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Q1 2024 Galapagos NV Earnings Call

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CORPORATE PARTICIPANTS

Jeevan Shetty *Galapagos NV - Head of Clinical Development Oncology*
Paulus A. Stoffels *Galapagos NV - CEO, Chairman, Interim Head of R&D*
Sofie Van Gijsel *Galapagos NV - Head of IR*
Thad Huston *Galapagos NV - Executive VP, CFO & COO*

CONFERENCE CALL PARTICIPANTS

Jacob Mekhael *KBC Securities NV, Research Division - Financial Analyst*
Judah C. Frommer *Morgan Stanley, Research Division - Equity Analyst*
Nevin Varghese *RBC Capital Markets, Research Division - Associate*
Philip M. Nadeau *TD Cowen, Research Division - MD & Senior Research Analyst*
Sean McCutcheon *Raymond James & Associates, Inc., Research Division - Senior Research Associate*
Sebastiaan van der Schoot *Kempen & Co. N.V., Research Division - Analyst*
Shan Hama *Jefferies LLC, Research Division - Equity Associate*
Xian Deng *UBS Investment Bank, Research Division - Analyst*

PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the Galapagos First Quarter 2024 Financial Results Conference Call. (Operator Instructions) Please be advised today's conference is being recorded.

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 welcome all to the audio webcast of Galapagos' Q1 2024 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 Paul Stoffels, CEO; and Thad Huston, CFO and COO. Paul will reflect on the first quarter of 2024 and present the corporate update. Thad will provide an operational update and go over the financial results. He will also discuss the outlook for 2024 and present concluding remarks.

You will see a presentation on screen. We estimate that the prepared remarks will take about 20 minutes. Then we'll open it up to Q&A with Paul and Thad, joined by Jeevan Shetty, Head of Development Oncology.

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

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Interim Head of R&D***

Eve, and thank you all for joining for today's webcast. I would like to take a minute to start with our foundation, our vision and mission, which we presented shortly after I joined Galapagos in 2022 and which informs all we do.

We aim to transform patient outcomes through life-changing science and innovation for more years of life and quality of life. And our vision is to eventually reach patients around the world. To that aim, we accelerate transformational innovation through the pursuit of groundbreaking science and collaborations with industry and scientific partners.

Since I joined a little over 2 years ago, we went through a very important company transformation. And with the recent transfer of the

Jyseleca business to Alfasigma, we have transformed Galapagos into a pure-play biotech with a revitalized pipeline and put in place the tools we need to meet our future growth ambitions.

Today, we are focused on driving value creation in our key therapeutic areas of immunology and oncology, where significant unmet medical needs remain for patients. Our strategy is to spearhead our efforts with indications that have breakthrough designation potential in oncology and immunology. And we are building a broad R&D pipeline of potential best-in-class cell therapies and small molecule drugs.

We put in place strong leadership with a track record of delivering transformative drugs to patients around the globe. We take a collaborative approach combining internal and external innovation. And our strategy is supported by a very strong cash position of EUR 3.6 billion as of the 31st of March 2024.

I'm pleased to present our new management team to you. We assembled a team of experienced world-class leaders across our therapeutic areas and platforms with top talent from companies such as J&J, Kite, Miltenyi, GSK and BMS. Combined, the team has brought well over 30 drugs to market. We strongly believe that we have the capabilities in place to drive value creation from here.

We are building our differentiated platform technologies to bring medicines to patients across the globe, working on small molecules, cell therapy and biologics. Thanks to the acquisition of AboundBio and CellPoint in 2022, we added cell therapy and biologics to our capabilities.

In cell therapy, we have an innovative, scalable, decentralized manufacturing platform that enables us to deliver fresh CAR-T therapies close to patients. And we have a unique R&D engine to discover and develop armed multi-targeting CAR-Ts for hematology and solid tumors.

We have a strong legacy of small molecule research and development in immunology, and we have now expanded our small molecule efforts to precision oncology. The teams are progressing our discovery and development efforts across multiple modalities, focusing on finding groundbreaking solutions for high unmet medical needs with the aim to accelerate time to patients.

Here you see our pipeline in our 2 therapeutic areas, oncology and immunology. We aim to deliver best-in-class therapeutics. In oncology, we are progressing our Phase I/II CAR-T programs, 5101 in NHL and 5201 in CLL and Richter's transformation, as well as our BCMA-directed multiple myeloma program with 5301.

In our early research, we have over 10 discovery programs across CAR-T and small molecules in both heme and solid tumors. In immunology, we are progressing our 2 Phase II studies with 3667 in lupus and dermatomyositis. And we have over 5 discovery programs across various inflammatory and autoimmune indications.

As we continue to broaden our pipeline, we continuously look for differentiated technologies that enable us to reach more patients with high unmet needs in an innovative way. Decentralized CAR-T cell therapy is a key example of that. CAR-T is one of the most remarkable advances in cancer therapy in the last several decades. Nonetheless, we see today that only 10%, 30% of eligible patients receive this therapy. Access is restricted for a number of reasons that go hand in hand with the fact that these products are produced in large and costly GMP facilities in a centralized way.

Centralized manufacturing faces significant logistical challenges, including cryopreservation of cells to allow for shipment. We address the limitation of existing CAR-T therapies with our decentralized manufacturing model. We have an exclusive global license with Lonza for the Cocoon manufacturing platform for the decentralized delivery of CAR-T cells in hematological tumors.

We are able to deliver fresh, fit cells with a median 7-day vein-to-vein time. This allows for greater physician oversight and for a production model near the patient that is globally scalable. Currently, we have 3 clinical trials running on the Cocoon with very encouraging efficacy and safety results in critically ill patients with NHL, CLL and Richter's transformation.

We are also actively rolling out our decentralized CAR-T network, both in Europe and the U.S. In the U.S., we collaborate with Landmark Bio for the Boston area and with Thermo Fisher for the Bay Area. And we are in discussions with other parties for additional centers. In Europe, we plan to add additional sites to the 5 that we currently have up and running in 3 different countries. We expanded our operations in Pittsburgh, Pennsylvania. As you remember, this is the site, which we added with the acquisition of AboundBio in 2022. And we opened an office in Princeton, New Jersey, where we are adding key capabilities in strategy, regulatory, operations and quality.

I would like to highlight our extensive work to rebuild and expand our earlier-stage pipeline, where we're making important progress throughout our therapeutic areas in both small molecules and cell therapy. We have over 15 programs in discovery across oncology and immunology, and we expect to deliver the first preclinical candidates this year and start first in human studies in 2025.

I would now like to hand it over to Thad for the financial and operational update.

Thad Huston ***Galapagos NV - Executive VP, CFO & COO***

Thank you, Paul, and thanks, everyone, for joining today. Let's take a look at the financial results for the first quarter. As a reminder, we transferred the Jyseleca business to Alfasigma and the transaction closed on January 31 of this year. As a result, the Jyseleca results moved to discontinued operations.

For our continued operations, revenue remained flat year-over-year and mainly consists of the linear recognition of the platform for the Gilead collaboration. We see an increase in R&D cost as compared to last year, which is mainly driven by our investments in oncology, both in CAR-T and small molecules.

We recorded a net profit driven by fair value adjustments, foreign exchange as well as EUR 25 million in interest income. We also reported net profit from discontinued operations of EUR 67 million, mainly driven by the one-time gain of EUR 53 million for the Jyseleca transaction with Alfasigma.

Now over to our 2024 guidance. You may have seen that we report an operational cash burn of EUR 125 million for the first quarter of 2024. This is on the higher end due to the phased transition of services for Jyseleca to Alfasigma, as announced last year, as well as timing of interest income and tax credits. We expect that our operational cash burn will continue to improve in future quarters, and we therefore reconfirm our full year cash burn guidance of EUR 280 million to EUR 320 million.

Our cash balance in Q1 2024 amounted to EUR 3.6 billion. With streamlined operations and a strong balance sheet, we are confident that we have the organizational setup and firepower to execute on R&D and collaboration opportunities.

Now turning to our outlook for 2024. We anticipate important regulatory progress with our CAR-T trials in the United States. Mid this year, we plan to submit the IND for our NHL trial, building on the tech transfer to our first U.S. site, Landmark Bio. In the second half of the year, we aim to submit an additional IND for 5201 in CLL and Richter's transformation.

We will share further data on the safety, efficacy and durability of our ongoing CAR-T programs. We hope that this will confirm the data with our decentralized CAR-T platform that we have observed thus far. We are preparing to expand our ATALANTA trial in NHL to the U.S., to initiate the Phase II EUPLAGIA trial in CLL and Richter's transformation in Europe, as well as expand our Phase I/II PAPILIO trial in Europe.

Operationally, we are working to add additional sites for our decentralized CAR-T manufacturing network, both in the U.S. and in Europe. We are also exploring additional partnerships for our CAR-T network across the globe. We also aim to execute on additional licensing agreements and acquisitions as well as research collaborations. Our business development efforts serve as an overarching purpose of accelerating breakthrough solutions to patients in need.

Let me conclude by coming back to the strong fundamentals that we have put in place to build a global innovative biotech company and the clear path that we have towards value creation. We are progressing our early stage pipeline, building on our renewed discovery portfolio based on best-in-class targets towards best-in-class medicines.

While we push forward internal programs, we are also very active in business development discussions to broaden our portfolio. We continue to execute on our scientific progress in our key therapeutic areas of immunology and oncology. We invested and we continue to invest in strengthening the team in key positions globally.

We benefit from a very strong balance sheet, and we commit to staying disciplined in our use of cash to focus our investments to maximize value. And we want to thank our investors for their continued support as we continue to deliver on our strategy to generate sustainable long-term value for shareholders.

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

Thank you. That concludes today's presentation portion of the conference call. I would now like to ask the operator to hand it over for Q&A.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). And now we're going to take our first question. It comes from the line of Xian Deng from UBS.

Xian Deng ***UBS Investment Bank, Research Division - Analyst***

Just one, please. As you mentioned, the tech transfer is due -- sorry, in the U.S., is due in H1 this year. So I was just wondering, do you think this is the gating factor for a rapid -- let's say, a rapid increase in progression of enrollment for the trial? And once you have all those centers set up, do you think we can expect to see a rapid enrollment increase and potentially a very quick progression to pivotal, let's say, dose expansion phase? Or do you think this is more of, let's say, strategic allocation of resources and capital? Please.

Jeevan Shetty ***Galapagos NV - Head of Clinical Development Oncology***

Thank you for the question. I can certainly start. Clearly, the gated step with regard to the tech transfer, this goes hand-in-hand with the IND for NHL and CLL. And we plan for that from mid-2024. And in quick succession to that will be the IND for CLL.

With regard to the tech transfers, clearly, the tech transfers are important to the point that you make regarding the patient recruitment. And these steps go hand-in-hand with regard to the recruitment which is already ongoing in our clinical program in Europe, but for it to be initiated and accelerate in the U.S.

With regard to the capital allocation?

Thad Huston ***Galapagos NV - Executive VP, CFO & COO***

Yes, we have qualified Landmark Bio in the -- just recently, and that site is ready. So that puts us well positioned for the IND filing midyear. We're also now in the process of getting Thermo Fisher also for the Bay Area in the second half and we're going to be adding additional sites. So we're very focused on expanding the number of sites, both in the U.S. and Europe, to help us build out our platform to support all of our clinical studies.

Operator

(Operator Instructions) The next question comes from the line of Philip Nadeau from TD Cowen.

Philip M. Nadeau ***TD Cowen, Research Division - MD & Senior Research Analyst***

Congrats on the progress. Just one from us. In terms of 5101, 5201 and 5301, when could we see the next data? We understand you're continuing to enroll patients, but any specific plans to present updated results from those programs?

Jeevan Shetty ***Galapagos NV - Head of Clinical Development Oncology***

Thank you for your question. With regard to the first 2 studies, we will be presenting data in upcoming hematology conferences this year, a combination of new data and also updated durability data.

With regard to your reference to the multiple myeloma study, the program has just opened very recently and just started recruitment. So a little bit early with regard to that, but there will be a continuous stream of data over the 2024 and beyond.

Operator

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

Nevin Varghese ***RBC Capital Markets, Research Division - Associate***

This is Nevin on for Brian. Just a follow-up on that question. So how are you thinking about advancing 5301 in multiple myeloma, especially in light of some of the other competitor products that are moving up in the treatment paradigm, and some of the other bispecifics that are expected to launch in the space as well?

And then how much additional value will the decentralized manufacturing process offer to multiple myeloma treatment versus either NHL or CLL?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Interim Head of R&D***

Well, the multiple myeloma program is in Phase I, dose-finding. We are learning about the 7-day vein-to-vein process, which we can also apply here and look about what type of efficacy and durability we can generate with that. Pending that, we'll decide going forward with additional studies, but that is ongoing as we speak in Europe. And hopefully, we'll have more data towards the end of the year or in beginning of -- quarter of next year on concluding.

We have seen, in both with the 5101 and 5201, is that the fresh cells provide significant good efficacy but also safety. And we do the learning exercise from the 5301 here to see whether the fresh cells approach and close to patients can generate a benefit for patients, both safety, efficacy but also durability. And then we'll decide next steps.

Operator

(Operator Instructions) The next question comes from the line of Judah Frommer from Morgan Stanley.

Judah C. Frommer ***Morgan Stanley, Research Division - Equity Analyst***

Yes. Can you hear me okay?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Interim Head of R&D***

Yes.

Judah C. Frommer ***Morgan Stanley, Research Division - Equity Analyst***

I just wanted to get your thoughts on maybe some commentary coming out of other CAR-T players. Gilead has discussed expanding toward the community setting given capacity constraints, and Bristol has expanded its partnership with Cellares and their Cell Shuttle system.

So just curious if you see these as confirming the need for point of care CAR-T. And does this invite incremental competition? And if so, do you feel that you're in the lead with the Cocoon system?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Interim Head of R&D***

Well, I think with the Cocoon system, we can provide several benefits. It's really scalable on a global basis, where you can go every corner of the world, but also every corner of Europe and the U.S. is possible.

Then second, there is still a very high unmet medical need because of access at the moment in many parts of the U.S. as well as in Europe. And I think we can provide access with a really scalable model to patients. I think that is a clear complementary platform which can be used to provide CAR-T.

As the indications expand and also the applications expand, like solid tumors, as you see the first results emerging from that, the need for capacity is going to be even bigger going forward. And that's where we think we are the first with a solid system to go decentralized,

close to the patient.

We bring benefit on 7-days vein-to-vein and can treat people with very high medical need and short life expectancy, which we have seen in our current trials, and hopefully combine that with capacity; but also combine it with the benefit of the safety and the efficacy, what we have seen already so far.

To be confirmed in Phase II studies, but we see a lot of benefits in the platform to be able to be available, we give good results, short life -- solving short life expectancy challenges and the broadening need for capacity growing NHL -- in -- sorry, in hemato and solid tumors.

Jeevan Shetty ***Galapagos NV - Head of Clinical Development Oncology***

And just to add to that, the platforms that you've shared, i.e., Cellares with BMS and the others. Really, we are quite differentiated from that by virtue of the fact that we're delivering fresh product, fresh cells in fresh product out. And we believe that the translational data that we are publishing and continue to publish show clear differentiation, and we'll continue to do so as the years go on, and we continue to share data.

Operator

We're going to take our next question. And the question comes from the line of Jason Gerberry from Bank of America.

Unidentified Analyst

This is Chi on for Jason. Maybe two on I&I for us. I'm curious, can you talk about your research and development efforts for CAR-T in the broader I&I landscape outside of lupus? And if the effort is still in early stage, when do you think investors can learn more about your efforts there?

And my second question is on 3667. Curious if you have any thoughts of exploring that agent in additional indications? For instance, filgo previously had some interesting Phase II data in uveitis, and Roivant recently provided some Phase IIa top line data with their JAK1 TYK2 inhibitor. So curious, do you think the mechanism of 3667 makes sense? Or whether the market opportunity for uveitis makes sense for you to explore this agent in uveitis?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Interim Head of R&D***

Well, let me start with the TYK2 program, your second part of the question. We are currently validating and do the proof of concept into the two indications, dermatomyositis and lupus. We are strong believers that the mechanism of action with the complete inhibition of Type 1 interferon signaling and not inhibiting IL-10 signaling, we think that we have a product which has a good chance of working there in these type of diseases.

And for that, so we will wait for -- we'll first deliver results on dermatomyositis and lupus before expanding into other indications. There might be a lot of other applications, but we have decided to first do the proof of concept or determine efficacy in those two indications before going further into others.

With regard to autoimmune and CAR-T, we absolutely are continuing to look at new technologies to step away from the integrated -- the integration of viral vectors into the genetic material. And there, we have internal efforts ongoing as well as external collaboration, we explore, on new mechanisms to develop CAR-Ts without integrating a viral vector system.

So that's ongoing, and we'll keep you updated where -- at the moment we have internal results or a BD opportunity which we pick up.

Operator

(Operator Instructions) The next question comes from Jacob Mekhael from KBC Securities.

Jacob Mekhael ***KBC Securities NV, Research Division - Financial Analyst***

I'm just curious when you refer to BD opportunities, I just would like to get a better idea of your approach here. Do you have a preference for licensing compared to M&A? Or are those equally on the table? And what are the factors that would influence your choice either way?

Thad Huston ***Galapagos NV - Executive VP, CFO & COO***

I think both licensing and M&A acquisitions are on the table. We look to see where we can find opportunities where their immunology or oncology, clearly assets that are addressing high unmet medical need, where we really have a high bar. But then also looking even at late preclinical to early clinical proof-of-concept types of things where we think that we can add substantial value. So we look at all. We also have done some research collaborations in early Stage 2 to broaden our portfolio.

I think one thing to point out here today, too, is we're sharing a bit more about the number of programs that we have in internal research. And Paul mentioned that we have 10 in oncology, another 5 in immunology. We want to continue to complement that and to build that out both in terms of CAR-T and small molecules.

So those are really -- and we see tremendous opportunity, obviously, given our firepower and where we sit today. But we also have a fantastic team to assess these BD opportunities and help bring in the best things that fit for Galapagos.

Operator

(Operator Instructions) The next question comes from the line of Sean McCutcheon from Raymond James.

Sean McCutcheon ***Raymond James & Associates, Inc., Research Division - Senior Research Associate***

Maybe to build on the last question. So for the next wave of potential assets within the portfolio, interesting to deal with BridGene, maybe using that as a backdrop for more macro commentary on the development strategy. They have targeted small molecules and covalent PROTACs. What is your view as you build out the portfolio on the state of play in targeted oncology? There's a lot of me-too assets for validated targets, but where do you think Galapagos could fit in?

And then maybe what's your view on the degraders and the optionality that, that might bring in oncology and immunology? And is that an MOA that you're interested in pursuing?

Paulus A. Stoffels ***Galapagos NV - CEO, Chairman, Interim Head of R&D***

Yes, we did a collaboration with BridGene focusing on precision medicine using new targets -- not new, but existing targets which are validated, but at the same time, offer the opportunity to be differentiated with next-gen therapy, with next-gen molecules. And that's where the combination of real unmet medical need, where there is no option, and we find a way to -- with combining the diagnostic tools with having precision medicine, we think that we can -- with the platform and with our team which we assembled, we can make differentiated medicines against a number of these targets.

We are accessing platforms like BridGene. We are -- you've also seen that we did a strategic investment in Frontier, which has a very broad KRAS portfolio on the multiple opportunities for both our products, but also collaboration with the platform.

So that's the approach we do, where every time, addressing a disease where there is no solution, allowing to go for good clinical efficacy leading to breakthrough designation and accelerated approval because of the high unmet medical need. So we basically better our process to being able to bring this type of medicines, as I just quoted.

I hope we will -- and hope, but we'll plan definitely to have a more extensive review on our early stage portfolio in one of the coming quarters. We'll see when we do that when we have the first results to present.

Operator

(Operator Instructions) Now we're going to take our next question, and it comes from the line of Sebastiaan van der Schoot from VLK.

Sebastiaan van der Schoot ***Kempen & Co. N.V., Research Division - Analyst***

In the past, you have mentioned that you see the CLL program as the most likely program to get fast proof of concept and get to the market. Can you provide your vision on the current progress of the program and the likelihood of a pivotal study after the update later this year? And maybe you can also put the results in context of BMS' recent approval in CLL.

Jeevan Shetty ***Galapagos NV - Head of Clinical Development Oncology***

Thank you very much for the question. First of all, I'll speak to the program, and then secondly to the data from Bristol-Myers Squibb. With regard to our -- CLL high-risk CLL and Richter's transformation studies. The expansion part of the study is to be initiated imminently. We've had very meaningful conversations with the authorities, the EMA in particular, with regard to our regulatory path forward. And we've got a clear path forward with regard to this. And the aforementioned IND also permits us to have the discussions with the regulators.

We want to align with the regulators, the U.S. authorities, the FDA, and really work out a program of one set of globally appropriate studies. We have a very clear direction in terms of what we wish to do in both the high-risk CLL and the Richter's transformation population. We believe we'll be able to have a very broad access and really help a significant number of patients in the process in this area, particularly Richter's transformation, which has a very significant unmet need.

To the second part of the discussion regarding the Bristol data with Breyanzi. We of course welcome new therapies for patients in this significantly underserved disease. But there are some important observations. What they have presented is a single-arm study with no patients suffering from Richter's transformation. In addition, the patients waited for a median vein-to-vein time of 36 days. And furthermore, the efficacy of less than 20% really does leave as an opportunity to improve this and really fundamentally impact on benefit to patients.

And so with that in mind, we are in a very strong position to know what data is out there. And clearly, with our unique platform, 7-day vein-to-vein, fresh to fresh, without any cryopreservation and the data that you have already seen, as well as the additional translational data, we feel very confident that we're going to be able to contribute significantly to patients.

Operator

Now we're going to take our last question for today. The question comes from line of Shan Hama from Jefferies.

Shan Hama ***Jefferies LLC, Research Division - Equity Associate***

Just also on business development. Should we expect yield as a string of pearls throughout the year? Or is it preferable to have the outright acquisition of one company with a number of derisked late- assets?

Thad Huston ***Galapagos NV - Executive VP, CFO & COO***

Yes. We continue to follow our plans to both assess the string of pearls, and we're in discussions with a number of different companies to look at earlier, late preclinical, early clinical assets. But we also assess larger transformations to try to have something that's near term to the market as well. And we continue to evaluate a number of larger potential BD opportunities as well.

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

Thank you. That concludes today's earnings call. Please feel free to reach out to the IR team if you still have questions. Our next financial results call is our H1 2024 call on August 2. Thank you all for participating, and have a great rest of your day.

Operator

That does conclude our conference for today. Thank you for participation. You may now all disconnect. Have a nice day.