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PRESENTATION

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Galapagos conference call.

I would now like to hand the conference over to your speaker today, Elizabeth Goodwin. Please go ahead.

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

Thank you, and welcome all to the audio webcast of Galapagos' full year 2020 results. I'm Elizabeth Goodwin, Investor Relations, also representing a great reporting team at Galapagos. This recorded webcast is accessible via our website homepage and will be available for download and replay later today.

I would like to remind everyone that 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 reflect on the operational highlights, and then Bart will go over the financial results and end with expected news flow for the year.

You'll see a PowerPoint presentation on screen. We estimate that their prepared remarks will take about 10 minutes, and then we'll open it up to Q&A with Bart and Onno joined by the rest of our Management Board.

And with that, I'll now turn over to Onno. Go ahead, Onno.

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

Thank you, Elizabeth, and welcome, everybody, to this webcast.

Before going into 2020 in overview, let's spend a couple of minutes on the ISABELA discontinuation last week. The Independent Data and Safety Monitoring Board contacted Galapagos with the fact that they had seen a dose-dependent mortality in the study, meaning that the arms treated with ziritaxestat showed more mortality than the placebo. And clearly, that was a case of death for this program. We immediately stopped the trial and informed the markets within 24 hours after the information was brought to our attention and after we could have analyzed the data.

On top of that, we also saw, when the data were unblinded, that the efficacy was below expectations, which was a disappointment as well. As a consequence, we have stopped all activities with ziritaxestat, all the trials and all further analysis for now. Clearly, a big disappointment. We had worked long and hard on this program, the original '1690 program, which was a big hope for IPF patients. The community was looking forward to the outcome of this trial with a potential solution to this deadly disease.

A big blow for Galapagos, but we stay firm with regard to our commitment to IPF. We have 4 development programs and a number of preclinical programs aimed at fibrosis. So we will be back in the IPF space with more mode of actions, with more trials. We think it's an area that needs new effective treatments. And we think we have a good franchise here. It's unfortunate that this has happened, but this is the risk we're running with new mode of actions.

Galapagos goes on roads that nobody else has gone before. And that means that we accept the risk associated with the novelty and the casualty that we have seen here with ziritaxestat is part of the business we're in. We will overcome this and we'll come back with new mode of actions for IPF.

If we can go to 2020 in review, then clearly, ziritaxestat discontinuation followed a couple of other disappointments over the last year. Most notably, the complete response letter that we received for filgotinib in the U.S. for rheumatoid arthritis, our partner, Gilead, received that letter. And based on that, the analysis with the FDA decided not to launch filgotinib in the United States for RA.

That doesn't say anything about other applications of filgotinib. We have a big trial going in Crohn's disease. And we have the data in ulcerative colitis. So it's not that filgotinib is dead in the U.S. But for RA, Gilead is not going to file the low dose.

On top of that, we also had a failure in a new mode of action program with '1972 in osteoarthritis. In the ROCCELLA trial, we didn't see efficacy there. It was a Phase IIb trial that we executed here. Unfortunately, with -- like with ziritaxestat, this is part of the business we're in, that with new mode of actions, you have a high chance that programs don't reach the finish line. I used to show a graph where we saw the attrition rate from 12 targets -- 12 novel targets, leading to 1 program in Phase III and these fallouts are part of this attrition that is the nature of the business we're in.

We also saw a number of very positive news over 2020, although they were overshadowed by the negatives. We had Jyseleca, of course, initiated on the European market. The EMA approved filgotinib/Jyseleca on the market, and we started commercialization in Germany and in the Netherlands, and we anticipate the other countries to follow shortly here in Europe.

As part of the restructuring of the filgotinib franchise, we were able to retain all European rights on filgotinib in Europe, and we will be now marketing Jyseleca all over Europe under the Galapagos name. So that is a big step forward for us. A firm commercial organization in Europe has always been our ambition. And with Jyseleca, we can achieve that.

We're also very active on the licensing end, where we got a number of new molecules, early molecules into the pipeline. The last one that we announced and the biggest one actually was OncoArendi, which is a molecule that we are developing for fibrosis, which is Phase II ready. So an exciting program. We're very pleased with that license with the -- from the Polish company.

We also did a divestiture. We sold Fidelta, our service division in Croatia, successfully. We think it's a win-win, both for Galapagos as well as for Fidelta because they are now part of a bigger CRO activity and -- where they play a very important role in the growth of that business, whereas within Galapagos, they were not very visible. So I think it's good for Fidelta. It's also good for us to focus on our core, core being developing new mode of actions.

Then we had a lot of clinical progression. We started our Toledo program in patients, the SIK2/3 inhibitor, '3970, that we started in 3 proof-of-concept trials. We started the TYK2 program in psoriasis. We had positive data of '1205 in the PINTA trial.

So a lot happened over the year, and this is really the beginning of a whole range of clinical data that we will see over '21 as well. And that is based on this deep R&D portfolio that we have been developing for a number of years where we're always focusing on quite a large number of validated targets that we progress through lead optimization towards preclinical candidates and then into clinical stage

programs.

And here you see, again, the attrition as well, but also the broadness of the pipeline. We're starting at the moment from 27 targets, we currently have 10 clinical stage programs. So it's a pipeline that will deliver a number of programs into patient trials over the years to come, and we remain extremely excited about this pipeline.

As you can see on the next slide, it's quite broad, especially on inflammation and fibrosis. Inflammation with filgotinib being our lead program there with trade name Jyseleca, of course, approved now for RA. It's submitted for ulcerative colitis in the EU, and we are expecting full recruitment of the Crohn's disease trial this year. So it remains a very important part of the Galapagos business.

Then a whole range of other molecules with different mechanisms, the Toledo programs, its SIK2/3 inhibitor, but you also see lower on the list an SIK3, '4399 which we're developing for inflammation. And other SIK inhibitors in there, other JAK/TYK inhibitors. We are continuing to broaden this pipeline, the whole range of new modes of actions that are in preclinical and moving towards Phase 1.

The same holds true for fibrosis, which is now led by '1205, a molecule that has been in the PINTA Phase IIa trial. We're preparing for a Phase IIb there with target here, GPR84. And you can see that we have a range of different mechanisms here in the fibrotic pipeline, including also Toledo program '4605. We remain committed to IPF and to fibrosis in general, and you can see that with this broad pipeline.

And then we have a couple of other programs outside these areas, and one that we will expand further is in kidney disease. It's an area that we think is very interesting. Our first program is in the CFTR inhibitor in PCKD. That program is in Phase II. So hopefully, we can get -- can show positive results there.

So all in all, I think a pipeline that we can still be very proud about. It's progressing rapidly. We have the resources, the people, as well as the financials to move those forward. And hopefully, they will deliver the data that we are all waiting for.

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

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

Thank you, Onno. And good morning, everyone in the States, and good afternoon in Europe, listening into this webcast.

I would like to say a quick few words about our efforts to build out our European commercial footprint, then I'll move into the financials and the outlook that will conclude the presenting part, and then we'll go into Q&A afterwards.

So on this one, we're very, very busy at the moment trying to roll out Jyseleca. We're building out infrastructure at Galapagos, and we are in the process of negotiating with the various payers throughout Europe to get reimbursement for the products. We had very interesting news earlier in the year that we have a positive NICE recommendation on Jyseleca, also for the moderate RA population, which is actually a novelty in -- not just in the class of JAKs but actually in all advanced therapies that, previously, these have not been available yet for patients with moderate RA and only for severe RA. So we're very happy with that particular bit of news, and we look forward to launching in the U.K. in the next coming months.

In Germany, the launch is on track. As you know, the German launch is run on the Gilead side. So also numbers are reported by Gilead. Now it's early days, obviously. It was first product sales in November and in December. So it's early days, but so far, so good. We're very happy to see with the numbers that we've seen. So launch on track there. And as Onno mentioned, in the Netherlands, we're also now in the market since a couple of months, but actually, in reality, mostly since 1st of January as the contract period starts in January in Holland.

In other countries, the process is ongoing, and that includes countries such as France, Spain, Belgium, but we're also now looking at the Nordic countries and Austria and Switzerland will follow thereafter.

All in all, we are planning to complete the transition of Jyseleca from the co-promotion structure that we had with Gilead, where it was 50-50 between the 2 companies, to a full operation run by Galapagos by year-end. So there's quite a bit of background work that needs to be done. The marketing authorization is going to be transferred. Structures are being put in place. But by year-end, we should be running this fully independently. And in the meantime, we'll make sure that we keep our eye on the ball with regard to the launch and make sure that we make a success out of the products in Europe.

Then moving on to the financials. As usual, I'll start with the perspective on cash. And as you can see here and as was highlighted in our press release as well, we have landed the year with a cash burn of EUR 517 million, which is in line with the guidance that we gave, which was between EUR 490 million and EUR 520 million, and this includes also the cash out, for example, for the licensing efforts that we've done on the OncoArendi compound in November.

What we always exclude from this cash burn are, on one hand, any cash proceeds from equity. In this case, this is a relatively small amount of EUR 28 million due to warrant exercises. And we also exclude currency translation effects, and those are meaningful in the year. The dollar has weakened significantly, about 10% over the year, and we've seen this in all of the quarters of the year already reflected in our cash balance. These are non-realized effects because this is purely representing the dollar position that we hold, which is roughly between 20% and 25% of our total cash balance. At the end of the year, we are -- we have a cash balance of about EUR 5.2 billion.

Then on the P&L, in the key financials for the year, maybe a couple of highlights there. First of all, on revenues. We have had a year of about EUR 530 million of revenues. And those are largely accounting revenues related to filgotinib on one hand, where we are recognizing all milestones, license income and portion of Gilead's (technical difficulty) periods of executing the development plan. And in the year 2020, we have recognized a little less than EUR 230 million for filgotinib. We've also had royalties, about EUR 16 million. Those are mainly related to our portion of milestones received by Gilead from Eisai for their partnering in Japan.

And then on the platform, we are recognizing in a straight-line of a 10-year period, the portion allocated to the platform as part of the 2019 Gilead deal. So the EUR 230 million that you see here is reflecting that straight-line revenue recognition and that will be continuing for the years to come. As a reminder, this number is lower in revenues than previous years -- than previous year. I should say, in 2019, we were recognizing 1 shot, EUR 667 million for ziri, and that explains the down in revenue on the top line.

Operating costs are up by about 35%, and the increase is really driven by 3 key elements: first of all, filgotinib, to a certain extent, that's mechanical because we're now paying 50% of the filgotinib costs and that's been reflected in -- on the revenue recognition side in revenues as well. And previously, we were paying 20% in 2019 still for half a year. So there's a mechanical increase on filgotinib. Then Toledo is clearly an investment focus for the company, and we've seen increases in investments in Toledo program. And then finally, S,G&A has gone up between the 2 years, reflecting the increase of the organization and specifically the rollout of our commercial efforts throughout Europe.

And then final comment here on the net loss, that includes a financial expense of about EUR 134 million. There's a couple of things underlying, but I'd like to highlight that more than 90% of this is noncash, it's really the translation effect of the dollar position that I was also showing on the previous slide on cash.

Then on outlook, on the next slide. First, maybe on the key events for the year. And then I'll say a few words about our outlook on cash burn as well. So key events on filgotinib, we file in Japan for ulcerative colitis. We also anticipate the first half of this year to get insights into the MANTA and MANTA-RAy trials. We anticipate an approval decision for ulcerative colitis in Europe. And finally, for the second half of the year, on filgotinib, we think that Gilead will have fully recruited the DIVERSITY trial, which we are running for Crohn's disease.

And then other readouts, the most meaningful ones there. Toledo, there are 3 POCs where we think we are going to have data; psoriasis, RA and UC. Then we also have, in January, disclosed a program, and we've disclosed the target -- the TYK2 target here where we're running a Phase Ib in psoriasis, and we anticipate data from patients there as well. And then finally, '555 is a JAK1 inhibitor that we're evaluating in osteoarthritis, and we should see patient data on that program as well during the year 2021.

Then I'll conclude on a couple of words on cash burn. We have refrained from giving a specific guidance, as you've seen in our press release of last night. Now in January, I think I have given some pretty clear direction as to where the cash burn would have landed and that number would be around EUR 670 million, which is basically an increase of about EUR 50 million expenses compared to last year, and those are connected to the launch buildup in Europe.

Now obviously, after the news last week on ziri, we've decided to take a good look at our portfolio and our cash burden. There will be an immediate, let's say, positive impact on our cash burn from the fact that the ziri trial is stopping. And beyond that, we will be coming back to you, hopefully, shortly with some further details about that exercise. The direction of the cash burn clearly is down and not up compared to the numbers that I have previously been talking about.

With that, I'd like to conclude and give the floor back to Elizabeth for Q&A.

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

Thank you both. And that does conclude the presentation portion of the audio conference call. I'd like to ask our operator, Anette, to connect us to any callers with questions for the executives. Go ahead, Anette.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And the first question comes from the line of Laerke Engkilde from JPMorgan.

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

Laerke Engkilde from JPMorgan. Two, please. Firstly, of course, appreciate that you're not going to give quantitative guidance on operational cash burn, but any further qualitative commentary you can make on how you see the development of sales and marketing spend in light of the discontinuation of ziritaxestat and when you expect to have more clarity on the R&D outlook would be much appreciated.

And then maybe secondly, how do you plan to address the sort of potential gap in the pipeline with the Toledo program unlikely to yield an approved therapy before 2025 and beyond assuming success?

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

Yes. Maybe let me take the first question and then the second question, Onno, I guess, you will take that one.

Sales and marketing spend evolution. So first of all, important to highlight that the business case for taking on Jyseleca fully in Europe was not built on ziritaxestat. It was built on filgotinib itself. And in January, we have highlighted a bit some key numbers in terms of our expectations for Jyseleca. We anticipate that we can make this a EUR 0.5 billion product in second half of this decade. We also anticipate that by then, this can be a contribution margin of approximately 50%. And we've also highlighted that we think that this is going to be breakeven in 2024, so after 3 years of investments.

So that should give you some direction as to how we think our spend would evolve. We do believe that by the end of this year, the structure is fully in place in Europe. Maybe a bit of full year effect in '22, but that should be it. So that is unchanged as a result of the ziri news.

Time for when we can give you further direction, at this stage, no precise time line, but I would estimate that latest by our Q1 reporting, which is end of April, beginning of May, we should be giving you some further clarity.

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

So to -- this is Onno, to address the second question regarding the gap in our pipeline. It's clear that with ziri out of there, we have a gap between the commercial product, Jyseleca, and our Phase II programs, and we would like to fill that. So we will be active on the in-licensing M&A activity this year to see if we can find a program likely in the fibrosis inflammation area to fill that gap. And I think there

are opportunities out there.

We have an interesting alliance, of course, with Gilead there, where Gilead will take on the -- has an option to take on the non-European rights. So even for an in-license program, they will get the option to take the non-European rights. So we are -- we have a solid partner there to market the product when it's in-license. So I think we are a good party to talk to. We're already quite active to analyze the opportunities and hope to find an attractive molecule.

With that said, it's clearly that we will remain focused on new mode of actions, novel targets. So that is also criteria for any program that we will in-license.

Operator

So our next question comes from Laura Sutcliffe from UBS.

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

Can I start with a broad question, please? So could you maybe just comment on whether, in aggregate, you think the pipeline, as it stands, has an acceptable commercial and clinical risk profile? And then something a bit more specific. On ziritaxestat, do you have any idea why you saw what you saw on safety? I appreciate it's early days, but I was just wondering if you had learned anything so far that you could apply elsewhere?

And then maybe if I can just sneak a third one in. On the MANGROVE trial, do you think you will get any fileable data from that study?

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

Yes. Let me start with the broad question and then Walid can follow-up with the ziri question. Yes, we believe the pipeline has the right balance on -- from a scientific point of view, risk point of view, clinical point of view as well as commercial. If you look at it, we think Toledo has great potential. We also have programs with smaller potential indications in there. It, of course, remains all a question of getting the product through these clinical trials to the patient. And with every new mode of action, that is a more risky business than if you go for a me-too product. But ultimately, we strongly believe that the innovation is what should drive our industry and that we, especially as biotech companies, should focus on getting these new mode of actions to patients.

We are in the situation, the lucky or the good situation, that we have enough cash to support these programs, that we can actually support a whole range of parallel Phase IIs and even Phase IIIs. So I think we will come back with a strong Phase III pipeline over the coming years, and we anticipate that a number of programs will actually reach the patient there.

Walid, do you want to continue?

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

Thank you, Onno. So regarding ziri, yes, it's a good -- very good question. We have looked at the data. It's difficult to see a very clear signal right now that points to a -- to give us sort of, as you said, a way forward to figure out how we can derisk other programs.

What we have observed is that this increase in mortality started manifesting itself when subjects have been in the trial for at least 6 or 9 months. So it didn't come until late. This is not due to any new tox signals, like, for example, a liver signal or anything else or cardiovascular signal. If you look at the mortality, at the high level, it does seem it's due to exacerbation of IPF, actually, which is a bit surprising.

And at this point, we need to look further into the data, look into the narrative, and it's a bit early days. But it's nothing that popped up that has linked to a mechanism of action that we could explain as of today or any tox finding that we've seen in our preclinical tox package. And we've looked at that in a lot of details, of course, as soon as we got these data.

And with that, I'll turn it over to Piet.

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

Thank you, Walid. So thanks for the question on the MANGROVE data. So MANGROVE is a Phase II study in ADPKD patients where we dose 60 patients. It's a placebo-controlled study. So this is the first step. So after this study, if we detect a good signal, we will need to do other studies in those ranges and then -- and a late study. So we are not pushing -- putting forward any filing data yet.

Operator

Our next question comes from Peter Welford of Jefferies.

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

I've got 3 questions. Firstly, is just, I guess, a bigger sort of picture question for Onno in the sense of -- or maybe for Walid in the sense that in hindsight, I guess, from a strategy perspective, do you -- has this changed the attitude of Galapagos towards sort of fast tracking, I guess, some development programs? But -- I mean I really think we've had -- there's been a lot of debate about discussions you had with FDA and the decision to move straight into ISABELA. I guess curious internally whether you sort of reevaluated from a risk perspective, what decisions you're willing to make? Or do you think this is just, if you like, unfortunate part of clinical development?

Secondly, then is a -- I guess, a technical question for Bart, just on the filgotinib share, the EUR 16.2 million. Am I right in saying that that's recognized in the other income part, if you like, of your revenue and not in the revenue part? I'm just trying to -- just from accounting perspective, just trying to understand where that EUR 16.2 million has been recognized?

And then thirdly, just thinking about sort of the European strategy and sort of cash burn. Is it possible for you to give us the rough cash burn or spend of ziritaxestat in 2020? I guess, just presumably from our back of the envelope, it would help because at least for the starting point, you have a rough idea, I guess, of how much ISABELA was cash burn during 2020 to think about for '21?

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

Yes, Peter, I'll start. This is Onno. And the good news of the failure is that you don't have to pronounce ziritaxestat very often anymore. So that's a silver lining. Yes, did it change our appetite for risk, the fast tracking? Well, clearly, we're going to review the various gating events and review also what we did with ziri as well as what we've done with '1972.

I think one of the things we -- maybe we -- I've said in an interview that we are maybe have been a little bit naive, optimistic, thinking that we could target this kind of big diseases like OA relatively simple. We had our molecule. We had good preclinical data, exciting Phase Ib data in healthy volunteers and then went into a large Phase II with 1-year treatment, 900 patients, and then we didn't see an effect. And now with ziri getting this tox signal and a disappointing efficacy signal, we need to rethink how we move programs forward.

On the other hand, as I said at the start of the call today, this is part of new mode of action development, and we will face more disappointments in the future. It's just that we need, once a while, a success that brings us to the patient. We also don't want to throw away the baby with the bathwater here. I think our innovative approach and rapid approach going -- with small effective Phase IIs is not something to immediately abandon, but I think we might fine-tune it somewhat to give us more certainty or at least less risky steps forward going from here.

Maybe Walid, you want to comment on that as well from a clinical point, and then we'll turn it over to Bart?

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

Yes. Thank you, Onno. I just want to say a couple of words on the ziri. I mean at the time when we got the FLORA data, we really debated this at length. And we didn't go in with eyes closed. I mean we were -- we had -- we went in with eyes wide open. We knew that we could take a path where we can do a Phase IIb study which would be long and costly and delay the program or take a more aggressive approach and go straight into the ISABELA program, which we ended up going.

However, what we did also is we put a lot of stop gap measures. We put the Data Monitoring Committee that meets -- it's a very robust committee that meets relatively frequently for a study like this to check on the safety but also on the efficacy on an ongoing basis. And also, we added the futility. And those are stop cap measures that will protect the patients, and that will protect us against excessive

investment. And I'd like to say that actually this is -- this happened.

The study stopped probably at about 50% cost of the whole program from a clinical perspective, which is -- and we knew from the beginning, is going to be higher than if we have done a Phase IIB, but that incremental investment could have gotten us to the patients ultimately 2.5 years earlier. And at the time, we debated that, and we knew we're taking a risk. But we thought that the incremental investment is worth that 2.5 years ahead of -- to bring the patients, which is an unmet medical need that is huge in this indication.

Of course, had we succeeded, we would have been a hero. Now retrospectively, we're saying, okay, well, maybe we shouldn't have done that. But I think, as Onno said, we'll have to take a look and see how we better balance the composition of our portfolio to have maybe a certain limited amount of programs like IPF, where you will have to invest a large time and resource and money until you get the initial results, and maybe other areas where you can have an early readout, psoriasis, RA, psoriatic arthritis and IBD. And that would be also another way for us to balance the risk of our clinical portfolio.

And of course, also Onno mentioned that -- very clearly that we will be taking a critical look at our gating events. How much data do we need to have to take the next step? And that's really good housekeeping in our part and a natural consequence of the disappointments that we've seen in our pipeline recently, and we'll be able to guide more on that once we have concluded our assessment.

Thank you. I'll turn it over to Bart now.

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

Thanks, Walid. Yes, Peter, your 2 questions. Filgotinib royalties, they're recorded in revenue. So they're not in other income. They're recorded in revenues. In other income, you'll find things like tax incentives and grants and stuff like that. So it's in revenues.

The second question, cash burn in ziri in 2020. We spent in 2020 about EUR 55 million on ziritaxestat. That's a net number, taking into account that we are sharing those costs with Gilead. And your question, obviously, is to what can you expect then in terms of 2021, let's say, immediate reduction as a result of the ziri stop. I would say it's in the vicinity of about EUR 40 million, Peter. So that's what I can tell you in terms of immediate consequences of the ziri stopping in 2021.

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

And can I just follow-up just on the filgotinib royalties, because I guess, just a little bit of confusion when I do the math, because I think -- previously, I think you've booked sort of a reimbursement of -- reimbursement income, I think, in the sort of first half of the year of about EUR 6 million, EUR 7 million or something like that. So I guess, it looks as though that -- presuming there was no reimbursement or anything like that in the second half of the year or something, am I missing something?

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

Now the royalty -- if you're talking about the royalties, it is EUR 16 million, that is all booked. That's all part of the second half of the year, it's actually all Q4. And it's connected to the Eisai deal that Gilead has disclosed with Japan.

There have been situations between the quarters on filgotinib revenue recognition as a result of changes to our development plan, changes to the structure that followed the transfer of some of these trials in Q4 to us. So there's a bit of moving parts there. So the net number that you've seen on the slides is what we recognized for filgo and the EUR 16 million is what's, let's say, to the royalties in 2020.

Operator

So our next question comes from Brian Abrahams of RBC.

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

Two for me. I guess, first off, what do you need to provide to Europe on MANTA and MANTA-RAy? And how clear are you as to what they'll be looking for from the interim blinded data to maintain the label or -- and/or authorization of Jyseleca?

And then secondly, just as you think about future cash burn following the ziri setback, I'm just curious, sort of bigger picture is your

predilection to, I guess, reprioritize and use the cash you would have otherwise spent on ziri to invest further in other assets? Or should we think about more, I guess, reduced spend, just, I guess, spend decelerating overall to preserve capital because you won't have those future revenues from the late-stage asset?

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

Thank you, Brian. This is Walid. I'll take the first question on MANTA. So Manta and Manta-RAy, those are both like 2 parts of 1 study. The -- as you guys might know from what's in the public domain, we look at a number of endpoints there. The primary endpoint is more than 50% reductions per concentration. But also we look at mortility, we look at morphology, we look at hormone levels and so on and so forth.

And those -- I think the interpretation of this is going to be difficult from the perspective of a primary endpoint is not -- also the study is not powered for statistical significance on the primary endpoint because health authorities have said that they will look at the totality of the data because there's no clear black and white way to interpret the data. Of course, unless the compound is toxic and causes a lot of things, then it becomes very clear, and that we will have to report immediately. But the data will be the totality of the data. And there's no clear definition of what would be an acceptable deviation and imbalance that you would see in one or the other.

So the expectation from the FDA is that we maintain those studies blinded until we finish the monitoring phase. However, we have obligations to the European authority and patients as well and in Japan, where we are marketing Jyseleca, to once we have the data from the 26-week that we present these data to these health authorities. And as such, we agreed with the FDA, there is going to be a small unblinded team that will have access to those data in order to prepare the documents that will be needed to provide to these -- to the health authorities in Europe and Japan so that we can adjust the label accordingly and be able to adequately inform the prescribers and the patients.

Bart?

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

I'll take the other question, Brian, on the cash burn. No, we are not going to reallocate the ziri spend to other assets. And the idea is we need to rightsize our total expenses for the year 2021 so the number will end up lower than the number that I was guiding for in January, including the EUR 40 million that I just mentioned on the ziri savings, including potentially a bit more.

Operator

So the next question comes from Matthew Harrison at Morgan Stanley.

Unidentified Analyst

This is Thomas for Matthew. For TYK2, do you think the psoriasis data can demonstrate any difference over the profile of the leading TYK2?

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

Thank you, Thomas. Did I understand you correctly, you meant the psoriasis study? Is that what you said? I didn't hear you very well.

Unidentified Analyst

TYK2 inhibitor.

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

Right. But what kind of data were you talking about?

Unidentified Analyst

The psoriasis, yes.

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

Yes, yes. Yes. So I mean that is a relatively small study. So I think directionally, it will tell us whether we are active, but I don't think it will give you a precision to what degree you can compare with competitors where you have much more advanced data. So I think directionally, it will give you an idea, and that's what we're looking for. But the study is 30-patient study, 20 on active with 10 on each dose, we're taking 2 doses in that study, and 10 on placebo. And its duration is 4 weeks as well because it's a Phase Ib. So directionally, we're going to have an idea, but to be able to have the precision with which to compare against the more advanced compounds, I think it would be a bit more difficult.

Operator

Okay. And now our next question comes from Rushee Jolly at Bernstein.

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

Rushee Jolly at Bernstein. And 2, please. Firstly, I guess a follow-on question on psoriasis. I mean I know the data is early, and you also have a Toledo asset that's entering psoriasis. But I wanted to ask maybe kind of longer term perspective on where you see the bar for success there and how Gilead can differentiate themselves? And the reason I'm asking is psoriasis is incredibly competitive as it is. But we could also expect to see another IL-17A on market later this year that perhaps sets a new bar in terms of efficacy?

And then secondly, I wanted to ask maybe a bigger picture question on management's view of value of the company today. You have a lot of cash on balance sheet. But perhaps you could comment on maybe the balance of cash burn and the requirement to invest in the pipeline. And perhaps your view of really what current pipeline and platform represent from a valuation perspective?

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

Okay. Let me take the first one. So the reason we're doing the psoriasis study is to have a quick assessment in a Phase I setting, which this indication lends itself to, to generate some initial clinical data to see whether we have a path forward. To be able to truly see whether we are competitive, our plan is to go into a psoriatic arthritis study, which is more of the indication that fit better with our outlook.

But it's a fair question. And I think the point that where we're coming from, I want to make 2 points. One is that we need to generate enough data with this asset, which so far looks very good. We want to generate more data with this asset so that we can ascertain, is this a competitive asset to continue to push forward for later-stage development or not? And number two, psoriasis right now is not a primary indication for us. It's an initial study to tell us whether we're on the right path.

Now once we do a full evaluation and we advance forward, if the competitors are on the market with psoriatic arthritis and psoriasis, it becomes an easy way to broaden into psoriasis. But all of that will be part of our assessment with commercial and positioning to see whether we have a way forward or not. It's still a bit too early to tell. The initial data will tell us directionally whether we're heading there. And then the next question is, is it worth investing in a Phase IIb psoriatic arthritis study, so then you can have much better precision with which you can compare to the competitors and see whether you have a differentiated drug there or not to be worthwhile investing further into.

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

Yes. Let me say a few words then on the second question, Rushee. So I'm sure you've all done the math. I think our total cash balance is sort of equal to about EUR 79 a share. So currently, in terms of value that we are getting in the Street, we are not getting value for cash, let alone we're not getting any value for our platform, we're not getting any value reflected for our pipeline that Onno was showing earlier. And that includes, if I got the number right, about 10 clinical stage compounds or compounds in development. And it doesn't include any value for Jyseleca either, which we think definitely has a value in Europe and abroad. So that's what I can say. It's not up to me to determine what the value appreciation is of shareholders in the company, but we do feel that there's a disconnect currently.

In terms of cash burn, as I highlighted, EUR 5.2 billion on the balance sheet reflected -- if you look at the cash burn plans that we were having, that's easily enough to live out the Gilead collaboration period until the end of the decade. And obviously, that's a fantastic opportunity for us as a company to demonstrate that we can create value scientifically and that we can bring compounds to later stages and to the market, and we see we have opportunities of our existing portfolio of bringing other compounds to the finish line as well in

that period. So definitely, we should be able to create value based on that cash rather than just see it as a spend on an annual basis.

So yes, let me conclude with that. We think that there is the technology, the clinical compounds, the marketed compounds and the firepower finally for business developments as well that should be part of the value of Galapagos.

Operator

And now we take a question from Phil Nadeau at Cowen.

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

Two for me also. First is on commercial. I'm curious to hear a bit more about your marketing message for Jyseleca in Europe. How are you differentiating it versus the other JAKs? And along those lines, do you think the recent data from Celgene's basically failed study helps you? Or does that hurt the JAK class? That's question one.

Then question 2 is just on the accounting. We are amortizing upfronts on the filgotinib payments over 4 to 5 years post 2019. Does the amount that we're -- we should be amortizing our model, does that change post the December agreement and the cash payments that you have coming up this year, next year?

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

Yes. So this is Michele here, Phil. I'll take the first part of your question on the messaging. So the messaging is leveraging the strength of the balance we have with efficacy demonstrated with Jyseleca across different line of treatment, so the bio-naive and bio-IR, and actually probability of safety data that also differentiated our profile in the clinical -- in the development programs. And this is the balance that we actually are bringing to physicians.

The feedback that we're getting from Germany, the Netherlands, Belgium and the countries where we have the promotion ongoing is really comforting and reflecting that. So that's really coming back also from the market researchers, the advisory boards that will reflect the strength of this profile. And these, as Bart indicated in the beginning, also reflect in the first indicators we get on the shares on the in-play market in the first weeks and months of promotional sales there.

On the impact of the Celgene's data, that, of course, is a double-edged sword, if you want. On one end, it strengthened the value of our proposition because, of course, it gives more attention to the safety data we have in our profile. Of course, on the other hand, it requires -- it creates a reflection from physicians about JAKs, which we know already was there in terms of the safety from the first generation of JAK. So Celgene's (inaudible). And again, on that, we still reflected that physicians appreciate the second generation. So the JAK1 preferential, and we see an opportunity there if this is reflected.

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

That's helpful. The second question was on -- yes, the revenue recognition.

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

The amortization of the filgo upfront.

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

Sorry, Phil. I was disconnected from the line for a second. Can you just do it one more time for me, the question?

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

Right. So after the Q3 renegotiation of the deal with Gilead, I believe we had about EUR 640 million in filgotinib upfront payments to amortize over 4 to 5 years in our model. I'm curious if that number has changed now post the December reorganization of the deal with Gilead and the payments that you expect to receive in 2021 or 2022? Is there less filgotinib upfront to amortize now over the next few years that we should take out on our model?

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

Yes. No, it's about EUR 800 million at the end of the year reflected in our deferred revenues that's going to be recognized over the next couple of years. So it's up because basically the extra payments that were negotiated as part of the agreements in Q4 are also partially put into the balance sheet and we recognized as development costs will be incurred over the next couple of years. So it's -- the same period going forward, let's say, another 3 to 4 years. And EUR 800 million -- approximately a bit more than EUR 800 million, and we'll have details in the annual reports to be recognized over that period.

Operator

Okay. And our next question comes from Jason McCarthy of the Maxim Group.

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

This is Michael Okunewitch on the line for Jason. So one thing I'd like to ask considering M&A seems to be -- or in-licensing as well seems to be a priority for 2021, and likely on the later stage of things, how does that work with? And how do you take into account the existing agreement with Gilead? Would they have an option on in-license program? And do you have to factor that into the price you're willing to pay considering they can in-license for EUR 150 million?

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

Good question. This is Onno. Yes, exactly. So Gilead has an option on everything we in-license. If we do it through an M&A or through a product license, they have an opt-in for the non-European right for a price of EUR 150 million, which, of course, has consequences of what Galapagos can do on its own regarding in-licenses. Or if not, we need to get Gilead at the table as well, which clearly is a possibility. Gilead, as you know, is very active in, in-licensing and M&A activities. So we could do a transaction where we get the rights for Europe and Gilead would get the right outside Europe and then we jointly do the further clinical development as in the current alliance. So that's a possibility. Not making it easier, of course, 3 people at the table, but our relationship with Gilead is such that I think it's a very workable way forward.

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

And then if you don't mind, I just want to ask one thing on IPF. Specifically, if '1205 and the chitinase have the same combination potential, as you had with ziri, considering both of those assets target the macrophage aspect of immune response?

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

Piet, would you like to take this?

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

I can take it. From a mechanism point of view, both the chitinase and GPR84 can be combined with other mechanism of actions. What we've seen in PINTA and what we need to study is that there was a negative PK interaction between '1205 and nintedanib. By negative, I mean where we saw more of toxicity. So in that sense, if you talk about the combo potential later of those 2 assets, we'll need to find the exact dosing for '1205 and nintedanib and that might be different from the dose we could give on the top of pirfenidone. But from a negative point of view, indeed, you can combine them with either pirfenidone or nintedanib.

Operator

And our next question comes from Evan Seigerman from Crédit Suisse.

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

So I know this has been touched on before, but current valuation suggests a negative enterprise value, could imply a number of things, one being that the spend -- your spend is not generating the value essentially. And I guess, what is your plan to really reverse this trend and convince the market that the spend in investment you're engaged with the portfolio and the pipeline is going to create value for shareholders?

Onno van de Stolpe ***Galapagos NV - Co-Founder, CEO***

It will come from the programs that we have plus, of course, the performance of Jyseleca in the market. We got to regain the confidence of the investors. We've lost that due to the CRL, due to '1972 and now the ISABELA trial. And it's a normal reaction that when things fail, people turn their back on the whole technology and the company. We are strong believers that we have everything in-house to bring new mode of actions to patients. We have a very exciting pipeline that I just showed you earlier. We have to deliver on that pipeline. We need to get programs through the various trials into Phase III and to the patients.

And if we can deliver that, I'm sure the investors will come back and the excitement will regain traction here around Galapagos. But for now, we need to focus on what we're good at and that is bringing these new mode of actions through clinical development, and we're going to look very closely, as already was discussed, about our processes, our gating events, our programs as well. And we'll report the market when we have done that analysis on what we're going to do for the years to come.

Operator

And our next question comes from Graig Suvannavejh from Goldman Sachs.

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

I've got 2, please. My first, just revisiting the current cash balance of EUR 5 billion and the topic of in-licensing and M&A. Are there particular themes that you can comment on and whether it is more asset specific? And is it indeed looking for something that's still in the gap in the late-stage pipeline? Or is it more around technologies? I know in the past, the company has talked about interest in perhaps RNA-based therapeutics or even protein degraders. So just wanted to visit that theme?

And then secondly, the company is currently focused on inflammation and fibrosis. And I think there's a view that inflammation is increasingly more competitive. Fibrosis is a tough space generally. And so I was wondering if the company has any interest in looking beyond inflammation and fibrosis? And whether -- if there was, whether that would have to contemplate a conversation with Gilead to make sure there was synergy there?

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

Let me give a shot at that, Graig. First of all, in terms of BD efforts, I would say there is indeed still the need to look at the technology side. We've done quite a few in-licensing deals over the last 12 months as well as some smaller technology-based deals as well. And we will continue that effort because I think it's good in terms of, let's say, rejuvenating the technology of our platform going forward.

I think, frankly, in terms of size, that's going to be probably smaller. I think when we are referring to larger transactions on BD, we're really talking more about later-stage assets. So more meaningful numbers as well in terms of cash spends thereon, but it doesn't preclude us from doing other efforts as well on the BD front.

With regard to the therapy area choices, it's clear inflammation and fibrosis are committed areas. We've also announced last year that kidney is an area that we're looking for and that is confirmed. And we -- actually, if we want to make changes on those, there is no need for us to talk with Gilead about it. It's really up to us to determine where our strengths are and where our focus should be. So that's not subject to a discussion with our colleagues from Gilead.

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

All right. If I could just follow-up for clarification just on M&A. Did you mean to imply that you would prefer to do smaller deals versus a larger deal? And I guess, if you are contemplating "larger deals," is there a size of a transaction that you think is appropriate for the profile of Galapagos?

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

Yes. I think it will be a bit too early to give specifics about exact sizes. But clearly, we're talking about something else than the EUR 25 million that we were talking with OncoArendi last year. That's what I would call the smaller deals that we would continue to be interested in, to look at, to refresh our earlier pipeline, but the BD that we're talking about here is clearly of larger scale. And we'll take that on as our analysis and evaluations progress.

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

Okay. Thank you. That's all we have time for today on the call. Please reach out to the IR team if you still have questions. Our next financial results call will be the Q1 results on the 7th of May. Thanks for participating today. Goodbye.