in Phase I. We're expecting the second one later this year. We believe Toledo can be really a game changer in how to treat inflammatory conditions. We're looking forward to the first clinical data there. If you go to the next slide, let's highlight the move into the commercial space for Galapagos. We do it step-by-step where, first, we'll use our own home territory, the Benelux, where we will introduce filgotinib in all indications, starting, of course, with RA. When that gets approved a bit later and if the data justify that also, of course, in IBD. So that is Crohn's and ulcerative colitis.

In 2021, we anticipate that everything going according to plan, that we can start launching filgotinib together with Gilead in the main countries in Europe, in IBD. As the next step and then we become really a worldwide international biopharmaceutical company is when we start to introduce 1690 in idiopathic fibrosis, where we will also do The United States and some countries in the rest of the world. So by then, we should have built the commercial organization worldwide. And that really shows our ambition and our mission to establish a global biopharmaceutical company and nicely on track to deliver that.

So with that, I'll stop my introduction and hand it over to Bart to talk about the financial highlights.

Bart Filius^ Thank you, Onno. This is a Bart Filius speaking, Chief Operating and Financial Officer. Good morning everyone in the U.S., good afternoon in Europe. My pleasure to take you through the financials of 2018 and conclude and also with a bit of background on our guidance for the year 2019. And as usual I'll start off with the cash position, which is shown here on this diagram. We've increased our cash position during the year with EUR 140 million as a result of, on one hand, successful placement in September that generated over EUR 280 million of cash proceeds in euros. And on the other hand, a cash burn, which netted out at EUR 158 million for the year, which, as you know, is a combination of cash income from milestones and upfront payments as well as the cash expenses that are the investments that we do in our R&D platform.

There's a small EUR 10 million in between, which is a currency translation effect that we exclude from our cash burn, which really is a translation of the dollar position into euros and that 1 year and 1 quarter, it's positive, but the other quarter, it's negative. This time, we have a EUR 10 million positive impact on our total cash position. So healthy financed with almost EUR 1.3 billion at the end of the year 2018. And then as a reminder, we also have roughly EUR 85 million of receivables from the Belgian and French governments that are not part of

our cash position but are due over a 4 to 5-year period from now on in the balance sheet as well.

So that with regards to cash. Let me then move on to revenue and other income. And I've chosen to give you a little bit more details this time than I've done in the past because there are some complexities that are driving the figure. But the bottom line is that we've had a very good year on the top line, doubling our revenues from EUR 156 million to EUR 318 million. And there's a couple of elements that are the big drivers of this doubling. First of all, and you've seen this in previous quarters, we have generated the positive revenues through the implementation of new accounting standard called IFRS 15. And as you can see here on this slide, EUR 56 million is that impact. Effectively, we've had a change of our equity position on the balance sheets with the opening balance sheet of 2018, and we're re-recognizing EUR 56 million of income that has been generated previously. EUR 12.6 million of that is in -- upfront and license in green and EUR 43 million in milestones, and those are connected really to the AbbVie and Gilead's partnerships that we have signed in previous years. So this part I would qualify as an accounting impact of the increase. More meaningful, the business side has generated two large transactions for a total of EUR 93 million, if we include also some cost reimbursements by Novartis. These are transactions on MOR106 with Novartis and on our CF program with AbbVie. And in terms of recognition, the Novartis is upfront is fully recognized in the year 2018 and the AbbVie upfront is almost entirely recognized in 2018. There's a little bit of work still ongoing in terms of hand-over of documents and paper works that makes us recognize a small portion still in 2019, but this is largely all in the revenue numbers.

And then there are some other movements obviously within all the aspects of our revenues, EUR 12.6 million in total that make up the total increase to EUR 318 million.

Then also in operating expenses on the next slide. I'll have a little bit more clarification as to the breakdown than I've usually done, because I thought it was important to highlight what's the big drivers behind the operating expenses. First of all, the overall number is increasing meaningfully to EUR 245 million to EUR 362 million in 2018. Research as well as SG&A are increasing, but not a material driver for the increase. And I should also add to that, that in SG&A specifically this is, to a large extent, driven by the higher valuation of outstanding employee warrants that we obviously need to adjust based on the value of the share price of Galapagos, which has gone up over the year. So as a result, you see higher SG&A expenses there, which is largely accounting. And the big driver though for the operating expense increase is in development costs. And as you can note there, there is our share of the filgotinib development costs, which, as a reminder, is 20% of the total.

We spent EUR 66 million in 2018. 1690 is the big increase. All the prep work for the ISABELA trial as well as the initiation of that trial and the preparation of the clinical products has led to a total cost of about EUR 70 million. And then there's other development cost for the multiple other compounds that we have in the clinic or in preclinical developments that are also increasing from 2017 to 2018. And maybe as an additional

insight between 'development other' and 'research', we invested roughly EUR 20 million in 2018 on our Toledo program that we've been speaking about in recent events.

Then finally, I'll go through net results, which is always a conclusion of all of the above. But I thought it was useful to make the bridge between '17 and '18 here as well. I'd say, the improvements of EUR 45 million in blue is really driven by what I would call operational evolution, so that's the -- there's some of the revenues going up and the cost going up at the same time, but the net is positive at EUR 45 million. The EUR 41 million orange is an improvement, which is all in the FX and financial lines. This is really the currency translation effect, which was negative in 2017 and it's now positive in 2018. So as a result, that generates a net result positive income of a little over EUR 40 million.

Maybe as a additional data point worth to mention is that over the 20 years of the industry of Galapagos, as Onno was just describing, we've now have accumulated losses of a little less than EUR 300 million, with about EUR 150 million of deferred income that has not yet flown through the P&L. So in other words, over the 20 years we've been able to build up this pipeline with a limited use of shareholder funds, which is then also reflected obviously in our positive cash position.

With that, I am -- concludes the 2018 results. And I'll move right on first to give you a perspective on the guidance for 2019 and then hand it over back to Onno for a view on the news flow for -- of our clinical pipeline for 2019. So if you look at the guidance slide, we had EUR 158 million of cash burn in 2018. We have guided for a cash burn of between negative EUR 320 million and EUR 340 million. First of all, I should explain that the cash burn of EUR 158 million included a positive of business development income from our transactions with Novartis and AbbVie, which was EUR 86 million, if you just look at the upfronts that were paid for those two deals. So essentially, there is an underlying increase, which is smaller than what you'd see on the face of the numbers and which is between EUR 76 million and EUR 96 million. And again, roughly 2/3 to 80% of that increase is driven by development. Here, you will see increases, again on filgotinib and 1690. But it's also worthwhile to mention that 2019 will be a year where we're going to be investing significantly also in Phase I programs, including a couple of Toledo programs as well. So the actual underlying projected cost increase is between EUR 76 million and EUR 96 million, leading us to a total guidance of EUR 320 million and EUR 340 million. And then obviously, that will take you through a little below EUR 1 billion as a projected cash position between EUR 950 million and EUR 1 billion at the end of 2019.

So with that, I conclude and hand it back to Onno for the clinical news flow.

Onno van de Stolpe^ Thank you, Bart. If you look at the news flow, that's divided in H1 and H2, and you will see the main clinical programs as well as earlier programs listed in bold. We've added the ones where actually new data will be released and I will focus on those. Clearly, we expecting the main news being the Phase I and Phase III top line 24-week

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data that will come this quarter. So we ask everybody to be patient for a couple of weeks. And that, of course, is a hallmark for the company because that concludes the RA Phase III data set of filgotinib and should be the basis for filing later on.

If you look at the second half of the year, you see quite a bit of clinical data coming out, mainly Sjögren's disease where the proof-of-concept will be disclosed as well as the lupus trial. So both of them are very important additional indications for filgotinib, large market, high unmet medical needs. So we're excited about those data sets to come.

Then later in the year, we also get the data for MOR106, the IGUANA trial, where we will share with you the primary analysis of the Phase II, and also the subcu bridging study where we expect to report data on the second half. And then we have a range of Phase I trials that will read out during the second half of the year, including the first trial with the first generation Toledo. So that will hopefully give us an indication on the safety and maybe some indication on efficacy. So we're excited about that. And the second Toledo program is expected to start Phase I before the end of the year as well. So we're all excited about the news flow that is coming towards us. We hope the data are positive and that they form good basis to further progress the pipeline going forward.

And with that, I would like to stop the news flow discussion and hand it back to Elizabeth so we can start with questions right away. Elizabeth, floor is yours.

Elizabeth Goodwin^ Great. Thanks, Onno. Thanks, Bart. That does conclude the presentation for today. So now I'd like to ask our operator, Tara, to connect us to any callers with questions.

+++ q-and-a

Operator^ (Operator Instructions) We will now take our first question from Brian Abrahams of RBC Capital Markets.

Brian Corey Abrahams^ We've seen several other JAK inhibitors run into issues related to safety and higher doses, and competitors take the strategy of filing based on lower doses. So a couple of questions along those lines. First of all, can you walk us through your view as to the reasons why JAK1 selectivity might be so important from an AE standpoint? And then secondly, specifically, might you consider filing on the 100 milligram dose. Do you think that profile would be sufficiently competitive there? Would you still need to complete MANTA if you were to file on this lower dose in the U.S.?

Walid Abi-Saab^ This is Walid, Chief Medical Officer. I'll take your call. So our view on JAK1 selectivity, I mean I think based on preclinical data and initial results from our completed double-blind, placebo-controlled trial as well as the open-label long-term extension of the RA program and DARWIN 3 that we keep recording on a regular basis, we believe that the profile that we have seen for JAK1 selectivity, particularly sparing the effect on hemoglobin and the platelets as well as the NK cells and the way they -- those would relate that to,

respectively, potential risks of anemia, potential risks of thromboembolic events and risks of infection or serious infection, potentially malignancies, we believe that the data, so far, are supporting our working hypothesis that JAK1 selectivity is giving us a more differentiated profile. Of course, we are waiting with bated breath the results of our 2 Phase III trials, FINCH 1 and FINCH 3, which will be available by the end of this quarter. Those are in more than 2,600 patients and should help us better define the risk/benefit profile there and see whether our working hypothesis is actually translating into reality backed by data. Regarding the filing of 100 versus not, so I've also spoken about this on a number of occasions. I'm very happy with the way we designed our FINCH 3 program where we fully evaluate 100 and the 200 milligram in those studies. And at the end of the -- when we have all the package with us, all the FINCHES -- again, by the end of this month, we will be in a much better position to make an assessment on the risk/benefit profile and whether we should file with both doses, one dose and so on and so forth. But it's really premature at this point to do it. If I may, however, extrapolate from the FINCH 2 data where we studied both doses in the biological incomplete responders, so those are the more hard -- more difficult to treat patients. With those when you look at the data, both on efficacy and on safety, what we see is you see a very good performance of the 100 milligram, very competitive. But we see also a better performance of the 200, so there seemed to be a dose response in terms of efficacy. But what stood out for us is the absence of any dose dependent uptick in adverse events or safety concern. If this profile continues to be confirmed in the FINCH 1 and FINCH 3 studies, then we would be in a very good place moving forward, but again, it's premature, we just wait -- we need to wait another few more weeks to be able to get the totality of the data, but that's where we are today.

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

Wimal Kapadia^ Wimal Kapadia from Bernstein. Just summing up from the first question, if, and you maybe you can't give too much color here, but if FDA do consider thrombosis to be a class effect, how would that the impact your expectations for filgotinib in terms of market potential? And then just following on from that, in your discussions with the regulators, is there a threshold event rate that FDA have in mind for thrombo events be considered worthy of a warning on a product label? And then just on cash burn and OpEx moving forward, how should we think of the acceleration beyond 2019? Do we expect a similar jump in 2020 and beyond and underlying the line expense increase? And then could you talk a little bit how the mix of OpEx will change between R&D and SG&A, assuming 1690 is a success in Phase III?

Walid Abi-Saab^ So Bart, I'll probably start with the filgotinib. I think it's really premature to be able to ask that question. It raises a (inaudible) to answer that question, sorry. (inaudible) a question anytime you want. But to answer that question about the class effect or not, I think we have two ways to see the totality of the data of the FINCH program. I think that's very important. We have more than 2,600 patients that are -- got to be treated initially, going to give top line results for the first 24 weeks. But then, shortly thereafter, we would

have the 52-week data. Those are going to a long way to help elucidate whether selectivity of JAK1 versus the other is going to play a role into this or not. This is a -- not a new thing. This is something that the team has been monitoring in detail. And it's very difficult because those are rare events and they do happen in this patient population. So you're trying to see whether there's a small increase or there is an increase in this rare event. So it's a bit difficult. The field is on it. We are on it, monitoring it and also trying to understand the biological underpinnings. And this also leads to the other question whether there is a predefined threshold that the FDA is looking for. And I believe the answer is no. We are not aware of it. If they have one in mind, they haven't clearly communicated on that. But when we were following the baricitinib AdCom, that topic did not come out very loud and clear as to a certain rate that they need to see this. I think when we look at randomized controlled trials, whether that's active or -- whether active or placebo-controlled over long-term, that's going to be the more defining way to analyze the data. And I think our FINCH data are going to be very important to help the FDA and make up their mind whether we do have an issue with filgotinib or not.

Bart Filius^ Okay, I will take the question on the cash burn and the lookout beyond to 2019. First of all, let me say that we are very proud to have so many opportunities to invest in at the company, that's why we're increasing our investments this year. Again, from previous year, basically it's a sign of the success of our pipeline, with not just the mid-stage assets that are well-known and well-spoken about, but also the earlier-stage initiatives that we have. And so to the extent that this success continues and we'll be expected to do is that you would expect also that the R&D expenses will also increase in later years. However, there is a caveat there, which is that we also anticipate an increase in milestones coming up in later years. So in 2019, just as background, there is very little in milestones included in this number guidance, EUR 320 million to EUR 340 million. The real material milestones are connected to our -- to the approval events for filgotinib in our partnership with Gilead. And those will come in the years 2020, 2021. So there, we are in a position where we might be seeing increasing R&D expenses being offset, while also increasing milestone events. With regards to SG&A, that will take up a larger proportion. I think still there will be relatively small compared to what we're investing in late-stage developments. But it will be increasing in 2020 as we are ramping up the preparations for launch. For filgotinib, in Europe, as you know, we have a co-promotion in the EU5 and Benelux, and we will also be bearing 50% of the initial launch expenses there. And also for IPF, even though that's maybe a little further out, we will be starting to invest a bit in launch preparation. So indeed, expect the selling components of SG&A to go up from where it is today.

Operator^ We will now take our next question from Christopher Marai of Nomura.

Christopher N. Marai^ First maybe just to follow up and clarify. We're getting the FINCH 1, 2 -- or 1, 3 readouts this quarter. Can you clarify if those might happen together or separately? Any chance they happen together? And then secondarily, let me follow-up on the selection trial.

Congratulations on full recruitment there. Should we be anticipating first quarter '20 readouts there? Is that reasonable? Could you maybe walk us through how some of that data may be read out? Thank you.

Walid Abi-Saab^ Thanks, Chris, for your questions. So yes, the FINCH 1 and 3 were (inaudible) by the end of this quarter. I don't think we're guiding at this point whether that will be 1 or 2 releases at the same time, but we expect them at the end of this quarter. Regarding the selection, I think, yes, we're very excited that we finished recruitment. As you can imagine, this is going to be 52-week trial, and then we have to gather the data. So currently, we're targeting first half of '20. Could be in the earlier part, but we haven't given that clarity yet.

Christopher N. Marai^ And then on 1690, could you maybe remind us of some of the ISABELA interim go, no-go decision-making questions? Is that safety specifically or efficacy? I know you sort of rushed this one after a small but exciting trial result. That's my last question.

Walid Abi-Saab^ Yes, sure. So actually, we do both. So take into consideration that we went from the FLORA study, which was in more than 20 patients, 12 week, into a very large program more than 52-week treatment in more than -- or in about 1,500 patients. We have to put checks and balances in place. So we have an independent Data Monitoring Committee that monitors the study on an ongoing basis. Their primary focus is to look at safety, but at the same time, it's their prerogative to look at efficacy as well. And they do make an assessment of risk/benefit. In addition to this, we do a futility analysis, which is something that we specify in the protocol. We haven't yet fully finalized it because we would like to have a discussion with the health authorities on this and come to an agreement. But that futility analysis will be done when approximately 1/4 of the patients have finished 52 weeks, which -- and by that time, we will take the totality of the data should it come. We will not stop treatment of the patient at week 52. All the patients will continue on whatever they were randomized on until the last patient clears week 52. You can imagine, when we take 1/4 of the patients who have done 52 weeks, there could be more than 80% of the patients already randomized under the trial and more than 25% of them who have gone beyond week 52. So we take all the totality of the data, which give us a lot of information to be able to assess whether we are going to hit futility. And in that case, if we have futility, then we will stop. There would be recommendation that would come to us from the independent committee that will look at the futility analysis to us, whether we should continue with the trial or not. That's kind of how it is currently framed. That depends. It's analyzed...

Operator^ We will now take our next question from Vamil Divan of Crédit Suisse.

Uy Sieng Ear^ This is Uy for Vamil. So could you sort of help us understand, I guess, the -- like what we should look for when FINCH 1 and Finch 3 reads out in the end of the quarter, what you would consider as success or to be better than the competitors?

Walid Abi-Saab^ Well, I mean, I think it's, for us, we've tested filgotinib in number of double-blind placebo-controlled trials in rheumatoid arthritis where we don't have any data yet in early RA, which is what FINCH 3 is going after. But honestly, I think we can extrapolate from the performance of filgotinib and when you look at it, how it's performing vis-a-vis the competitors. Our expectations are that we will be performing in the top range in terms of efficacy. Our expectations also from our safety data so far -- again, expectations is that they're going to be coming to be a very good and positively differentiated. Those are our expectations. Let's see what the FINCH 1 and 3 data will look like at the end of this quarter, but that's where we are today.

Operator^ We will now take our next question from Adam Walsh of Stifel.

Xiaodong Zhang^ This is Edwin Zhang for Adam Walsh. So my question is on MOR106 in atopic dermatitis. You plan to do a new combo study with topical corticosteroid. So what is the thinking behind this? And what difference do we expect compared to the current IGUANA Phase II study?

Walid Abi-Saab^ Piet, are you taking this? Or am I taking this?

Piet Wigerinck^ For me, the same. I can answer it. So this study is to bring us closer to the daily practice. So up to now we're doing a proof of concept. We do a very clean dose ranger where patients are only on the drug. And so the topical steroids sitting on top of that is a study that brings us then closer to the daily practice where some of the patients get treated. And we want to study that indeed, or proof in that study, that adding MOR106 on top of corticosteroids gives an additional benefit to these patients. So this is a study that prepares us well for Phase III to see whether we can safely include patients that have been on topical for a while, while stepping into Phase III. So it is more of a kind safety study that informs us on how we will design and how we need to include or exclude patients that, that have been recently on a topical steroid than anything else.

Operator^ We will now take our next question from Lucy Codrington of Jefferies.

Lucy-Emma Mary Sarah Codrington-Bartlett^ I've just got a couple. You mentioned that filgotinib is due to start the Phase III for psoriatic arthritis in the second half, but there's no mention of a Phase III in the ankylosing spondylitis indication. Is this something that's under consideration? And then secondly, we noticed that the -- all remaining deferred income has now been classified as current at the year-end. Does that imply that the outstanding upfront from Gilead will be recognized as R&D costs in 2019? Or how are you thinking about that? And then finally, if you could provide any color on the recruitment rate into the ISABELA trial and if possible, any kind of information regarding the background medications that the patients are on.

Walid Abi-Saab^ Bart, do you want to take the finance question first, and I'll do the others?

Bart Filius^ Yes, let me do that, Walid. Hi, Bart here. On the deferred income, you're right. It's all classified as current deferred income, which means that we anticipate that we recognize this in full in the next 12 months, so this should be part of 2019 revenues indeed. The small caveat is that you don't know exactly what the actual spend is, so it might be that we're just going to be slightly short or slightly earlier. But we anticipate next 12 months, indeed, to recognize the full remaining amount of the upfront from Gilead. Walid, for you.

Walid Abi-Saab^ Thanks, Bart. So for the filgotinib, I mean, the data from the TORTUGA study in ankylosing spondylitis were very positive. As you've seen, they're published in a top-tier journal. So I think we haven't guided specifically. By we, I mean Gilead and us having guided specifically about the start of the Phase III. But I think we can say that preparations are underway, and we should expect to hear more in subsequent updates from that. Regarding ISABELA, so we're currently in the start-up phase of the study. We just held a large investigator meeting in the U.S., where we had upwards of 75 attending for the North American side. Next week, actually, we're doing a very large one in Europe as well, and the next couple of months afterwards, we're going to be doing one in South Asia and Latin America. The initial feedback from a lot of the sites and the KOLs is there's a very high level of engagement and great excitement about this program. And I can say that we're off to a good start. Regarding background treatments, as you recall, that study is designed to go on top of standard of care. And our goal in the trial is, at the end of the day, we will end up in a combination of patients where we would be mimicking what is essentially the current standard of care in the U.S. and on major European countries. So specifically, about 1/3 of patients would be on nintedanib. About 1/3 will be on pirfenidone, and 1/3 would be on neither anti-fibrotic treatment. Now of course, during the conduct of the studies, we will make sure that the proportion of patients in each of the arm, placebo, low dose and high dose, would be equivalent between these various subgroups so that we don't have overrepresentation [with that]. So we will do adequate certifications to make sure that doesn't happen.

Operator^ We will now take our next question from Phil Nadeau of Cowen and Company.

Philip M. Nadeau^ Just 2 from us. First on the filgotinib regulatory filings. Firstly, you mentioned that you expect to file once the FINCH data are complete, but it doesn't specify in what -- in which territories. Could you maybe give us some sense of when -- what your current expectations are for the filing time lines in Europe versus the United States? And then second on the IGUANA trial. I'm just curious, what would you consider proof-of-concept data from that study? What do you think would yield a competitive profile?

Walid Abi-Saab^ So Philip, I'll take the filgotinib question, and then I'll turn it over to Piet for MOR106. So regarding regulatory filing, I think after the data from the FINCH 1 and FINCH 3 become available at the end of this quarter, we will have discussions with the regulatory authorities in Europe, Japan, and also in the U.S. to figure out essentially the filing plan for filgotinib. So I think more details on

this and the sequence of it greatly depends on the outcome of these discussions. And I think Gilead and us will be guiding on this with more clarity a bit later in the year after we've had those discussions.

Piet Wigerinck^ Okay. Thank you, Walid. On the IGUANA MOR106, which is a large dose ranger IV study, the goal is set for our study there to be in the range where we've been in the Phase Ib. That's where we've shown that this is a treatment which is competitive to the efficacy seen and safety seen with dupilumab. And so the ambition is to be clearly within that range of efficacy.

Operator^ We will now take our next question from James Quigley of JPMorgan.

James Patrick Quigley^ Only a couple left. On MANTA, so you've had the -- Gilead have announced they've expanded their recruitment outside of just ulcerative colitis. Any sort of indications? I understand it's early, but what's been the feedback so far on willingness to recruit patients from those sites and especially in just in the sites that you were involved with in the Phase II development? And looking at the U.S. market in general in RA and the potential pricing reforms have been tabled for sort of the drug pricing going down to -- or removing rebates, and rebates have been quite a big important part of HUMIRA. So again, I appreciate it's not yet through yet. But how does this impact your thoughts around the market for RA and the potential for the JAK inhibitors class to penetrate into the biologics? That's about it.

Walid Abi-Saab^ So James, I'll take the MANTA question. So as you know, we discussed with the FDA opening up the recruitment to other indications. So within IBD, we were going to expand beyond UC to go into Crohn's disease. There are also some opening up of some of the inclusion/exclusion criteria as well. And then in the rheumatic diseases, we're going into RA, psoriatic arthritis and ankylosing spondylitis as well. So initial feedback has been positive. I think John McHutchison, in the -- few weeks ago in the -- in 2018 end-of-year results, stated that he saw an increase in the recruitment in MANTA. And I think that's a good sign that -- of the initial response. But I would imagine as we start activating more of these changes on the ground, we'll see things to continue to move in that direction. Bart?

Bart Filius^ Yes, I'll take that one -- the other question, James, on drug pricing reforms and the impact on the market. So to be honest, it's -- in all fairness, James, it's a bit early to comment on that for 2 different reasons. On one hand, we don't know where those reforms ultimately will lead to and if -- and if and to which extent they will become policy. So that's really a bit difficult for me to start commenting on now. And at the same time, we also haven't seen the full profile of filgotinib, where we don't -- where we cannot really comment yet on the positioning it will take in terms of pricing. One thing I think will always stand out and that is that if there's a differentiated molecule that there's also an option in a very good market for it. As long as you can serve patients, you can get a good price both in the U.S. and in Europe. And we hope to demonstrate that through the programs that we're running together with our partner, Gilead.

Operator^ We will now take our next question from Emily Field of Barclays.

Emily Field^ Hello?

Operator^ Yes, your line is open.

Emily Field^ Sorry, I couldn't hear. Yes. Just a couple of quick ones. I was just wondering, do you guys intend to publish the data from MANTA publicly? And then how do you determine whether that's going to be determining for filing in the ex-U.S. geographies? Also just for the Toledo program, what shall we be looking for in terms of incremental news flow, I guess, over '19 in the coming months? And then on your cash position, in the context of the increased cash burn versus the milestones that you expect in the coming years, how do you feel about your overall cash position? And do you expect that you would need to raise any additional capital this year?

Walid Abi-Saab^ Okay. So this is Walid. I'll try -- we'll try to take them chronologically then. So for publishing MANTA, I think it's too early to say that. I don't think we've had any discussions with Gilead on this, so it's really difficult for me to speculate. I would imagine these would be important data, in general, for the field and knowing Gilead, they probably would be open to do this. But I'll have to leave it to them. In terms of whether MANTA data are required U.S. or ex-U.S. and so on, so forth, this will be -- we will know this after we've had those discussions with the health authorities. As I indicated earlier, we're waiting for the FINCH 1 and 3 results by the end of this quarter, after which, we will engage in those discussions with the health authorities, and we will be able to better guide in subsequent earning calls, probably, you'll hear it first from Gilead, as to whether these things are needed or not and in which geography. I think Piet, you're next.

Piet Wigerinck^ Yes. Thank you, Walid. So on the Toledo program incremental news flow for this year, so we have an ongoing first-into-human SAD, MAD study ongoing. So we probably will report out on if that's completed, and that's for the first compound, 3312, which the plan is move into patients this year, that as well. We would clearly announce the start of that study. And then we have the second compound, 3970, moving quickly behind, and the plan then is to announce when we move into first into human as well early second half of this year. In the meanwhile, we have a large drug discovery program, as we indicated before about half of the scientists that work on inflammation are working on that program within the company. And we expect to select additional novel molecules from different chemistries and with different properties over the course of this year. Thank you. Over to Bart, I think.

Bart Filius^ Yes, I'll take the last question, Emily, regarding your -- regarding the cash position. Obviously, we feel comfortable with the current balance sheet of almost EUR 1.3 billion. Even with the increasing spend this year, we're in a good position, I think, also at the end of 2019. So from that angle, no necessity to raise additional capital. At the same time, we will never fully rule that out. Obviously, what we can

say is that, over the history of the company, we've always been able to raise additional capital only at share price levels, which are higher than previous equity financings. So we've always been very conscious of the dilutive effect of any financing. And we will remain to be that in the future as well, but we're comfortable with the current position.

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

Dane Vincent Leone^ So a few from me. Just one on the IPF. I think in your own words, you said that you started kind of a daring Phase II based off of a somewhat limited Phase I program. I was just curious. It's been a topic of debate with investors regarding that move into a much larger program after that dataset. Could you just kind of remind us how your team thought about the data points that came out of that program in terms of what you specifically were looking at for the signal that gave you the confidence to scale up that program so rapidly? And then I just have a follow-up on the Toledo program after that.

Walid Abi-Saab^ Thanks, Dane. Thank you for your question. You're probably off by one phase in your question. We started doing Phase III based on good data from a Phase II study. We're looking at -- in that trial, we were looking to find evidence of target engagement and its safety profile that would look good. If you recall that the treatments that are available currently on the market, some are significantly from adverse events, and actually, despite the fact that these patients are pushing ahead of a deadly disease that is as bad as a severe form of cancer they choose not to be on the drug. It's about 1/4 drop out every year from treatment. So when we saw the results, actually, we were very positively impressed. Not only we had the target engagement we were looking for, a reduction on LPA, but we also have seen effects on the functional vital capacity, which is one of -- with the primary endpoint that the FDA looks at, and there were clearly a trend between us and placebo, a significance at week 8, although the study was very much underpowered for this success. Those data were corroborated when we also used home spirometry, which also gives you confidence that those effects are not just, by chance, that you managed to pick up when you saw these patients on few occasions in the office. And then when we used the more sensitive imaging technique of FRI, we also managed to detect a signal that indicates that our patients are stabilizing on drug and on placebo, they continue to deteriorate. So when you take the totality of the data, we felt that these data are convincing enough for us to be able to move to the next stage. And then when we thought about the next stage, we balanced the unmet medical need that's out there with the potential risk that we would be taking by engaging in it. But we felt that if we put the right checks and balances, as I described previously, in terms of the safety of the patients as well as the preparing for protecting the company against these investments, we felt that this was a -- the right move that will balance the -- getting the drug to the market potentially 2.5 years earlier than otherwise if we were to do a Phase IIb than a Phase III and an engagement -- and getting into the study going. Now what was great is after we did all this and moved forward, we had a great validation of this mechanism of action by another company, which is BMS. So they've done a trial, which they recently published and their drug

works downstream from us on targeting the LPA1-receptor. And there was a nice dose-dependent effect that demonstrated a validation of this target. Now unfortunately, for that molecule and actually for the patients as well, this compound will not move forward because they've seen some target -- off-target activity, I should say, and they led them to stop it. But for us, it was a great external validation of -- with the decision that we made based on the FLORA data.

Dane Vincent Leone^ I just want to follow up with a quick question on the Toledo program. So we are going to get first-in-human data from this program in the back half of the year from, actually, a number of the compounds. I'm just curious, in terms of what you would be looking for, for that first data, is this the situation where we're looking at a novel mechanism of action? Were you going to be looking at biomarkers to see that the compounds are doing what you would expect them to do from the translational work? Or is this a pathway or approach that you feel is already well validated and you're going to be looking more at the toxicity of these compounds? I know you'll look at the data in totality, but I'm just trying to understand the balances of what your team has confidence in versus what's kind of the unknown variable at this point.

Piet Wigerinck^ Okay. Thank you for the question. On the Toledo program, it's quite clear that it's something completely novel so -- as part of the Phase I, indeed, would like to see a target engagement and that would give us confidence on how we might or we should translate the animal model data to the patient. It's also completely novel. We'll watch carefully safety as well, but it's a complete novel mechanism of action. We don't have anything external there, where we can hook our signs up to, so we have to develop this ourselves. So there is a target engagement biomarker included, and that's going to be the first anchor point. And from there, we'll move on. And that's the primary goal of for the first compound. For the second compound, once we've done that translation, we should be able of moving faster, and I just include that probably in the first to human with more as a check with those data points and move them more quicker to the indications, which are of most interest. So thank you.

Elizabeth Goodwin^ Okay. Thanks, Dane, and everyone who's asked a question today. I'm afraid we've run out of time, and so if you have any questions that you were not able to ask, please send them to me or Sofie van Gijsel and the IR team, and we'll try to get answers for you.

So that does wrap up for today. Please look for publication of our annual report 2018 on or around March 29. And we thank everyone for participating today. Look forward to speaking with you all soon. Bye-bye.