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HALF YEAR 2024 GALAPAGOS NV EARNINGS CALL

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CORPORATE PARTICIPANTS

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- **Paulus Stoffels** *Galapagos NV - Chairman of the Board, Chief Executive Officer*
- **Thad Huston** *Galapagos NV - Chief Financial Officer, Chief Operating Officer*
- **Jeevan Shetty** *Galapagos NV - Head of Development Oncology*

CONFERENCE CALL PARTICIPANTS

- **Operator**
- **Brian Abrahams** *RBC Capital Markets - Analyst*
- **Philip Nadeau** *TD Cowen - Analyst*
- **Judah Frommer** *Morgan Stanley - Analyst*
- **Jason Gerberry** *Bank of America - Analyst*
- **Sean McCutcheon** *Raymond James - Analyst*
- **Jacob Mekhael** *KBC Securities - Analyst*

PRESENTATION

Sofie Van Gijsel *Galapagos NV - Head of Investor Relations*

Welcome all to the audio webcast of Galapagos' H1 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 half of 2024 and discuss our pipeline and programs. Thad will provide a financial and operational update and 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 Stoffels *Galapagos NV - Chairman of the Board, Chief Executive Officer*

Thank you, Sofie, and good afternoon, everyone. I would like to start with bringing back this slide that we showed at our first quarter results, summarizing our vision and our strategy to drive value creation for all stakeholders. We transferred Jyseleca and successfully transformed Galapagos into a pure-play biotech with a revitalized pipeline and we are investing in the elements that we believe we need to make our strategy successful.

We focus on our key therapeutic areas, oncology and immunology, 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 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, taking a collaborative approach combining internal and external innovation. And finally, our strategy is supported by a strong cash position of EUR3.4 billion at the end of June 2024.

We are building a pipeline and a manufacturing network to support our cell therapy vision, and we are optimistic that it will enable us to accelerate future growth.

In the first half of this year, we delivered on a number of important milestones. Let's start with our regulatory achievements. We are pleased to share that we have submitted the IND to the FDA for the ATALANTA Phase 1/2 study of GLPG5101 in refractory, relapsed non-Hodgkin lymphoma. Obtaining regulatory approval is a crucial step to conduct clinical trials with our cell therapies in the US, which is a key element of our growth strategy.

We submitted a CTA with the European Authorities for the EUPLAGIA Phase 1/2 study of GLPG5201 in refractory, relapsed chronic lymphocytic leukemia and Richter transformation. We made important clinical progress with our Phase 1/2 studies of GLPG5101 and GLPG5201, respectively, and we presented additional encouraging safety, efficacy, durability and translational data at scientific conferences.

We are making significant progress with our proprietary pipeline now comprising of 20 small molecules and cell therapy programs. I will give more color on this in the following slide.

We're also significantly expanding the footprint of our cell therapy manufacturing network, not in the least, through the agreement signed with blood centers of America for the US territory. And finally, with the collaboration announced with Adaptimmune, we took an important first step into the cell therapy solid tumor space with TCR T-cell therapy.

Now over to our pipeline. In our two therapeutic areas of oncology and immunology, we aim to deliver best-in-class therapeutics. In oncology, we are progressing our Phase 1/2 CAR-T programs GLPG5101 in NHL and GLPG5201 in CLL and Richter transformation. As mentioned, I'll come back to the clinical progress presented at EHA for GLPG5101.

We presented additional encouraging safety, efficacy and translational data with GLPG5201 at EBMT in April this year in 14 patients with relapsed, refractory CLL and Richter transformation, showcasing deep and durable responses in this critically ill patient population.

In the PAPILIO Phase 1/2 BCMA-directed multiple myeloma program with GLPG5301, we observed one case of parkinsonism. Patient safety is a key priority and therefore we temporarily pauzed enrollment according to protocol guidelines to evaluate this event.

Parkinsonism has been reported previously in BCMA and CAR-T cell therapy studies and we believe that with the implementation of a comprehensive and specific measure, this can be safely managed. The study protocol was amended and submitted to the EMA in June and we anticipate resuming recruitment in the coming months and aim to report data from the study at medical conference in 2025.

While we advance therapies that we have developed internally, we believe that a robust pipeline should also include promising therapies developed externally. Thanks to the collaboration and licensing agreement with Adaptimmune signed and announced at the end of May, we also added TCR T-cell therapy to our pipeline.

Through the option to exclusively license Adaptimmune's next-generation TCR T-cell therapy uza-cel targeting MAGE-A4, we took a first step in head and neck cancer at potentially additional solid tumor indications with our decentralized manufacturing platform.

In their Phase 1, SURPASS trial with centrally manufactured uza-cel, Adaptimmune has already shown encouraging results in head and neck cancer with an overall response in four out of five patients.

Initial in vitro results suggest that uza-cel produced on Galapagos' decentralized manufacturing platform yields fresh, fit early phenotype T-cells in seven days that could potentially improve efficacy and durability compared to uza-cel centrally manufactured on Adaptimmune's platform. In addition, the vein-to-vein time of seven days is important for patients in whom rapid access to treatment is vital.

In immunology, we are progressing our two Phase 2 studies with GLPG3667 in lupus erythematosus. As we work to advance programs in development, we are also investing in our discovery portfolio in small molecules and cell therapies to identify the programs of tomorrow.

We are making important progress throughout our therapeutic areas and we have over 15 internal programs in discovery across oncology and immunology with small molecules and cell therapies. We also continue to scout for external innovation to further build our early-stage pipeline.

We recently expanded our strategic collaboration and licensing agreement with BridGene Biosciences to include the discovery and development of a highly selective oral SMARCA2 small molecule or PROTAC.

In 2025, we expect to initiate at least four IND or CTA-enabling studies and at least one first-in-human study. From '26 onwards, our aim is to fuel the clinical pipeline with at least two new clinical assets annually across cell therapy and small molecules.

As mentioned, we were happy to present encouraging new data from our ATALANTA study with GLPG5101 in NHL at the EHA Conference in June. A quick reminder about the design of the study, which consists of a Phase 1 dose escalation part and a Phase 2 expansion part. The study is a basket trial in critically ill NHL patients.

The CAR-T cells are manufactured using our decentralized platform with a vein-to-vein time of seven days. The Phase 1 primary objectives are to establish the safety profile and recommended Phase 2 dose. The Phase 2 primary objective is efficacy as measured by objective response rate.

Here, you see the pooled Phase 1/2 efficacy results for 31 patients. We observed high objective response and complete response rates over the different indications. In patients with diffuse large B-cell lymphoma, seven out of nine patients responded and complete responses were seen in five out of nine patients.

In patients with follicular lymphoma or marginal zone lymphoma, complete responses were observed in 16 out of 17 patients. In patients with mantle cell lymphoma, complete responses were observed in all five patients.

Looking at the responses over time, we saw that the results were durable in the majority of responding patients. 10 of 14 patients responding in Phase 1 had an ongoing response at data cut-off with a median follow-up of 13.1 months.

Four patients in Phase 1 progressed after initial response, two had a CD19 positive relapse, one had a CD19 negative relapse, and one patient was unconfirmed.

In Phase 2, which started more recently, all 14-patient responding had an ongoing response at data cut-off with a median follow-up of 4.2 months and one patient in Phase 2 progressed after an initial response.

Turning over to the safety results now. It is a busy slide and I will not get into detail, but summarizing. We see the vast majority of CRS and ICAN events were low-grade. This is very encouraging and confirms the data that we have previously shared at ASH in December of last year.

As we previously disclosed, two deaths occurred during the study. One intra-abdominal hemorrhage which was caused by Grade 4 disseminated intravascular coagulation in dose level two and one Grade 5 urosepsis event was reported in follow-up more than six months after infusion and while the patient was in complete response. One additional patient died due to disease progression.

This updated patient set of 33 patients in total confirms the data presented earlier on 23 patients. The observed safety, efficacy, and durability are very encouraging, providing additional data to show a potential beneficial role of a short vein-to-vein time, robust in vivo expansion and preservation of early T-cell phenotype on clinical outcomes.

The data demonstrate that with our innovative cell therapy manufacturing platform, we can infuse fresh, fit cells with a median vein-to-vein time of just seven days with high complete response rates across indications in heavily pre-treated patients.

I would now like to hand it over to Thad for the financial update and the outlook for the remainder of 2024. Thad?

Thad Huston *Galapagos NV - Chief Financial Officer, Chief Operating Officer*

Thank you, Paul, and thanks everyone for joining today. Let's take a look at the financial results for the first half of 2024. During the first half of 2024, we have worked on strengthening the foundation for future growth. We divested Jyseleca, which enabled us to focus on our priority programs and invest in our pipeline and in building our global cell therapy network. You will see our strategy reflected in our financial results.

In January of 2024, we transferred the Jyseleca business to Alfasigma, as a result the Jyseleca results moved to discontinued operations. For our continued operations, revenue remained fairly stable year-over-year and mainly consists of the linear recognition of the platform for the Gilead collaboration. A small part is coming from the remaining Jyseleca royalty income and inventory sale of the product to Alfasigma.

As explained in our Q1 earnings call, we see an increase in R&D costs as compared to last year, which is mainly driven by our investments in oncology, both in cell therapy and small molecules.

We reported a net profit driven by fair value adjustments in forex as well as EUR49 million in interest income. Also we reported a net profit from discontinued operations of EUR71 million, mainly driven by the one-time gain of EUR52 million for the Jyseleca transaction with Alfasigma.

Now over to our 2024 guidance. Excluding business development activities to-date, we reconfirm our full year cash burn guidance of EUR280 million to EUR320 million. The updated cash burn guidance accounting for the deals that we executed in the first half of the year is EUR370 million to EUR410 million for 2024. This is mainly driven by the Adaptimmune collaboration which accounts for EUR79 million.

We reported an operational cash burn of EUR250 million in the first half of 2024. Note that this comes in on the higher end due to (1) the announced collaborations with Adaptimmune and other smaller business development transactions. (2) the phase transition of services for Jyseleca and Alfasigma, which mainly happened in Q1, as well as (3) the timing of interest, income and tax credits. Our cash balance at the end of H1 amounts to EUR3.4 billion, supporting us to execute on research and development and collaboration opportunities.

In the last couple of years, we closed strong partnerships to build our cell therapy capabilities, entered into R&D collaborations and licensing agreements, and executed on acquisitions and equity investments. We continue to focus on strategic business development to bolster our pipeline and optimize our operations.

I would like to highlight the collaboration that we closed a few months ago with Blood Centers of America as a partner for our cell therapy platform in the United States following the earlier announced collaborations with Landmark Bio in Boston and Thermo Fisher in the Bay Area.

The collaboration significantly advances the expansion strategy of our platform in the US as BCA's national network will allow us to manufacture our cell therapy products close to the patient across the US. The network will support our planned pivotal trials and help us gear up for commercial readiness.

Now, turning to our outlook for 2024. We anticipate important regulatory progress with our CAR-T trials in the US. To recap what Paul explained, we submitted the IND for our NHL trial. We also submitted a CTA to start the Phase 2 dose expansion with GLPG5201 and we are on track to submit the IND for GLPG5201 in CLL and Richter transformation later this year.

In H2, we will also share further data on the safety, efficacy, and durability of our ongoing CAR-T programs, GLPG5101 and GLPG5201. Operationally, we are working on opening additional sites for our decentralized cell therapy manufacturing? both in the US and in Europe.

We will leverage the BCA collaboration to open sites across the US and are exploring additional partnerships for our cell therapy 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 our 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 an 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.

Thanks to the progress made, our goal now is to initiate at least four IND CTA-enabling studies and at least one first-in-human study in 2025.

While we push forward internal programs, we remain active in business development. The Adaptimmune collaboration announced is a good example of how our BD efforts broaden our portfolio as it marks our first expansion into TCR T-cell therapy in solid tumors.

We continue to execute on our scientific progress in our key therapeutic areas of oncology and immunology, and most notably our CAR-T programs with GLPG5101 and GLPG5201.

We have invested and continue to invest in strengthening our team in key positions globally. Finally, we benefit from a very strong balance sheet. 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 deliver on our strategy to generate sustainable long-term value for shareholders.

Sofie Van Gijsel *Galapagos NV - Head of Investor Relations*

Thank you, Paul and Thad. 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

Thank you. (Operator Instructions)

Brian Abrahams from RBC Capital Markets. .

Brian Abrahams *RBC Capital Markets - Analyst*

Hi, there. Thanks so much for taking my question. Congrats on the progress. I'm wondering if you could maybe talk about some of the key aspects that you were able to kind of get through with regards to manufacturing site readiness, QC to get the FDA, I guess, over the line and facilitate IND submission for GLPG5101. And then kind of along those lines curious, what's left to be done for GLPG5202 in order to facilitate that IND filing? Thanks.

Thad Huston *Galapagos NV - Chief Financial Officer, Chief Operating Officer*

Yeah. So we've been working actively, obviously, to prepare for some time the tech transfer to Landmark Bio to help set up the IND filing. We have completed that process and have just recently submitted the IND.--

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Jeevan Shetty *Galapagos NV - Head of Development Oncology*

Let me add, Brian, we had multiple interactions with the FDA pre-IND submission in order to be able to understand what the expectation was so we could optimize our proposal for the FDA. And we just now submitted and it is being evaluated and we'll follow -up as we get more questions through the process and hopefully finish this within the timeframe.

Thad Huston *Galapagos NV - Chief Financial Officer, Chief Operating Officer*

Then we anticipate we're going to file the GLPG5201 later this year.

Jeevan Shetty *Galapagos NV - Head of Development Oncology*

Yeah. We first had to get, like we said before, we first had to have the transfer of technology to Landmark Bio. And so, the second one, as we complete the first one, we'll start to continue with the second one hopefully before the end of the year. That's the goal.

Brian Abrahams *RBC Capital Markets - Analyst*

Great. Thanks so much.

Operator

(Operator Instructions).

Philip Nadeau from TD Cowen.

Philip Nadeau *TD Cowen - Analyst*

Good morning. Thanks for taking our question. We just had one on the parkinsonism that you mentioned for GLPG5301. Is that similar to what's been seen for the other BCMA CAR-Ts? Any difference in the severity or quality of the side effect? And can you go into a bit more detail about the protocol amendments that were submitted? Were those changes to monitoring or were there dosing changes recommended? Thanks.

Jeevan Shetty *Galapagos NV - Head of Development Oncology*

Thank you. Thank you very much for the question. With regard to the PAPILIO study and the case that you're describing, it is a feature of patients increasingly more so and with the increasing use of BCMA-targeted CAR-T therapies is becoming more recognized. We haven't seen anything in this particular patient which was an atypical patient presentation that is different from what is out there in the limited literature that there actually is. In an abundance of caution, we ourselves undertook to pause the study and really interrogate this particular patient history.

And we did this by internally reviewing all the components of the patient's characteristics as well as seeking external guidance and advice. And it's consistent with what has previously been recognized. We have undertaken a number of steps, additional specific safety measures.

So moving forward, we feel very comfortable with the continuation of the study and in fact have submitted the protocol to the EMA in June and we anticipate resuming the recruitment imminently. I concur with you that the changes that we've made are to components of monitoring and I hope that answers your question.

Philip Nadeau *TD Cowen - Analyst*

That's very helpful.

Jeevan Shetty *Galapagos NV - Head of Development Oncology*

Thank you.

Operator

(Operator Instructions).

Judah Frommer from Morgan Stanley.

Judah Frommer *Morgan Stanley - Analyst*

Yes, hi. Thanks for taking the questions and congrats. Just a couple on Adaptimmune. I guess, first, just any thoughts you can share on how the first-gen afami-cel asset may have influenced your decision to partner on the next-gen asset? And then secondarily, I guess, from a size perspective and from an indication perspective, I think, you said this is fairly indicative of what business development efforts could look like going forward. Just could you be a little more specific on whether that's modality indication or just the size of the deal? Thank you.

Paulus Stoffels *Galapagos NV - Chairman of the Board, Chief Executive Officer*

Yeah. Let me say we were very impressed with the Adaptimmune team as well as with what they have been doing in the clinic and the result on afami-cel. As we saw that initially 12 months ago, even 15 months ago when we started the discussion on the TCR-T, which peaked their interest since a long time. And so that led to evaluating whether we could produce the TCR-Ts on our platform.

We took about 12 months to do that and came out with it, as I said in my prepared remarks. Well, there's some feedback here, in my prepared remarks that the phenotype which we could create in our seven-day production process was very encouraging for potential additional benefit with the TCR-T product.

That led us to a further discussion and conclude a collaboration on uza-cel, starting with head and neck where they had their initial data.

As I remarked on, four out of five patients are responders and there we are starting now collaborating on expanding those studies and working together on uza-cel. But, yes, afami-cel was a very important driver for us to start a discussion and led to the conclusion.

Thad Huston *Galapagos NV - Chief Financial Officer, Chief Operating Officer*

Yeah, I would just add, I think, I mean, to me, it's clear that business development is going to be key to broadening our portfolio. And, of course, doing great licensing deals with great partners like Adaptimmune is one way to do that. We also continue to look at doing acquisitions as well and to try to find potential partners.

We see that we have and are building a nice pipeline in cell therapy as well as small molecules. You also see our early pipeline in discovery can really be complemented through business development activities as well.

Judah Frommer *Morgan Stanley - Analyst*

Thank you.

Operator

Brian Abrahams from RBC.

Please ask your question. Okay. Just give us a moment. There are no questions from this line. Now we're going to take our next question. And the next question comes from the line of

Jason Gerberry from Bank of America.

Jason Gerberry *Bank of America - Analyst*

Hey, guys. Thank you for taking my questions. Just one quick follow-up on the protocol amendment. It sounds like I just want to confirm this is more to do on the monitoring side rather than the mitigation side as I guess the understanding out there is that there's limited strategies you can incorporate to mitigate the severity of the parkinsonism. And how many patients did you dose with

GLPG5303 before you saw it? And with the onset of action consistent with what we've seen with other CAR-Ts, which is typically kind of 90 days to 120 days after the infusion? Thanks.

Jeevan Shetty *Galapagos NV - Head of Development Oncology*

Yeah. Thank you. Thank you for the question. Yeah, just to reiterate the, with regard to the changes made to the protocol, they are indeed to do with monitoring and to more closely follow the history of patients. As I said, this was an atypical patient, and the neurological component of monitoring has been further fortified. We will share imminently. Clearly, the study is about to be reinitiated. We will share all of the data regarding safety, efficacy, patient numbers in 2025.

Jason Gerberry *Bank of America - Analyst*

Thanks.

Operator

(Operator Instructions).

Sean McCutcheon from Raymond James.

Sean McCutcheon *Raymond James - Analyst*

Hi, guys. Thanks for the question. Can you speak to the BridGene SMARCA2 project and the BridGene approach as it compares to the other assets in the space? So maybe more broadly the landscape in SMARCA2? And then beyond that, what's your view on the opportunity within SMARCA4 loss-of-function mutation, which drove you to select SMARCA2 as the first target molecule for the collaboration? Thanks.

Jeevan Shetty *Galapagos NV - Head of Development Oncology*

Thank you for your question, Sean. As you know this SMARCA2, it is a dependency in the SMARCA4 deficient non-small cell lung cancer population. So we think 4% to 8% of the population, in fact. So the big challenge really is determining the selectivity against the SMARCA2.

The problem of toxicity is quite well known, particularly cardiovascular, in essence. And so looking at our approach, which is really about how best to innovate and using combinatorial skill sets, the strategies that we have -- we are familiar with are really PROTAC and you know other companies that are in the space. We have a certain expertise in small molecule oral ATPase.

So the strategy what we propose is really using the best of our own internal capabilities and knowledge and the best partner, which we believe is BridGene with the PROTAC. So really leveraging BridGene's PROTAC expertise with our own internal innovation machine and specifically the selective small molecule ATPase expertise.

And so our intention is to build the best-in-class oral selective PROTAC and to accelerate time to patients. We believe whilst there are a number of companies working on different parts of this approach, we are combining both to what we believe will be a best-in-class product for patients. More widely, we have a significant pipeline of small molecules which we will share more information with you in the coming months and years.

Paulus Stoffels *Galapagos NV - Chairman of the Board, Chief Executive Officer*

Yes, as Jeevan is saying we have set up a team, which is focused on best-in-class targets, combining a lot of expertise brought together by different experts on platforms and especially small molecules. In addition, we have the CAR-T platform, but we'll start to disclose this as soon as we go into the clinic with the first ones. At the moment, we consider this as a competitive edge from our side, do not disclose yet what type of approaches we take to the new targets we have chosen.

Operator

(Operator Instructions)

Jacob Mekhael from KBC Securities.

Jacob Mekhael *KBC Securities - Analyst*

Hi, there, and thanks for taking my question. I just want to come back to the adverse event that was seen in the multiple myeloma trial. Just curious, what happened to the patient and if that adverse event was reversed. And perhaps a follow-up on that, given the competitive nature of the multiple myeloma space, how much of a priority is GLPG5301 compared to your other programs? And does this adverse event scene change how you think about this program at all? Thank you.

Paulus Stoffels *Galapagos NV - Chairman of the Board, Chief Executive Officer*

Yeah, we have a principle, and I think it's a clinical principle, that we can't share private data on individual patients so that we can't share the status of the patient at this moment. So what -- this is the first part of this study with a dose-finding. So we evaluate further on, as the study restarts, what the doses and the safety efficacy profile will be with the fresh cell therapy production approach.

And based on that, we evaluate whether there is a future for the product in the competitive landscape of the BCMA. Of course, what you have seen with CLL and NHL data, as I presented, we see very encouraging data in very advanced patients who really can benefit from our approach, close to the patient, fast access as well as a high-quality cell therapy which can be given and that resulting in good safety and efficacy.

And so GLPG5101, GLPG5201 are key priorities. With GLPG5301, we are evaluating the benefit, risk-benefit safety, and we'll come back to that with the first when we have the dose findings done. So all focus on making sure we start in the US, we start our next studies in Europe, and trying to get our critical studies all started in '25 and still focusing on submission and approval in '28. Yeah. So that is the goal what the top priority for us.

Jacob Mekhael *KBC Securities - Analyst*

Okay. Thank you.

Operator

Thank you. (Operator Instructions)

Dear speaker, there are no further questions. I would now like to hand the conference over to Sofie van Gijsel for the closing remarks. Please go ahead.

Sofie Van Gijsel *Galapagos NV - Head of Investor Relations*

Thank you, operator. Please feel free to reach out to the IR team if you still have questions. Our next financials results call will be our Q3 2024 results on October 31st. Thank you all for participating and have a great rest of your day.

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