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Q4 2019 Galapagos NV Earnings Call

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PRESENTATION

Operator

Good day, and welcome to the Galapagos Full Year 2019 Results Webcast and Conference Call.

At this time, I would like to turn the conference over to 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 2019 results. I'm Elizabeth Goodwin, Investor Relations. This recorded webcast will be accessible via the Galapagos website homepage and will be available for replay later on today. So that your questions can be included, we request that you call in one of the telephone numbers given in last night's press release. Here's the one for Belgium, +32-2404-0659 and the code is 8371984.

I'd 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 go through the operational highlights and Bart will explain the financial results, and we'll end with the expected future news flow. You will see a PowerPoint presentation on screen. We estimate that this presentation will take no more than about 15 minutes, and then we'll open up the call to a Q&A session, including Bart and Onno, who will be joined by Walid Abi-Saab, CMO; Piet Wigerinck, CFO; and Michele Manto, Chief Commercial Officer.

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

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

Thank you, Elizabeth. Good morning, good afternoon. What a fantastic year we've had. Our anniversary year, 20 years, has been a hallmark year for the company. We saw a fantastic great clinical progress in our programs, exciting research results and a substantial growth of the organization. But our real hallmark moment of the year was the announcement of the strategic alliance with Gilead for a

10-year period. You see here on the slides the data on that alliance. For us, it's very important that we now have a 10-year independent future as a company where we can build out into a global leader in this sector.

Gilead obtained an option to license in programs after Phase IIb for the whole world except for Europe. In Europe, we will build our own commercial organization. They paid us an upfront of almost EUR 4 billion. They paid EUR 1.5 billion as an equity investment to get up to 25% of stock in Galapagos, and we made a very nice option arrangement where when they are licensing a program, they pay us a milestone and they pay us royalties between 20% and 24%.

This deal is unique in the life sciences, and it's really a science-related deal. We are going -- jointly going to work on new mode of actions that we're going to move to the clinic as fast as possible. Galapagos is in the lead in any therapeutic area that we choose up to the end of Phase II, after which Gilead has the option to opt-in and after that, it's a joint program. We are very, very excited about it, and we believe this will greatly accelerate our programs and help to build a pipeline for Gilead, but really for us to build first a European organization, and in the end a global organization to market our new mode of actions.

So if you look at the pipeline development, we saw really good progress in all the programs. Of course, with filgotinib, we saw the FINCH 1 and 3 data in rheumatoid arthritis, which really supports the potential best-in-class profile of the filgotinib molecule. Based on the FINCH data, we submitted or Gilead submitted for approval in Europe, U.S. and Japan, and so in the U.S. and Europe, we expect filgotinib to be entered into the market after the summer.

We also initiated with Gilead the Phase III program in psoriatic arthritis, the PENGUIN program. But we also saw a lot of other progress in other programs; in osteoarthritis, the ROCCELLA trial was fully recruited, and we are expecting the readout in the second half of this year. Same with the NOVESA '1690 trial in systemic sclerosis, we're expecting the readout in the second half of this year. This program is the second indication for '1690 after IPF, the program that is ongoing, so really expanding the opportunity for this molecule.

And in IPF, we saw the second molecule in Phase II, '1205 going into the PINTA trial, of which we're also expecting the results in the second half. ISABELA, the Phase III program in '1690, is going extremely well. The recruitment at the end of the year, we had over 600 patients recruited already, and we're on track to reach full recruitment near the end of this year. And then our TOLEDO program, the program with the code name TOLEDO, of which we will give more information after the summer. We are moving forward with a number of different molecules. And actually, the first 2 molecules hit the clinic last year, '3312 and '3970. We're very excited about that program. And of course, there's much more behind this. We're seeing a very nice progression in the research activities. And you can expect significant news flow in 2020.

So filgotinib, if you look at the pipeline now, clearly has reached the point of approval, but many different disease indications are being tested. Look at IPF and fibrosis where we have multiple programs in research, Phase I, Phase II. In osteoarthritis, the '1972 program, we're waiting for the outcome, but we also initiated research activities there that, hopefully, is going to bring multiple molecules for OA also into the clinic.

TOLEDO, already discussed, with a number of different programs and then in the research, in various different research areas, we have over 30 programs, a very exciting pipeline that we're extremely proud about.

If we go to the next slide, look at our commercial organization buildup. Last year, we have made very good progress in building a commercial organization in Holland and Belgium, in France, Italy and Spain, and we are completing that commercial organization in the coming months to be prepared for the launch of filgotinib in rheumatoid arthritis. So that is our first step into commercialization.

Then when filgotinib is hopefully getting approved in ulcerative colitis in '21, we will market filgotinib for that area in the Benelux as well as in England,the U.K., and Germany. So we do a step-wise approach in building the commercial organization, and that should then be followed up, hopefully, with '1690 in IPF where we are going to market all over Europe, but that will be beyond 2022. So that is how we are moving forward in the commercial activities.

And with that, I would like to hand it over to Bart to talk about the financials. Bart?

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

Thank you, Onno, and good morning, everyone in the U.S., good afternoon for those listening in here in Europe. A pleasure to give some color to the financials as well as give some perspective on what the year 2020 is going to bring us both in terms of numbers and in terms of scientific activities.

As you can see here on the first slide, let's start off with what we believe still is the most important KPI for Galapagos, which is the cash position. And we've ended the year, as you have seen, with a very strong cash position of EUR 5.8 billion. It's called cash and current financial investments, so some of these are invested in shorter money market funds, hence qualification, current financial investments here.

Some smaller items that are, as usual, excluded from the cash burn definition itself are the cash proceeds from warrant exercises and some currency translation effects, but then we get into the more meaningful elements that have given rise to the increase in the cash balance during 2019. First of all, as Onno was pointing out, the investment by Gilead in terms of equity in the company. These are all euro denominated, so 1.3 billion in euros.

And then the actual cash flow consists of 2 buckets. On one hand, there is the cash flow from the upfront from Gilead, in euros, that's a net of EUR 3.5 billion. And then the remainder and for transparency purposes, we've taken a separation of the 2, as I've done also in the third quarter reporting because our guidance was focusing on the cash burn, excluding the income from Gilead collaboration. And we've landed that number at EUR 334 million, within the range that we were guiding for throughout the year of EUR 320 million to EUR 340 million.

So a very healthy balance sheet position that we have to invest in future years into our R&D platform. I would understand that the accounting of the transaction is a bit complex, and I've explained and clarified some of this as part of the Q3 results. But let me reiterate a couple of points there as well. And let's first start with the upfront, the allocation of the upfront transaction price.

So we started off with about $4 billion. In euros translated, that's EUR 3.5 billion. There is some accounting for the equity investments that Gilead has put into Galapagos, most notably the premium of EUR 85 million on the shares, which would also go into our deferred income total. And then on the other hand, there was a set of warrants that we've given as part of this transaction to Gilead, one to get to the 25% level and a second one to get to the 29.9% level, and that is basically resulting in a liability of about EUR 60 million, which is, again, a decrease of the total purchase price that we need to allocate.

So that gives us EUR 3.6 billion of purchase price to be allocated. Three key components therein -- first of all, in terms of immediate recognition, the license that Gilead has taken on '1690 is there for EUR 667 million. And then the 2 others are actually going to be recognized over the next years. First of all, filgotinib. For filgotinib, we have allocated EUR 640 million, and this will be recognized as long as the, let's say, development plan of filgotinib is still active. So as long as we're still involved in participating in those expenses, and we estimate this to be for a period of 4 to 5 years given all the other indications that we're working on with filgotinib. So this recognition will be over the next years in function of the completion of that development program. And then the remainder, about EUR 2.3 billion, is allocated to the rest of our platform, the rest of our R&D activities, and we'll recognize this linearly over the next 10 years. So you would expect every year to find EUR 230 million of this in our top line in our P&L numbers.

Overall, at this moment, we have about EUR 3 billion of deferred income on our balance sheet, so the EUR 3 billion is still to be recognized over the next 10 years.

Then let me get to the full year results themselves. And here as well, I've broken out both the results as reported on the far right. And in orange, the impact of the Gilead collaboration, and I'll do a deep dive on that orange part in a second. But as we reported, we are reporting a profit this year with EUR 150 million of net results and we are reporting a top line of close to EUR 900 million.

If we do a deep dive, actually, on the next slide, on the orange column, you see the various numbers that are the result of the Gilead collaboration. And first of all, in revenues, the big impact there is the recognition, as I just pointed out, on 1690, EUR 667 million that we

recognized in 2019 in 1 shot. Then there is some movements on the remainder. On filgotinib, it's actually a negative, which might sound a little bit awkward, but this is because we are combining the 2015 agreement that we had with Gilead on filgotinib with the current agreements on filgotinib and we're reassessing the overall completion, and that led to some derecognition of previous upfront and milestones from the 2015 agreement. So that's a negative -- one-time negative in 2019, and as I was just pointing out, we'll be recognizing filgotinib deferred income over the next 4 to 5 years.

And then the platform itself for the 4 months that we had the deal closed, we've recognized EUR 81 million on the platform.

Operating expenses is a smaller adjustment there. But the 2 key components are, on one hand, that we're sharing now cost for '1690, 50-50, so that is actually a positive of EUR 18 million. On the other hand, for filgotinib, we went from 20% to 50% of cost here and that's in the negative of EUR 33 million. Bonuses and fees has also had a negative effect of a total of EUR 23 million on the operating expenses.

And then the last is on financial results, and this is all related to derivative accounting and Fx accounting, which is, to a large extent, noncash. And I already reported that also back in the Q3 webcast. We are recognizing derivative accounting negative of EUR 140 million connected to the evolution of the share price of Galapagos between the signing of the deal and the closing of the deal, and the other EUR 40 million are recognition of the evolution of the Galapagos share price between the approval of the warrants at the AGM in October and the actual exercise that Gilead has done in the month of November.

So it's all accounting, noncash-related, but this is the way to appropriately account for both those instruments and are both the result of an increase of the Galapagos share price.

Then on Fx, EUR 58 million, of this EUR 35 million is realized Fx and the remainder is nonrealized on the dollar position that we maintain after the Gilead collaboration. And the realized Fx basically represents the slight strengthening. It's basically $1.12 to $1.11 of the dollar on the euro between signing and closing of the deal over summer and was already reported in our 9 months data.

So overall, we see a lot of impact from the filgotinib collaboration. I'm happy to take any questions on this if that's useful, either during the webcast or later on as well.

Then let me move to the operating cash burn look out for 2020. We're guiding for a cash burn between EUR 420 million and EUR 450 million. This basically is an increase compared to the EUR 334 million that I was mentioning in 2019, but it also includes an estimated milestone of $200 million or I should say milestones because it's multiple estimated $200 million of milestones upon approval in RA for filgotinib in the U.S., Europe and Japan.

So actually, the underlying cash burn is increasing more than just EUR 100 million compared to the 2019 number that I just presented, and there is really 3 key components to highlight here. Two are connected to research and development and one is connected to the commercial launch.

Research and development costs, we anticipate for the year 2020 to be increasing between 35% and 40% on the P&L basis, which is actually a similar percentage as we've done in 2019 vis-à-vis 2018 as well. And therein, there is 2 elements. One is mechanical, that's the filgotinib cost share. It is going up from 20% to 50%. So as a result of that, obviously, we are increasing our R&D spend on filgotinib. And the other one is 2 investments in -- or 2 additional investments, I should say, in discovery and early development.

And finally, the third bucket of -- that's driving the increase in cash burn is the preparation for the commercial launch in SG&A expenses, which is obviously ramping up now as we are getting ourselves ready for launch in EU5 and the Benelux.

Then if I go to the next slide, I'll pass on the financials, and I'll move to the more qualitative elements of 2020 and the thing to highlight, and Onno mentioned that already, is the significant number of data readouts that we're going to be having during 2020. We're actually expecting no less than 5 patient data sets during the year. To start off with ulcerative colitis, filgotinib in Phase III, which will come in the second quarter. And then in the second half of this year, we anticipate the results of the PINTA study, the NOVESA study, the ROCCELLA study and, finally, also our first patient data set on TOLEDO.

The activity level in 2020 is increasing significantly. We are anticipating to be executing over 80 clinical trials in 2020 on more than 10 different molecules. So this includes Phase I, Phase II, Phase III plus supporting clinical trials to all of the molecules that we have in our rich pipeline.

And then finally, and certainly, least but not -- last but not least, expected approvals for filgotinib in RA in U.S., Europe and Japan will make this also a transformational year again, 2020, for Galapagos.

Let me close with that and open the floor to questions.

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

Thank you very much, Bart. That does conclude the presentation part. We are going to open up the line now to callers. We don't manage the queue at Galapagos, so I do ask that everyone limit themselves to 1 question to give everyone an opportunity to ask.

So with that Eileen, our operator, can explain what the procedure is to pose a question over the phone. Go ahead, Eileen.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We will take our first question from Dane Leone from Raymond James.

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

Congrats on a stellar year. I just wanted to get some more color in terms of some of the readouts that are coming up. Could you just provide a bit more around what depth and detail we would expect from the ulcerative colitis program as it reads out? And I guess, I'll just leave 1 follow-up. Can you provide a little bit more out of what we would see around the TOLEDO program this year? You said you would give more color in the second half of the year. But I guess, what are you hoping to entail or what type of unveil would that actually look like?

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

Dane, this is Walid. I will take your question on filgotinib. So as usual, we and Gilead have been, or actually Gilead has been leading this, the way that we disclose top line on our Phase III trials is to give the high-level picture for efficacy, but also the key safety elements, and I think that's what we should be expecting. And then the details of this will be shared at an upcoming scientific meeting.

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

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

Thank you, Walid. Dane, thanks for the question. So for the TOLEDO program 2020 is an important year. We have an extremely ambitious program to run. So -- and that will include the selection of next PCCs, and typically, we plan for more than 1. The start of Phase I for '4399 and then we plan as well to generate patient data. So we have 2 assets there running, both '3312 and '3970, and when we present or around the moment when we present the first patient data, we as well plan to disclose the target to the public. So that's what we have on the agenda for the TOLEDO this year.

Operator

We will take our next question from Rushee Jolly from Bernstein.

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

So on filgo, we're going to see the UC data in 2Q and Crohn's next year. So would you be able to talk through what you consider your internal bar for success to be in each indication? But also how you think of potential positioning with respect to the TNFs and also Entyvio?

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

I don't know if, Michele, you want to take the positioning part, and I'll take on the first part?

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

Yes, that's okay, Walid.

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

Yes. I mean, I think for us, as you know, we do not have any data with filgotinib in UC. However, we have data in Crohn's, but also we have seen how other JAK1s have performed in UC and also have their performance in other inflammatory indications like RA, PsA and AS. And if you look at the totality of the data that we have so far from Phase II and also from Phase III with filgotinib, you can expect what level of efficacy you would see that would be on top of the range when it comes to the JAKs that are being tested in that space and safety to be best-in-class, which is what we have seen so far.

So we expect that those would be the type of data that we would see in UC by sort of pegging this on performance and other indications, particularly also with Crohn's where we have very good data with FITZROY. And with that, I'll turn it over to Michele for positioning.

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

Yes. So thank you for the question. So in UC, there is still a high unmet need, so we have 1 out of 8 patients that are already treated with advanced treatment. So there's a clear need there. And as Walid indicated, so there are still questions to be addressed with the readout. But with the profile, we can see that some of these unmet needs can be addressed with a drug with like the potential of filgotinib. So on the durability of response, the safety profile, the quick onset of action, these are all needs that the patients have in UC, and we're really comfortable that we'll have a good -- very good opportunity there.

Operator

We will now move to Christopher Marai from Nomura Instinet.

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

Just with respect to your IPF programs, could you elaborate on the type of update we might get from the futility analysis for '1690 in IPF? And will it be efficacy based only or we also get some sense of safety? And then just remind us of the duration of exposure that patients will have had to '1690 at the time of the futility analysis, like what duration they've been exposed to the drug? And then secondarily with respect to your PINTA program in IPF, how does this asset compared to other GPR84 programs out there? And then how would you look at potential combinations with '1690 and/or running 1 program versus another based on success? Would you continue both programs?

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

All right. Thanks, Chris. Well, let me start with the first part of the question. So with the futility, actually, what we will be sharing is just simply whether it's a go or a no go. Just to remind you, this program is a program with 1,500 patients where the primary endpoint is after 52 weeks of treatment, however, patients will continue on whatever drug they were randomized to, placebo or active, until the last patient finishes the 52 weeks. By the time we will have the cutoff for the futility, I think we have about 1/3 of the patients who would have been exposed to 52 weeks. And probably the majority, if not all the patients, would have been recruited in the trial. It's hard for me to guess exactly the duration of exposure, but you can look at when we started, which was earlier this year -- earlier last year, I should say, we're in 2020 now, and kind of guess a little bit of where we would be.

We also, just from a safety perspective, because I think you asked a bit of a question on that. On a regular basis, we've been looking at safety, us on a blinded way, but the external data monitoring committee in an unblinded manner. And on a regular basis, we've been getting, of course, the thumbs up, keep going the way it is, and we don't have any safety signal. So I think -- I hope I answered all of your pieces around the ISABELA program, and I'll let Piet tackle the question on PINTA.

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

Okay. Thanks for the question and allowing me to shed some light on '1205. '1205 is our small molecule GPR84 antagonist, which we develop indeed in Phase II for IPF. You asked to compare to other GPR84s, so I assume you want to compare GLPG1205 with the

Prometic compound PBI-4050, I believe. We tried our best and it's virtually impossible to, on a scientific level, compare the 2 of their quite different agents. So '1205 is a nanomolar antagonist of GPR84. The Prometic is a micromolar compound acting on GPR84. That's quite clear, whether it's an antagonist or an agonist, we could not figure out in our assays. Our assays are not fitted to have a clear sensitive measurement on agonist versus antagonist. It's also a dual compound. It has dual mechanism of action, so it's very hard and frustrating also for us but also for you to understand that to compare those 2 compounds at face value because there is not a single assay where both show a result. So that is for the competitors.

Combining with '1690 is a great question. So as you know, we have a plan to really play big in IPF. We really believe patients deserve much better treatment than the ones that currently are there. And probably we'll need to build up our cocktails with one compound after the other. So indeed, it's in our mind, if the data of '1205 are as good as we hope, that at a certain stage, we can go and combine it with '1690. But there is no actual study in the planning currently because we probably first will await the Phase III data of '1690 before we start on a combination study. Having said that, as soon as we have the data on '1205 is good, we will do whatever is needed and best to bring to the market and patients as quickly as we can.

Operator

We'll take our next question from James Quigley from JPMorgan.

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

Just 1 for Michele, really. On the commercial build-out of the teams, how are you progressing? And how are you leveraging the Gilead sales force and the Gilead influence? And is there anything that you haven't got or that you need to sort of -- to progress and to move forward in order to be competitive versus AbbVie? And I also would love to get your view on the class black box warning and how this could affect the uptake across the inflammation conditions?

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

Thank you for the question. That's the first point on the commercial buildup on that. I say I'm really pleased with the progression that we're having on the buildup on our European commercial organization. And we are really attracting and keep attracting strong talent with deep expertise in the field in RA, in inflammation, in the countries at the international level. So with knowledge of the scientific community, the payer's environment, the competitive arena, and that's progressing very well, so that we'll be ready for the approval and then the reimbursement processes, the registration, the prelaunch activities. And we are doing that, of course, as Galapagos because we want to build our commercial footprint as Onno illustrated at the beginning. And we are doing together with Gilead, which is also a big opportunity to put resources together, also the different type of companies we are, as a biotech and a very established strong organization as Gilead is in the country, so that there's a lot of synergies and common learnings we can have in this process.

On your question about competition, well, I know that competition very well. I've been in this field of immunology for more than 10 years. And of course, it's something that we take seriously. At the same time, we see 2 things. There is one and still big unmet need, also in rheumatoid arthritis, still very few patients, 20%, 30% of the patients achieved a real sustained remission. So there is need there for newer therapies, better therapies. And I would say also newer JAKs in that sense. So the space is there. And at the same time, also, we want to play smart. We are building, I'd say, a strong commercial and medical infrastructure where we want to leverage the strong data we have on filgotinib, the potential best-in-class we have there, and play it smart in the payer environment, play it with a patient who can benefit most and take that a competitive edge.

Does that answer your question?

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

It does, thank you very much

Operator

We will now move to our next question from Adam Walsh from Stifel.

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

Let me add my congrats on all the success over the past year. On 1690, real quick, the Phase II in systemic sclerosis, can you just remind us what we'll be looking for when those data mature? And whether or not you think there's any read-through between any of the efficacy data points in that trial and what we might hope to see in IPF?

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

Adam, it's Walid. Thank you for the question. The -- just to kind of give a little bit of background. This is a small exploratory Phase II study in 30 patients in systemic sclerosis. It will be 6 months in duration, double-blind, placebo-controlled. We will have a 2:1 randomization on drug versus placebo. So we expect 20 patients on drug and 10 patients on placebo. The primary endpoint will be the modified Rodnan skin score. We will also look at other endpoints that are commonly used in systemic sclerosis.

We will also look at FVC, but we don't expect there to be a lot of changes because we didn't specifically select patients who have SSc-ILD. So we didn't select patients who have interstitial lung disease with (technical difficulty) in systemic sclerosis. And since we were looking at those patients, we measured FVC. So from a read-through perspective, I think there will be -- literally, my expectations are very low because, again, it's -- we're dealing with a read-through for IPF because this is a small study to give us an initial signal or foray into the systemic sclerosis space. If you've been following that space, it's really a very difficult disease. It's heterogeneous in terms of progression of the disease, but also the endpoint, which is the modified Rodnan score, is notoriously variable. And also, it goes one way in the early part of the disease and another way in the later part of the disease. So you have to be very careful when you select your patients.

So all of this is to tell you that this is our initial foray exploration into that space. We would -- obviously, if we have positive data, we would be very excited that it will determine the next step. But if the data are not positive from the perspective of a p-value that's being hit because it's an exploratory, it will still guide us to see whether we want to continue looking in this patient population and certain subpopulations in that group and things of that sort going forward.

I hope I addressed your comments.

Operator

We will take our next question from Emily Field from Barclays.

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

Yes, I was just wondering which of the readouts expected in 2020 could lead to an opt-in decision from Gilead. I'm assuming that '1205 could result in that decision. And then also, would the POC in '3312 qualify? And also just kind of on that same topic, do you expect to continue developing '3312 into commercialization? Or [well] the sign is that more be kind of used to inform the development of the rest of the TOLEDO program?

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

This is Bart speaking. Let me give you a perspective on the opt-in of these 5 and then I'll have -- ask Piet to comment on the progress on '3312 and whether we take that forward onto commercialization. So in the 5 readouts, we have filgotinib, which obviously is already part of the Gilead license. We have also '1690 for the NOVESA trial, and it's a license by molecule, so that's also already part of the alliance. And then the others, the one that is definitely a triggering clinical trial, as we call it, is '1972, the OA program, so that will lead to a decision by Gilead whether they opt-in or not. On PINTA, it's not strictly speaking a triggering clinical trial, but it might still lead to an opt-in. We'll see what that data set will bring. And finally, the TOLEDO program will definitely not be an opt-in moment that will be later on, as usual, the contract defines the opt-in to be after a Phase IIb program, and we're not there yet with the TOLEDO program.

So Piet, maybe you can comment on '3312 and the path forward there?

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

Yes. Thank you, Bart. So '3312, I always make the comparison to filgotinib, the moment we saw filgotinib as the best drug we ever sold in our models of RA. So '3312 is the best drug we've ever seen in our models for IBD. So in that sense, I'm here the hopeful guy -- that hopes that this drug can make it into market because it's simply the best. So whether we will get there, it depends on many, many clinical studies we still need to do, but good drugs typically make sure that they get to the market. So we're hopeful that we can do that.

Operator

We will take our next question from Ellie Merle from Cantor Fitzgerald.

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

Just on ulcerative colitis, curious about how you're thinking about this phase compared to the S1P1 class. If we have positive Phase II readouts this year, what do you think are the key advantages or key points of differentiation for JAKs versus S1Ps given the potential for both being orals in the space?

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

It's Walid. You broke up initially. I think I got the gist of your question, comparing the JAKs to S1P. I mean I think the S1P data that I have seen so far, there are a couple of things that actually stood out for us. One is the speed of onset. I think also by virtue of their mechanism of action, you would expect that, that it would be a bit slower. So I would imagine that there, there would be a potential differentiation for the JAKs. We've seen the JAKs work quite rapidly, and actually at the very first time, what they look at the changes in symptoms, you can see an improvement in these patients. I would imagine that would be a positive differentiating factor.

The second part, and we'll have to see, is what is the liability -- the cardiovascular liability with S1Ps. I know historically they've been plagued with questions about slowing heart rate. The distribution of these receptors in the heart are well documented. And it remains to be seen in larger trials whether we do still see some slowing of the heart rate and potential exclusion of certain portion of the population. And what would be the safety longer term will have to be seen. It's a bit too early to really comment on that part.

Operator

We will now move to Lenny Van Steenhuyse from KBC Securities.

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

Some weeks ago, we saw the first equity investment in a third-party with Fibrocor. I was wondering if we can expect these smaller participations as now a fundamental part of the future strategy looking for external innovation? And if we can expect similar deals going forward in 2020?

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

Yes, I'll take this question. This is Onno. Yes, clearly, we have said when we did the deal with Gilead that acquisitions are going to be a strategy going forward. So we are looking at opportunities out there. But clearly, we will take our time, look how it fits within our organization and in our pipeline. There will be no major, major acquisitions. There will be bolt-on acquisitions to what we currently have. We have a great pipeline. We have a great R&D organization. So it's not that we have a lack of programs. But in the areas where we are active, we're always looking at additional molecules that could complement our own efforts to build a stronger franchise. So we're always looking to the outside world and see if there are no mode of actions there that could complement our own efforts, and the Fibrocor deal was clearly in that direction. And you might -- and you can expect more acquisitions going forward.

Operator

We will take our next question from Brian Abrahams from RBC Capital Markets.

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

Two quick ones on TOLEDO. I was wondering if you could talk about any additional insights on the activity and therapeutic window that you've gained from the ongoing preclinical and healthy volunteer work that you're doing? And then on filgotinib, just curious in your level of confidence in the potential for priority review based on the voucher and when you'd expect to hear back from the FDA on potential filings, et cetera?

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

Piet here. So on the TOLEDO, we typically bring forward drugs we believe are safe and that's as far as we typically comment on the terms of safety margins with any of our novel drugs. And that's where I would like to keep it with the TOLEDO as well.

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

So the question on TOLEDO, I think we can confirm that indeed the FDA has accepted the filing for filgotinib and classified it as a priority review with the goal date in the second half of this year.

Operator

We will now move to Patrick Trucchio from Berenberg Capital Markets.

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

My question is regarding the more than 80 clinical trials in 2020. Can you frame for us what proportion of these trials are evaluating novel mechanisms and what proportion are improving on existing mechanisms? And then secondly, with the early stage pipeline broadening substantially in 2020, how many Phase II and III clinical trials could Galapagos have up and running in 2 or 3 years from now?

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

I guess we've been discussing who needs to answer this question, because it spans a bunch of things. I think we can say that those are actually -- when we say 80 clinical trials, it encompasses everything. So the trials that we have ongoing, that you're familiar with, Phase III and Phase II, plus a lot of the supporting Phase I studies, the drug-drug interactions and so on and so forth. But we mentioned this number to give a scope of the amount of work and how the pipeline is actually progressing. I don't -- I'm not sure what you mean by improving on molecules that we have. I think Galapagos has been consistently going after sort of novel mechanisms of action with all these programs that we have, and we will be seeing, over the next 2 to 3 years, I would say, upwards of maybe 20 different Phase II trials and novel indications. I think we've talked also about TOLEDO by itself evaluating about 10-plus indications that we're going to be going after.

So I think it's a very healthy combination of Phase II, evaluating new diseases, new pharmacology, plus also all the supporting Phase I studies to enable us to move these programs from Phase I to Phase II to Phase III as well, as we're moving forward.

Operator

We will now move to Phil Nadeau from Cowen & Co.

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

Just a follow-up to Brian's question on the TOLEDO program. Do you still expect to disclose the mechanism when '3312 starts the UC proof-of-concept trial at some point this year? Could you give us maybe a little bit more clarity on exactly when that disclosure will happen? And maybe could you remind us how '3312 versus '3970 and '4399 differ? What should we expect to see different between a pan-TOLEDO versus a TOLEDO 2/3 and TOLEDO 3?

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

Thank you, Phil, for the question. So I Onno promised that we will disclose the target this year, so that's a promise from us to all of the investors. So the mystery will be there for a number of months, but we will help you out of your dream there and bring you back to the reality in course of this year. That's a promise. I can spend, I think, too much time to really explain the difference between all of the different profiles. I think '3970, as I said before, is a compound that behaves well across tissues. So it has intrinsically the same

pharmacokinetic profile than '3312, but behaves much more different after oral dosing in every tissue and that means skin, joints, GI tract. '3312 is a compound which has the same mechanism of action, but really only scores well in -- scores much better in GI versus other tissues. So that's why we target this to the IBD space. (inaudible)'4399 is part of TOLEDO but [AVN1]only has the anti-inflammatory activity. It does not push the pro-inflammatory cytokines. So it's really a different compound as it's only pushing down the (inaudible) cytokine and that currently we have only a couple of diseases in mind for that compound. But that whole explanation could take more than an hour which we don't have over here now.

Operator

We will take our next question from Peter Welford from Jefferies.

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

Couple for Bart on the financial side, if you don't mind. Firstly, just on the revenues. Is it possible at all to give us some sort of split, I guess, of the EUR 238 or so, whatever split that is with regard to the other income as far as where the sources of those revenues came from during 2019 just to help us with modeling purposes? And then also just with regards to the European collaboration for the profit share, where should we think about as that launches your share of profit? Is that going to be booked as an offset to your sales and marketing expense? Or how should we think of that? And can you perhaps give us some sort of idea, I think sales and marketing expenses ticked up quite a lot in the fourth quarter. I appreciate the color on R&D, P&L expense. Is it possible to give us any insight as well into how we should think about that line, given clearly, I imagine there's quite a lot of ambition to expand, by the sound of it, the headcount there? So how should we think about that line going into 2020?

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

Peter, thanks for the questions. Let me try and give you a couple of answers. Hopefully, I'm capturing them properly. In terms of revenues split out for 2019, the revenues itself, I explained, I think, in the earlier slides, are highly driven by the EUR 670 million of the license on '1690. And then there is the filgotinib revenue recognition. In addition, there is some other income that we have, which is about EUR 50 million in 2019, which is mainly connected to grants and tax credits from the French and Belgium governments, and we have a bit of income as well in revenues from our fee-for-service subsidiary, Fidelta.

In terms of guidance for 2020, and specifically the sales and marketing line, what I've been trying to do in the guidance is to give you the 3 key drivers. So 2 of those are in R&D and represents the 35% to 40% of increase on the R&D line. The third is in SG&A, and all 3 are, let's say, of similar size. Don't want to get into more precision now because sometimes our numbers are influenced by some accounting entries here and there. They are noncash, but similar size, the 3 buckets, 2 of which are in R&D and the last one in SG&A. And that's clearly connected to indeed the build-out in the commercial infrastructure. The way we're going to be accounting for that going forward is that we have both our own expenses, which will show up in operating expenses, and we will have the share of, let's say, the profit share which will be initially the lost share from the Gilead side. So to the extent, it will become a profit-sharing -- will end up, obviously, in the top line, to the extent there will be still a loss, which is what's going to be in 2020, is going to show up in our cost of sales lines as well.

Operator

We will take our next question from Matthew Harrison from Morgan Stanley.

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

This is Connor, on for Matthew. You touched on this briefly before, but on PINTA, could you just provide some more detail on what kind of data you need to see out of '1205 to move it into further study? And then would you expect to wait Phase III data from '1690 to start a Phase III? Or would you potentially consider a combination study between the 2 as a first step?

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

Okay. Thank you for the question on PINTA. So PINTA is a Phase II study with 60 patients, so they are well balanced in terms of background treatment, where 1/3 is on nintedanib models, 1/3 on pirfenidone, 1/3 on local standard of care in countries where none of these 2 is -- none of these drugs is readily used. So we have a well-balanced study. We'll have readouts in terms of FVC, as well we have included FRI. So that will give us the sufficient readouts to decide whether it is on its own is a promising drug and whether we see that this is on its own for IPF is a promising drug, we will move it forward. Certain stage, we will, for sure, try the combination with '1690, but

that is not the first thing that we need to do next, but it's really on our agenda as soon as we have the Phase III readout of '1690 that we can start and study the combination of those 2, assuming, of course, that both have been successful to that stage.

Operator

We will now take our next question from Benoit Louage from Degroof Petercam.

Benoit Louage ***Banque Degroof Petercam S.A., Research Division - Research Analyst***

Mine relates to the ROCCELLA trial. I was wondering whether the primary endpoint on cartilage thickness would be the main decision-maker in order to go and decide to go into a Phase III or whether you would also aim to achieve a certain level of pain relief? And also maybe what the current regulatory perspective is on novel disease-modifying drugs for osteoarthritis?

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

Yes. Thank you very much for that question, Ben. Yes, indeed, the primary endpoint and the way the study is powered is to detect whether we do have a change on cartilage thickness and the medial part of the knee as measured by MRI. Of course, moving forward and getting regulatory approval would require both demonstrating effects on structure as well as on function or pain. So those endpoints actually will be looked at as part of the trial. But again, the trial itself was powered on the structural changes.

In terms of what will it take to take us to Phase III. I think, obviously, we need to see a clear effect on the structure. But also, we need to see some trend on either pain, as you indicated, or on function as well. And that's why it really is very difficult to a priori set the guidelines very clearly for this because the results could come out in very different flavors and it could very well be that certain subset of patients would have to be looked into in order to progress this forward.

This is a very huge unmet medical need. And the agency just as the scientific community and also the pharmaceutical industry are working together to figure out a path forward. Often, it's like the chicken or the egg. You almost need data of a compound that actually is able to move the needle so that you can have fruitful discussion concretely with the health authorities about what will constitute the next step forward. And that's really what we intend to do. We're working with the best academic collaborators. Our partner, Servier, is also very well versed in this space, and we will be putting our heads together and talking to regulatory authorities based on our data to figure out a clear way forward for the Phase III program.

So I hope that answers your question.

Benoit Louage ***Banque Degroof Petercam S.A., Research Division - Research Analyst***

Yes very helpful thank you very much

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

And with that, I'm afraid we're going to have to call this a day. I realize there might be some folks who had some questions that we're unable to get in. Please reach out to the IR team, and we'll make sure you get your answers. Our next scheduled call will be for the Q1 2020 results at 8:00 a.m. Eastern on the 8th of May, and we thank everybody for their participation today, and wish everyone an excellent weekend. Thank you. Goodbye.

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