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CORPORATE PARTICIPANTS

Bart Filius *Galapagos NV - President, COO & Member of Management Board*
Michele Manto *Galapagos NV - Chief Commercial Officer & Member of Management Board*
Paulus A. Stoffels *Galapagos NV - CEO, Chairman & Member of Management Board*
Sofie Van Gijsel *Galapagos NV - Head of IR*
Walid Abi-Saab *Galapagos NV - Chief Medical Officer & Member of Management Board*

CONFERENCE CALL PARTICIPANTS

Charlie Mabbutt *Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst*
Dane Vincent Leone *Raymond James & Associates, Inc., Research Division - Research Analyst*
Jason Matthew Gerberry *BofA Securities, Research Division - MD in US Equity Research*
Jeroen Van den Bossche *KBC Securities NV, Research Division - Financial Analyst*
Matthew Kelsey Harrison *Morgan Stanley, Research Division - Executive Director*
Peter Verdult *Citigroup Inc., Research Division - MD*
Peter James Welford *Jefferies LLC, Research Division - Senior Equity Analyst & European Pharmaceuticals Analyst*
Philip M. Nadeau *Cowen and Company, LLC, Research Division - MD & Senior Research Analyst*
Stephen Lanpher Mallon *RBC Capital Markets, Research Division - Senior Associate*

PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the Galapagos Financial Results Q1 2022 Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded. (Operator Instructions) I would now like to hand the conference over to your speaker today, Sofie Van Gijsel. Please go ahead.

Sofie Van Gijsel ***Galapagos NV - Head of IR***

Thank you, operator, and thank you, and welcome all to the audio webcast of Galapagos' Q1 2022 results. I'm Sofie Van Gijsel, Investor Relations, representing the reporting team at Galapagos. This recorded webcast is accessible via the Galapagos' website homepage and will be available for download and 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 involve risks and uncertainties Galapagos' actual results may differ materially from the results expressed or implied in these statements.

Today's speakers will be Dr. Paulus Stoffels, CEO; and Bart Filius, COO, CFO and President. Paul will reflect on the corporate and strategic highlights, and Bart will go over the operational and financial results.

You will see a presentation on screen. We estimate that the prepared remarks will take about 20 minutes. Then we'll open to Q&A with Paul and Bart joined by Dr. Walid Abi-Saab, CMO; and Michele Manto, Chief Commercial Officer. And with that, I'll now turn it over to Paul.

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Good morning, and thank you, Sofie, and I'm very pleased to be here for the first time at the quarterly results for presentation for Galapagos. Joined 4 weeks ago and very happy to be on board working with the teams here. I spent the first 4 weeks on reviewing with the Board and with the teams across the organization the research and development project, but also the commercial opportunities. And I'm fascinated and impressed by what the team has been doing over the last years, and where we are today and especially with the capabilities of what the team has brought together. And so I hope today we will be able to talk to you a little bit about where we are, but also shortly about where we will go. But first about why I did share the company, and it was mainly driven by -- I was one of the co-founders more than 20 years ago of the company, and I've always been very close with Galapagos and Onno on the progress of the company. And the mission of the company is very similar than what I have been driving for my whole life, is bringing new and novel medicines to patients around the world, with a real focus on how can you make patients live longer and better lives and especially focused on quantifying what do we do on years of life, but also improving on quality of life.

A founder spirit is drive in Galapagos as a main driver for success of the company. And then the second is a very important point on our

fully integrated company. And I'm convinced and even more than before I joined on April 1 that Galapagos has the opportunity to become a fully integrated and remain an independent European biopharma. There are strong development capabilities and discovery capabilities in the company. I went with the team to all of them and the capabilities are there to make a real difference in R&D. Filgotinib is the example on how the company went in a very unique way from discovery through development to commercialization. And with that, you have a real end-to-end company with all the capabilities. And now Jyseleca is a really growing franchise in Europe, and the team will report to that later in the meeting. The long-term collaboration with Gilead is a very strong one. We interacted -- I interacted already many times with Gilead, while I'm here. and it's really a collaboration where we can count on the strength of our own teams, but also in interaction with Gilead on the strengths of what Gilead can bring as our global partner for development and for commercialization. And last but not least, a strong balance sheet, which gives us the opportunity to really focus on what matters is short-term focusing on significant transformation of our pipeline and bringing multiple new opportunities to the clinic and hopefully to the market.

Just to highlight one small thing. If what the observation on how can we accelerate? Two things. I think focus on high unmet medical need indications in the existing, but also most likely in new disease areas. Going -- we will continue to work on our first-in-class targets, but we'll move gradually and choose more also to work on best-in-class targets, and make sure that we move in the pipeline to much more to closer to proof of concept than what the company has been doing in the past. And that will allow us to go faster into the clinic, make our choices faster and accelerate new products into the market. We will do this on internal and external opportunities. And as the market is difficult for many companies at the moment, we are receiving very many inbound calls for companies to collaborate with us, and especially those with assets in late preclinical and early stage clinical are of very high interest to us. What is not the intent here, I think, for us is to do a large acquisition. The best way for us to create value is to function in the space, late preclinical, early Phase I proof-of-concept, and add real value with our teams to the portfolio. And so based on that, we hope to, in the next few months, do several new deals where we're bringing in select opportunities in the preclinical Phase I space. We are looking in the Phase II, Phase III space on new opportunities, which we can bring in, in parallel to accelerate our presence in the market going forward, and that mainly in our existing therapeutic areas.

So a combination of accelerating the R&D pipeline with bringing select opportunities into later stage to smaller select acquisitions or smaller select licensing deals. And hopefully, with that, we can accelerate the pipeline and accelerate the value creation in the company and create a real great future. We will come back to you in the second half of the year with the overall strategy for the company once we have been able to work with the teams internally and with our Board to put everything in place and move forward on the new strategy. Bart with this, I'll give it to you.

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

Thank you very much, Paul, and good morning, everyone, in the U.S. Good afternoon, everyone, in Europe. Thanks for listening into this webcast. For me now, a chance to give you a perspective on the operational highlights for the quarter. And I'll start off with our current state of our pipeline, which you can see on this slide, highlighting 3 programs here. First of all, obviously filgotinib. Jyseleca has a marketed product, which has a study ongoing, the diversity study in Crohn's disease. That study is fully recruited since the third and fourth quarter of last year, and we anticipate to see the full results, including maintenance data in the beginning of 2023. So that's a big trial that we are waiting data from, let's say, first half next year. The second one to highlight, and Walid will probably be able to give you some further insights during the Q&A, but it's '3667, our TYK2 inhibitor, we're obviously watching with some interest Deucra from BMS and seeing how that is progressing, both on a clinical and regulatory point of view. And we are finding our own path towards identifying the right indication for this asset, and it will take, let's say, the external environment into account when making that selection. And our ambition is to start a Phase II program in the course of this year still. And then the last one I'd highlight here is our CFTR '2737, which we're evaluating in polycystic kidney disease in a 1-year trial. That trial is also fully recruited since late last year. And there, as well, we anticipate in the first half of 2023, the data set from this proof-of-concept study.

Then if I move to our marketed product, Jyseleca, we are very proud to have our first marketed products available for patients in Europe. And we're also now the marketing authorization holder, which we've taken over from Gilead at the end of last year. And we've launched now in 2 indications, rheumatoid arthritis since the beginning of last year, and since late last year also in ulcerative colitis, and I'll go in a bit more detail on that path to growth.

On the next one, the growth trajectory for Jyseleca in RA on track in Europe, we are reporting sales of EUR 14.4 million in the first quarter.

As you can see from the quarter-on-quarter evolution, that growth curve is doing nicely. As a reminder, in Q2 '21 and Q3 '21, there was a stocking effect that's inflated the Q2 numbers and probably reduced a bit the Q3 numbers. But otherwise, it's a pretty linear growth curve that we're seeing here. We're very happy with the results in the first quarter at EUR 14.5 million. We also have received on top of the EUR 14.5 million, a EUR 1 million milestone from our partner, SOBI, who is launching now in the Eastern European countries and Portugal and one milestone was due in the first quarter. Based on this, we are confirming our guidance as we've given that in February that we think that we're going to be able to achieve between EUR 65 million and EUR 75 million of sales. In the meantime, the review under Article 20 by the PRAC is still ongoing. The review of the class that is, all the JAKs are being evaluated, and we anticipate to hear more from CHMP and later on the European Commission in the next couple of months. So we'll see where that lands. Then if we move to a little bit more detail on market share evolution, we see a very nice increase of the class, which you see here on the left in dark green where the market share of the JAKs in Europe is now approaching 20% data point last March 2022. So that sees -- shows that there's a good appetite for an oral agent in this market. And the 4 agents that are out there are together growing the class very nicely. Our own market share there in, and this is the market share in the dynamic markets across the EU 5 countries is now approaching 5%.

You need to take into account here that some of these countries, such as Italy and Spain are only on the market since the fourth quarter of last year. So we are quite pleased with how we see this curve evolving. If you go on a more qualitative basis, we've also evaluated. This is our own market research. We've also evaluated how we are comparing Jyseleca to other JAKs that are out there, both in terms of efficacy and safety. And also here, you see in the blue line, the outcomes for Jyseleca and in the various gray colors the other agents in the class. And it's good to see there's a fourth agent in the class. The message around Jyseleca is resonating very well in efficacy terms. We are among the leaders in the class. And actually, on the last data point in safety, we are rated highest in the class. So that brings, let's say, a good ground for growing Jyseleca further and making this available to more and more patients, good brand awareness as well.

In terms of reimbursement, as you can see here, we are slowly covering the map of Europe in dark green. Those are all the countries that are fully reimbursed, and those are the most meaningful ones in terms of market opportunity. And with our partner, SOBI, we are in progress to also tap into markets in Eastern Europe as well as in Greece as well. And so we're coloring the map dark green as we go, and we're now reaching full potential in RA. And if I go to UC, important to highlight here that there's really a big need for novel treatment options. Remission rates are suboptimal. Patients are also steroid dependent with existing therapies. There's safety concerns. And then also the oral formulation, obviously, is a key asset for Jyseleca in these markets, which, by the way, we estimate to be a market of around EUR 1 billion in total. And we're seeing good reception of Jyseleca when it enters into the market. It's now still available in a couple of markets only, which include Germany, the Netherlands, Norway, Sweden and Austria, as you can see here. So we're gradually also getting reimbursement in those markets. But there where it's available, the receptivity is very good and also the positioning of Jyseleca in relation to other oral agents and the market share of Jyseleca in relation to other newly available treatments then is developing positively.

That all leads to a business case, and I've shown this before, which has, we think, a potential to reach EUR 0.5 billion across Europe, and that's across Europe and across 3 indications. We now have 2 approvals in RA and in UC, and we hope to get the approval upon positive data in the course of next year for Crohn's to get the approval for Crohn's as well in either late '23 or in the beginning of 2024. And the 3 indications together should help us to reach a EUR 0.5 billion peak, which we estimate to be achievable by the second half of this decade. And when we do so, we think it's also a very healthy financial opportunity with the contribution margin of around 50%, including cost of goods and royalties that we pay back to Gilead. And then we have a good patent life still ahead of us. 2035 is with the extensions the estimated time line for patent exclusivity. So a good number of years for positive cash flow for Jyseleca after a breakeven, which we still anticipate in 2024.

Then if I move on to the financial results for the quarter, first, always look at the cash, which remains our main financial KPI, EUR 4.6 billion of cash position at the end of March. If you exclude the usual exclusions around some warrant exercises as well as on fair value adjustments to the dollar-euro exchange rates. If you then look at purely the operational cash burn, we're landing at EUR 77 million for the quarter. As a reminder, this compares to an overall guidance that we've given between EUR 450 million and EUR 490 million. So this is clearly below the 25% that you would expect in 1 quarter. But as a reminder as well, we've received in the quarter a last payment from Gilead of EUR 50 million for some of the renegotiations we've done around the development portfolio on filgotinib. So it's unusually low for the quarter, but we're comfortable to confirm our guidance between EUR 450 million and EUR 490 million.

If I then look at the P&L, we see a couple of important elements. As usual, we have revenue recognition from our deferred balance sheet position and that actually, at the end of March is still EUR 2.3 billion of not yet recognized revenues for both the platform and filgotinib, and the combined of the 2 is a little over EUR 110 million in terms of recognition in the first quarter. But then we're also adding the EUR 14 million sales that I spoke about before for Jyseleca. We've also recognized royalties of EUR 5 million in relation to Jyseleca. This is connected to both the Japan performance and the approval in Japan in ulcerative colitis and the EUR 1 million milestone that we received from SOBI as well.

On the operating costs, we see an improvement or a decrease compared to last year. Two main programs where we have reduced expenses, one obviously ziritaxestat; and the other one, our Toledo program, leading to a net result of negative EUR 13 million, which is helped with a favorable currency result and net other financial income of EUR 10 million. We take a longer look at our cash flow. Again, if you take the EUR 450 million, EUR 490 million guidance for the year and take the midpoint there at EUR 470 million, it's important to highlight that part of this cash flow is not recurring because it's actually the investment of Jyseleca that should, by itself, fall away once we reach breakeven status a couple of years down the line. So it's really important in a recurring basis to look at what's colored in orange roughly at EUR 350 million that we're spending on research and development on a cash basis per annum. And then later on in the decade, once Jyseleca will start to generate positive cash flows, actually, that will help our overall net cash flow in the right direction. Obviously, this is excluding any business development activity or any other programs that we are potentially licensing in, but for the current portfolio, this is what we believe is the envelope to look at.

Then let me conclude with the last slide. We think the foundations for future growth for the company are there. We have a novel target engine and a differentiated pipeline. Through BD, we'll be focusing, as Paul was alluding on breakthrough opportunities to fill our pipeline further. On the commercial side, we're rolling out successfully Jyseleca in Europe, first in RA and UC, and then hopefully later on also in Crohn's disease, with a very, very healthy balance sheet in terms of cash, EUR 4.6 billion, and as a reiteration, you see the numbers of guidance there that we're confirming from our earlier announcements in February. And then with the arrival of Paul as CEO to the company, we believe we've got the foundations for the growth of Galapagos into the future. So thanks for that with the presentation. I suggest, Sofie, we go from here in the Q&A.

Sofie Van Gijsel ***Galapagos NV - Head of IR***

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) The first question comes from the line of Matthew Harrison from Morgan Stanley.

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

Great. appreciate it. Paul, maybe if I could just start with you. I was wondering about your comments you made upfront. Can you just give us some sense around what you're thinking about late stage versus early stage? I know it sounds like the focus here is on early-stage in-licensing, but you also mentioned some late stage. So maybe just what you're thinking about there? And are you thinking about a few programs in early stage and 1 in late stage, et cetera?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Yes. The value creation power, let's say, of Galapagos is around moving assets from preclinical to early clinical proof of concept, and making sure that we are responsible for a significant part of the value creation. That's where we need to bring in assets in that area. But as said, we will not stop by looking at, and we are doing that actually on looking at Phase II assets. I think less about Phase III assets because their strategy is set, most of the value is created and prices are extremely high to bring in attractive assets in late stage where a limited added value can be generated by a company like us. So if I talk about clinical assets, we'll talk about Phase I/II. And -- but the focus is going to be around that proof of concept for the new targets and the best-in-class targets we are working on.

We might expand to other therapeutic areas that will go together -- or disease areas -- that will go together with the opportunities we see will broaden our capabilities in the development organization accordingly as we move forward.

Operator

Next question comes from the line of Dane Leone from Raymond James.

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

Congratulations, and congrats on joining the organization, Paul. Maybe a targeted question for me just to keep things moving. It seems from your commentary that you're not apt to do a larger acquisition, which has been an area of huge debate with investors. Does this mean that any acquisition would probably come out of the cash balance that is held under Galapagos and could be argued as unaffiliated with the Gilead partnership? And if so, could you maybe give us an estimate of what that cash balance would be and could be used for a deal that would really only benefit Galapagos?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Well, I'll first do a part, and then I want Bart to weigh in here. So we don't look like that. At the moment, we look at what are the best possible opportunities. We work with our partner closely. We could decide that, we have the freedom to decide to do it from our own cash balance, but we also can do it together with Gilead. And that gives us an additional opportunity to tackle bigger global assets. So we look at both, and our teams are very much interacting with the Gilead teams on this. So yes, we have both options.

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

Yes. I would add to that, Paul, that the Gilead contract today and, as you know, has a lot of flexibility and basically is very fit for purpose, I think, for both earlier stage assets and also for, what we call, more mid-stage assets. And as a reminder, if we license something in, then Gilead automatically gets the right to opt in at the end of Phase IIb or, I would say, at a pre-pivotal stage against a milestone of $150 million. So that, I think, is economically still a very applicable range. But indeed, we could also sit down together with Gilead and see if there's opportunities that are more interesting upfront already, where Gilead might step in or we might adjust the terms. So there's a lot of flexibility, I think, in that relationship and also a lot of willingness at the side of Gilead to make sure we do the right thing and we create value for both shareholders and patients.

Operator

Next question comes from the line of Brian Abrahams from RBC Capital Markets.

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

This is Steve on for Brian. Congrats on the progress. Maybe looking at the SIK targeting asset, '4605 and fibrosis. I'm curious if you can speak a bit more on your thinking of optimizing the SIK inhibitor for fibrosis and maybe how that might differ from what you've done in, say, UC or psoriasis and what mechanistic data give you confidence that salt-inducible kinase is a good target there?

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

Yes. Thanks a lot. This is Walid. I'll take this question. I apologize for my voice. I'm kind of a bit under the weather. The -- one of the specific characteristics of '4605 is that it's much more enriched in tissue. And in the animal model that we have, it performed quite well in model of IPF. However, as you know, we've run a large program in IPF based on a battery of preclinical assays that, in the end, actually did not translate in the clinic. So what we're doing right now is actually essentially strengthening our preclinical assay, adding more assays to better convince us of the link between the animal data and human data. In addition, we're taking the learning from the ISABELA study in terms of design of the trial and improving what would the next trial be before we march forward with the next compound.

So with regard to '4605, it's still being evaluated under these circumstances. And we should be able to come to a conclusion in the next 3 to 6 months as to what are the next steps with this asset going forward.

Operator

Next question comes from Charlie Mabbutt from Bernstein.

Charlie Mabbutt ***Sanford C. Bernstein & Co., LLC., Research Division - Research Analyst***

I'm Charlie Mabbutt from Bernstein. So Paul, I guess, what are your initial thoughts on the TYK2 and Toledo programs? And do you see a chance that you could maybe deprioritize those and allocate your capital elsewhere?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Well, first, we are going to come to the final conclusion on Toledo, the TYK2 programs. As we are exploring what -- how can we maximize the chance of success there? We'll do our best in the evaluation in the next few weeks and months and then see what comes out. But that is an opportunity if that doesn't come out positive that we'll absolutely reprioritize resources in other direction and put them at work. So there's a very objective evaluation with the whole senior team ongoing on the probability of success, and how can we get to next steps with these assets and then we'll come to the conclusion. There's also a lot of new information in the market around TYK2, where we're also learning from what the opportunities can be, and we are comparing that to where we see the TYK2 evolving to. So more news to follow in the next few months.

Operator

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***

Paul, I just wanted to put a finer point on the commentary about capital deployment. If I hear you correctly, it sounds like maybe more structured license type transactions where the upfront dollar out is smaller, and the bigger milestone payments that come due in those types of deals more better aligned with the typical Gilead opt-in. Because I think there's obviously a perception out there that the bulk of the value skews to the U.S. end market where Gilead could just jump in and reap a tone of the value. So am I thinking about kind of the commentary the right way in terms of the types of deals that you'd be contemplating?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Yes. My experience in my previous life and long before has been always like derisking as we go and pay the large dollars that -- when it really shows to work, is a better value proposition than taking a high risk at the beginning with a lot of uncertainty. So it's not a dogma, but when the right opportunity comes around, we'll look at it. But for us, the first target is being able to, with reasonable amounts of upfront, adding new products to the pipeline and de-risk them.

With regard to your comment on Gilead, having worked for a long time in the U.S. and seen what commercialization means in the U.S., I think the deal with Gilead for me was the strength to join the company. We have a strong partner, with a very good deal where we capture a significant part of the U.S. commercialization, and that gives us the opportunity to focus completely on R&D progressing the assets and have a partner who pays decently for us. I would challenge companies to get the value out of an -- a small European companies to get the value out of the U.S. versus what we have with Gilead as a deal.

I think still that is a strength for the organization because if they step in the Phase II/III for the pivotal concept, as Bart was saying, they pay a significant part of the development as well as take up the whole preparation of commercialization in the U.S. And I think it's a strength in this collaboration that we have this Gilead partnership. And that's also why I joined. I think strong company in Europe, big -- sorry, big balance sheet, very good R&D organization and a strong partner to work with in the U.S., I think, is, for us, an ideal situation.

Operator

Next question comes from the line of Phil Nadeau from Cowen & Co.

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

Paul, congratulations on taking over the CEO role. Two related questions for you on R&D strategy. First, in your prepared remarks, you mentioned that Galapagos is going to maybe focus more on unmet needs. Could you elaborate on that? How is that -- how is there a shift in strategy versus in the past? And then second one, criticism of Galapagos' R&D strategy in the past has been that perhaps the Phase II trials of proof of concept studies didn't sufficiently derisk programs before they were moved into large and expensive Phase III programs that ultimately failed. Do you think that, that is a fair criticism? Do you envision doing proof-of-concept studies differently in the future?

Paulus A. Stoffels *Galapagos NV - CEO, Chairman & Member of Management Board*

Yes, it's -- well, I'd say, for the first drug, Jyseleca, filgotinib, it was a successful strategy because it went from -- beginning from the discovery to the market. And in Europe, Japan, at the moment, it's fully approved indication by indication. So it works. The areas, inflammation and fibrosis are very challenging areas. They are very high risk and very competitive. And so moving into areas with a small -- with very high medical need. And again, going back to my past on how do you focus on areas with very high medical -- unmet medical needs, find very good assets and connect both and accelerate, I think is the best place for us to be going from first-in-class, and that's maybe building on your comment here, first-in-class targets to trying to see what are the best-in-class targets and move from that point rather than from first-in-class and take a really high-risk strategy as well as combining that with medical needs, should accelerate time to market significantly.

And when we come back, the discussion will be what can we do within the next 3 years, the next 5 years, the next 7 years, and come with a clear view on how are we going to organize a pipeline to make sure that in the midterm, we have in the short to midterm, we have significant value creation with this pipeline.

Operator

Next question comes from the line of [Bryan Garnier].

Unidentified Analyst

Congrats on starting your new role. I may have missed some of your answers. So I'd like to ask probably 2 questions. So regarding your BD strategy, if I understood you correctly, you're in the early stage because you're going to focus more on the first in class type of preclinical to Phase II proof of concept and looking for multiple deals. And it seems like you guys want to kind of expand into new disease area that initially -- that didn't focused to on -- regarding the late stage, this is not your primary focus, but any, I would say, best-in-class targets that kind of aligns with the Galapagos' initial areas of focus you guys would consider, would that be a fair representation? And then also, regarding the late stage, what I understood was you guys are more focused on licensing in rather than actual buyout of the company?

Paulus A. Stoffels *Galapagos NV - CEO, Chairman & Member of Management Board*

I'll start with the last point, licensing versus buy-in will fully depend on what we want to bring on board. Is it the asset only? Is it asset and the people and new capabilities, new expertise as well as, of course, the price? So it is -- but it will be focused on, can we bring in a real differentiated asset, which -- with capabilities if we do an acquisition? With regard to your comment on best-in-class, yes, we're going to make a good balance between first-in-class and still look at assets which are in our pipeline and evolve and see where we can get to best-in-class with transformational assets closer to the clinic or in early stage. If that is -- and do I miss anything back on the answer? No, I think I was -- initially, you were difficult to understand for us, so that's why I missed on the first part, but I hope I answered your question with this.

Unidentified Analyst

Just one more question. I don't think you have mentioned, but would you be still considering any commercial rights, any drugs that are -- assets that are already approved in the U.S., for example, let's say, beaten down U.S. biotech that needs infrastructure in Europe? Would that be something...

Paulus A. Stoffels *Galapagos NV - CEO, Chairman & Member of Management Board*

Yes. That's something I missed, and we missed to say is that there is a lot of interest because we have a commercial organization in Europe, which is -- which has been set up, which is functioning. There is a lot of interest from biotech inbound interest to see whether they can talk to us about our commercial capabilities. And if there is a good opportunity from a U.S. biotech who wants to partner in Europe, we will take it on if it fits our objectives and our infrastructure, but that's definitely one piece of what we can add to our portfolio here.

Operator

(Operator Instructions) And your next question comes from the line of Peter Verdult from Citi.

Peter Verdult ***Citigroup Inc., Research Division - MD***

Pete Verdult, Citi. Just a few for you, Paul, quick ones. In September, Q3 is still the right time frame for us to think about getting your official strategic outlook for Galapagos. Secondly, I realize you're not going to go into details, but can you just characterize the general or current BD environment. You've got long-standing experience. I just wanted to get a sense whether the pullback in the sector creates opportunities or whether you still have very well-funded public and private companies that retain unrealistic valuation expectations?

And then lastly, you've already alluded in your -- in the Q&A that you're willing to enter therapeutic areas outside of Galapagos' historic focus. But what are the appetites for adding new modalities beyond Galapagos' small molecule focus?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Again, I'll -- Bart will take part of it, but around the time frame of September and -- we'll be ready, we'll inform you timely on when we will do this and will work in the next 3 to 4 months, 5 months with the Board, with the executive team. On indication and modalities, yes, we will consider biologicals as an option for us to go. And also in indications, yes, we'll evaluate that, but it's too early to talk about that. As I said earlier, it goes together with the opportunity and the capabilities we can bring on board. And we are looking at that when. When we bring in a new modality, we have to bring in at the same time, capabilities, and that is one of the ways we look with BD at new opportunities at this moment.

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

Yes. Maybe let me take the question on the opportunities that are arising as a result of the pullback in the market, and I can only confirm what I think makes sense that's indeed the case, get a lot of inbound from companies that actually have some very good science in the company and some very, very interesting opportunities, but not necessarily always the funds to bring those to the next stage, and create the value that they think they can create with that. So I think the market is definitely favoring the position Galapagos is in at the moment. So we can use our cash balance, and we'll continue to do it with prudence, but there are definitely opportunities out there for us as a company that is interested to license in.

Operator

Next question comes from the line of Peter Welford from Jefferies.

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

It's really -- I guess not wanting to play the devil's advocate, but I mean given the comments you mentioned at the start about the fact that you've been very impressed by the platforms and the sort of technology and what Galapagos does as it has done over the years. Why, I guess, not instead concentrate on, yes, perhaps choosing different targets and better perhaps deciding whether to be, as you said, best-in-class maybe different modalities, but just continue leveraging the existing platform and then also pursue I can give a bolt-on deals to leverage the commercial infrastructure in Europe, which is clearly under leveraged at the moment. I guess, I'm sort of curious as to what necessarily the skill set that Galapagos has in the preclinical Phase I necessarily that there is perhaps a better use of the capital rather than rebuilding the pipeline internally? And you just talked about what it is that drives the urgency, I guess, to bring in the pipeline programs to do that rather than rebuilding organically?

And secondly -- sorry, second is related to that. Sorry, I just earlier. The second is just related to that. Can I just ask as well, when you think about the modality, are you interested in things like, I guess, thinking Protacs and be sort of novel. So it's still sort of a small molecule, but it would perhaps be additive to the current platform? Or is really anything on the table? You mentioned biologics before. Are you -- is this really a totally blank canvas from where you take Galapagos in the future?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Yes. I think maybe I was not clear enough on that, but it's a real full evaluation of the pipeline and the opportunities. And when I talk about what I'm proud of Galapagos, and if you look at the capabilities in biology, in medical chemistry, in formulation, in toxicology, I've worked in many organizations, and I see end-to-end the capabilities to really bring -- late development to really bring medicines to the market. We can now deploy this, whether it's on the existing targets, which are still there in the pipeline and see whether we can -- they have a good chance to get to the market, or like you say, best-in-class, which we can bring in through licensing and acquisition and we start from that as well as select opportunities in commercial if they come by. So we are going to use the capabilities of Galapagos to

maximize value creation by bringing assets into the pipeline using the capabilities. And do we have a blank sheet? Well, we are an independent company who can make our decisions. So we have a strong team at the company. We'll evaluate it, and we'll come back on what we keep, what we shed and what we bring in to create a new pipeline for the future. And I hope we can positively surprise you when we did that review later this year with you.

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

So can I just quickly just follow-up just in terms of -- you mentioned there's a lot of companies that are that are obviously short of cash and there's a lot of opportunities, which I think, unfortunately, we could all see at the moment in the U.S. market. I guess, briefly, what is it that when you -- particularly when you're negotiating with these deals, what is it that you think makes you a more attractive partner than perhaps some of the bigger companies such as your ex-employer? Because obviously, I mean, they have even bigger war chests of cash. But could you just talk a little bit about what you think it is that perhaps makes Galapagos a better partner of choice for some of these smaller companies.

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Yes. I think when you talk to companies, many founders and many people who have built such a company want to be -- continue to be part of the opportunity and are what they have built on. And I think we are more agile. We can move fast, but we also have a very big flexibility in how can we organize our collaborations, bring in people and make them part of the future. And I think, yes, it's attractive for people to be in an agile, fast-moving company, with -- where they can play an important role going forward. And when we talk to companies, yes, we want to have talent. We want their capability. So it's -- we don't buy assets for the asset we buy assets for the capabilities plus the product, and that's where we -- I think we can stand out.

Gilead as a partner there is the strong U.S. commercialization. So we can offer to what we do also the partnership with Gilead and bring a global partner into the picture. So I think we have the flexibility, the agility and the speed to move and bring people in an environment where we can really operate in the biotech agile way.

Operator

(Operator Instructions) The next question comes from the line of Jeroen Van den Bossche, KBC Securities.

Jeroen Van den Bossche ***KBC Securities NV, Research Division - Financial Analyst***

And also from our side, congratulations on definitely an exciting and successful launch of Jyseleca. Maybe one question and a follow-up on that. How are you looking at the EMEA or the EMA review in September? What is the risk towards Jyseleca you would -- if you can establish that already? Or do you think it's going to remain mostly with Xeljanz And how would that eventually impact your pipeline where you still have JAK1 inhibitors in development?

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

Yes. This is Walid. I'll take that question. Look, this is the Article 20 that's initiated in Europe by EMA and being operationalized by PRAC is a procedure that they do whenever they need to evaluate fully the risk benefit of the class. Having said that, the items that they've been looking at. And in this particular case, actually it was triggered by the oral surveillance study plus, if I understand correctly, an observation study with Olumiant. So the adverse events that they've been looking at, have been things that have been working on all the time. And one of the benefits of coming sort of essentially the last one to the body is that all of those things we've been monitoring for the past number of years, and we've been communicating back and forth with the EMA on these topics throughout the review process of RA and actually more recently in IBD.

So it's really difficult to speculate, honestly, on what that would look like because until we hear back from EMA and PRAC where do they stand. And this by the way will be public, it will be really hard for me to speculate. That would just be my opinion. But let me reiterate one more time that we truly believe and have a very strong confidence in the totality of the data package that we've been accumulating. The fact that we've been following these adverse events --or special events since over time and that we believe due to our preferential action on JAK1, in addition to the judicious dose selection that we've done with Jyseleca. We believe that our adverse event profile and the risk-benefit profile is very positive for this compound. And I think we've seen this through the continuous update that we've been providing to you from our longer-term studies, how they favorably compared to what's on the market. In addition to , as you've heard

from Bart, and perhaps Michele can talk even more about it now, how we are performing in the market with Jyseleca. And I think that reflects also the attitude and the comfort level of these physicians who are quite aware of all these pieces. So I hope I addressed your points from my perspective, and I'll maybe turn it off to Michele, if you want to say a few more words about the performance.

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

Yes. So thank you, Walid, and good morning, good afternoon from me as well. It's in the performance for Jyseleca and also the evaluation of efficacy and safety that Bart presented in the first part of the call today. And that also complements very nicely with the insides we get through deeper market researchers and advisory boards and feedback from prescribers, rheumatologists and gastroenterologists, where we see that they actually see the value of the JAK1 preferential mode of action. And actually, the interest in that feature of Jyseleca rose with the presence of data and other JAK inhibitors to actually see the difference between the different molecules actually come into a view of, say, the older and newer JAK inhibitors with us, with Jyseleca being in the newer -- seen as a newer JAK inhibitor, JAK1 preferential inhibitor.

Also in the general terms of the market, the JAK class hasn't been, in general, touched by the procedure. There were already clear behaviors and beliefs by the prescribers. And then, in that sense, the trend is continuing and allows a good base for our growing performance.

Operator

Thank you. There are no more questions at this time, I would like to hand back over to Sofie for final remarks.

Sofie Van Gijsel ***Galapagos NV - Head of IR***

Thank you, operator. That concludes today's call. Please feel free to reach out to the IR team if you still have questions. Our next financial results call will be our H1 2022 results on August 5. Thank you all for participating, and have a great rest of your day.

Operator

That does conclude our conference for today. Thank you for participating. You may all disconnect.