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PRESENTATION

Operator

Good day, and thank you for standing by. Welcome to the Galapagos Full Year 2023 Financial Results Call and Webcast. (Operator Instructions) And please note that today's conference is being recorded.

I would now like to turn the conference over to your first speaker, Sofie Van Gijsel from Investor Relations. Please go ahead.

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

Thank you, operator, and thank you all for joining the audio webcast of Galapagos Full Year 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 highlights of 2023 and present a corporate and pipeline update. Thad will provide an operational update and go over the financial results. Paul will discuss the outlook for 2024 and present concluding remarks.

You will see the presentation on screen. We estimate that the prepared remarks will take about 20 minutes. Then we'll open it up to Q&A with Paul and Thad joined by Jeevan Shetty, Head of Development Oncology; and 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 all for joining today's webcast. I would like to take a moment to look at the turnaround we are realizing and how we set up the company for future growth and value creation.

First of all, we redesigned our scientific approach, and now we have a patient-centric focus on two therapeutic areas: immunology and oncology. In our core therapeutic areas, we pursue best-in-class medicines with multiple modalities. Today, we are a pure-play biotech with strong end-to-end R&D capabilities. We focus on breakthrough medicines and high unmet medical needs.

We took a fresh look at our early-stage discovery work and broadened our modalities beyond small molecules. Our aim is to nominate a set of preclinical candidates this year that have the potential to enter the clinic next year. We also expanded our scope to bringing in external innovation as we believe that combining internal and external innovation is the best approach to accelerate our pipeline.

Importantly, last year, we embarked on a strategic review of our commercial product, Jyseleca, and now transferred the product, the dedicated teams and related activities to Alfasigma. We strongly believe that our transformation to a pure-play biotech company allows us to focus on our research and development efforts.

We have expanded our end-to-end R&D capabilities, especially in our more recently added therapeutic area of oncology. Today, we are a smaller focused organization with approximately 700 employees. As a result of the organization measures we took, we were able to significantly bring down our cash burn. Thad will come back on how this frees up resources to redeploy in future growth. In conclusion, we believe that we have made significant progress in resetting the company to drive value in 2024 and going forward.

As I mentioned, we have broadened our biological scope from small molecules to cell therapy and biologics. We have a long history and strong legacy of small molecule research and development in immunology, and we have now expanded our small molecule efforts into oncology. Thanks to the acquisition of AboundBio and CellPoint in 2022, we added cell therapy and biologics to our capabilities.

In cell therapy, we have an innovative decentralized manufacturing platform for CAR-T, our clinical pipeline and groundbreaking research capabilities. We will continue to build expertise to discover novel biologics. The teams are working hard to progress our discovery and development efforts across the three modalities with a laser-sharp focus on finding solutions for high unmet medical needs with the aim to accelerate time to patients.

Now let's have a look at our pipeline today. In immunology, you can see that filgotinib has been removed following the transfer of Jyseleca. We have trials running with our selective TYK2 inhibitor, 3667 in dermatomyositis and SLE. Recruitment is progressing, and we are on track for Phase II readouts in '25 and '26, respectively.

For strategic reasons, we decided to discontinue the development of our CD19 CAR-T in refractory SLE. We have seen multiple players entering this area in a short timeframe. The field has become highly competitive and in light of the risk benefit and time to develop, we made this decision. We believe that the cell therapy approach will be a game changer for patients with autoimmune diseases, but for the long-term success, it will be important to have an approach providing CD19 CAR-T-like benefits with an optimal safety profile.

Summary, we remain committed in immunology as a core therapeutic area. And in our early research, we are working on multiple preclinical targets with small molecules and other modalities and continue to pursue external opportunities.

In oncology, we made important progress with our three clinical stage programs, the CD19 CAR-T 5101 in non-Hodgkin lymphoma, the CD19 CAR-T 5201 in chronic lymphocytic leukemia and Richter's transformation patients and also with our program in BCMA-directed CAR-T 5301 in multiple

myeloma. I'll come back to very encouraging preliminary data in NHL and CLL in a moment. Also in oncology, we are progressing multiple targets across modalities, and are on track to nominate preclinical candidates over the course of 2024.

At ASH in December last year, we presented the encouraging safety and efficacy data for our EUPLAGIA program in CLL and Richter's transformation with 5201 in a heavily pretreated patient population. I will not go over the results in detail, but summarizing, we observed an objective response rate of 93% and a complete response rate up to 63% at dose level 2. Moreover, at dose level 2, 100% of the Richter's transformation patients responded to treatment. We also observed encouraging safety results with no CRS higher than or equal to grade 2 -- 3, sorry, and no ICANS reported.

The data informed our decision to select dose level 2, 100 million cells as a recommended dose for the Phase II part of the study. The study is ongoing, and we continue to collect more follow-up data. We now have the first patient in an ongoing response for over 1 year.

Turning to our ATALANTA program in NHL, for which we presented Phase I and II data at ASH last year. We observed encouraging efficacy in patients with multiple subtypes of relapsed or refractory NHL, again in heavily pretreated patients. Overall, an objective response rate of 86% was observed with high rates of complete response. Also for ATALANTA, we observed an encouraging safety profile. The study is ongoing, and we are collecting data on more patients with longer follow-up time. We now have the first patients also in this study in an ongoing response for over 1 year.

2023 was also a busy year in building out our global point-of-care network. You will remember that we have an exclusive global license with Lonza for the Cocoon point-of-care device in blood cancers. We started the tech transfer to our first U.S. site, Landmark Bio, and hope to finish this in the coming months. This is an important step in the rollout of our clinical trials as the tech transfer data will be part of the anticipated IND submission with the FDA.

We recently entered into a strategic collaboration agreement with Thermo Fisher out of the Bay Area, and we aim to sign on additional manufacturing sites in the near future. Our aim is to establish a proximity network of sites that can deliver to hospitals in the vicinity. In Europe, we have five clinical trial centers up and running across three countries: Spain, Belgium and the Netherlands, and we are actively working on opening additional centers.

Late December, we launched our third clinical study on the Cocoon with the BCMA CAR-T 5301 in multiple myeloma. Internally, we also strengthened and continue to strengthen our capabilities in oncology. This includes quality assurance, clinical and regulatory talent, both in Europe and in U.S.

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

Thad Huston - *Galapagos NV - CFO & COO*

Thank you, Paul, and thank you, everyone, for joining the call. As Paul indicated, 2023 was a turnaround year and we now have a focused R&D organization ready to accelerate our pipeline and create value. We completed our transactions with NovAliX for our Romainville site in France and with Alfasigma for Jyseleca. These transactions enable us to significantly reduce our cash burn while allowing for the redeployment of resources in building our portfolio.

We continue to be disciplined in our cash use internally, but also when assessing and executing business development opportunities to accelerate and expand our pipeline.

Meanwhile we have significantly increased our capabilities and expertise to support our growth in our key therapeutic areas of interest, immunology and oncology, as we continue to build on our R&D organization, including in the U.S.

As Paul stated, we successfully closed the transfer of Jyseleca to Alfasigma in January of this year. Galapagos transferred the entire Jyseleca business to Alfasigma, including the European and U.K. marketing authorization, sales, marketing and all filgotinib development activities as well as approximately 400 employees across our European operations. Upon closing, Galapagos received EUR 50 million upfront and is entitled to potential sales-based milestones of up to EUR 120 million. In addition, Alfasigma will pay royalties in the mid-single to mid-double-digit on European sales to Galapagos. Galapagos will pay up to EUR 40 million in development cost to Alfasigma before June 2025.

We also streamlined our remaining workforce and operations to align with the renewed focus on innovation. This had an impact of approximately 100 positions throughout the organization. The transaction allows us to realize considerable savings to invest in future growth, and we expect annualized savings between EUR 150 million and EUR 200 million as of 2025.

Here, you see the Jyseleca performance. We realized EUR 112 million in net sales in 2023 and EUR 30 million in the fourth quarter, delivering on our restated guidance of EUR 100 million to EUR 120 million. Jyseleca is approved across Europe for RA and UC, and currently over 21,000 patients benefit from the drug. With the transfer of Jyseleca to Alfasigma, we believe we've secured the best option for patients, our people and the product.

Let's first go over the key financials for 2023. With the transfer of Jyseleca, the Jyseleca financials are now moved to discontinued operations. We will continue to receive royalties for sales by Gilead and Alfasigma going forward.

In our full year 2023 revenues, you will see EUR 230 million of revenue recognition related to the Gilead collaboration. As a reminder, this is a linear recognition of revenue for the value of the platform. I would also like to point out the reduction in OpEx, down 8% year-over-year due to a decrease in R&D costs and SG&A. We delivered a net profit for the year, mainly driven by increased collaboration revenue due to the positive catch-up effect of the revenue recognition for filgotinib. We also report higher financial income as a result of our capital in 2023 versus 2022, driven by an increase in interest income on -- and money market funds, in part offset by a decrease due to exchange rates.

Here, you see a clear split between our continuing and discontinued operations per financial item. As you can read from the slide, our discontinued operations for the Jyseleca business had a positive contribution to the bottom line of our P&L with a net profit of discontinued operations of EUR 216 million. As explained, this is driven by positive catch-up effect in the revenue recognition for filgotinib.

Now a few words on our cash position and guidance. Our cash and cash equivalents were EUR 3.7 billion at year-end 2023. Our operational cash burn for 2023 reached EUR 415 million. This lands within our 2023 guidance range of EUR 380 million to EUR 420 million. Thanks to the transfer of Jyseleca, we expect to realize significant savings and our 2024 guidance is now within the range of EUR 280 million to EUR 320 million. The transfer also allows us to redeploy resources to invest in our business and pipeline, and we will continue to be focused on managing our resources effectively. Please note that our guidance excludes potential future business development activity.

And that brings me to the next slide. We've been very focused on our plans to execute one or more additional deals to accelerate our pipeline in oncology and in immunology across modalities. We put the bar high, taking a science-driven approach and a focus on strategic, highly selective partnering. As you know, we have a partnership in place with Lonza. And in 2023, we entered into partnerships with Landmark Bio and Thermo Fisher as manufacturing sites for our CAR-T network. In January, we announced the collaboration with BridGene. While early stage, we believe that the collaboration has the potential to accelerate our internal efforts in precision oncology with small molecules.

Last night, we announced that we participated in a Series C financing round with Frontier Medicines, a U.S.-based biotech company. Frontier Medicines is a pioneer in precision oncology with a unique technology platform and a pipeline of potential best-in-class assets that fit with our oncology strategy. We are excited about the company and the potential of a future collaboration. We continue to explore possible acquisitions and licensing opportunities as a key priority for our operations.

I'll now hand it back over to Paul for the outlook and concluding remarks.

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

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

In terms of trial progress, pending IND approval, we plan to start the Phase II expansion cohort over ATALANTA trial in NHL in the U.S. We also aim to expand our Phase II EUPLAGIA trial in CLL and Richter's transformation in Europe, opening additional clinical trial centers for the study and expand the Phase I/II PAPILIO study in multiple myeloma across Europe as well.

In 2024, we expect to present program updates on our ongoing clinical studies in NHL, CLL and Richter's transformation as well as multiple myeloma at key scientific conferences.

As I mentioned, we remain very active in business development. We are exploring additional partnerships for our CAR-T point-of-care network across the globe. We also aim to execute on additional license agreements and acquisitions as well as any research collaborations and strategic equity investments. Our business development efforts serve our overarching purpose of accelerating breakthrough therapies to patients in need.

Let me conclude by coming back to the strong fundamentals that we put in place to build a global innovative biotech company and a clear path we have towards value creation. We are progressing our early-stage pipeline, building on our renewed discovery portfolio based on validated targets towards best-in-class medicines. We aim to deliver on our scientific progress in our key therapeutic areas of immunology and oncology and continue to focus on business development. We are strengthening our R&D team capabilities, building a world-class team in Europe and the U.S. We benefit from a very strong balance sheet, and we commit to staying disciplined in our use of the cash to focus our investment to maximize value.

We want to thank our investors for their continued support as we deliver on our strategy to generate sustainable long-term value. Thank you.

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

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) We are now going to proceed with our first question. And the questions come from the line of Brian Abrahams from RBC Capital Markets.

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

I was wondering if you could elaborate a little bit more on where you are with regard to the tech transfer and the potential U.S. IND filing. It looked like maybe the timelines were pushed back just a little bit. And I guess I'm curious where you are with respect to overall standards and quality measures with relation to the FDA requirements for the IND, whether U.S. manufacturing is up and running yet and the number of runs that you've had so far, your expectations, I guess, for what else needs to be fulfilled in order to file those INDs? Congrats on the progress.

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

Yes. We are on track with the transfer. We are in the middle of the validation runs. We are expecting outcomes there. We are preparing the analytics, et cetera. That is all going on, transferring all of the different capabilities. And yes, that will take the following months in order to be able to submit around mid-this year an IND.

Technically, the NHL came faster than the CLL to all the technical steps, but the first now, the NHL transfer, and then very quickly afterwards because that's the opening IND and then the second one will be the CLL IND later this year. So that is the current timelines. Of course, all pending technical success and regulatory, but we aim to submit two INDs this year, one after the other.

Operator

We are now going to proceed with our next question. And the questions come from the line of Xian Deng from UBS.

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

So my question is around your determination -- sorry, your discontinuation of the CD19 in lupus. I was wondering if you could elaborate a bit more on decision-making process here. How much has this actually to do with the FDA investigation on the T cell malignancy?

And also just wondering, since you discontinued this program, does it mean that you don't think CAR-T, in general, is a good idea in lupus? Or you just think the current version you have is probably not good enough. So maybe, I don't know, whether you think you put on a new target or a new condition activation or things like that. Any thoughts on that would be great.

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

Well, first, you have seen yourself that many, many companies entered the space and started the CD19 CAR-T in lupus. Companies with CD19s, which are much more advanced than ours. We are developing that at the moment in oncology. We don't have a product approved. Other companies can use their approved products in that space, and that is competitively very difficult to catch up with.

Second, yes, we believe very much in CAR-Ts for autoimmune diseases. And the malignancy, while it is extremely -- while CAR-Ts in oncology happen to have very high benefit risk profile as a life-saving medicine, in autoimmune diseases it's in people who have a very significant unmet medical need. But that the benefit/risk profile for the long time, we think, could be overcoming, hopefully, the malignancy challenge. That will give us the opportunity to then continue with new types of technologies in CAR-T or in other modalities in this space.

But we all recognize that this was the breakthrough in autoimmune disease over the last year or 2 years and the progress there is fantastic. But for us, at this moment, to devote a significant investment into it was not justified.

Operator

We are now going to proceed with our next question. And it comes from the line of Phil Nadeau from TD Cowen.

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

We were curious in 3667, the TYK2. Obviously, that's another competitive area. Can you give us some sense of what you need to see in the ongoing studies to be confident that 3667 is sufficiently differentiated to warrant further investment in later-stage studies?

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

Daniele, can you answer this question?

Daniele D'Ambrosio - *Galapagos NV - Senior VP & Head of Immunology Therapeutic Area*

Yes, sure. Thank you for the question. As you know, we have our TYK2 inhibitor in two Phase II studies ongoing, one in dermatomyositis, one in lupus. They're going to do readout in 2025 and 2026, respectively. What we'll be looking for is a best-in-class profile for this molecule. And we believe, based on the preclinical data we have and the initial promising data psoriasis, that this molecule is differentiated in terms of cytokine inhibition profile. And of course, the data will tell when we have the release or the readout next year basically.

Operator

We are now going to proceed with our next question. And the questions come from the line of Jacob Mekhael from KBC Securities.

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

Based on the two manufacturing agreements in the U.S., your approach seems to be more of a near point of care rather than at the point of care. Will this be the way forward in the U.S.? Or do you also plan to work with hospitals to manufacture at the point of care?

Thad Huston - *Galapagos NV - CFO & COO*

Yes. We do think that this is going to be more the model for the U.S. as you have basically third-party manufacturing sites that are near the hospitals, so creating a hub environment in major metropolitan areas, not necessarily specifically in the hospital setting.

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

And will you still be able to deliver fresh cells and maintain the 7-day vein-to-vein time with those agreements?

Thad Huston - *Galapagos NV - CFO & COO*

Yes. We do believe that, and we're looking actively to expand our network to cover the U.S., at least for the clinical phase and then expand further from there. So we think that the 7-day fresh cells are obviously good for patients and also showing the initial data with the really strong safety profile and efficacy. So we're going to be looking to expand our network in 2024 and beyond.

Operator

We are now going to proceed with our next question. And it's from the line of Jason Gerberry from Bank of America.

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

Just a follow-up on the CD19 SLE question. So do you see there being other opportunities in autoimmune diseases that you'd consider moving forward in with development programs, maybe categories with fewer ongoing studies or less crowded? It seems like there's a big disadvantage to being late order of entry in this space and maybe from a regulatory development perspective maybe that gets more complicated. So wondering just kind of how you see the broader autoimmune landscape from a development standpoint.

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

Daniele, can you start?

Daniele D'Ambrosio - *Galapagos NV - Senior VP & Head of Immunology Therapeutic Area*

Yes, sure. Thank you for the question. Indeed, we do see opportunities across a number of indications for this approach. It is extremely promising as Paul was mentioning before. There are a number of different B cell-driven diseases, which can be targeted.

The question here is to make sure that we have the optimal CAR-T, the optimal product to develop in these indications. And this is where we think we will look for the best possible modalities to be successful in this area. So there is potential across a number of different indications. And we are not going to exit this, but we're going to look for best-in-class approaches.

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

And we have also been looking, in addition to that, to neuroscience indications like multiple sclerosis and myasthenia gravis. There are very extensive possibilities as well as probably eventually entering not just into very late-stage patients, but much earlier in the disease. And then also in other diseases like Crohn's disease and diseases which today at late-stage people with very, very challenging situations in the IBD. There are multiple possibilities here, which are possible.

So the future, I think, with this discovery is very, very good.

Operator

We are now going to proceed with our next question, and it's from the line of Emily Field from Barclays.

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

I just wanted to press a little bit more on the lupus decision. And specifically more -- obviously, I know you commented that it's quite a crowded space, but malignancies are obviously in a lot of approved CAR-Ts ahead of you and the differentiation there is point-of-care manufacturing. So I was just wondering if you could kind of walk us through why maybe that wouldn't be of differentiation -- a point of differentiation in lupus or are some of the competitor efforts also working with faster CAR-Ts there, so it wouldn't have the same advantage? Just maybe a little bit more color on sort of that competitive landscape specifically.

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

Well, in the competitive landscape, first, there are many, and there are many in front of us. So I think that's where catching up with those who are in front of us from a development perspective is the first challenge. And if you then want to differentiate going forward, you have to have a differentiated product, which shows benefits differently than the leaders. And that's where I think we have to step back, evaluate and don't invest in a product which could be -- end up as a me too at the time of arrival in the market.

So we clearly decide with the group that we always will work on something -- on products where we can differentiate. And that's including in oncology. We are looking at high unmet medical needs, as you have seen with CLL and Richter's. We find a space where we think we can do better and more than others with our platform, with the way we deliver cells fresh. But that -- we don't see that platform here deliver that type of benefit because it's not needed in lupus or in autoimmune disease. It's much less time dependent.

We are focusing on Richter's on patients with 1-month life expectancy, and there time to result, superior success is important. And so the multiple in front of us, the multiple -- and so the people who are far in front us are multiple, to repeat here, didn't give us an opportunity to be differentiated. And that's why we discontinued.

Operator

We are now going to proceed with our next question. And the questions come from the line of Sean McCutcheon from Raymond James.

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

With your involvement in the Frontier Series C and recent discovery deal with BridGene, can you walk us through the thought process of starting to build out that deeper pipeline in oncology, specific focus areas? And can you talk a bit about the aim within targeted oncology as it relates to target selection and how all of this will inform your further BD efforts?

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

Yes. So far, we focus on -- our focus is on precision medicine approach in oncology. And so there, Frontier complements our activities internally, especially with a new very strong platform. And their proprietary chemoproteomics powered drug discovery engine with covalent chemistry and machine learning is quite impressive for us to be able to get access to that type of technology for bringing best-in-class -- first-in-class and probably best-in-class drugs in the space of precision medicine.

It's all known that these groups are working on KRAS on p53 on multiple other targets and the combination of a chemistry platform with these type of targets -- equivalent chemistry platform with these type of targets could deliver best-in-class medicines and breakthrough products for development. And that's why we focus on, yes, high unmet medical needs, this type of breakthrough chemistry platforms and accelerate time to patients and to results.

And that's why we made a choice to -- our chemists with significant experience in the space made a choice after a long consideration on this is the one we want to go forward with.

Thad Huston - *Galapagos NV - CFO & COO*

Yes, I would just add, we're definitely going to look to deploy capital in different ways, obviously, doing research collaborations, sometimes early, equity investments potentially in companies, licensing, acquisitions, all different types of ways to access innovative products in oncology.

Operator

We are now going to proceed with our next question. And the questions come from the line of Peter Verdult from Citigroup.

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

Peter Verdult, Citi. Sorry to come back to autoimmune aspirations at Galapagos. Paul, I don't want to put words in your mouth, but are you effectively saying that to go forward in autoimmune, you would have to have an allogeneic construct rather than autologous? Is that basically the long and short of it? And if that is the case, what's the environment like or landscape for you to get those capabilities sooner rather than later? And if I'm wrong, could you just tell me why I'm wrong and where the differentiation could be.

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

No, I definitely don't make the statement here that it's allo versus autologous. I think the autologous have shown the effect and a very significant and -- yes, breakthrough type of effect. It is CAR-T with the same or different targets, or with the same or different production methods, which includes vectors or not. And so that is where our short-term objective will be, can we find differentiated CAR-Ts with probably different production methods and as well as potential targets, yes?

But it's not -- for us, it's not allo versus auto. We don't have allo technology, and it's a long way for us to enter that, and that's not one of our strategic goals.

Operator

(Operator Instructions) We are now going to proceed with our next question. And the questions come from the line of Sebastiaan van der Schoot.

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

I believe that during the strategic presentation, which was, I think, 15 months ago, that you had a Vision 2028 strategy, thereby, you announced that you would want to produce also bispecific CAR-Ts, ADCs (inaudible) 2023 to 2025. Can you maybe expand on how...

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

Sorry, Sebastiaan, can you get closer to your phone because it's very difficult to understand. So -- or can you repeat your question, yes?

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

Is this better?

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

Yes, it looks like better.

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

Okay. Great. So during, I think, the strategic update in 2022, the vision 2028 vision, you mentioned that you also wanted to add on bispecific CAR-Ts and also ADCs into the pipeline between the period of 2023 and 2025. What is the current status on that?

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

Yes. On ADCs, we have left that space. We are not going to invest in ADCs. We did extensive evaluation. But also, again, for us, we didn't see the benefit-risk profile, the differentiation, which we thought was going to work for us to bring an ADC to the market. ADC requires totally different technology with significant expertise. And as we are developing already one new platform in the company, CAR-T, we didn't think it was appropriate for us to take a second platform on.

So that is -- on bispecific CAR-Ts where that doesn't require us to build an internal production manufacturing activities, we are looking at -- we are -- we have certain bispecific research activities in our Pittsburgh biological research site. But also there, we are looking for, can we find additional products through our BD activities, whether it's a platform or whether it's platform or drug.

So bispecific or multi-specific -- bispecific CAR-Ts -- sorry, I'm talking about bispecifics. Bispecific CAR-Ts, yes, we have next-generation CAR-Ts in the pipeline, which we hopefully will be reporting on late next year or early next-'25 on time to clinic.

What I was mentioning also when I misspoke on the CAR-T, we have bispecific research ongoing in the company in our lab in Pittsburgh, but that is very early and nothing to report on that.

Operator

We are now going to proceed with our next question. And the questions come from the line of Shan Hama from Jefferies.

Shan Hama - *Jefferies - Analyst*

So just on M&A and business development. I believe prior communication was a global deal at CAR-T. Could you just clarify if the still stands? Also, could you provide timing for business development and perhaps M&A firepower? Finally, just in relation, would an outright acquisition or an in-licensing deal be preferred?

Thad Huston - *Galapagos NV - CFO & COO*

Yes. Our company's strategy is to look at where we can create value. We definitely see kind of early clinical assets that we think that we can -- we either license or acquire would be something of interest to us in the oncology space. We look at also assets outside of CAR-T as well to diversify and broaden our portfolio, small molecule assets as well. So we want to we continually scan the universe for many different types of targets.

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

Let me add. It's a very high priority for us now that we transferred Jyseleca, we free up resources, we want to accelerate the pipeline and we try to add a clinical stage to our pipeline. But we have, again, differentiation, time to market and, for us, our capacity to develop. We evaluate that and we -- the focus is on bringing a differentiated medicine.

We have done extensive activities over the last year, and we are continuing the discussions. You will -- you can expect from us to do transactions in 2024, yes.

Operator

We are now going to take our last question. And the questions come from the line of Manos Mastorakis from Deutsche Bank.

Manos Mastorakis - *Deutsche Bank AG, Research Division - Research Analyst*

So there is a lot of enthusiasm and promise on the centralized model. But I'm wondering whether you expect to see any pushback or hurdles in your effort to roll out a broad network of centralized machines producing autologous products locally. And I'm coming from a standardization or quality control point of view here, are there any milestones regard the discussions with the FDA and potential green light from the FDA on this aspect until you...

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

So the start of our platform is one of where we highly automate and highly standardize, work towards a fully closed loop system-- -- fully closed system to produce CAR-Ts. And we are very far advanced to that, after administering the apheresis, the white blood cells, and the selected white blood cells and the vector, there's no interaction anymore between that and administering to the patient. So it's about highly automated, highly standardized way of producing followed by a highly standardized and automated way of doing the quality release.

And that is pulled together in a very expert way at the moment. And we are doing -- we are using that today in our clinical trials in Europe. So we're delivering CAR-Ts as we speak in the hospital with local release. A lot of work goes into the standardization of the quality release. Also, push the bottom type of testing rather than any manual handling of the testing. And that's the basis of it.

The process also allows to start sterility early in the process because we have a fully closed system, which allows us at the moment, what we do is to release on day 7 on -- when the cells come off the machine, and that has yielded a very good clinical result. We interact extensively so far with the European authorities as we are doing our clinical trials and with multiple local authorities in Europe. And so far, so good. We have been able to progress everything with the technology as well as with the clinical applications.

Our team has had discussions with the FDA as pre-IND and we're part of that -- of the global consultation on this. Those activities are ongoing. As part of the consultation, they asked us to have a first site up and running in the U.S., fully validated to be part of the IND. And that is the work we are doing in the first half of this year to make sure we can submit our INDs around midyear, one after the other, NHL and CLL. So out of those discussions, we'll learn again a lot, but we are anticipating that we will be able to bring these systems.

The benefit now of going to the largest sites close to the hospital, like, for example, in the Bay -- Thermo Fisher and Landmark Bio in Boston allows us to transfer once to highly specialized technical teams, which can serve a whole region, yes? So our Landmark Bio site will be able to serve the whole Boston area. With 1- to 2-hour drive, you can reach every hospital in the vicinity. And the same in the Bay area with the Thermo Fisher site on UCSF campus. And there you can use the whole Bay area with fresh cells from that site.

So it makes our life simpler, probably much more effective and much less risk if we do the system which we're building now in the U.S. and going to many, many hospitals in the same region. So we are derisking by automating, derisking by standardizing, derisking by standard operations and training. So by bringing this together into very tight express sites.

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

Thank you. This concludes today's call. Please feel free to reach out to the IR team if you still have questions. Our next financial results call will be our first quarter 2024 call on May 3. Thank you all for participating, and have a great rest of your day.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect your lines. Thank you.
