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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the Galapagos H1 2023 Financial Results Conference Call. (Operator Instructions) Again. Please be advised that 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' H1 2023 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 operational highlights and provide an update on our pipeline. Thad will go over the commercial and financial results. You will see a presentation on screen. We estimate that the prepared remarks will take about 25 minutes. Then we'll open it up to Q&A with Paul and Thad joined by Michele Manto, Chief Commercial Officer; and Daniele D'Ambrosio, Head of Immunology.

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

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

Thank you, Sofie, and thank you all for joining today's webcast. I'm very pleased to introduce to you Thad Huston. Thad joined Galapagos as our new CFO, COO as of July 1. Over the years, Thad gained experience through several positions in finance, commercial, BD and operations. He joined us from Kite Pharma, where he was Senior VP Finance and Corporate Operations. And before he was CFO of LivaNova, a listed medtech company. That was the CFO of J&J Medical Devices and CFO of Janssen R&D in earlier years. Thad spent 4 years in China as the President of Janssen China for Janssen. Thad and I have known each order for quite some time. I worked together with Thad at J&J, where he held a number of leadership positions for more than 25 years. And he was instrumental in the transformational phase of Janssen Global R&D. It goes without saying that his knowledge of R&D and cell therapy is a perfect fit for our company. We are very excited to have Thad on board.

On today's call, Thad will present the operational and financial section. Thad?

Thad Huston ***Galapagos NV - CFO & COO***

Thanks for the introduction, Paul. And it's great to be here. I'm so excited to be joining forces with you again together with the Galapagos team to create value for our stakeholders.

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

Thank you, Thad, and happy to work again together and work with the teams.

Here you see a slide summarizing our vision and mission statement. At Galapagos, we want to transform patients' outcome to life changing science and innovation, aiming at bringing more years of life and quality of life. In order to achieve this, we go for groundbreaking signs with an entrepreneurial spirit and a collaborative mindset.

At the R&D Day back in November '22, we introduced the course that we have set out for the company in order to unlock significant value. On this slide, you see a snapshot of how we have been executing on the transformation of the company over the last 18 months. We continued to roll out a commercial organization in Europe for our first product, Jyseleca. In mid-'22, we announced the acquisition of CellPoint and AboundBio propelling us into the space of next-generation CAR-T therapeutics. We refocused the R&D organization on 2 therapeutic areas: immunology and oncology. And late last year and early this year, we presented encouraging initial safety and efficacy data on the 2 CD19 CAR-T trials in relapsed refractory NHL and CLL in point of care setting with our Cocoon platform. In parallel, we accelerated the discovery portfolio both in small molecules and biologics. And we also announced and completed the restructuring of our discovery activities. We transitioned the Romainville discovery activities to NovAliX in France.

Let's move on to our pipeline as it stands today. As mentioned, the pipeline is refocused on 2 therapeutic areas: immunology and oncology. I will come back on some of the programs in more detail below. In summary, in immunology, unfortunately, the Phase III trial in Crohn's disease did not bring us the results we had hoped for. But we have RA and you see on the market with a registrational trial in AxSpA out of the gates now. We are progressing our TYK2 in dermatomyositis and SLE and aim to start a patient study with our CD19 CAR-T '5101 this year in severe refractory lupus. Meanwhile, we are working on multiple exciting preclinical targets that we are eager to push forward if we see a best-in-class potential.

In oncology, we made good progress with the CD19 programs. I will come back on that later. We plan to start BCMA program in multiple myeloma with '5301 after the summer. Meanwhile, with AboundBio as well as via external collaborations that we intend to close we keep working on next-generation CAR-T and leverage our point-of-care Cocoon platform for those. Here is a reminder of our progress with TYK2i '3667, we initiated the Phase II trial in dermatomyositis and dosed our first patients with top line results expected in 2025. We also progressed '3667 in a lupus trial, and we opened the first study centers that are in the process of screening patients and there, the top line are resulted -- the top line results are expected in 2026.

Now let's move to oncology. Today, the approved CAR-T products are manufactured to central production, which has several limitations. For example, product needs to be frozen and needs to be shipped. As mentioned, with the acquisition of CellPoint last year, we pivoted into cell therapy with a point-of-care solution striving for infusion of fresh cells -- a fresh cell product with a 7-day vein-to-vein time in a decentralized setting close to the patient. Here, you see a picture of that many of you've seen before, of the Cocoon point-of-care solution.

We have exclusive license from hematological cancers with Lonza for the Cocoon in the point-of-care setting, allowing us to invest in that platform and give -- provide global access to hospitals. The teams are further optimizing the CAR-T production process and automating the quality release testing, simplifying the point-of-care manufacturing on site. Today, only a small portion of patients that are eligible for CAR-T received a treatment, high unmet need cancer patient populations that are not helped today would benefit from CAR-T therapy.

These are patients with fast progressing cancers that can be helped by quick access and the 7-day vein-to-vein time as well as patients with poor prognosis or with cancers for which no standardized treatment strategy is available today. And as mentioned before, within the pool of patients that have been found eligible for CAR-T treatment, we see that today only 10% to 20% receive CAR-T products due to

barriers in terms of logistics, manufacturing, limiting access to the products. Our aim is to increase the addressable patient population, leveraging the point-of-care model.

Let's move to the programs update on our CD19 CAR-T trials. Here you see the design of the CD19 CAR-T Phase I/II trial in relapsed or refractory NHL. This is a basket trial recruiting patients with diffuse large B-cell lymphoma, follicular lymphoma, mantle cell lymphoma and marginal zone lymphoma. Encouraging initial results have been communicated on 7 patients with an overall response rate of 86% and a complete response rate in all of the 86% of the overall responders. Only mild ICANS and CRS were reported and the median vein-to-vein time for administration was 7 days. This quarter, we made an important progress in our Phase I trial in NHL. We decided to recruit additional patients to generate larger data sets for specific subpopulations of patients with high unmet medical needs. This allows us to build a robust package in support for our pivotal study. We submitted an abstract to a future scientific conference and plan to provide updated safety and efficacy data on the NHL trial before the year-end. The Phase II expansion part of the NHL study is already open and we are actively dosing the first patients in indolent lymphoma as well as in mantle cell lymphoma in those cohorts. We selected our first U.S.-based point-of-care manufacturing site and tech transfer activities have started. We are preparing an IND submission, which we'll plan to submit in the first half of '24.

Here you see the design of the CD19 CAR-T Phase I/II trial in relapsed/refractory CLL. Earlier this year, we announced encouraging initial results on 7 patients with an overall response rate of 100% and a complete response rate of 86%. Advanced CLL and especially patients with Richter's Transformation remain a high unmet medical need patient subgroup. And as announced earlier this year, we are encouraged by the initial safety and efficacy results. No CRS above Grade 3, and no ICANS were reported and as mentioned the median vein-to-vein time was 7 days for this initial patient population.

The first half of the year, we made important progress in our CLL clinical trial, and we are now closing to complete the Phase I recruitment with the last patient identified. In the first half of 2024, we aim to initiate a Phase II dose expansion part of the study, and we established the recommended Phase II dose based on the safety profile efficacy observed. As for the NHL study, we submitted an abstract to a future scientific conference and plan to provide updated safety and efficacy data on the CLL trial before the year-end.

Now over to our discovery portfolio. Last year, we implemented a new operating model and R&D strategy with a goal to accelerate innovation and rebuild our product pipeline to achieve shorter time to patients. We build on strong therapeutic area expertise in immunology and added oncology, bringing in new top talent and capabilities. Additionally, to complement our internal discovery, we are combining internal and external innovation. We now apply a best-in-class target approach going through transformational products in high unmet medical needs. The research teams have performed an internal exercise and identified and selected a set of targets and indications in immunology and oncology.

We can now build on both our expertise in small molecules and our innovative biologics discovery platform with the team of Abound Bio. For Immunology, on the cell therapy front, we have nominated a preclinical candidate that is a fully human CD19 CAR-T targeting a unique epitope and with differentiated binding kinetics. And the small molecule teams identified over 5 targets across several immune indications that fit with our renewed approach and -- that are currently in different stages of clinical development -- preclinical development, sorry.

For oncology, the team of AboundBio identified over 5 targets across hematology and solid cancer indications and multiple differentiated armoring strategies have been set forward alongside a multi-targeting approach. We certainly see an opportunity to leverage our small molecule expertise in oncology, which ties in with our aim to deliver precision medicine. A review of the landscape has been done, and the teams have identified 5 targets across cancer types. Our aim is again to nominate the first clinical candidate from the Discovery portfolio in '24.

So this concludes my review of R&D with the strategic change we made over the last 12 months. And now I hand it over to Thad.

Thad Huston ***Galapagos NV - CFO & COO***

Thank you, Paul. I will provide an operational and financial update for our first half results, and then I'll open the call for Q&A.

We had another soft quarter in Q2 for Jyseleca with the sales coming in at EUR 28 million or EUR 54 million for the first half of 2023. We see a number of headwinds for Jyseleca with the slowdown of the JAK class, reflecting the impact of the Article 20 outcome and label change, increased competition in UC and the effect of the miss in Crohn's disease as a third indication. We are evaluating various strategic options for Jyseleca, and more information will follow later this year. As a result of the slower growth in sales for the first half of 2023, we have lowered our 2023 net sales guidance to EUR 100 to 120 million for the year. A few words on our cash position. Our cash and cash equivalents reached EUR 3.9 billion at the end of Q2 2023.

Our operational cash burn for the first half of 2023 reached EUR 224 million. Although the second quarter burn is higher compared to Q1, we are confirming our full year cash burn range of EUR 380 million to EUR 420 million. The higher burn in Q2 is partly due to a prepayment for future services from NovAliX as part of the collaboration agreement with NovAliX in Q1. Also for our cash balance at the end of the year, we anticipate positive contribution from interest income offsetting the higher burn rate in Q2, and we expect approximately 3% return on our outstanding cash balance.

Finally, we continue to be disciplined and remain focused on managing our resources effectively while we continue to pursue opportunities to drive value and growth. Going to our P&L. We reported a net profit of EUR 28 million in the first half of 2023, in part driven by higher revenue recognition for filgotinib. Collaboration revenues increased mainly due to revenue recognition related to the collaboration agreement with Gilead for the filgotinib development amounting to EUR 155 million in the first 6 months of 2023 compared to EUR 115 million in the same period last year. This increase is primarily driven by a positive catch-up of revenue explained by a decrease in the total estimated remaining cost to complete filgotinib development. This was a consequence of the top line results from the Phase III DIVERSITY trial filgotinib in Crohn's disease and our decision not to submit a marketing authorization application in Europe. The revenue recognition for the platform is stable quarter-over-quarter at EUR 115 million year-to-date. Jyseleca's sales were EUR 54 million in the first half of 2023, and we received a sales milestone of EUR 1 million and EUR 3 million in royalties for Jyseleca year-to-date.

We also saw a reduction in total operating expenses of EUR 50 million or down 13% versus prior year due to lower R&D expense in Q2, primarily due to a prior year impairment and a decrease in subcontracting costs due to portfolio rationalization as well as lower sales and marketing expenses in Q2. And we also received higher interest income in the first half of 2023.

Before we move on to the outlook for 2023, a small word on our BD approach. I want to highlight that BD is key to our vision to create shareholder value. M&A is essential to our success, and we have a clear M&A road map, and we will deploy capital to broaden and strengthen our portfolio.

Let's look ahead with the outlook for the remainder of 2023. It's important to note that our next progress update on '5101 and '5102 and NHL and CLL will be in Q4 2023. We hope to confirm the encouraging safety and efficacy data on a larger patient pool and present more durability data to further validate our point-of-care approach with the Cocoon platform. Also in oncology, we aim to make regulatory progress with an IND submission for a CD19 in the first half of 2024. The CTA for our BCMA candidate '5301 has been approved, and we aim to initiate the trial this year. We also submitted the CTA for our CD19 '5101 in refractory SLE. We also planned several trial initiations. We recently dosed the first patient in AxSpA with filgotinib in the first patient in dermatomyositis with '3667. The lupus trial with '3667 has been initiated, and we hope to dose the first patient soon. We also aim to kick off another trial in severe lupus patients with the CD19 CAR-T this year. We'll also execute on the NHL and CLL expansion cohorts with the CD19 programs and start the Phase Ib multiple myeloma with BCMA CAR-T '5301.

As we continue to execute on our company's transformation, we are focused on accelerating our early-stage pipeline, building on our renewed discovery portfolio. We continue to broaden our late-stage pipeline, pushing forward our internal programs and scouting for new business development opportunities. We aim to execute on our plans in oncology, progressing our CAR-T programs and expanding our footprint with our Cocoon platform. Following the changing market dynamics and revised sales guidance for Jyseleca, we are evaluating strategic options for Jyseleca. And we commit to stay disciplined in our use of cash to focus our investments to maximize value.

Thank you all for your support and your interest in Galapagos. And now let's open the line up for Q&A.

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

Thanks so much, 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

(Operator Instructions) We will now take the first question from the line of Brian Abrahams from RBC.

Joe Kim

This is Joe on for Brian. Can you elaborate more on the strategic options you're considering for Jyseleca? And I guess you mentioned that you will be looking at subgroups for your CD19 CAR-Ts. Can you also talk a little more about these subgroup analysis, please?

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

Yes, Thad, why don't you take the first one? I'll follow up.

Thad Huston ***Galapagos NV - CFO & COO***

Yes. So we are adapting, obviously, to the changing market dynamics in the environment and obviously taking our responsibility as a company to ensure that we're creating long-term value. We are going to do this strategic evaluation of various scenarios and options for Jyseleca as quickly as possible, and we anticipate coming with an outcome of that assessment in the coming months, and we can provide an update at that point in time. So we can't provide any further details at this call.

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

Yes. And for the subgroups, we had, as I said, indicated in the call, several indications within the NHL within the NHL and we are missing a few patients in some of the subgroups to have a complete response comparing to the competitors as well as for submission with the regulatory authorities. And that's why we are -- have continued to recruit until we have in each of the subgroups the patients we need. So -- and that will happen in the next few weeks, 2 months or so, and we'll have an update on that in -- before the year-end.

Joe Kim

Got it. That was very helpful. If I could ask a follow-up. On IND filing for the -- in the first half of next year for CAR-T cells, can you also comment on the level of engagement with the FDA and ahead of the filing? And if you could just talk about some of the requirements for the filing. And can you share with us your latest strategy there? Any specific regions of focus? And how are you thinking about prepping the potential clinical sites ahead of the filing?

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

The most important critical step for us is to have a clinical trial, a production center ready, which has to be submitted with the IND. There we have done an extensive evaluation of centers. And the first tech transfer to the U.S. site is active. And so that will -- that is determining the timing of our submission for the IND. Before that, we had a very good engagement in a pre-IND meeting with the FDA on all the aspects we need to start clinical trial. And so what I just told you was the having the first center validated on U.S. ground, on U.S. soil is the critical step, and that's why we indicate that we'll start -- we'll submit IND first half of next year. But since the first one is ongoing, I think that will be quite optimistic in the course of the earlier months in the next year. So that's where we are. Obviously, we are trying to focus closer by home at the moment. So we started at the East Coast, and we'll reach out later to other parts of the U.S., but that's where we start the first scan of potential centers. And as we speak, that's ongoing, multiple centers are in discussion and contract discussions.

Operator

(Operator Instructions) We will now take the next question from the line of Emily Field from Barclays.

Emily Field ***Barclays Bank PLC, Research Division - Head of European Pharmaceuticals Equity Research***

Just on the Jyseleca point. I was just wondering if while you're going through this review, will you be making any changes to the commercial promotion of the product? I saw that you're initiating the AxSpA Phase III study. So one -- so any changes on the R&D side while this review is ongoing or anything operational that would change? And if I could just slip in one more, just any initial color you could provide on the small molecule discovery program in oncology, would this maybe move into solid tumors? Or would you expect this to be in hem-onc? Any color you can provide would be great.

Thad Huston ***Galapagos NV - CFO & COO***

So regarding Jyseleca in the promotion, of course, we're going to be evaluating and doing a deep dive analysis. It's a very thoughtful analysis market by market and understanding kind of how we can maximize the potential value of the asset, also looking at just the resources and obviously supporting the current promotion of the product and let's just see how we can further optimize that. And we'll come back with more details after we do this assessment.

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

Yes. And your comment on AxSpA, it will be going on until we conclude on the options what we do going forward. And in oncology, we both are working in solid and heme oncology, hematological oncology. And we'll use 1 of the next meetings to give you further detail on the different targets, the different fields and will bring in our Head of Research for having that discussion or having that presentation. So wait for an update there for one of the next meetings where we will come back.

Operator

We will now take the next question from the line of Jason Gerberry from Bank of America.

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

Mine was just as you look to move the BCMA CAR-T program into the clinic, just curious, sort of as you've evolved with the CD19 program and optimize the manufacturing process. How portable is that to new antigen-directed BCMAs or, I guess, CAR-Ts in terms of the process? Are there meaningful changes? Or is there a lot that you can leverage as you move into new CAR-T programs?

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

Yes, that's a very good question. And we can leverage the entire package and entire system. We have done the validation of the BCMA on volunteer sample or voluntary blood, which is done. And so -- and now we are waiting -- we are starting the initiation of the study to do on patients, on patient blood. It is like -- it's like very transferable and so far with good valuation for the BCMA. Of course, then you work on disease material in the next phase, and so we'll be able to confirm that in our next report. But we see no issues on transferring the process. It's a very simple process, automated process where, of course, the vector is different. The cell growth has to be studied, but so far so good. We see no issues in scaling up the BCMA. And of course, what we did with CD19, we observed in the clinical trials, a very good efficacy and safety profile because of the way we produce cells and the 7 days vein-to-vein, fresh vein-to-vein, very difficult to dissect what is the cause of the good efficacy, good safety but we observe that it works. And that's now the next phase for BCMA. We'll do the same. We do a study, evaluate and we'll look at the results before making commitments to go forward with the full development.

Operator

We will now take the next question from the line of Mike Ulz from Morgan Stanley.

Michael Eric Ulz ***Morgan Stanley, Research Division - Equity Analyst***

Maybe just a quick follow-up on Jyseleca, just given you're starting the strategic review, can you give us a sense of when you might be able to provide some final decisions there?

Thad Huston ***Galapagos NV - CFO & COO***

Yes. Thanks, Mike. We are -- we're actively working on this. The process is ongoing. I think it's going to -- we'll have an outcome of that assessment in the coming months. And we can provide an update then. I'm obviously new onboard and here in just over a month. So of course, we're all working very hard to do a very thoughtful assessment.

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

Thad did a deep dive on the whole organization, the commercial organization, the operations in the last month and now ready to engage in next steps. It will take some time. And like Thad is saying next few months or a couple of months, we'll bring clarity and an outcome.

Operator

We will now take the next question from the line of Brian Balchin from Jefferies.

Brian Balchin ***Jefferies LLC, Research Division - Equity Analyst***

So with regards to the sales cut for Jyseleca, but what about the peak sales target of 400 million. I don't think that's baked in label restriction just yet should we be expecting further cuts there?

Thad Huston ***Galapagos NV - CFO & COO***

Yes... sorry, go ahead, Brian. I'm sorry to interrupt.

Brian Balchin ***Jefferies LLC, Research Division - Equity Analyst***

I was going to squeeze in a second one. How confident are you then being able to get a CAR-T on the market by '26, '27 as previously stated, given pushed timelines?

Thad Huston ***Galapagos NV - CFO & COO***

Yes, I'll take the first part on the Jyseleca. I mean obviously, the higher sales number, EUR 400 million is probably given kind of where we are with sales trends, probably not likely. So we want to do also a thorough assessment of the sales potential and revise our models and forecasts and then obviously come back when we do this assessment and look at the overall business case.

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

Yes, Brian, on the timing of the CAR-T to market, it will depend on how we choose our indications, as we indicated -- as we have shown in the first 7 patients and then the patients within that on Richter's Transformation, we see like a very strong effect in a very high medical need. And we are deciding as we go already based on the basket study and then the broader CLL activity on where should we focus to really address a very high unmet medical need in order to get this accelerated recruitment, but also accelerated development part.

And so for now, while we set the target around '27, it's '26 -- late '26, '27 that still would be possible if we get breakthrough designation and have a very high unmet medical need to be addressed. But to be decided when we move for the pivotal study and discussions with the regulatory authority. The demand is very, very high. So what we see in our clinical trial, especially in these indications, people flock to the clinical trials to get in. So especially in the high medical need -- unmet medical needs. So hopefully, we can -- we're broadening the centers in the world, including in the U.S., recruit fast, and have a very strong observation. That's what we hope, as we see in the Phase I/II study. If we see the same observation in the pivotal study, we can still reach this time frame.

Operator

We will now take the next question from the line of Xian Deng from UBS.

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

This is Xian from UBS. Maybe just for -- one question for Thad, please. Given now this is your first appearance as the new CFO, so just wondering if you could share some of your thoughts on the first impression of Galapagos? What's your overall strategy here? I mean, of course, you have the Jyseleca commercialization, you have internal R&D and you have, of course, M&A. And so just wondering what you like the most? Where do you want to change? Will you accelerate M&A? So yes, any thoughts that would be great.

Thad Huston ***Galapagos NV - CFO & COO***

Thank you so much for your question. And yes, I'm just incredibly excited and honored to be part of this team. I think, obviously, working together with Paul again. We've been through transformations in the past. And certainly, we think that there's a tremendous -- I believe there's a tremendous opportunity for us to really drive an innovative approach to bringing life-saving therapies to patients in Galapagos. And I think we're doing some things that the other players are not doing that I think is really exciting. And of course, I have a CAR-T

experience and oncology experience, I think, can also be beneficial in terms of what could be done with point of care and also just so excited to think about what are the possibilities for us to really allocate resources to do business development deals, to further innovate and to make a difference for patients. It's not easy, of course. I mean there's a lot to do, but it's also the opportunity that we have. It's not also lost on me that where our valuations are and to see that there's a tremendous opportunity to change that.

Operator

We will now take the next question from the line of Phil Nadeau from TD Cowen.

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

We wanted to ask about the program of moving your CD19 into autoimmune diseases and particularly lupus. Given the size of the market, those programs have created a lot of excitement for some other companies. Can you talk about the time line of your investigations in SLE. When could that trial start, when could we see data? And then maybe more generally, what's the value proposition for point of care in a more slow moving disease like lupus.

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

Yes. The status is that we submitted in Europe our clinical trial applications. So we'll wait for that outcome in the discussion, and we hope and trust that we can start the study later this year. What is attractive as a complement to our CAR-T network is that, of course, the hematologists, they do -- the rheumatologist is the physician who treats the patient. But in this intervention, the hematologist is doing the application. And that's where this goes very well together with the point of care in centers where we have - in the centers where we have today our point of care CAR-T they're already asking where they can participate. So they see the benefit of the manufacturing on site. There also, again, yes, will we see benefit from a fresh approach, the current approach which Erlangen used was a fresh cell approach done, produced locally, what are we going to see from the approach we are going to do in the clinical trial centers. So I think the benefit of the complementarity on the sites where this is done as well as the approach we have taken and the centers where some of the first patients has taken to their approach on treating patients. Will we see better results or different results, of course, to be determined. But I think before the year-end, we'll be significantly on recruiting in this trial.

Operator

We will now take the next question from the line of Dane Leone from Raymond James.

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

Congratulations on all the progress. Kind of a consistent question for me that I hear from a lot of investors. You have -- you still have a sizable cash balance to draw down on for more meaningful external asset acquisitions. And on kind of counterbalancing that, you still are retaining quite a high R&D burn rate even with Jyseleca activities maybe winding down a bit or continuing to wind down a bit. How are you thinking about balancing that out going forward and perhaps even into 2024, if you could entertain that far into the future. Are we still expecting to do something more meaningful on the business development front perhaps away from cell therapy and more into traditional I&I or what we kind of see on the table from your team today is probably going to be the core area to build out from, and we should expect maybe more bolt-on acquisitions to supplement the activities that are already ongoing internally. And what can we get that cash burn down to now that we are winding these larger I&I studies down with filgotinib, while ramping up maybe more targeted studies with the cell therapy platform?

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

Yes. First, let me start, and Thad will follow up. First, we absolutely just don't focus -- do not focus only on CAR-T. The reason we stepped into CAR-T, we were able to bring 2 teams together with AboundBio and CellPoint which accelerated us in oncology. And we are there now since 13 months -- 13 months ago, Galapagos had no oncology. We were able with 2 teams, bringing them in, the teams, the capabilities and the products to where we are today. It allows us to have a fast time to market in the next 4, 5 years.

And that was the main reason to enter oncology via the big door and go fast in transformation therapies. In parallel, I can tell you, our BD teams have been evaluating many options, which are not in the CAR-T space, complementary with some of the capabilities we have in the company, but also considering other fields. So -- but we have a very high bar for bringing products in. Either they come as a product with a strong team and that typically would be an acquisition or they come in as a strong product, but the product is the core here, where

you have to have, address a differentiate -- a high unmet medical need and where we can reach the market with a differentiated product. That is the definition for us to do a good BD.

And then secondly, it has to be a global deal, yes. We can -- we could consider or we can consider local deals in Europe, but that's not value creating enough for the money we spend. So we always will try to go global deals, highly differentiated products in a very high unmet medical need. That are the criteria, and we hold all our BD discussions we do against that. So that's how we tackle BD, and I hope we can bring significant deals in the next 18 months working on that.

Thad Huston ***Galapagos NV - CFO & COO***

Yes. And addressing the cash burn, I mean it's clear that actions have been taken this past year to reduce the cash burn from even the prior year operationally we're going to continue to be very disciplined and focusing on managing our resources effectively to really continue to drive the long-term value and also growth and finding those opportunities. Also as Paul mentioned, the deals that we're really going for fit our M&A strategy. And at the same time, I think that we are seeing some benefits in interest rates that also help our interest income as well as we're going to make good portfolio decisions and allocate resources appropriately.

Operator

(Operator Instructions) We will now take our next question from the line of Sebastiaan van der Schoot from Kempen.

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

I just wanted to ask regarding the delay in the IND filing towards H1 '24. Can you maybe go into the fact that you are still discussing why the IND has not come off the ground? And then also quickly, you talked about different CD19 CARs and also one specifically for autoimmune disease, can you maybe highlight what the differences are between autoimmune disease and oncology that would require a different CD19 CAR?

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

Yes. First, on the IND, we had the pre-IND discussion. And so to submit the IND, the FDA required to have a site validated on U.S. soil. And that takes some time as we need to transfer technology, first install the technology, transfer the technology and validate. And that will take us up till the end of the year. At that moment, we can submit an IND when that validation is done. And that is the basic reason why taking -- getting to a contract, getting to centers on -- and have that done took maybe somewhat longer than expected.

But basically, the IND requirement was the most important one that it brings it over the year-end. The difference on the CD19 CAR, there is no clear insight what type of CD19 CAR will work best. The Erlangen used the Miltenyi CAR-T, which is very well known. We are using a different CAR-T for ours, which one developer sells, one we licensed in. So we'll use 1 of our 2 CAR-Ts to go into the SLE, but it's not clear which ones will work. They will have to experimentally be proven that they work. So it's very difficult to predict what safety and efficacy will be for the different products. So that's all I can say at this moment on that.

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

Okay. Got it. And maybe then I can squeeze in the last question, as I'm also the last in queue. You mentioned for non-Hodgkin's lymphoma that you are already in dose expansion. Does it also mean that we will get results from the dose expansion by year-end and that you can maybe prepare for a study in 2024 for Phase II in non-Hodgkin's lymphoma?

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

It -- the non-Hodgkin's lymphoma is divided in the different buckets, as I described it in my talk. 2 of them are in expansion. We'll present all of the data later this year, but we'll make a decision based on the highest unmet medical need and the most urgent clinical benefit we can deliver as the first indication we will bring forward. And that's where the diffuse large B cell is still one which we have to recruit additional patients in and that we'll do in the next weeks. So you will see all the data we'll have in that abstract, which will be submitted and available and will become available hopefully at an upcoming call.

Operator

(Operator Instructions) And we will now take the next question from Jacob Mekhael from KBC Securities.

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

I have one just regarding the ATALANTA trial. You mentioned that you will include more patients or certain subpopulations. Does that mean that the planned trial size of 45 patients will now be larger? And if so, how many patients have been recruited so far and how many additional patients do you plan to recruit? And I have a follow-up on that as well, on the IND that will be filed in the U.S. for the CD19 CAR-T. Do you also plan to file an IND for the BCMA CAR-T as well? And what is the expected time line for that?

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

Okay. I have very difficult to understand the first part of your question. You should repeat that. But we can start on the IND for the BCMA. Yes, we'll file that. At the moment, we have a dose finding study done in Europe. So that will take some time, and that's not for this year, of course, that will take another several months before that will be done. The first part of the question, I missed.

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

So just the planned trial size for the ATALANTA-1 trial is 45 patients. I'm just curious, is that still the same? Or is that going to be increased?

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

Yes, it is in that range. The dose finding is - was indicated at about 15 patients and then the expansion dose was about 30. So the total size of the population is about 45. It depends a little bit how many patients will be in which of the subgroups in the study. We won't stop recruiting patients until we close the study. So we'll, we will be around that number at the end.

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

Okay. And I just have one more question actually. Also on the IND for the U.S. Will those trials be an extension of the Phase II trials? Or do you expect that in the U.S., you will go into a larger trial that builds on the data set generated in Europe?

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

Yes, it's the latter -- we want to use the data we have in -- generated in Europe to start a pivotal study in the U.S. and Europe and so in parallel we'll submit an IND as well as go to the European authorities to do a clinical trial in Europe in order to get to our pivotal studies and get to the outcome.

Operator

There are no further questions at this time. I would like to hand back over to the speakers for final remarks.

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

Thank you very much, operator. 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 will be our Q3 2022 results on November 3. Thank you all for participating, and have a great rest of your day.

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

Thank you all for participating. Have a good day.

Operator

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