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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the first half 2022 financial results conference call. (Operator Instructions) Please be advised that today's conference is being recorded.

I would now like to hand the conference over to your first 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' H1 2022 Results. I'm Sofie Van Gijsel, Investor Relations, representing the reporting team at Galapagos. This recorded webcast is accessible via 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. The company's 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 Bart Filius, COO and President. Paul will discuss the highlights of H1, and Bart will go over the operational and financial results. You will see a presentation on the screen. We estimate that the prepared remarks will take about 20 minutes. Then we'll open it up to Q&A with Paul and Bart joined by Walid Abi-Saab, Chief Medical Officer; and Michele Manto, Chief Commercial Officer.

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

Paul Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Thank you, Sofie, and welcome to this first half review of the year.

Let me say, I think we have made very good progress, and we'll hope to give you a good insight on where we are with the company. We'll focus on the full half year, but first on Q1, you probably have seen that and remember that JYSELECA was approved in the U.K. and Japan in -- for UC, and that EU PRAC review started on all JAK inhibitors, and we'll come back to that later on. That review is ongoing, and we'll expect the information by the end of the year.

In Q2, a lot of change is happening in the company. First, I joined in -- on April 1 as CEO of the company, joining a team which I know for a long time and with a lot of enthusiasm working together with the team on how we can create a very value-creating pipeline as a

company. First, I must say, we are very proud on JYSELECA. We got a reimbursement in 15 countries for RA now, 6 countries for UC, and you will see that in the review of Bart where the results of that are following on the European sales. And I think we are all very happy about that. I'm very proud that we can progress JYSELECA in this way.

In the pipeline, we kicked off a whole program of reviewing the pipeline on -- in our capital allocation accordingly. And so we made a move on acquiring 2 companies, CellPoint and Abound in order to move into oncology. We moved in a very exciting part of oncology with CAR-T, both with new CAR-T products, but also with a very transformational platform where we can bring CAR-T to the point-of-care, and we'll highlight that in the presentation, which is -- which we are now in clinical trials, testing it out.

But on the other hand, we also made the decisions to discontinue 4 early-stage programs in order to focus our resources on the most value-creating programs we have in the organization. If you look at the pipeline, and you will see here what we are working on. First, we have the JAK inhibitor, filgotinib, with very good results in RA and UC in Europe. But we expect data from Crohn's disease out of our Phase III in the first half of next year. And that will then hopefully be given additional accelerated boost to the sales in Europe as this type of compounds are very highly needed in the market. We are starting with the TYK2 '3667, a study in dermatomyositis. We'll come back on that. It had good results in the Phase I. And building on that, we have chosen a selected indication to bring it into the clinic.

We are still further evaluating our SIK compounds, SIK3 '4399 is in healthy volunteers. And we are looking for the data to -- before deciding what indication and where we are going with that. And then the several SIK compounds in two entry and previous combinations, we have now decided to look at what can 1 bring, SIK2 bring and see how we can move that forward. And that is still under evaluation by our teams.

As indicated, the CD19 CAR-T is now in Phase II clinical trials, come back to that. And then we are -- we have committed to make 3 next-gen CAR-Ts through AboundBio in the next 3 years in transformational CAR-T products. Still 1 product which is in preclinical in fibrosis, SIK2/3 '4605, and then the kidney program, we also expect results first half of next year and decide then whether we go forward with that or not.

We discontinue 4 compounds of '555, '3121 and then '4716, '4586. As you see on the slide, the first 2 are in inflammation. The second 2 are in fibrosis. And both were through a deep review and on a scientific review, but also a prioritization exercise. And we -- the '4716 and '4586 are compounds, for which we have returned the rights back to the original owners of the company. The '4716, we continue still to evaluate that -- sorry, I missed here. The '4586, we are continuing to evaluating other indications but not anymore in fibrosis.

So in dermatomyositis with the TYK2, we chose a selected indication of a high unmet medical need to explore the activity of TYK2: the compound '3667 TYK2. In - the compound showed clinical activity in psoriasis in Phase Ib and was well tolerated. Dermatomyositis is a chronic autoimmun disease of skin and muscle with an estimated incidence of 2 to 10 cases per 100,000. And it -- the key drivers for it are the Type I/III interferons as well as the IL-23 pathways. It's a severe disease with muscle weakness, rash and papules, and we hope to start the study before the end of the year. That is the aim, and the teams are working on doing that. So that's a new indication with the TYK2 we are starting by the end of the year.

A few words on the acquisitions of CellPoint and Abound. As I already said, we would bring with CellPoint and Abound, a disruptive CAR-T manufacturing where we can go to point-of-care with a 7-day vein-to-vein process with a clinical stage pipeline. The acquisition of Abound is a complementary to that, which can -- for us, and we are working with Abound on the next-generation CAR-Ts, but it also brings us broader biological capabilities in antibodies. The -- that all supported by the fully integrated pharma -- biopharma capabilities with our end-to-end development capabilities at Galapagos as well as our commercial presence in Europe today. And hopefully, future with these products in -- globally.

There is still a very significant unmet need in heme CAR-Ts as of today. And there are three very important points with CAR-Ts. One is access, second is durability, and three is the toxicity. And with our approach, we hope we can address each of them. First, the manufacturing constraints and logistics, people need to wait. There is limited access on a global scale with a centralized production and often valuable time gets lost for patients with high drop-out rate leading to mortality. And that provides an opportunity to accelerate on site with a 7-day vein-to-vein, access to CAR-Ts on a very large scale with a very high added value to patients and physicians and

hospitals to be able to manage their own CAR-T process in the hospitals and priorities for patients.

Durability, high relapse rates today. And the second one, the use of humanized antibodies and CAR-T constructs as we are working on would probably go to redosing, the current or most murine constructs and therefore, redosing is not working. The high relapse rate, most likely, we need multiple binders multi-specific. And that could prevent the relapse rate, and therefore, provide durability.

Toxicity, as we use fresh cells at going into the system, but also going out, meaning there is no freezing in the whole process. The cells are much more viable. We have still proved that it really is a differentiator, but it's highly likely a differentiator on how the cells can be produced as well as can be given to patients. And hopefully, with that, we can provide - prevent toxicity and with that, reduce intensive care hospitalization at hospitals.

So there -- the opportunity there is for us to show the differentiation both on the CAR-T construct, but also on the 7 days vein-to-vein point-of-care model in the hospitals.

At the CellPoint, here in all the demonstration, if you compare 7 days vein-to-vein versus the 15 to 17, even up to 30-day process in the centralized where transportation takes time, freezing in 2 directions. And then, of course, the central GMP facility, which is a huge investment. We can all go around that by using a scalable point-of-care incubator combined with the cassette. And on the right side, you see how we do that with an automated rapid, efficient and scalable tool, production incubator, including integrated quality control and release. And that will allow us, at the moment, and we do it consistently in the hospital and clinical trials now, 7 days fresh cells vein-to-vein.

Next slide. The collaboration, which is also a very big enabler for us, is with Lonza, very experienced CMO, who has developed this tool. And it's existing out of 2 elements. One is the Cocoon incubator. And second is the cassette, which is a fully closed cassette, where the production of the CAR-T is happening. What CellPoint has done is built an xCellit platform around it, which is a quality system and data system, which monitors the whole process as well as collects all the data. And with that, we succeed now in providing quality released products within hours after the end of the process.

On the extreme right side, you see that this will also be provided in multiple units for hospitals with many CAR-T production needs. And there, a very limited space is needed in a GMP environment to be able to produce this type of -- the CAR-T and use this type of systems. It's regulatory compliant with the FDA. It has the CE mark, highly automated, and it is very well proven as a manufacturing tool today.

Abound brings us a highly experienced team, and that was very much needed as we were not in oncology, with a proven track record of multiple industry partnerships, both in CAR-T in antibodies, but also in ADC. And in antibodies, they did both in infectious disease and oncology multiple partnerships. And so with that, we acquired a research team, which allows us to state that our goal is we will bring 3 differentiated CAR-Ts in 3 different indications in the next 3 years. We are aiming for 1 per year. And with that, we use their fully human multi-specific and multifunctional CAR-T capability. We have access to bispecific antibodies and antibody drug conjugates, and that will help us also innovating with our chemistry here at Galapagos, where we can combine the biology with the chemistry. And so with that, working on improved efficacy and hopefully preventing cancer relapse.

We -- with the 2 acquisitions, we brought very quickly end-to-end oncology capabilities in-house, and we are building on that and strengthen it with new talent, which we are bringing in.

The Phase I study, the I/IIa study with the CAR-T in Cocoon is going well. We are enrolling patients at the moment in the Netherlands, Belgium and Spain in the Part 1 of the study. We have now 5 enrolled in NHL, 4 in CLL, a very robust program. We continue to be able to do it in 7 days, vein-to-vein, in the clinical trials, in the hospitals, locally produced. Part 1 is a dose escalation where with 15 patients at 3 doses going from low-to-high, from a very low dose to an extensive dose. And then follow-up with that is the dose expansion where we include 30 patients, and that will lead then to the conclusion at the dose we get out of a dose finding as a pivotal Phase II dose. And the low-dose cohort is now completed for both trials, and we'll be able to present data in the upcoming meetings before the year-end.

With that, Bart, I would like to give it to you and go over the financial results. Thank you.

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

Thank you, Paul, and good morning, everyone in the U.S., and good afternoon in Europe. Happy to be with you this afternoon and on a Friday and to give you a bit of background on our performance in the numbers as well as our commercial operation.

So if we can go to the next slide. On JYSELECA, as a reminder, it's our first marketed product. We are also the marketing authorization holder since we've taken that back from Gilead. We are reimbursing 15 countries in rheumatoid arthritis and now 6 countries in ulcerative colitis. And we anticipate that the vast majority of Western Europe is going to be reimbursed in UC by the end of this year. So that process is going well. And I'll say a few words about how the drug is received in that indication in a few seconds. And lastly, noteworthy for everyone, we'll have Phase III top line data in the first half of next year in Crohn's disease, and that should hopefully enable us to make an extra indication part of the life cycle of JYSELECA.

And maybe first in the performance in the market. And on the next slide, you see the quarterly sales as of basically the very first quarter when we were in the market at the time of beginning in Germany in the Q1 '21 up until now in the second quarter of 2022, where we've reached a level of EUR 21 million of revenues in the quarter with a good quarter-on-quarter growth compared to the first quarter of the year. But actually a good straight-line extrapolation of where we've seen the growth in the fourth quarter of last year.

And with that, it's becoming clear that we can be a bit more optimistic on our anticipated full year sales. Actually, we take an additional EUR 10 million on the guidance. We go from EUR 65 million to EUR 75 million to now a range between EUR 75 million and EUR 85 million, of which the first EUR 35 million has been realized in the first half year. There's also a milestone that we got from SOBI in the second quarter, the second milestone this year for starting countries in Eastern Europe. So also that part of the business is starting to gain traction. So very pleased with that.

On the next slide, a bit of detail, as I promised on the UC. Here, we see essentially what our market share is on the left in the German market in UC in 2, 3 different lenses. First of all, we look at the dynamic market share, obviously. So these are patients eligible for a new treatment option. There, our overall market share is 12%, but noteworthy is that actually in the switch category of patients, we are the leader in terms of initiations with 25%, and this is not just among JAKs, obviously, but this is across classes, including biologics, including small molecules.

So this gives you a flavor as to what the unmet need really is in this indication, reflected again on the right. Still the remission rates with patients are truly suboptimal in UC. Many therapies still require patients to remain on corticosteroids, the treatments are complex and safety concerns persist. So we think that with JYSELECA, we have a very good proposition to address those 4 elements of unmet need in ulcerative colitis. And that's also even if it's early days in Germany, but that's also reflected in the pickup that we get in Germany.

And then, if I move on and obviously, Michele Manto, our Chief Commercial Officer is available for any further questions on the commercial side. But as I move on for the financials. Our cash burn for the quarter -- for the half year, I should say, has been EUR 217 million. That is our operating cash burn. As usual, we exclude a couple of elements there in, first of all, a little bit on the warrant exercise to the far left. We had a positive EUR 70 million currency translation effects. As you know, we keep a portion of our cash balance in dollars. The dollar has appreciated against the euro. As we report in euros, we get a translation effect, which is favorable by EUR 70 million for the first half of the year. And then, we also highlight the acquisitions, CellPoint and AboundBio. We actually were able to sign and close them at the moment of announcements. So the cash that we spent on that in the second quarter at the end of June was EUR 133 million, and that remains with the cash burn and operating cash burn of EUR 217 million.

Our full year cash burn and our guidance towards that full year cash burn, we have increased by EUR 30 million. I think I preannounced that at the end of June, when we said that through the acquisitions of CellPoint and Abound, we would also incorporate some additional operating costs. At the time, I mentioned EUR 25 million to EUR 50 million. We've landed now at a EUR 30 million increase of our range, which brings our range between EUR 480 million and EUR 520 million. And that's all against a very healthy cash balance at the end of June of EUR 4.4 billion.

On the next slide, maybe the highlights on the P&L. I won't dwell on that too long, but revenues and other income, EUR 290 million. A

good portion of that is still driven by revenue recognition from both the filgotinib and the larger Gilead transactions, both of them EUR 415 million in the quarter. And then the -- sorry, for the half year, and then the sales of EUR 35 million, royalties of EUR 6 million, which are relating to the Japan business from JYSELECA and the milestones for SOBI there as well.

The operating costs are a bit higher on the sales and marketing side. The big effect there is that in the year 2021, we were still sharing our expenses on commercial with Gilead for 50%. That's no longer the case in 2022. So as a result, net sales and marketing line is going up. And then second element, noteworthy for the first half of the year is the impairment that we've taken for the transaction with OncoArendi, which relates to the molecule '4716 that Paul was describing before, which we handed back to that company. And we've taken an impairment of EUR 27 million, which is included in the R&D line of our P&L. Our net loss is EUR 32 million negative, a good, obviously, efforts by the financial income here of EUR 68 million to protect our bottom line, which is to a large extent driven by currency effects.

And then I conclude with the last slide. Our strategic priorities. We start when we go into the second half of the year, to give a bit of reflection on, let's say, the later years. But first, 2022, what's still upcoming. We're still in the midst of our scientific and strategic review. So a number of discontinuations that we've announced are a result of that, but there's more work, I think, that we are doing in terms of how to organize for our future. And we are also with this presentation, inviting you all to join an R&D update, the Capital Markets Day on the 5th of October that we're going to be holding in the U.S. where we're going to give more details about this -- about the outcome of this scientific and strategic review.

We also have very much on the agenda, the desire to execute additional business developments. We believe the CellPoint and Abound transactions were very powerful, but there's more we think we want to do and need to do to restore our pipeline in a general sense. And we're obviously also focusing on making sure JYSELECA remains a success and continues to grow.

Our guidance numbers I already talked about, so those are there for reflection. And then for the later years, really the key objectives for us as a company, make sure we get JYSELECA to where we had promised it to be, which is EUR 0.5 billion peak sales number in the EU. We want to make sure we develop a catalyst rich pipeline across therapeutic areas. So again, there's more to be done there, both through internal innovation, but especially also through external innovation as well. And then thirdly, a focus on building our point-of-care cell therapy network with multiple differentiated CAR-Ts is a core priority for us in the next years as well. But again, more to come on R&D updates on October 5.

And with that, I give it back to Sofie who can guide us through the Q&A. Thanks, everyone.

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

Thanks very much. 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) And your first question today comes from Brian Abrahams from RBC.

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

I guess bigger picture, you've announced some deprioritizations within the pipeline. I was wondering if you could maybe talk a little bit more about the overall rationale, what you're looking for in the assets that you're going to be moving forward? And I guess, sort of bigger picture, how much this reflects your overall strategy in terms of what indications you'll be focusing on? Or is this more of an asset-specific decision process? What should we be looking for going forward as you continue to prioritize the pipeline?

Paul Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Yes. Let me give a high-level answer to this. We -- first, we will focus on real added value, which is very logic, but addressing medical needs with highly differentiated compounds and then look at the competitive market on where are we on a global base and see then how

we can in that market make competitive products, which create significant value. For that, you need to have a focus. And definitely, our focus will continue to be on inflammation.

As you have seen with oncology, we entered into oncology with specific technologies, specific indications, and we are going to further expand that in the future, probably to CAR-Ts in solid. We also have a good -- we are building a good capability in biologics and small molecules in oncology. So oncology will be a significant focus. But again, evaluating very careful how we, as Galapagos, can make a difference with molecules which are differentiated and bring value to patients and then also to our shareholders.

We are continuing to evaluate fibrosis as a part of our portfolio. We -- but carefully looking at whether from a capital allocation perspective, that can continue to be part of our portfolio as it is a long-term, highly challenging and -- highly challenging environment with no validated -- or limited validated targets and limited validated endpoints. So we'll carefully look at our therapeutic area of focus, good assets within that and then look at the timeline and how we can deliver a pipeline in the '25-'28 time frame because that's the goal here. If not earlier. We hope to be earlier.

Operator

And your 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***

First one just on '3667. Just curious how you see your molecule potentially differentiating from Pfizer's dual TYK2 JAK1, which is moving into Phase III for dermatomyositis. I know it's early days, but I'm not sure if there's anything even there in terms of your approach versus their dual inhibition approach or any pharmacological differences that you think are important? And then on the cell therapy front, just can you talk about the investment needed, how you plan to scale that over time as you get important derisking data in the next year or so?

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

All right. I'll start with the first question on '3667 and then I pass it on to Paul. Regarding the compound from Pfizer, that's JAK1 TYK2. I think there's been some data with it showing this profile of JAK1 TYK2. However, in our case, '3667, our molecule is a selective TYK2 inhibitor. I think that will play a significant different profile, particularly around some of the safety questions that one has to take into consideration here. But at the same time, there's an element of specificity in dermatomyositis in blocking interferon alpha. And it's not very clear how an additional JAK inhibition will add into it. Whether the compound from Pfizer will have the right risk-benefit profile will have to be judged based on the results of the data.

In our case, '3667, we have shown in psoriasis that we have a clearly active compound demonstrating, again, in line with the TYK2 inhibition. In addition, we have seen evidence of pharmacodynamic activity at the doses that we have used in Phase I. These were demonstrated in ex-vivo assays and the dose that we are electing to test and move forward has demonstrated these positive profile on pharmacodynamic engagement, but also safety and tolerability profile. So overall, we feel quite positive, particularly about the selectivity of our TYK2 and the likelihood of success in this indication. And based on that, we are proceeding with our Phase II study.

With that, I'll pass it on to Paul.

Paul Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Well, with regard to the investment in the CAR-T over time, there are 2 elements to this. Our collaboration with Lonza offers us a that's a very stable existing platform, which is scalable, where we don't need to deploy hundreds of millions of dollars before we can even start working in the market. So it's a collaboration with Lonza. During development, we will focus on -- we have to, of course, cover the investment for clinical trials, the development of the product. But as the platform is stable and functions very well at the moment, we have validated with volunteers but also with patient now.

We think that, that provides us a competitive time in order to get with new CAR-Ts to the market. We will have a scaled system in hospitals where we can have a very competitive way of doing clinical trials, very attractive for hospitals to collaborate in that. So the combination with the existing Lonza platform where we can build ourselves on as well as the capabilities we've built step by step in the

different indications will give us a functioning instrument to run several clinical trials in parallel. I think the speed which we can take here as well as the collaboration with Lonza will give us a very good cost-effective way of getting to clinical trials in this space.

Operator

Your next question comes from the line of Charlie Mabbutt from Bernstein.

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

I'm Charlie Mabbutt from Bernstein. So firstly, on the TYK2. I'm interested to hear what other indications you are discussing internally? And if you'd wait for this Phase II readout before starting in the other trials? And I'm also wondering if you think it makes a difference to go for a different indication in Phase II versus the competition for the selective TYK2s, if they can then use a proof of concept? And then secondly, I noticed that your year-on-year spend for Toledo has sort of halved in the R&D line. So should we read anything into this in terms of your confidence in the program?

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

Thank you, Charlie. It's Walid, I'll take both -- all 3 questions. So on the TYK2, we've taken -- so we've -- in order to decide the way forward, we have actually taken a step back and taking a look at the regulatory environment, particularly as it pertains to psoriasis and the fact that TYK2 is a member of the JAK family. And we have questions whether the FDA is going to be quite liberal in interpreting this connection between TYK2 and JAK1. We felt that going into psoriasis is going to be a bit hasty and we'd rather wait for the PDUFA date, which is upcoming in -- towards the end of September for the BMS compound.

We were evaluating ulcerative colitis as another indication. And you've seen data from Deucra, which were not positive, and that's giving us pause. We're discussing still internally with our teams but also externally with experts to see whether there is a way forward, whether we do understand why TYK2 inhibitors did not perform in that indication. There could be other reason for Deucra in particular that might not essentially read out for the rest of the TYK2 inhibitors, but we're still evaluating that process.

Then we looked at indications where there's good rationale for essentially based on mechanism of action, good rationale for success, and we came out with essentially dermatomyositis, which is an interferon-driven disease, and we have clear data from our compound of our blockade of interferon alpha. Another indication that is on our radar screen still is lupus, and we were very happy to see the recent data from deucravacitinib showing positive lupus data.

So in the context of evaluating our overall investment in the pipeline, as we've been talking about, we will be discussing moving forward with lupus with '3667. It's on the agenda. We will not necessarily having to wait for the results of dermatomyositis before we move forward, but those were options that will be on the table for us to discuss.

Talking about the Toledo program. I think it's no secret that we're evaluating this as you've heard. We need to take stock of the data that we had. We had some compound -- 1 compound, in particular, move forward with clinical studies that were small in nature, but they generated data that have mixed results. We have if you remember, with '3970, the SIK2/3 inhibitor, we had positive results in psoriasis, but they were not competitive. There were some encouraging data on objective measures in ulcerative colitis as well. But the exposures that we achieved with that molecule were not good enough to test the hypothesis.

We have a series of other molecules that have been in late-stage discovery, and we're trying to evaluate whether we will have enough of heterocyclic index to go forward, whether its selectivity for SIK2 versus SIK3 is the way to go. And we should be able to speak more to it later in the year when we discuss further our R&D platform. But I think it's fair to say that we are not going full steam ahead as we were before. We slowed down to be able to fully evaluate this and take the appropriate decision in light of the totality of the platform.

Having said that, I still think we are the leaders in understanding the SIK2/3 or actually the total SIK inhibition and their role in inflammation. And I think we will be in a better position to bring 1 to patients if there is a positive risk benefit that we conclude from this. So I think you have to be a little bit more patient with us, but we will come back with more details and rationale for the way forward.

Operator

And your next question comes from the line of James Gordon from JPMorgan.

James Daniel Gordon ***JPMorgan Chase & Co, Research Division - Senior Analyst***

James Gordon from JPMorgan. A couple of questions, please. First one was JYSELECA. So I saw you took up this year's guide, but you haven't increased the EU peak sales. So is it the case that your longer-term sales expectations haven't changed at all, it's just consensus as being overly cautious in the initial modelling? Or is there a possibility that the peak sales could be higher now? So how are you thinking about that?

Second question was on the amount of collaboration with CAR-T. How do we think about modelling the profitability? So let's say there was EUR 100 million of sales. How much of that actually could end up as profit for Galapagos versus what actually goes to launch? Can you help us think about how to model that properly?

And then third and final question for the October 5 R&D event. In terms of what we're actually able to hear at the event, is there going to be a significant new clinical data? Is it more about things that you're planning to start? And might you have inlicensed any further assets by then that you're going to talk about? Could you elaborate a bit on what we're going to find out at that event, please?

Paul Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

I think we got the first 2 of your questions. The third one we could not understand. .

James Daniel Gordon ***JPMorgan Chase & Co, Research Division - Senior Analyst***

The third one was the CMD. Is there going to be significant new clinical data? Or is it more about what trials you'll start or maybe talking about further assets that you're going to inlicense? What do you think should we look forward to at the R&D event?

Paul Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Okay.

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

Should I take a couple of those questions, Paul?

Paul Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Absolutely.

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

So first question, James, on your peak sales -- on our peak sales expectation. I think it's a bit too early after a great quarter and an upgrade of our guidance for the full year by EUR 10 million. So then we visit immediately the peak out there, which is in 2027. So I think that's still a bit too early. But we are obviously very pleased with what we're seeing in terms of the performance this year, both in qualitative sense in terms of how it's perceived in the marketplace and quantitatively in terms of what we are seeing in terms of sales. So happy with that outcome. .

On Lonza and how to model that. Actually, at this stage, we're not giving out details on the distribution of share and royalties between us and Lonza. But what I did say, as part of the announcement in June is that we believe that including the royalty that we would pay to Lonza, we believe that we have the distribution of share and royalties between us and Lonza. But what I did say as part of the announcement in June is that we believe that including the royalty that we will pay to Lonza, we believe that we have a very differentiated and very competitive cost of goods position with our CellPoint approach. Hence, I think a good opportunity in the market to compete with others with centralized manufacturing on a cost point of view. So I think that's not exactly the answer now that you would love to have in terms of details. But that's, I think, as far as we're okay to go right now.

And then last point on the Capital Markets Day. I think it's going to be a very interesting day. I think we're going to go really across the company in terms of giving perspective on where the strategy of the company is going in terms of indication choices. We're going to give

insights in our cell platform -- cell therapy platform with also some external speakers. We're going to give some insights into our thoughts around dermatomyositis. We're going to also do a deep dive on JYSELECA and the end market performance of JYSELECA. So I think it's going to be an extremely interesting and rich day. Let's say, the big data set that's up and coming from Crohn's, obviously, is coming at the beginning of next year. Therefore, that will not yet be available on the October 5 when we do the Capital Markets Day.

Operator

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

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

I was wondering if you could just give us a little bit of a view on how far you are through the portfolio review? Obviously, you discontinued 4 compounds here. Just how broad should we be thinking about? And how much more work do you have to do at this point to sort of understand where you are? And I guess, secondarily, obviously, you've made the pivot into oncology. Should we be thinking about pivots into additional therapeutic areas? Or do you think the therapeutic areas that we know about now are set?

Paul Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Let me say, we have the internal review where we look internally, but we have also a very extensive external review on what business opportunities we can bring in at the moment. So it goes in parallel, we're looking strategically, what are the assets and the portfolio prioritization internally as well as looking at additional potential short-term acquisitions as the market now is very -- looking for very -- many biotech companies are looking for partnerships now, and it's a great opportunity for us to evaluate that.

We will mainly focus on -- at the moment on oncology and -- in oncology and inflammation. In the past, we have said we are looking at select infectious disease opportunities if they would be there. But oncology and inflammation will be the key. And we'll evaluate internally our fibrosis assets and see whether there are still compounds, which are valuable and worth in the acquisition -- in capital allocation. Where we are is like, let's say, we are in the middle of the review as I'm -- we are in the middle of the review and one-by-one, this is the first reporting to you. And on the Capital Markets Day, we'll be able to give you further insights on long-term strategy, both on oncology and inflammation, other assets in the company as hopefully by then, but maybe not yet next opportunities in acquisitions or licensing.

Operator

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

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

The question is on JYSELECA. Could you go into maybe a bit more detail about what drove the strong quarter-over-quarter growth? Was it specific indications UC versus RA or specific geographic areas? And then second, you mentioned the EU product review coming out later this year. What is Galapagos' opinion on the potential scenarios for the conclusion of that review? And how could they impact JYSELECA's long-term potential?

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

It's Michele speaking. I'll take the first question on JYSELECA in the quarter. And then I think I'll pass then for some conclusions on PRAC and the article 20 to Walid for some considerations there. So yes, it's been a strong quarter. You've seen acceleration. And actually, this comes from the different variable needs to that the launch of UC has contributed, especially Germany and the Netherlands are the first countries that had the reimbursement immediately after EMA approval at the end of last year. But of course, it is early days for the indication. So it's a very strong contribution, but of course, at a different level now to compare with RA, which is on the market now 1.5 years.

Other part of the acceleration has come by the full activation of the geographies. So we have countries like Italy and Spain, which have typically long reimbursement timelines so they came really online at the end of last year. And still with the timeline, which is very competitive, we benchmarked against the fastest JAKs into national and regional reimbursement in those countries, and we really come very strong against those benchmarks. So that's been pleasant to see an upcoming from strong stake or engagement planning across units and in the countries in the past 2 years -- 2, 3 years when we said the prelaunch, so that's coming to fruition.

Also, we've seen an acceleration in Germany, which is, of course, the largest country. I would say, with the full integration of the transition from the Gilead teams, we've seen that also coming strongly through also with better customer engagement after the lockdown period with Covid. So that to say that there is a strong dynamic we see. So that also brought us with confidence to increase the target for this year, seeing this dynamic to continue for the future.

For the regulatory position, Walid, I will pass to you.

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

Yes. Thanks, Michele. Look, it's difficult for us to comment really on the potential outcomes. This is a procedure that it has to take its course. We're working and collaborating with EMA and answering their questions. As you can imagine, none of this was a surprise. These are adverse events of special interest that we've been monitoring for years and been in discussion with the health authorities about them for some time. but at the same time, PRAC has to go through their process, and we expect to have feedback by the end of the year. But before then, it will be really very difficult for us to speculate on potential outcomes.

Operator

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

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

Congrats on the very strong performance. Maybe 2 quick questions. With the expansion into more BD activities to the cash burn future, will that still be on target as was communicated in the past? And I'm now looking at 2024 and beyond? And then the other question is more on the CAR-T situation where, obviously, by going through this decentralized approach, there will be a lot of advantages that were discussed. Maybe could you say who would be the legal manufacturer of those materials? Would that be the hospital or Galapagos? And how will you manage the GMP requirements? Which percentage of hospitals do you see this? Or is the majority of hospitals that are using CAR-Ts to your knowledge, also ready for the GMP setting?

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

Let me take maybe the first question, Jeroen, on the BD activities and the implications for the longer-term cash burn. So as a reminder, what we've shown in the past and is still very valid, was an overview of our R&D spend and our commercial spend. And for everyone on the phone, that was about [EUR 350 million], [EUR 150 million] in terms of distribution. And we anticipate still that JYSELECA breakeven can be achieved in 2024 resulting then in the R&D envelope that we were highlighting on those slides.

Now in all fairness, obviously, and I think I've made that clear several times that if we do meaningful BD and if we increase our expenses because of that, those -- that envelope might change. It might obviously change. There is no let's say, full commitment to state the envelope is the envelope and we're not going to go beyond it because we want to make sure that we invest behind the right programs. And we'll take that accordingly. So more to follow on that front. Obviously, we'll give precise guidance for 2023 and then later on for 2024. And if BD evolves, those numbers will obviously will also evolve, we'll make sure we'll put good money after good projects.

And Paul, do you want to take or should I take the CAR-T?

Paul Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

No, I can take that -- as you say, Jeroen, it's a very attractive manufacturing proposal to decentralize, especially for the benefit of patients. The marketing authorization holder will be Galapagos and we will be responsible for the release of the product. So we will be responsible for the GMP requirements and training at the hospitals and we'll have -- because the system allows us to do that, we can do a centralized release based on the information we receive from the instruments around the world to check on quality and be able to release that.

So this is the strong proposal of CellPoint. It's not just the local manufacturing but it includes a fully integrated data system and quality control system as well as quality release that this will allow us within the time frame we can do it today within 3, 4 hours to give a release after the product has been completed manufacturing. And that is a very strong -- I think a very strong proposal from a time, but also

from a GMP. We'll have to train, and that's what we do already. People in the hospitals who work with us on this manufacturing are trained and will be inspected. And there will be a quality system, which manages all of that. So that is -- but it's our responsibility in the end as marketing authorization holder, we are responsible for the product, which the patients will receive.

Operator

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

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

As we look ahead to the R&D Day in October, how much can you just preview for us about your ability to unveil what the real compound library is at Galapagos and possibilities with targets that are not currently in your stated portfolio and ability to go into new or novel indications? And the basis for this question is, it's obviously early days for you, Paul, but the salt-inducible kinase portfolio has been many years in the making, and it still feels like to the majority of investors, there's no proof of concept there, and it's a very high-risk endeavor. And then TYK2 in the CAR-T space are very competitive. .

So I think where the valuation of the company currently is within the eyes of investors, there still needs to be differentiated assets brought out of the internal compound library. And if not, and if they don't exist, then really there needs to be a more aggressive move on the BD front. So putting it all together, I guess, one, what's your conviction that there's still differentiated assets that are yet to be unveiled in the pipeline that we might see in October? And then secondly, what's your updated view on additional external asset acquisitions?

Paul Stoffels ***Galapagos NV - CEO, Chairman & Member of Management Board***

Well, we'll give a full update on the status of the internal pipeline, as we will have finished a strategic review. We can give some insights -- significant insights on where we are going and certain new indications we'll pursue and especially also with our new capabilities in biological in CAR-T, we will be able to give you some insights on what our capabilities are to go into next. We still have to decide how much we disclose from a competitive perspective, but you will see the capabilities, we'll be able to show some -- the first results of at least in -- from the life testing. We'll give you a very deep insight in why we think that our CAR-T point-of-care is really differentiated. And that both from an efficacy, hopefully starting -- we can't show efficacy data yet because we are not long enough in the study, but we can show the first biomarkers and the first safety results and whatever we have. And that will see -- give you a good insight on.

Then we can give you time lines on -- by when. Because with the CAR-T capabilities, we can go very fast on the next-gen CAR-Ts, and we can both bring in products from outside. And there is a lot of interest at the moment from people who are approaching us to bring additional compounds which are not in our pipeline today, but in partnership to the market and what we can bring from inside. And we'll also have a good view on what we can bring from the inside small molecule space at that moment.

It's always difficult to provide prospects on business development opportunities as they -- if they are not concluded. So if we conclude them, we'll be able to bring them. But if we're not concluded, we can give an indication in what space we are looking, and we'll give a good strategy review. But we're very clearly focused on extreme to an accelerated pipeline of value creation over the next 3 years. That is the goal. Hopefully, we can give you confidence in our strategy that we'll be able to deliver.

Bart, anything to add from your side?

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

No.

Operator

And your last question today comes from the line of Rosie Turner from Jefferies.

Rosie Turner ***Jefferies LLC, Research Division - Equity Analyst***

Just one more on '3667, if I may. Just thinking about the broader kind of market dynamics in dermatomyositis. Just thinking about how that plays out because I think we've got Ultomiris in Phase III, albeit not reading out until 2024 and the same I think we've got an IG

study coming from CSL also in the indication. So I'm just wondering where you see kind of TYK2 is fitting in within the treatment paradigm? And then just if you could give us any potential in terms of the size of the indication in terms of kind of total revenue size?

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

So maybe I'll tackle the first part and then, Michele, maybe you take on the second one, around the commercial element.

When we evaluated the space, we see a large unmet medical need. Currently, what's approved in the market is IV, there's no oral treatment. And we believe that the mechanism of action for TYK2 inhibitor, particularly with clear effects on inhibiting interferon alpha pathways should give us a very good likelihood of success in that space.

I think commenting on other competitors who are moving into Phase III, we haven't really seen a very convincing Phase II data. So sometimes companies take risk and move straight into larger indications. And we'll remain to see whether this is going to provide the right risk-benefit profile at the end of these studies. But the studies that we had available and we looked at with positive data in terms of clinical efficacy that we can compare to, we don't think that we would be at a disadvantage, and we think we have a very good likelihood of success there. We have to run the study. And at the end of it, see if we have a positive risk-benefit profile, but that's the first step that we need to do and then we will take it from there.

And I'll pass it on to Michele for the commercial end.

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

Yes. So this is an area of high unmet need, as Walid indicated. So also the current standard of care is quite limited. So that offers some interesting price possibilities. I would say that now having a plan for the timing of this launch might be a bit early. But what I can say about that is that, that's an area to fully build. So there is a high value high potential for market actually building with all the diagnose and treatment rate to be set and also to have the follow-up of the existing drugs which are not customer friend -- patient-friendly as well in terms of use. So also the oral component will play a big role into that. We need to have a further view then on the profile and the competition there to come with more solid numbers that we'll be able to share.

Operator

I will now hand the call back over to Sofie for closing remarks.

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

Thanks very much. That's all what we had time for today's call. Please feel free to reach out to the IR team if you still have questions, and we hope to welcome you at our R&D update on October 5, which we will have in New York as an in-person event. Thank you all for participating, and have a great rest of your day.

Operator

Thank you. This concludes today's conference call. Thank you for participating. You may now disconnect.