

THOMSON REUTERS

EDITED TRANSCRIPT

Q2 2019 Galapagos NV Earnings Call

EVENT DATE/TIME: JULY 26, 2019 / 12:00PM GMT



CORPORATE PARTICIPANTS

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

CONFERENCE CALL PARTICIPANTS

Adam Anderson Walsh Stifel, Nicolaus & Company, Incorporated, Research Division - MD & Senior Analyst
Anastasia Karpova Kempen & Co. N.V., Research Division - Research Analyst
Brian Corey Abrahams RBC Capital Markets, LLC, Research Division - Senior Analyst
Christopher N. Marai Nomura Securities Co. Ltd., Research Division - MD & Senior Analyst of Biotechnology
Dane Vincent Leone Raymond James & Associates, Inc., Research Division - Research Analyst
Dylan Edward Dupuis SVB Leerink LLC, Research Division - Associate
Eliana Rachel Merle Cantor Fitzgerald & Co., Research Division - Research Analyst
Emily Field Barclays Bank PLC, Research Division - Research Analyst
Evan David Seigerman Crédit Suisse AG, Research Division - VP & Senior Equity Research Analyst
Graig Suvannavejh Goldman Sachs Group Inc., Research Division - Executive Director & Senior Equity Research Analyst
James Patrick Quigley JP Morgan Chase & Co, Research Division - Analyst
Matthew Kelsey Harrison Morgan Stanley, Research Division - Executive Director
Patrick Ralph Trucchio Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst
Peter James Welford Jefferies LLC, Research Division - Senior Equity Analyst
Philip M. Nadeau Cowen and Company, LLC, Research Division - MD and Senior Research Analyst
Rushee Singh Jolly Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst

PRESENTATION

Operator

Good day and welcome to the Galapagos H1 Results Conference Call. At this time, I would like to turn the conference over to Elizabeth Goodwin. Please go ahead, ma'am.

Elizabeth Goodwin Galapagos NV - VP of IR & Corporate Communications

Welcome, all, to the audio webcast of Galapagos' first half 2019 results. I'm Elizabeth Goodwin, Investor Relations and this recorded webcast and -- is accessible via the Galapagos website home page and will be available for replay later on today. So that your questions can be included, we request that you call in to one of the telephone numbers given in last night's press release. I'll give you the one for Belgium, that's 32-2404-0659 and the access code is 6080337.

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 in 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 2019 news flow we expect in the second half of the year. You'll see a PowerPoint presentation on screen. And we estimate that this part will take about 10 minutes. And this will be followed by a question-and-answer session with Bart and Onno who will be joined by Walid Abi-Saab, our CMO. And at this point, I'd like to hand over to Onno to begin the presentation. Go ahead.

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

Thank you, Elizabeth. Pleasure to have the word and talk to you about the operational highlights of the first half. Clearly, a fantastic first half on all aspects, the clinic, the commercial operations start and, of course, the deal with our friends from Gilead recently announced that I'll come back to in more detail. But let's first look at the clinical delivery over the first half. A lot of news on filgotinib where we had the excellent FINCH 1 and FINCH 3 Phase III results in rheumatoid arthritis. Clearly, a hallmark data set for Galapagos and Gilead. We also completed the recruitment in our Phase III ulcerative colitis trial as well as in Phase II trials in Sjögren's and lupus. And we're nicely on track to build our commercial organization within Galapagos for the European market where we will be operating in rheumatoid



arthritis.

In IPF, we -- after starting last year 1690 in IPF with ISABELA study, we went for the second indication in sclerosis. We started the NOVESA Phase II trial. So very nice that we went into the second indication so rapidly. And we strengthened the IPF franchise by licensing 2 compounds from -- early stage compounds from Fibrocor and Evotec.

In osteoarthritis, we completed the recruitment in the Phase IIb trial together with Servier, actually 6 months ahead of schedule, so we're very pleased with the rapid recruitment there. And we will be looking forward to the data next year on that trial. And in MOR106, we started an additional trial, the GECKO Phase II trial. That's a program we're doing together with MorphoSys and Novartis. Novartis licensed its compounds from us last year. An effort in inflammation, we were very pleased to have our first Toledo compound in the clinic. We started Phase I with 3312 and the second one is on its way to enter the clinic shortly. So Toledo is getting shape, and we believe this could be a very, very important program for inflammation going forward.

So let's look at the deal with Gilead. Of course, you've all heard about it and seen many of the details, but let's highlight some of the facts, again, in the next couple of slides. It's clearly a deal that is transformative for Galapagos and very innovative for the industry, I must say. It's the largest life science collaboration in history of the life sciences, so that's a hallmark for, I guess, also European biotech. I'm very pleased with the model where we remain independent for a very long time and get enormous amounts of funds to really go after innovation, innovation and innovation. So that is really what the focus of this deal is and that should be very good for patients going forward. It's based on our unique discovery engine especially our target discovery where we have the adenoviral collections come up with noble targets for various diseases. And then followed by very rapid drug discovery, capabilities that Galapagos has to move programs rapidly into preclinical and then towards the clinic.

But clearly, we can benefit from the expertise that Gilead has in chemistry, in developments, formulation and, of course, the infrastructure to market drugs worldwide. Clearly, we are not at all in the commercial side of business yet. We will now focus on Europe as -- for the commercial aspects of the business and leave the rest of the world to Gilead, which we believe is a very good step for us. And this will all lead to further acceleration of the current programs but also of new programs. We now plan to double our R&D efforts and hopefully come up with new mode of actions rapidly to improve the lives of patients.

And with this current structure, we have our work ahead to roll out commercial infrastructure throughout Europe and build that over the next couple of years in all the various countries so that in the 10 years' period we will be a fully equipped European biopharmaceutical company and then wander out to the rest of the world after that period of time.

Let's look a little bit about -- at the financials of this deal. It's quite complex and it's large. We got a \$3.95 billion upfront payment to do this deal. Interestingly, Gilead has no say in where this money will be spent. It's all up to Galapagos if we -- on what therapy areas we'd target but also what acquisitions we would do. There are no limitations and there's no impact from Gilead in that. They're also doing an equity investment at this point of 1.2 -- \$1.1 billion, which is at a 20% premium to the 30-day average when the deal was announced and that increases their stake to 22%. They get 2 warrants to further increase the percent to 29.9% over the next couple of years. And they received an opt-in for all the programs that we currently have for all the rights outside Europe as well as on programs that we are going to develop over the next 10 years. They pay us an opt-in fee. I'll come back to the numbers and certain milestones as well.

Also very interesting to note is that after they opt-in, they're going to pay 50% of all the Phase III cost. So we're splitting the cost worldwide, which reduces the risk of this Phase III tremendously. And we're still getting a very nice royalty on sales that they're making outside Europe between 20% and 24%.

So let's go through the specific programs details here. First, on the platform. It was very important when we talked about this deal, that there would be no barriers, there will be no secrecy between the 2 companies. So we are sharing all the targets that Galapagos is working on, also future targets that we discover, and there will be full transparency to Gilead to maximize the science collaboration between the 2 companies. We plan to exchange scientists back and forth to maximize the opportunity -- the synergy between the 2 companies. We can do it because it's very clear what happens later on when they can opt-in and not opt-in. So I think all of that is very nicely worded in the contract and I think is -- it will benefit the science tremendously.



As part of the deal, we revised the current filgotinib collaboration where we actually taking on larger part of the expenses. It's going to be 50-50 going forward as of now of the development cost, and Galapagos is getting a bigger say in the European commercialization. So in the Big 5 countries, Galapagos will have a big impact on the commercialization of filgotinib in the various diseases. For 1690, our IPF drug, we provided the license as part of this deal for all rights outside Europe. We will continue in Europe. We will market that, of course, like all the other drugs, but they will market it outside Europe. And they paid -- they will still pay a \$325 million milestone if the drug gets approved in the U.S. In 1972, it's a little bit different because that is in a partnership with our French partner, Servier, where we only have the U.S. rights unencumbered. So Gilead gets an option for those rights after the Phase IIb that's currently running the ROCCELLA trial. They will pay us an \$250 million opt-in if they want to exercise the option and \$750 million in further milestones downstream from that.

For the rest of the world, Servier has the rights and we are getting royalties from Servier on sales in the other territories. These are substantially lower than the ones Gilead is paying. Servier is single-digit royalty. It's the deal that was signed with Servier when we were at the target stage, very early stage deal. And then all other programs including Toledo and Toledo actually consists of a number of different programs. With every single program, there is an opt-in fee when Gilead exercises after -- decides to exercise after Phase II study of \$150 million. And as I said before, we'll share all further development costs 50-50 between the parties. And we're getting on all the programs, except for filgotinib, where we get royalties between 20% and 30%. For all other programs, we get royalties between 20% and 24%.

So I think this is -- these are the program highlights. And of course, these are very large numbers, hence, a very impressive deal. I think what is important, more from a holistic point of view, is that we have found a very innovative way, I think, to work together and still keep our full independence on going forward both on an equity point of view where we will remain an independent company on the stock market but also on a science point of view which is very important for us, that we can continue to do what we believe are the right things to invest in, in the science. And for the next 10 years, it's clear that we have a very close marriage with Gilead and the start has been a very good, good relationship, very high energy, a lot of adrenaline. We had actually the honor of Dan O'Day visiting Galapagos last week and talking to our staff and that went extremely positive. Deal's very well received within the company, so I think it's been a very positive outcome of 6 months of negotiations. And we're all very pleased that this is now done. Of course, we still are waiting for the competitive review in the U.S. which we expect that to end in the next 4 weeks or so and then the deal will be delivered.

With that, I would like to hand it over to Bart, who has been extremely instrumental in getting the deal together, but he can now talk about the financials.

Bart Filius Galapagos NV - CFO & COO

Thank you, Onno, good morning, everyone, in the U.S., good afternoon in Europe. Obviously, the focus of this call is to a large extent on this transaction with Gilead, but we also have to report the second quarter financials. So I'll do this with 2 slides that those of you that are following the company have seen before and they'll describe basically the French Evolution over the second quarter of this year. So the first slide there is on cash as usual. We are ending the cash balance sheet at EUR 1.15 billion at the end of June. And if you look back, you take out a couple of specific items which you always do, such as capital increases and translation effects, but then the actual net cash burn is a little more than EUR 150 million over the first 6 months of the year. And as a reminder for everyone, the guidance that I've given at the beginning of the year for total cash burn is between EUR 320 million and EUR 340 million. So the 152 that you see here on the chart is coming pretty close to 50% of that number.

So this is just to say that the cash burn over the first 6 months is completely in line with our expectations. Now, I've chosen not to change the guidance for the full year even though we all understand that the ultimate operating cash burn will be different because of the Gilead transaction, but I felt it was more relevant to highlight the underlying operational cash burn, which indeed we confirmed to be on track as per previous guidance. But then, clearly, we anticipate a significant cash in the quarter of the second half of this year, \$3.95 billion upfront in dollars and \$1.1 billion in equity stake including the premium in dollars as well.

So then over to P&L. The highlights, again, revenues are a little higher than they were in first half in 2018. This is -- there's 2 elements that are supporting that. First of all, for MOR106, we are actually recording the reimbursements for the expenses that we make by Novartis in our revenues that drives part of the increase. Secondly, we've also achieved a milestone of \$25 million in our collaboration



with AbbVie for the final completion of the FALCON study, so that's also in these numbers included in the first half year.

Operating costs are clearly higher than they've been in the first half of 2018, fully in line with expectations. And the key drivers are really the middle late-stage development expenses. And then, within that bucket, obviously, 1690 is -- its expenses are increasing significantly versus last year as the Phase III program has really come off the ground in 2019. So as a result of those 2, revenues being a bit higher, operating cost being clearly higher as well, then the net result is negative compared to first half of 2018 by about EUR 35 million, which also includes a bit of financial income and expenses.

Then my final slide to highlight what is still to deliver in terms of a key news flow over the second half of this year, and that's quite a bit. Maybe first to highlight is that we have achieved all of the guidance as we have presented in the first half of the year. As you see on these slides, with one exception of one Phase I starts that we were anticipating for first half 2019, which is now going to be first half of 2020. On the second half of the year, there is data coming on 2 more filgotinib indications. Onno already spoke about those, Sjögren's and lupus is still to come in the second half of the year. We're also anticipating the start of the Phase III program in psoriatic arthritis. And obviously, a key event for filgotinib are also the filings in Europe and the U.S. They'll be [anticipating] in the second half of this year.

In fibrosis, we will have our PINTA study with 1205 fully recruited by the end of the year. And we already achieved, ahead of schedule, the ROCCELLA study fully recruited and on MOR106 there is one specific Japanese study that we're starting in the second half of the year. And then there's quite a bit going on also with the earlier programs in Phase I. We anticipate top line data Phase I for our first-generation Toledo compounds. That's going to be something to look out for in the second half of the year, clearly. But we're also starting to further Phase I's run within noble agents 3667 and with a -- what we call a second-generation Toledo compound 3970 as well. And then finally, we hope by the end of this year if Phase I allows, we hope to start a proof-of-concept with our first Toledo compound in IBD with 3312.

So that's with regard to the news. There's still a lot to come in the second half of the year. And then, as the year progresses, we'll start giving also some guidance as to the key data events -- the numerous key data events, I would say, in 2020 that will come in the next 12 months. So with that, I'll stop. And give the word back to Elizabeth to lead us through the Q&A.

Elizabeth Goodwin Galapagos NV - VP of IR & Corporate Communications

Thank you, Bart and Onno. That does conclude the presentation portion of the call today. (Operator Instructions) I'd like to ask Jenny now to connect us to any callers who may have questions for our executives.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And we'll hear first from Rushee Jolly of Bernstein.

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

Rushee Jolly, Bernstein. Firstly, on cost-price, the Gilead deal. I mean you already outlined that you intend to hire commercial operations in Europe. So how should we think about the level of incremental sales and marketing spend? And maybe what time period can we expect saving for this? And likewise, for R&D as well.

Bart Filius Galapagos NV - CFO & COO

All right, Rushee, let me take that. Bart Filius speaking. First of all, on the commercial cost, maybe good to highlight to everyone on the phone that the economics of the filgotinib structure have not changed except for the development cost here. So we're still in Europe sharing all expenses 50-50. So to the extent that we are incurring further expenses on our P&L as opposed to on the Gilead P&L, it will be shift in line items compared to previous guidance. So it's not going to be the commercial cost, I think, which is going to be the key driver for increasing in cash burn. On the other hand, we do anticipate, as Onno was speaking to, a significant increase in our research and development costs. This will not be from one year to the next. This will be a gradual increase over the next couple of years. First of all, we all know that it will take a bit of time to get to this doubling of infrastructure both in terms of people and fixed infrastructures, that will take a couple of years. And at the same time, obviously, a large element of our expenses in development is depending on the actual results that we achieve. So where we do see increases next year and more detailed guidance will come over the next, let's say, 6 months.

But where we do see meaningful increase next year is in development cost regarding the Toledo program, which we were anticipating, by the way, already independent of the year -- of the Gilead transaction. I hope this clarifies a bit the question, Rushee.

Operator

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

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

Just one on your new -- large cash balance. So how do we ensure that you're basically really going to be using this to generate shareholder value? What are your strategic priorities in terms of spend aside from increasing R&D?

Bart Filius *Galapagos NV - CFO & COO*

Yes, thanks for the question. Bart again. So clearly, our priorities are indeed on the research and developments. For now what we've said is that we are intending to double those investments in innovation and that it will take a couple of years to materialize. We actually are inviting you and others here on the phone also to attend our R&D day on 14th of November of this year, where we're planning to give some further details on our plans for the next couple of years. But obviously, we will maintain our same threshold, our same focus on high-quality innovation in Galapagos, as we have demonstrated over the past couple of years going forward as well. So we're not in a hurry to work on this, other than that we want to make sure that it is invested behind the right and the good ideas for true innovation for patients. And in terms of track record, let me add then also that we have been able to do this very successfully over the last 3, 4 years as well. Our cash expenses have also doubled in that period and even more than doubled. So there's ample opportunity, I think, from within our own company to invest in R&D and make sure that the cash balance is used in a wise fashion.

Operator

And -- so we'll go next to our question from Emily Field of Barclays.

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

I was just wondering if the FDA thus far has seen any of the preliminary data from the MANTA studies. When you expect the MANTA and MANTA-RAy to be fully enrolled? And if you expect you will need this full data to file assuming the SELECTION trial is successful?

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

This is Walid. I'll take your call. Good morning, everybody, in U.S. and good afternoon, for the rest. So regarding the meeting with the FDA, we did have a discussion with the FDA including all the FINCH data and the available MANTA data, which were blinded. So there was no unblinding of the MANTA study and that formed the basis of the discussion that Gilead actually led with the FDA. At the end of that, we agreed that we can move forward and file in the U.S. regardless of the MANTA study. Of course, we will include all the data available from MANTA, from all the other open label also studies that are ongoing, but the completion of the MANTA program will not be needed prior to filing. And I believe you asked a question about SELECTION and I don't think that, that was a subject of the discussion, but I don't think this will be necessarily treated any different than the program in RA because in the end, we are generating more data by that time.

Did I answer your question? I'm not sure if I captured all the pieces of your question.

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

How enrollment is going since the addition of the MANTA-RAy study?

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

Right. So we have not been guiding on this. Gilead is going to be taking the lead and sharing information. But to a great extent since MANTA is not on the critical path for filing, I believe this is essentially not critical information to guide for this. But I can assure you that recruitment is going up more on the side of MANTA because we increased the size as we talked about and with discussions with the FDA we increased the inclusion/exclusion criteria, modified them to be able to allow us to recruit faster. And also MANTA-RAy with the engagement -- with the number of sites, so we will be seeing this, but we're not providing any specific details on this.

Operator

And we will go next to Brian Abrahams of RBC Capital Markets.

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

Congrats again on the Gilead deal. Continuing on filgotinib, what are your latest expectations on a potential label relative to competitors in RA from an efficacy and safety standpoint? Any compromises you might expect on the label that has enabled filing before the completion of MANTA? And how much can be interpreted from blinded -- on safety from blinded sperm counts?

Walid Abi-Saab Galapagos NV - Chief Medical Officer

Yes, thanks, Brian. So, look, we've been very pleased with the results of the FINCH program. I think we've been saying this for a long time, that our highly selective JAK1 profile for filgotinib is going to translate into a very beneficial risk/benefit profile and that materialized. And from there to sort of specifically speculate on what the label would look like, I think that would be quite premature. I think that, that is a review issue that the FDA will have to weigh in on, of course. And I cannot sort of put the cart in front of the horse in that case. In the event of the MANTA and evaluating the blinded data, I think that would give you a general sense of certain changes that you would see whether it will make you feel more or less comfortable. Again, I don't want to go into the details of this, but suffice to say when the data from the blinded MANTA program plus the totality of the FINCH program were discussed with the FDA, we felt comfortable that we can move forward and file in the U.S. this year still.

Operator

And our next question comes from James Quigley of JPMorgan.

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

Just one quick one on the JAK1/TYK2, which was discontinued. Is TYK2 still a mechanism that you look to develop drugs for? Especially given that the (inaudible) drug is progressing relatively rapidly. And I believe that's all.

Walid Abi-Saab Galapagos NV - Chief Medical Officer

Yes, thank you, James. Yes, TYK2 is an area that we're interested in developing compounds in this area. And as you've been -- as we've been saying for a long period of time, having also our own JAK1 which is very advanced, that filgotinib offers an opportunity to consider combination treatment which would really enable us to address key unmet medical need in these indications. Just keep in mind how much more improvement is needed in these patients. I remind you, we talk about ACR50s of around 40% or 50%. ACR70s at around 20% or 30%. Those numbers should be ACR70s at around 70% or 80%. There's a huge room for improvement. Combination therapy with filgotinib is an important strategy. Toledo will be also a very important strategy for us to achieve those goals and that's what we're striving towards.

Operator

And our next question comes from Ellie Merle of Cantor Fitzgerald.

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

Congrats on all the progress. Just one on sort of your M&A and PD strategy. Given your very strong cash position now, can you just elaborate a little bit on how you're thinking about this? And I guess what therapeutic areas or modalities you think would complement your discovery efforts?

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

Yes, this is Onno here. I'm happy to answer your question. It's clear that we will be on the lookout for compounds that could complement our portfolio. Clearly, fibrosis, inflammation remain important, but we will be expanding the therapeutic areas with our internal research. Well, we're already doing that, we will accelerate that expansion and diversification. And clearly, we will also be looking for compounds in those areas as well. Don't expect any major acquisitions for now. But most likely there'll be more compound licenses. And maybe technology platforms as they really complement what we currently have internal. So we're -- there will be a busy time ahead for us.



Operator

And we'll go next to Peter Welford of Jefferies.

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

I wanted to ask about your earlier preclinical Phase I type and drug discovery efforts. Firstly, I guess, just with regards to discussions with Gilead, were there any particular new areas they wanted you to increase efforts in perhaps? Or any disciplinary agreements reached in spot areas that they would like to see you move into. And I wonder about 3667, is that a brand new class or is that similar to any of the drugs that you already have within your pipeline?

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

I'll (inaudible). There has been no pressure or not even mentioning by Gilead of areas of interest for them to go into. That's really clear from day one that, that's off limits. We determine what we think are the right areas to focus on. And they only have information rights. So we're going to inform them regularly on what we're doing, but they will not be able to influence our program. Walid?

Walid Abi-Saab Galapagos NV - Chief Medical Officer

And this is Walid. So for the study 667, I -- we're not disclosing the target today. But what I can tell you that it is not a backup compound to any compound that we have in our pipeline. So I think it's safe to assume that it's a new pharmacology.

Operator

And we go to our next question from Matthew Harrison of Morgan Stanley.

Matthew Kelsey Harrison Morgan Stanley, Research Division - Executive Director

I guess for me, just a question broadly on Toledo. I think, Onno, on the Gilead call you suggested you're planning to start, I think, 10 Phase II study sometime next year and going to have a very broad effort towards finding the potential areas in that program. Can you maybe outline for us what you think is important about the Phase I data and how this will get this year? And then when you might start to disclose some of the indications and the breadth of that program?

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

Yes, this is clearly, Walid, in a better position to answer. So Walid?

Walid Abi-Saab Galapagos NV - Chief Medical Officer

Thank you, Onno. Look, I mean, we've said -- we've identified this area a couple of years ago, and we were very impressed with the data that we've seen. Pre-clinically, we decided to invest heavily in it from a chemistry and biology. We view this program as a new platform that's going to make us -- give us the opportunity to address a number of unmet medical needs. And as such, we are advancing these programs -- these various molecules forward with a various level of selectivity for certain subtypes. If you think of them as a JAK, JAK1, JAK2, JAK3 so on and so forth. And there's a huge element of learning from the clinic that we're going to take back to the lab to help us inform what's going on. And it's in the same spirit that when we go broadly into indications, in the inflammation space and perhaps fibrosis as well, that we want to sort of learn and adjust the best molecule with the best selectivity to the target indication.

So what we learned from Phase I, first, the most important part of us -- part of the learning in Phase I is about the safety and the tolerability of these compounds. So that's why we're very excited that we're able to get into clinic and we're advancing forward. So by the end of the year, we share more information about it. But there are also certain pharmacodynamic endpoints that we're including in these trials to also guide us about sort of which type of cytokines might be affected, and so on and so forth. But it's very important that you think of this that we're taking a really large approach, a platform approach, where these molecules are going to be informing each other and guiding the subsequent development to be niche towards the best indication that will address the most important unmet medical needs, but also to help us to speed up development by learning from compounds that are more advanced to influence the ones that are going -- that are coming -- [that are here].

Operator

And we'll hear next from Anastasia Karpova of Kempen.

Anastasia Karpova Kempen & Co. N.V., Research Division - Research Analyst

Quick question. On coming (inaudible) Sjögren's, can somebody please explain what made you comfortable growing in this indication, given that JAK is not directly related in the pathology and in modulations of (inaudible) indication that haven't been any (inaudible) drugs

Walid Abi-Saab Galapagos NV - Chief Medical Officer

I'm sorry, I didn't quite catch. You're going in and out, but I'm assuming you're asking about what is the rationale for why we went into Sjögren's syndrome. Is that what you're saying?

Anastasia Karpova Kempen & Co. N.V., Research Division - Research Analyst

Yes. And how comfortable are you with the positive outcomes?

Walid Abi-Saab Galapagos NV - Chief Medical Officer

Well, look, I think, the preclinical data that we had convinced us that this is an indication that we have a likelihood that we could work. Of course, in that indication there's still a significant unmet need and the nature of the Phase II study that we put in place was maybe more exploratory, just as you said, because it's not as well formed and advanced, say, for example, compared to ankylosing spondylitis or psoriatic arthritis. So the nature of the Phase II study is more exploratory to cast a wider net and look at various end points to see where we need to go next. As we indicated, the results will be shared in the second half of the year. And we will use that information to guide what would be the next step and whether filgotinib is going to be able to address an unmet medical need in Sjögren's syndrome, to take it forward.

Operator

And we'll hear next from Dane Leone of Raymond James.

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

Congratulations on the update. And since I was not on last call, congratulations on Gilead deal. So the one question for me, maybe a bit of delayed question, but it's one that's been percolating quite a bit within the investment community here in the U.S. When you look at some of the complicated programs that you and Gilead are going to tackle such as the Toledo program, a lot of people have been debating whether it's a fair comparison to the complicated algorithm that was the CF program that your team undertook in partnership with AbbVie. And the question comes out is how are you structuring some of the decision-making here between the 2 teams because what we saw with that AbbVie partnership that somewhat dissolved over time -- I know the back story's a little bit more complicated, but there -- it seemed to be finally come down to a difference of opinion on how to accelerate some assets from early testing to later testing between the 2 teams, and ultimately, the conflict resolution had to occur. So just from a high-level, how are you thinking about managing that type of conflict resolution, when you have these complicated programs like Toledo and other ones, presumably, that will occur over the life of this partnership?

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

Yes, that's a good point. This is Onno. It's completely different than in the previous collaboration with AbbVie, where it was a complicated decision-making and conflict resolution. Here, it's quite simple that we have final say on all aspects with regard to the programs until the end of Phase II. The Phase II -- the final Phase II has to be a qualifying Phase II for Gilead's exercise its option -- to decide to exercise the option or not. If they exercise the option, then it's going to be a joint collaboration. And there's a clear dispute resolution described in the contract with the final say ultimately related to the territory. So we will always have final say on Europe, and Gilead will always have final say after they exercise the option in the territories outside Europe. And that makes it all quite a bit more clear and straightforward to exercise. So ultimately, that could lead -- it's not desired, but it's a possibility that we would do a separate European Phase III if we have, by example, a major issue with Gilead on how a Phase III would be designed worldwide or the planning of that Phase III. So that's all being discussed, and we think it's very elegantly resolved in the contract that we have signed.

Operator

And we'll hear next from Graig Suvannavejh of Goldman Sachs.



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

This is a question about bD. Given the company's traditional focus on small molecules and you talk about platforms that you're looking at, can you just give us additional color? Are you looking at, say, biologic approaches or (inaudible). Any color there on the platforms you're looking at.

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

Well, it's not our of first priority to see if we can get the live molecules into our platform or in our pipeline, but also not excluding it at this point in time. It's still very early days. We have to sit together with the teams and see what makes best sense to move forward. But clearly, we will be looking at new areas for Galapagos, including RNA, which seems to be a very attractive area to expand into. So we will be open for various different technologies to enter the research engine of Galapagos.

Operator

And our next question comes from Christopher Marai of Nomura Instinet.

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

Just number one on capital allocation. I was wondering if you could comment on any interest in potentially reacquiring rights to some of the compounds that you currently have collaborations or partnerships around, obviously, outside the Gilead collaboration. And then secondly, maybe Walid can help us understand what the target is for Toledo.

Bart Filius *Galapagos NV - CFO & COO*

Maybe I'll take the first question, Chris. It's Bart speaking. So on your capital allocation. No, that's not on the agenda to look for reacquiring certain rights that we previously licensed. I think everything that's been licensed to third-party has been out for good strategic reasons more than anything else. So that's not on the agenda. The Toledo target question, I'll hand it over to Walid for that, I'm sure the answer is going to be relatively short. Walid, you want to comment this one?

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

Well, thank you, Bart. I think you could have answered it. Look, we're not sharing the target for Toledo. We've been saying this. It's important for us to do this for competitive reasons. And our objective will be or our plan will be to do it sometime when we start our numbers -- multiple Phase II trials, as we said previously.

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

The Toledo target, that is?

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

I'm sorry I didn't hear what you said, Chris.

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

Does the R&D day in November make sense from the perspective of releasing the Toledo target, that's my last question. Congrats on the collaboration.

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

Yes, thank you Chris. No, I think it will be more in next year sometime after we start our Phase II trial with -- multiple Phase II trials at the same time. That's been our target.

Operator

And our next question comes from Pasha Sarraf of SVB Leerink.

Dylan Edward Dupuis *SVB Leerink LLC, Research Division - Associate*

This is Dylan Dupuis sitting in for Pasha. Just two quick questions. Number one, are you going to be bringing in-house any discovery programs or discovery targets that Gilead is currently working on? And then number two, how does your plans to expand your R&D, how does it impact your previously stated goals for bringing x amount of compounds through different stages of development?

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

I'll do the first part. Yes, there is a possibility that Gilead -- or is likely that Gilead is working on similar programs that we have programs on. We haven't checked it yet because we're still in a period that we cannot share that kind of information, but we'll do that immediately after the conclusion of the transaction. And if there's an interest to join efforts on programs, we will do that. There's also possibility that they will continue independently, but both options are described in the contract. So it's very well possible that we will jointly work on a program that Gilead already has efforts on.

Bart Filius *Galapagos NV - CFO & COO*

Yes, I'll take the second part of the question. And I think this is also one that -- to discuss in more detail on the R&D day in November. But clearly, if we are going to invest more in our discovery platform and programs, we would anticipate higher output also from those program. So previously, we've always guided for 3 preclinical candidates every year coming out of our discovery efforts. And yes, you should expect this number to go up, clearly, if we are increasing our investments here as well.

Operator

And we'll hear next from Phil Nadeau of Cowen & Company.

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

Congratulations on the progress. First, on the Sjögren's and CLE data that we're going to see for filgotinib in the second half of the year. Given that both of those have a variety of symptoms, can you give us some sense of what data would serve as proof-of-concept, kind of what changes on what endpoints? And briefly, just a housekeeping item, do you have any sense of how the upfront is going to be accounted for? Is it going to be amortized? And if so, over what period?

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

Yes, I think for those studies, again, I think I mentioned this a little bit before. We were being a bit more exploratory. Gilead has done -- and I say "we", I used the joint "we". So we're looking at various endpoints. For cutaneous lupus, the endpoint itself for cutaneous lupus is actually a typical endpoint we would look at. I'm sorry, I can't remember on top of my head, to be honest with you. But we're also looking at other manifestations of lupus that some of these patients will also have. So again, those studies tend to be more exploratory in nature, that we're looking at virtually all things that we can look at that would be affected in this disease with the idea that this will guide the next study which could be either Phase II or Phase III depending on how robust the data and how convinced we are with these findings. Off to you, Bart.

Bart Filius *Galapagos NV - CFO & COO*

I'll take that one, Walid. On the upfront accounting, I feel, yes, that will be amortized over years. Basically, it's going to be spread out in different buckets. There's parts of the upfront that will be allocated to 1690. There will be parts allocated to the platform, to other molecules, to filgotinib. So it's a relatively complicated exercise. At the end of the day, what I expect is that we will have roughly 15% to 20% recognized in one shot in the 2019 accounts. And the remainder being recognized over the period of the collaboration, so that's a 10-year period with some fluctuations over years. We'll be a little bit more in the early years and then winding down towards the later years. I'll give full details on that in our Q3 call in October, once we will have closed the transaction and then also finalized the accounting of that transaction. But this gives you an idea as to how we're thinking about this at this stage and then full clarity will come in a couple of months.

Operator

We'll hear next from Adam Walsh of Stifel.

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

On the ROCCELLA Phase IIb trial with the 1972 in osteoarthritis, that enrollment's now complete. Are the primary endpoints a reduction in cartilage loss by quantitative MRI? I'm just wondering what results would be considered positive or sufficient to trigger Gilead to opt-in? I think those results will be coming in about 12 months now. Can you give us a sense for kind of what the thresholds there are? That will be great.

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

Adam, this is Walid. So as you've correctly indicated, that trial, the primary endpoint, is a reduction in cartilage loss as measured by MRI at the same time -- over a 12-week -- 12-month period. At the same time, we're looking at the usual suspects, the WOMAC with all its subscales. Also measures the [pain], the patient's assessment, looking also at joint space narrowing by x-ray, not expecting also that this trial with the size that you would be able to see something on a joint space narrowing, but still those would give you directionally where things are heading. There are no specific discussions with Gilead as to its threshold that will make them opt-in. Actually, that -- probably question is more appropriate to ask Gilead than us. What it would look like and their opinion. But look, this is an area of high unmet medical need and there's a very high potential reward financially if things move forward. There's no treatment to modify the disease. And Gilead is very, very excited about this program as are we. And when the data become available, we'll be sitting together poring over it. And I think the decision whether or not they opt-in is probably better asked to them and not to us.

Operator

And we'll go to our next question from Patrick Trucchio of Berenberg Capital Markets.

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

My questions regarding filgotinib in Europe. Can you remind us how we should think about the necessity of the MANTA studies and data in the EU filings? And when in 2020 we should anticipate the potential launch in RA in the EU?

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

So we've talked about the filgotinib filing in Europe. That's now discussions with EMA. There was no need to have the result of the MANTA trial before we file. So the plans for filing in the EU is in the second quarter and probably the earlier part of the second quarter, if I can be a little bit more specific. And then with that, one will expect launching sometime next year probably in the second half. Bart?

Bart Filius *Galapagos NV - CFO & COO*

Just I thought I heard you say second quarter. Third quarter is what filing right, Walid?

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

I'm sorry, I meant -- sorry -- yes, yes. I meant second half, sorry.

Operator

And at this time, there are no other questions in the queue. I'll turn the call back to our presenters.

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

All right, thanks, everybody. This does conclude the call today. Our next scheduled call is going to be the third quarter 2019 results on the 25th of October. We thank all the callers for their support and participation and wish everybody a very happy summer. Thank you, bye-bye.

DISCLAIMER

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.



JULY 26, 2019 / 12:00PM GMT, Q2 2019 Galapagos NV Earnings Call

In the conference calls upon which Event Briefs are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT BRIEFS REFLECTS THOMSON REUTERS'S SUBJECTIVE CONDENSED PARAPHRASE OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT BRIEF. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2019 Thomson Reuters. All Rights Reserved.

