REFINITIV STREETEVENTS

EDITED TRANSCRIPT

Q3 2021 Galapagos NV Earnings Call

EVENT DATE/TIME: NOVEMBER 05, 2021 / 12:00PM GMT

CORPORATE PARTICIPANTS

Onno van de Stolpe *Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO*
Bart Filius *Galapagos NV - President, COO & Member of Management Board*
Piet Wigerinck *Galapagos NV - Chief Scientific Officer & Member of Management Board*
Walid Abi-Saab *Galapagos NV - Chief Medical Officer & Member of Management Board*
Michele Manto *Galapagos NV - Chief Commercial Officer & Member of Management Board*
Sofie Van Gijsel *Galapagos NV - Senior Director Investor Relations*

CONFERENCE CALL PARTICIPANTS

Dane Vincent Leone *Raymond James & Associates, Inc., Research Division - Research Analyst*
Ernesto Luis Rodriguez-Dumont *Cowen and Company, LLC, Research Division - Research Analyst*
Jason Matthew Gerberry *BofA Securities, Research Division - MD in US Equity Research*
Matthew Kelsey Harrison *Morgan Stanley, Research Division - Executive Director*
Peter James Welford *Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst*
Rosie Turner *Barclays Bank PLC, Research Division - Research Analyst*
Stephen Lanpher Mallon *RBC Capital Markets, Research Division - Senior Associate*
Jeroen Van den Bossche *KBC securities, Research Division - Research Analyst*
Wimal Kapadia *Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst*

PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and welcome to the Galapagos Financial Results Q3 2021 Conference Call. (Operator Instructions) And just to remind you all, this conference call is being recorded.

I would now like to hand over the call to Sofie Van Gijsel. Please go ahead.

Sofie Van Gijsel ***Galapagos NV - Senior Director Investor Relations***

Thank you, operator, and welcome all to the audio webcast of Galapagos' Q3 2021 results. I'm Sofie Van Gijsel, Investor Relations, representing the reporting team at Galapagos. A replay of this webcast is accessible by the Galapagos website home page and will be available for download for replay later on today. I would like to remind everyone that we will be making forward-looking statements during today's webcast. These forward-looking statements include remarks concerning future developments of the pipeline and our company and possible changes in the industry and competitive environment. Because these forward-looking statements include 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 President. Onno will reflect on the operational highlights, and Bart will go over the commercial and financial results as well as the expected newsflow for the year. You will see the presentation on screen. We estimate that the prepared remarks will take about 20 minutes. Then, we'll open it up to Q&A with Onno and Bart, joined by the rest of our management group.

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

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Thank you, Sofie. Good day, everybody. Thank you for joining this webcast. You already experienced and heard the changes. We have a change in IR as well as in leadership. This will be the last webcast where Elizabeth will be part of the Galapagos team and Sofie is taking over. And also, this will be the last webcast where Piet Wigerinck, our CSO is present. So I would like to thank both of them for their fantastic services over the years and their contribution to building the company to what it was. It has been a fantastic journey and an honor to work with you guys. Thank you very much.

Let me give you a short Q3 update, if I can get the next slide. We reported positive Phase 1b data with our TYK2 molecule in psoriasis. We are excited about this mechanism and about our molecule. We're planning for 2 Phases 2b next year in psoriasis as well as in ulcerative colitis. So we're moving forward with that one.

We reported biological activity in our SIK program with '3970, both in UC and psoriasis, although we also had a disappointment in RA, where we didn't see any activity. It's clear that we are unlocking a new mechanism for the treatment of inflammatory diseases. We still have 1 trial going in Sjögren's disease that will read out next year. And we are busy in research to come up with new SIK molecules with specificities to tackle the problem of the activity in these diseases.

Good news that after quite a long time, the DIVERSITY trial is fully recruited. That's the Crohn's disease trial with filgotinib that is in the Phase 3 and that will read out next year. And then, we're very pleased with the positive CHMP opinion on filgotinib for ulcerative colitis and we're expecting any day now the approval by the EU for filgotinib in ulcerative colitis in Europe.

In the meantime, we are launching filgotinib, Jyseleca in Europe, that launch is on track, and we will be reporting the sales of the first months, and Bart will give more view on that, and you can ask questions to Michele later in the Q&A regarding the start of the commercialization in Europe by Galapagos. And as you know, we are in full recruitment action regarding a new CEO and a new CSO, and that is ongoing. We got good candidates, both in the for the CEO as well as the CSO, identified. Clearly, the CSO candidate will only join after the CEO has been appointed or at least been announced. So a little bit of patience there is necessary.

If we go to the next slide. We are very pleased that we have taken over all responsibilities regarding the Crohn's disease trial with filgotinib, the DIVERSITY trial from Gilead. It's good for Galapagos to be in the driver's seat here and to move this program forward. The details are that we got a payment of Gilead of EUR 50 million for this handing over of the trial. And also importantly, we were able to negotiate a reduced royalty rate of the sales that we have to pay to Gilead in Europe of 5.6% to 10.5% on all indications of filgotinib. So also in RA as well as in UC when filgotinib gets approved in Crohn's disease. So that's an important achievement for Galapagos. Gilead remains responsible for all commercial activities outside Europe, and we have taken over the majority of all the commercial activities in Europe, and that will finally be finished by the end of the year.

So if we go to the pipeline in the next slide. You see -- the problem that we are having in the pipeline, you see filgotinib advanced to commercial filing with UC, Phase 3 with Crohn's disease. But after that, we have a big gap with the rest of the pipeline after the failures we have had earlier in the year in IPF and in OA, but we now have an earlier-stage pipeline with programs in Phase 1 and Phase 2. It's very promising, but we need to progress these molecules towards the later stages as soon as possible. You see the SIKs here, the TYK2 that already was mentioned. We have, in fibrosis, very exciting molecules that are still very early, but hope to make a big difference there. And then, we have one program in kidney disease that is currently in Phase 2a, which is a CFTR molecule that Galapagos developed.

So we are moving forward to our pipeline, but we will need time to progress that to the later stages and therefore, filling the gap with BD is an important one, objective of the company, and Bart will discuss more in that respect.

With that, I would like to hand it over to our President and Chief Operating Officer, Bart Filius.

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Thanks, Onno. Good morning, everyone, in the U.S., good afternoon in Europe. I'm pleased to say a few words about the commercial performance of Jyseleca in Europe, as well as on the financials, including some update on our cash burn guidance, that I'll speak to in a few minutes.

But first of all, Jyseleca in Europe, we are very pleased with how the launch is going in rheumatoid arthritis in Europe. Here on this slide, you see a view on sales, which is actually a combined view of the sales booked by Gilead and Galapagos, which we felt is the best way to show the performance of the products in the markets in Europe. So in gray, the sales are booked by Gilead, in orange, the sales are booked by Galapagos, and that represents basically the handover of the commercialization efforts and the supply chain efforts from Gilead to Galapagos. A big chunk has happened in June, July and more to come by the end of the year. So they're still a little bit flowing through the Gilead P&L, but the vast majority is now on the Galapagos side in orange.

As you can see here, the curve is going up quite nicely. In June, July, there was an exceptional stocking. If you basically subtract roughly EUR 1 million in June and add it in July, you see the curve lining up towards the September numbers. That's because of the handover in Germany specifically, we've made sure that the product was in good supply at the level of the wholesalers. Doesn't really affect at all our

economics because, obviously, we are still sharing 50-50 all the profits and losses with Gilead in 2021. So a nice curve upwards. Total EUR 16 million year-to-date, of which EUR 6 million is booked by Galapagos, and we're happy with that trajectory.

Then, maybe on the next slide, a bit of perspective on the markets. First of all, this is EU5 on the left, where we see the split in the RA market between the Anti-TNF class, the JAK inhibitors and the other biologics. And we see a nice 17% share of the JAK class and still growing and that's indeed, across the 5 key countries in Europe. And then, on the right, it's a graph that we've shown also when we did our Q2 results in August. The growing market share of Jyseleca. This is specifically in Germany. In all of the other countries, it's really too early days yet in France and the U.K. We launched, I mean, I think it was June, July, and Italy and Spain are just now going to be launched. So this is really focusing on our performance in Germany, where we're now clearly ahead of 4% of share of the dynamic markets. So those are those patients that are eligible for new prescriptions because of either switches or patients that are naive to therapy. So growing market share there, and we're pleased with that position.

Also qualitatively, on the next slide, we do our own market research, obviously, where we are trying to see how the product is perceived, both in terms of efficacy and safety. And we are really happy to see that despite the fact that we are in many countries just literally months into the marketplace. Across the EU5, we are really among the other JAKs in terms of efficacy and in terms of safety as well. So really being perceived at par with molecules that are -- that have been in the market 3, 4 years earlier. So we're also happy with what we see in terms of the perceptions on the products.

Then, on the reimbursements, we see progress as well, and we're hoping to finalize the key parts of reimbursement this year. We're now in 14 different countries. That's all in dark green. There are some procedures still ongoing, as you can see here, Germany and Denmark. And there are some submissions to be done still. But the key countries are there. The EU5 is there, the Nordics, the Belgium and the Netherlands, Benelux countries are also fully reimbursed. So we're now fully ready to roll with RA, with Jyseleca going forward. And maybe lastly, also worthwhile mentioning is that we have signed a contract with a third-party distributor for Eastern Europe, Portugal and Greece, which we felt was the most operational savvy and economically logical thing to do for the promotion of Jyseleca in those territories.

Then, a bit on cash. We have an acceleration to report on our savings program. You've seen the press release, we are reducing our cash burn by EUR 50 million, coming to a level around EUR 550 million range between EUR 530 million and EUR 570 million, and we were coming from a range between EUR 580 million and EUR 620 million. And as a reminder, that was already a reduction compared to what we had initially announced in the year when we were still more in the area of around EUR 680 million. So the big driver here is our cost reduction program that we've started to implement as of the results of the ziri setback earlier in February. And initially, we had anticipated that we would materialize this year, about half of that program or EUR 75 million. We're now adding another EUR 50 million to it. So we're making really good progress on that front in cost savings.

Another word here on this slide, still, it's a slide that I've shown before, but I'd really like to emphasize how our cash burn is split up. Because on one hand, there is the R&D investments, around EUR 350 million currently. And on the other hand, there are the Jyseleca investments, and these are fully loaded costs. So that includes the sales and marketing expenses, but also G&A expenses and also the cost that we're running for the trials, such as DIVERSITY and all the long-term extensions on the initial trials.

And we obviously anticipate to make the Jyseleca franchise breakeven in 2024. So the way to look at this from a cash burn point of view as the company is progressing is that all things being equal, which we know they're not going to be, but all things being equal, the R&D side and Jyseleca being at 0 cash burn in 2024. We should be able to significantly reduce our cash burn annually. And then, if you go to peak years '27, '28 for Jyseleca, where Jyseleca as anticipated to contribute significantly to our cash inflows, we should be able to significantly reduce our cash burn further. So we're in very good shape, I think, from a cash burn point of view, also on the medium and long-term.

Then a few words on the actual results. First, on cash, EUR 377 million is our cash burn for the 3 -- for the 9 months, leading up to the end of September. As usual, we exclude specific items, such as the currency and the Fidelta proceeds and a little bit on warrant exercises as well, and our total cash balance stands at EUR 4.9 billion at the end of that quarter.

On the key financials, more details obviously to be found in the reports. I'm also happy to take any further questions, but it's not highly eventful in terms of key financials. Perhaps a quick word on revenue recognition. That's slightly more complicated this quarter as we had the DIVERSITY amendments. It's a bit technical, but frankly, what happens is that we are adding budgets to our total development costs for filgotinib. And as a result, the way we account for this on the IFRS percentage of completion is going down. And technically, as a result, our revenue recognition for the quarter was therefore reduced. And that's a one-off effect that you see in Q3. That's why we're a little lower than our run rate of revenue recognition that you've seen in earlier quarters, but that should be moving forward going to the normal levels.

And as those budgets evolves, as a reminder, if we are able to reduce our spends on our development budgets, we would actually get a positive effect on revenue recognition here. Because overall, there are still EUR 700 million on our balance sheet in terms of deferred revenue for filgotinib next to the EUR 1.8 billion that is on our balance sheet in terms of deferred revenue on the rest of our platform. And that all combined EUR 2.5 billion is still to be recognized over the next 8 years.

There are sales and royalties on Jyseleca revenues as well. Operating costs are flat versus where we were year-to-date Q3 2020. That is basically, on one hand, an increase on the commercial and G&A expenses. On the other hand, it's a decrease in the R&D expenses. Last year, we were ramping up throughout the year, in terms of expenses. This year, we're ramping down, but as a net-net results, we're more or less flat versus 2020. And then, to get to the net loss, we this time have a financial income gain in currency. And we have obviously the Fidelta disposal that we took in January as well.

Moving to the outlook. A lot of the event that we were anticipating have indeed occurred and materialized. We discussed many of those. Still to come is the anticipated approval for ulcerative colitis by the European Commission, and that is hopefully imminent. And then, lastly, there is also the anticipation that we will have fully recruits the MANGROVE trial with '2737 in polycystic kidney disease.

Then maybe lastly, before we move over to the Q&A, a slide that we've been showing before. Really, we're laying the foundations for future growth with the company with following our strategic review that we've done in March with 4 key focal points. First of all, on R&D, continue to discover and develop novel targets, our business model there is unchanged. There is a gap in our pipeline we will progress our existing programs from pre-clinical to clinical and from Phase 1 to Phase 2 and hopefully, in due course, also to Phase 3. So a focus on R&D and focusing on the right opportunities there. The second thing that we want to get right is the commercial launch. And that's -- we've spoken about that in some detail. And next year, we'll be adding ulcerative colitis to the indication. So that's an extra challenge and an extra opportunity for the company.

On the BD front, no specifics to report today, but we are definitely very active on that front. We definitely want to bring in, let's say, opportunities, both in earlier R&D as well as in commercial stage. So we're active in discussions on several opportunities. And as soon as we've got something to report there, we'd be happy to bring that to the public domain. And then, lastly, our focal point on the financials, clearly, disciplined cost savings is what we are executing on. And all the time, while, as Onno was speaking to that, searching for a new CEO and CSO in that announcement to be expected in the next months to come.

With that, I'll conclude. We're indeed 20 minutes over the hour, so roughly in the time that we were given by Sofie and Elizabeth. So I suggest we hand it back to Boston there, and we start with the Q&A. Thank you.

Sofie Van Gijsel ***Galapagos NV - Senior Director Investor Relations***

Thanks very much Onno and Bart. So this concludes the presentation portion of today's audio conference call. And I would now like to ask the operator to open up the line for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Wimal Kapadia from Bernstein.

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

So I guess, just one. Just curious to hear your thoughts on the recent failure of Bristol's Ducra in UC. How that potentially changed your thinking about your own TYK2 program, if at all? Any read across any comments would be much appreciated.

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

If I -- this is Walid, I'll take this question. Good morning, and good afternoon, everybody. It's surprising, actually, for us to see these data because TYK2 inhibitors are expected to work in ulcerative colitis by inhibiting signaling through IL-23. As you know, IL-23 inhibitors demonstrated efficacy in ulcerative colitis. Nonetheless, I think, pertaining to the information that we know about Ducra and what's been shared by BMS, it might be a question of those.

I think they mentioned that they have an ongoing other study -- another study, where they're evaluating a higher dose. We also know that in ulcerative colitis, you, in general, need a dose that's two to threefold higher what works in other inflammatory conditions such as psoriasis and RA. So it's not surprising that might be a question. In our case, we feel quite comfortable with the compound that we have, our selective TK2 inhibitor.

Right now, we're finishing the Phase 1 studies as well as the pre-clinical work that will enable us to do chronic dosing and enable us to move into Phase 2 for psoriasis as well as ulcerative colitis. So we continue marching forward. If it's a matter of dose, ultimately, we just have to do the assessment of our molecule in these indications to see whether we have the necessary exposure to produce these effects because I don't think we question the mechanism of action here. It might be a compound specific dose-limiting effects.

Operator

Our next question comes from the line of Dane Leone from Raymond James.

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

Thank you for the updates on the progress. I guess, I'll use my one question to ask this. Has the Board and management going through the process of looking at new leadership and/or the way the company should be run forward considered actually breaking up the company? We have a recent example of bluebird bio splitting company effectively into a commercial asset and an asset that is still in the development phase. Why wouldn't you consider that given you -- as you pointed out, have a big gap between filgotinib being a commercial asset and then a very early stage R&D portfolio, where you could have 2 companies that have 2 different necessary skill sets to run them, maybe be more efficient on an operating perspective? So I would appreciate your thoughts there.

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Yes. And of course, this is in the scenario we have discussed internally as well. We think that keeping the 2 together makes most sense for Galapagos at this point in time. We believe that filgotinib is a sound business case for us in Europe. It's (inaudible) positive, although, of course, we have high start-up costs, we are convinced that we can turn this around into a profitable enterprise. We brought filgotinib to the market. We are still planning to build a European commercial infrastructure with more than filgotinib. Of course, that has now caused a delay with the delay in the further molecules coming to the market, but we think we can fill that gap. So we believe that to bridge this, we ought to go into a BD M&A scenario rather than splitting up the company, which would have been quite a bit destruction of capital for Galapagos. It will be very difficult to retain the people that are currently marketing filgotinib in Europe. So we believe that keeping it all together and fixing the problem that we currently have in the pipeline through an external acquisition is the best option to create shareholder value.

Operator

Our next question comes from the line of Jason Gerberry from Bank of America.

Jason Matthew Gerberry ***BofA Securities, Research Division - MD in US Equity Research***

Just wanted to come back to the commentary about how you guys are evaluating BD and sort of juggling that in parallel with the CEO hiring decision? Are you guys aggressively looking at larger, more transformational type deals or just smaller type of transactions until you get a CEO in the seat?

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Yes. Jason, Bart speaking here. No, I think that's a great question. And obviously, pending a new CEO nomination, one should not expect BD, which is completely different from the strategic direction that we've given to the company and that the Board has pointed out. So our focus in BD clearly is on the inflammation area or the fibrosis area, areas that we know very well and that we're committed to, and potentially on the commercial side, if there are opportunities for Europe specifically, where we can leverage our commercial infrastructure a bit better. So I think, it's really bolt-on transactions of that nature that we're looking for. But I think pending a new CEO nomination, you should not expect a large transformational deal that will completely change the course of the company or the size of the company for that matter.

Operator

Our next question comes from the line of Rosie Turner from Barclays.

Rosie Turner ***Barclays Bank PLC, Research Division - Research Analyst***

There's 2 that I want to ask. I guess, it would be useful to hear a little bit more about this partnership actually in Eastern Europe, Portugal and Greece and any economics you can give us around that? And whether that deal will extend into UC as well?

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Michele, will you take that?

Michele Manto ***Galapagos NV - Chief Commercial Officer & Member of Management Board***

Yes, sure. About -- the question's about the partnership in the rest of Europe?

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Yes, Eastern Europe.

Michele Manto ***Galapagos NV - Chief Commercial Officer & Member of Management Board***

Yes. So absolutely. So that's the decision we took to have that role with a company that have already an infrastructure build there, and it's about the whole, say, internal pipeline of Jyseleca. It's about relaunch, of course, and that will be extended in due time after approval to their indications for ulcerative colitis and Crohn's disease that will allow to optimize our P&L by, of course, getting a boost on the topline without having the need to invest in operations there. Is answering your full question?

Rosie Turner ***Barclays Bank PLC, Research Division - Research Analyst***

Yes, that's great.

Operator

Our next question comes from the line of Matthew Harrison from Morgan Stanley.

Matthew Kelsey Harrison ***Morgan Stanley, Research Division - Executive Director***

I guess I was just curious if you guys have any interaction with AbbVie related to the CF program or have any idea what's going on there? And any thoughts on the outlook for that?

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Matt, it's Onno. Of course, we have a bit of an idea of what's going on there. We get updates from AbbVie on a 6-month basis, but they're quite brief. So not a lot of detail. So we don't know much more than you know from what AbbVie has published. The good news is that AbbVie is talking about the same numbers of molecules, the Galapagos numbers that were part of the collaboration as being part of their triple combo. If that is true, then that's good news for Galapagos if it ever reached the market because, as you know, the royalties are linked to the number of molecules that are in the triple combo. We have a basic royalty and then add a royalty percentage based on one molecule and a percentage based on the second molecule. So yes, we hope that 2 of the 3 molecules come from our stable, but we have no confirmation from AbbVie in that respect.

Operator

Next question comes from the line of Stephen Mallon from RBC Capital Markets. Stephen, you might be on mute. Can you mute yourself, please?

Stephen Lanpher Mallon ***RBC Capital Markets, Research Division - Senior Associate***

Sorry for that. This is Steve on for Brian. Wondering, can you share with us any additional insights related to pre-clinical safety of the Toledo molecules? And whether you have any greater clarity on the relative compound specific versus target specific safety, toxicity and tolerability there?

Piet Wigerinck ***Galapagos NV - Chief Scientific Officer & Member of Management Board***

Thanks for the great question. I want to refer to what we shared on the profile of the Toledo compouds as we did before. And in principle, we never share details on specific organs of any kind. So we are pleased with the profiles we've seen. We have sufficient margins. And they have allowed us to move the first compound into Phase 2. We have another one in Phase 1. And based on what we've seen, we hope to -- with the next compounds especially focused to hit other targets harder and as well to come up with a selective SIK2 and an selective SIK3 together with the combined disorder 3, axes we have up today, but the profiles make us comfortable to play on those 3 axes.

Operator

Our next question comes from the line of Peter Welford from Jefferies.

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

Can I just ask just regarding the cost and the sales force ramp. When we think about the sales and marketing spend, should we consider that the current run rate is going to modestly increase going into 2022, given, I guess, you're already beginning to take on full control from Gilead? Or will there be a further ramp as we consider the UC indication? And perhaps you can give us some idea of what you're thinking regarding the incremental, I guess, headcount that could be needed for UC? And I had 2. Can I just -- for a clarification. Just on the CEO search that you're doing, could we just ask, is the criteria for the CEO search a scientifically focused CEO? I mean, you talked about BD in the pipeline such as that Bart retains the sort of COO commercial role? Or is it a much broader search for a CEO? And it's not -- we shouldn't limit ourselves to that thinking when we think about the Board's search for a replacement?

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Peter, it's Bart speaking. Let me take the first point on the cost, and then maybe Onno can say a few words about the CEO search question. So I think with regard to where we are now in terms of organization, there's a slight ramp up still to be done on UC, and there's also some country transfer still to be done from Gilead to Galapagos, but it's not huge anymore. So I think we're at a run rate as to be anticipated. But one word of caution is that we are, next year, no longer sharing our expenses and our results with Gilead 50-50, but we're taking on 100% of both the topline and the costs. So we'll give a bit more detail for your expectations for 2022 when we do our results announcement in February, as usual, because on one hand, we're going to see ramping up revenues. On the other hand, we're going to see this cost share changing from this year to the next. Net-net, all-in-all, I do not expect it to be a major, major deviation from where we are this year in terms of costs.

Onno van de Stolpe ***Galapagos NV - Co-Founder, Chairman of the Management Board, MD & CEO***

Yes. Regarding the CEO profile. Clearly, we have already communicated that it has to be an individual with a strong R&D background, and that is important for the future of the company. We have the partnership with Gilead. We got EUR 5 billion in the bank to bring novel molecules into the clinic. So we wanted -- or the Board wants the CEO that can really guide that process and take strategic leadership there. But on the other hand, it's obvious that with a company that has a product on the market that is looking for strategic BD activities. We need somebody with the right experience and the right weight in that area as well. So I think all-in-all, there's going to be a very seasoned executive. But clearly, somebody who has -- who has her or his feet very strongly in the research because that is something that remains at the focus of this company.

Operator

Our next question comes from the line of Phil Nadeau from Cowen.

Ernesto Luis Rodriguez-Dumont ***Cowen and Company, LLC, Research Division - Research Analyst***

This is Ernie Rodriguez for Phil. Just 2 for us. First, I wondered if you could provide some color into the next-generation Toledo compound. Any update on the development from there? Are you still expecting for candidate to enter it in 2022? And what you're looking for? And then, the second thing is in terms of Jyseleca potential in IBD in the U.S., can you provide some color in your strategy or discussions given that with the results of MANTA-RAy's study available?

Walid Abi-Saab ***Galapagos NV - Chief Medical Officer & Member of Management Board***

So should I take the first question, this is Walid, and then, I'll pass it on. Yes. So I think we -- I think partly, Piet has answered some of it before. So as you know, our first foray into that space was with '3970, and we were pleased to see evidence of clear clinical activity in psoriasis and biological activity in UC.

But what was clear to us from looking into these data is that we need to inhibit these enzymes longer -- for a longer period of time, and that's currently what we're working towards. That's one of the axis with the SIK2 inhibitor to come up with compounds that will enable us to inhibit these 2 enzymes throughout the day for a longer period of time so that we can fully test the potential in these indications.

In addition, also, there's a lot of learning that's happening with this whole platform. And we at Galapagos are at the forefront of elucidating the role in inflammation, which we're very proud of. But that will take also time and diligent effort to be able to get selective compounds. We have one, which is the SIK3 inhibitor currently in the clinic, and that will drive a lot of information and tell us the way forward in that space.

In addition, as Piet also mentioned, another major axis is for us to work on generating SIK2 inhibitors, and those are still in the research phase, but hopefully, will go into the clinic. So in terms of the way forward, there's going to be a lot of analyzing of the data that we have pre-clinically. But also clinically with '3970 and soon with '4399, which is the SIK3 inhibitor and doing sort of the forward and back translation, so to speak, bench to bedside and back -- bedside to bench so that we can better position our molecules going forward.

For this coming year, we expect to have at least a SIK2 inhibitor into the clinic in Phase 1 and be able to better test the hypothesis whether inhibiting those 2 enzymes will provide better efficacy in ulcerative colitis and rheumatologic indications as well.

Bart Filius ***Galapagos NV - President, COO & Member of Management Board***

Yes. Let me take the second half of the question with regard to Jyseleca in the U.S. I think with the scrutiny that the class has come under in the U.S., it has become increasingly unlikely that Gilead will be launching Jyseleca in the U.S. markets. Obviously, there's still an important study, the Crohn's study to read out, and that will come once it's -- let's say, early 2023. But honestly, I think we're focusing very much on Europe and some other territories in the rest of the world. But I think the chances of Jyseleca reaching the market in the U.S. are very slim.

Operator

(Operator Instructions) We have a follow-up question coming from the line of Rosie Turner from Barclays.

Rosie Turner ***Barclays Bank PLC, Research Division - Research Analyst***

In thinking about UC, I guess, in terms of the hopefully upcoming approval and then launch. What are the economies of scale of already having your approval? And does that actually mean, I guess, we're now rolled out in 12 countries, is that going to be a quicker process the second time around?

Michele Manto ***Galapagos NV - Chief Commercial Officer & Member of Management Board***

Yes. This is Michele. I'll take this question. So definitely, when we built the countries in the past months and the organizations, therefore, are -- we're already thinking ahead for the addition of UC. So we did an evaluation country-by-country and together with external help of experts and consultants to find the most efficient, effective model -- operating model for each country, which in a way, allows us to flexibly add personnel so, sales force, medical organization to address that additional target group of the gastroenterologists, of course, between in a way, which is efficient.

So in some countries, we'll add a same parallel forces to the existing array and some others will enlarge the scope of activity of the rheumatology team to also address that. And that's very good because this makes us efficient country-by-country, looking at the different systems. There are countries like Germany, which are office-based and countries like France, which are hospital-based where all the prescribers are in the same building, in the same place, both rheumatologists and gastroenterologists.

So in that way, we have already started, of course, hiring where we need and diligently, also considering the different reimbursement time. So they are ready to go, say, in Germany, and will take more time in Italy or Spain, where the reimbursement takes a year longer as a standard in the industry.

Operator

We appear to have one question that just got registered. It comes from the line of Jeroen Van den Bossche from KBC securities.

Jeroen Van den Bossche ***KBC securities, Research Division - Research Analyst***

Maybe one question surrounding Jyseleca to go. Can you provide some further insight on what the physician and feedback is on the product thus far, specifically in Germany? Any specific things you need to be aware of? How do they look at it compared to their peers? And are there specific patient populations for which it is, let's say, more appropriate?

Michele Manto ***Galapagos NV - Chief Commercial Officer & Member of Management Board***

Yes. So here, Michele, again, thank you for the question. So the feedback we are getting is consistently positive on the profile and the efficacy and safety profile we have and actually they're referencing back to the JAK1 preferential features that filgotinib has.

And actually, that has become a clear reason to believe about the differentiating profile, which is actually recognized in the market research of the life that Bart presented earlier in the prepared remarks, and it is recognized in Germany and in the other countries. So that's very comforting because this sets the base for the continued performance of Jyseleca, even in the current situation with the JAK class. But it's a good point of differentiation and positive comp.

In terms of experience, we're also getting that back from physicians. They see the rapidity of effect, the speed of effect, the onset and also in the patients that are already for a longer time on the drug. So say, 1 year in Germany, as we launched a year ago, also they have that persistent effect. So consistently with the expectations we had a flow engine with the position that we have executed across the geography.

Operator

That appear to be the last question coming from Mr. Van den Bossche who is from KBC Securities. We appear to have no further question at this point, sir. So I hand the conference back to Sofie.

Sofie Van Gijsel ***Galapagos NV - Senior Director Investor Relations***

Thanks so much, operator. So this concludes the Q&A portion for today. Please feel free to reach out to the IR team if you still have questions. Our next financial results call will be our full year 2021 results on February 25 of next year. Thank you all for participating today, and have a great rest of your day.

Operator

Ladies and gentlemen, thank you for your participation. This concludes today's conference call. You may now disconnect your lines. Thank you.