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Corporate Speakers:

- Srikant Ramaswami; Galapagos NV; Senior Vice President and Global Head of Corporate Affairs and Investor Relations
- Paul Stoffels; Galapagos NV; Chair and Chief Executive Officer
- Thad Huston; Galapagos NV; Chief Operating and Chief Financial Officer
- Jeevan Shetty; Galapagos NV; Head of Clinical Development Oncology
- Valeria Cnossen; Galapagos NV; Executive Vice President and General Counsel
- John Mellors; Galapagos NV; Head of Cell and Antibody Therapy Discovery

Participants:

- Xian Deng; UBS; Analyst
- Philip Nadeau; TD Cowen; Analyst
- Brian Abrahams; RBC Capital Markets; Analyst
- Faisal Khurshid; Leerink Partners; Analyst
- Judah Frommer; Morgan Stanley; Analyst
- Chi Fong; Bank of America; Analyst (on for Jason Gerberry)
- Sean McCutcheon; Raymond James; Analyst
- Jacob Mekhael; KBC Securities; Analyst
- Sebastiaan van der Schoot; Van Lanschot Kempen; Analyst

PRESENTATION

Operator: Good day. Thank you for standing by. Welcome to the Galapagos Full Year 2024 Financial Results and Business Update 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 Sri Ramaswami. Please go ahead.

Srikant Ramaswami: Thank you, Operator. Good afternoon, to all of you who are on the call from Europe. And good morning to all of you in the United States. Thank you, all for joining us for Galapagos' full year 2024 financial results and business update conference call. Last night we issued a press release outlining these results. The press release, along with today's webcast presentation can be found on the Galapagos website.

Before we begin, I would like to remind everyone that we will be making forward-looking statements on the call. These forward-looking statements include remarks concerning future developments of our company and our pipeline and possible changes in the industry and the competitive environment. Actual results may differ materially from those indicated by these statements and are accurate only as of the date of this recording, February 13, 2025. Galapagos is not under any obligation to update statements regarding

the future or to conform to these statements in relation to actual results unless required by law.

Joining us on today's call from Galapagos' senior management team are Dr. Paul Stoffels, Chair and Chief Executive Officer; and Thad Huston, Chief Operating and Chief Financial Officer.

With that introduction, let me now turn the call over to Dr. Stoffels. Paul?

Paul Stoffels: Thank you, Sri. Thank you, all for joining us today. 2024 was a productive and transformative year for Galapagos, in which we made significant progress streamlining our business operations and advancing our leadership in cell therapy in oncology. One of our key accomplishments last year was the progress we made advancing GLPG5101, our flagship CD19 CAR-T clinical development program in multiple hard-to-treat NHL indications.

We were particularly pleased to receive FDA's IND clearance to begin clinical studies in the U.S. and with the compelling new results from the ATALANTA study we presented at the American Society of Hematology Annual Meeting in December. I will discuss those results in greater detail later on this call.

Throughout 2024, we focused on building our leadership position in cell therapy, where we executed a number of key partnerships and collaborations in support of those goals with companies such as Lonza on our decentralized platform, Thermo Fisher for the development of an ultra-rapid PCR sterility test together with miDiagnostics and Excellos part of Blood Centers of America to broaden our DMU network in the U.S.

Separately, in 2024, we also signed an agreement with Adaptimmune for TCR T-cell therapy in solid tumors.

Finally, we completed the transfer of the Jyseleca business to Alfasigma, which provided us with savings of approximately EUR 200 million and for which we remain eligible for royalties on European sales. Based on this strong foundation, we are continuing to evolve our strategy for building Galapagos as a global leader in cell therapy.

Toward that end, we are excited to start the new year with a focus on accelerating value creation by executing on our plan to separate into two publicly-traded entities, Galapagos and SpinCo. SpinCo, a newly created Belgian company, will invest to build a pipeline of innovative medicines through transformational transactions with Gilead as a partner. Galapagos will focus on accelerating global oncology leadership by addressing high unmet medical needs with a decentralized manufacturing platform and with full ownership of all other programs.

As many of you know in 2019, Galapagos entered into a 10-year global Option, License and Collaboration Agreement, or OLCA with Gilead. Since that time Gilead, Galapagos and the biotech industry as a whole have all evolved. Post separation, SpinCo will assume

the OLCA agreement with Gilead. Galapagos will be able to focus on executing its strategy for accelerated growth and sustainable value creation as a leader in the development and innovative manufacturing of cell therapies in hematological and solid tumors, further supporting our mission to bring transformational medicines to patients across the world.

As such, we will seek partners for our small molecule programs including our TYK2 inhibitor, and we will discontinue future small molecule research. By separating into two entities, each company will have the flexibility to allocate resources, pursue tailored strategies and maximize opportunities for growth and impact. We are offering a win-win for our shareholders as we can create even more value as independent entities with unique strategies in our respective areas of expertise.

Let us now turn to the new and exciting opportunities for Galapagos as we forge ahead with the development and delivery of life-changing cell therapies to address patient needs in oncology. This planned transaction allows Galapagos to focus on leadership in cell therapies based on the following strong fundamentals. Firstly, we are well capitalized to advance our portfolio and platform toward value-creating milestones.

Importantly, the termination of the OLCA for Galapagos gives us the autonomy to fully invest in and partner our own assets and programs and to realize the rewards of our future achievements. We remain focused on providing broader and faster access to cell therapies with our innovative decentralized manufacturing approach and a goal of seven days vein-to-vein time. Not only does this bring logistical and cost benefits, but by providing patients with fit cells, we believe we are improving efficacy and safety and offering a solution for many more patients, especially those patients with a very short life expectancy.

We are advancing our cell therapies currently in clinical development, which we believe have potential to be best-in-class through the delivery of fresh and fit cells. In addition to our six European clinical sites in the Netherlands and Belgium, we are expanding the ATALANTA clinical trial in the U.S., where we are engaging with leading cancer centers in Boston. Our aim is to start pivotal studies in 2026. To support our ongoing clinical trials and to ensure pivotal readiness, we are expanding our decentralized manufacturing network in the U.S. and Europe, giving patients direct access to our therapies and limiting logistical constraints. We are also building global partnerships with hospital networks and healthcare organizations to increase access significantly.

All of this is being done in a highly cost-effective way that takes advantage of our automated, closed sterile production system with limited manual work and is designed to improve access and reduce the cost of goods significantly. We will also look to partner our platform with cell therapy companies, leveraging our unique manufacturing platform and network for broader access, for example, as we did with Adaptimmune in solid tumors. To support sustainable value creation, we are building a pipeline of next-generation cell therapies that have the potential to address some of the limitations of current therapies by taking advantage of combination, targeting and armoring to best treat

a range of hematological and solid tumors. Most importantly, our ambition in cell therapy and the planned separation are designed to benefit the patients we serve by both accelerating and expanding our ability to bring new medicines to market.

Our decentralized manufacturing was designed to overcome the limitations of current cell therapy manufacturing, which is centralized and bears higher cost burdens with longer production and delivery times and delivering cryopreserved cells. A 7-day vein-to-vein time is designed to provide fresh fit cells, which we believe enhance the therapeutic profile by producing highly potent cells that are less exhausted, less toxic and persist longer. We currently have six operational and approved manufacturing sites in several European countries and are actively expanding in Europe and the U.S. with Landmark Bio in Boston operational for ATALANTA.

We believe the advantages of our Cocoon process make it ideal for near point-of-care manufacturing, given its close system, lean design, user-friendly interface, data monitoring capabilities, automation and scalability. We have a long-term strategic collaboration with Lonza for the supply of Cocoons and cassettes. We truly are excited by the opportunity ahead for Galapagos to lead in cell therapy drug development, and this decentralized manufacturing platform is core to that strategy.

Moving forward, Galapagos will focus on unlocking the broad reaching potential of this decentralized cell therapy manufacturing platform as we advance a robust cell therapy pipeline. In line with our goal to be a more focused and streamlined organization, we are implementing a strategic development approach for our CD19 CAR-T portfolio by prioritizing resources on GLPG5101, our most advanced assets cleared for clinical development by the FDA and the European regulatory authority and with the fastest path to market.

In order to fully realize that potential, we are accelerating and expanding the ATALANTA Phase I/II clinical study of GLPG5101 into additional aggressive lymphomas, such as Richter transformation and in chronic lymphocytic leukemia, where we believe we can drive the greatest impact for patients. Our plan is to move into pivotal studies in 2026 with an aim to have a first approval in 2028. As part of this focused strategy, we are deprioritizing activities related to GLPG5201, our second CD19 CAR-T candidate, pending the advancement of GLPG5101 in Richter transformation and chronic lymphocytic leukemia.

In tandem, we are advancing the Phase I/II study of GLPG5301 in multiple myeloma, while also strengthening our early-stage pipeline of next-generation multi-targeting armored cell therapies for hematological and solid tumors. To ensure long-term innovation and value creation, we expect to advance one of these preclinical assets into first-in-human clinical studies in 2025.

Further reinforcing our commitment to delivering transformational therapies, we are progressing uza-cel, a TCR-T candidate for head and neck cancer through our partnership with Adaptimmune. We believe that the combination of fresh, fast and fit has the

potential for transformative impact, and we can see from the data recently presented at ASH, a promising safety and efficacy profile for GLPG5101 in patients with mantle cell lymphoma, marginal zone lymphoma, follicular lymphoma and diffuse large B-cell lymphoma.

As of April 25, 2024, data cutoff, 49 patients received CD19 CAR-T cell therapy infusion, and safety results were available for 45 patients, and efficacy was available for 42 patients. As you can see, we achieved high overall response and complete response rates. Here, we show 100% of patients with refractory/relapsed mantle cell lymphoma, 95% of patients with refractory/relapsed follicular lymphoma and marginal zone lymphoma and 54% of patients with refractory/relapsed and diffuse large B-cell lymphoma achieved a complete response.

At dose level 2, the complete response rate was 71% and the overall response rate, 86% for diffuse large B-cell lymphoma. Of evaluable patients achieving complete response, 80% were minimal residual disease negative and remained in complete response at the time of data cutoff. We are seeing very reassuring safety data with low levels of ICANS. This translates to less patients in need of intensive care, less time in hospital and more time at home with family. Not only are we seeing strong data around the response rates, but we are also seeing that those response rates are durable.

Across Phase I, Phase II, 32 of 37 or 86% of responding patients had an ongoing response at the time of last assessment or end of study. Of the 15, minimal residual disease evaluable patients with a complete response, 12 patients or 80% achieved minimal residual disease negativity and remained in complete response and data cutoff. The median study follow-up was 3.3 months for follicular lymphoma and diffuse large B-cell lymphoma with a range of 0.9 to 21.2 months and 4.4 months for mantle cell lymphoma with a range of one to 24.4 months. GLPG5101 showed an encouraging safety profile with the majority of higher than or equal to grade three events being hematological. 96% of patients, 47 of 49 received an infusion with fresh CD19 CAR-T cell therapy, of which 91.5%, 43 out of 47 achieved a vein-to-vein time of seven days, eliminating the need for bridging therapy.

Of note, strong and consistent in-vivo CAR-T expansion levels and products consisting of stem-like early memory phenotype T cells were observed in all doses tested. The summary of these data underscore our enthusiasm for going all in on GLPG5101, a flagship CD19 program. Our new strategy positions us to build on the clinical success we have seen thus far. Turning now to our small molecule programs in immunology, where our most advanced candidate is our TYK2 inhibitor GLPG3667. Preclinical and first-in-human clinical data showed GLPG3667 to be a selective and potent inhibitor of TYK2, resulting in near complete inhibition of type 1 interferon signaling for a 24-hour cycle, which is supportive of a once daily administration.

We intentionally selected SLE and DM as our first indications because type 1 interferon plays a key role in both diseases. Our Phase II program offers an attractive partnership opportunity. I'm pleased to report that we recently completed screening in the SLE Phase

III enabling clinical study ahead of schedule and anticipate top line results for GLPG3667 in SLE and DM in the first half of 2026. Beyond SLE and DM, TYK2 inhibition offers potential in several other autoimmune indications, further expanding its market opportunity. A bold new strategy is focused on advancing our cell therapy leadership.

As such, we are seeking to partner a promising small molecule portfolio, which was built on more than 20 years of research and where we have identified more than five programs in both oncology and immunology. The continued unmet medical need in a number of immune-mediated diseases offers a significant market opportunity and should make our programs an attractive opportunity for companies already operating in immunology. As you can see on this slide, we have an exciting year ahead with the potential to achieve a number of value-driving catalysts.

Moving ahead with our focus on cell therapy, patient recruitment is ongoing in Europe with leading cancer centers in Boston to be activating following U.S. FDA IND application clearance of 5101. We continue to build out our DMU network and are focused on building the infrastructure and attracting talent to support the start of registrational studies with GLPG5101 in 2026 as well as our planned global expansion. Our aim is to complete the Phase III enabling studies with our TYK2 inhibitor in SLE and DM while seeking partnerships. We progress our early-stage next-generation cell therapy pipeline in hematological and solid tumors including uza-cel.

With that overview, let me turn the call over to my colleague, Thad Huston, for an overview of the exciting transaction we recently announced and for a review of our full year 2024 financials. Thad?

Thad Huston: Thanks, Paul. We remain very excited by the opportunities we can create by separating Galapagos into two entities. Paul has reviewed the benefits for Galapagos as an independent company that can now fully own its programs and platform. But now let's look at how we plan to create value from SpinCo.

Over the past few years, there have been significant advances in science, technology and clinical development of new medicines. Unfortunately, the capital markets have been tight over this time period, leaving many companies struggling for financing. For companies with capital to deploy, such as SpinCo, we believe this creates multiple opportunities to build value. Here, you can see the initial actions that are planned for setting up SpinCo for success. We expect to complete the separation around midyear for SpinCo and to prepare for listing on Euronext and NASDAQ.

In the coming months, during the separation, SpinCo will appoint a seasoned executive team and independent nonexecutive directors with proven track records in biotech company building and strategic transaction execution. A prospectus will be made publicly available at least one month prior to the spin-off, and all Galapagos shareholders are to receive SpinCo shares on a pro rata basis proportional to their ownership of Galapagos shares. Turning now to our financial results.

For our full year 2024 financial results, our total revenues are EUR 276 million, which includes EUR 35 million of supply revenues related to Jyseleca and EUR 241 million in collaboration revenues. Research and development expenses were EUR 335 million, which is a 39% increase year-over-year driven by our expansion of oncology CAR T. G&A and sales and marketing expenses were flat at EUR 134 million.

We had a net profit for the year of EUR 74 million, driven by EUR 185 million from fair value adjustments, currency exchange and interest income as well as the net profit from discontinuing operations, which includes a gain of EUR 53 million on the sale of the Jyseleca business to Alfasigma.

Now looking at our balance sheet. We ended 2024 with approximately EUR 3.3 billion in cash. Our cash burn for 2024 was EUR 374 million, excluding business development or cash burn was EUR 293 million, which is within our guidance range of EUR 280 million to EUR 320 million. Upon separation, Galapagos will be capitalized with approximately EUR 500 million in cash, which is expected to provide runway to 2028 as our normalized cash burn is projected to be in the range of EUR 175 million to EUR 225 million.

SpinCo is expected upon separation to be capitalized with approximately EUR 2.45 billion. Following the separation, Galapagos will be focused on accelerating the development of our flagship CD19 CAR-T program through our innovative decentralized manufacturing platform. Our aim is to start pivotal studies in 2026, aiming for a first approval in 2028. We will continue to develop next-gen cell therapy programs in hematological and solid tumors. We plan to initiate clinical development of a novel CAR-T candidate in 2025. We will also develop a worldwide decentralized manufacturing network for the delivery of our cell therapy.

Importantly, we will have the autonomy to partner our decentralized manufacturing platform and network as well as our differentiated cell therapy pipeline. With this focused strategy, we are also implementing a significant restructuring to realign our footprint and to reduce our cash burn. Turning to the opportunities we have by creating SpinCo, where we are equally excited by its potential to create value by focusing on building a pipeline of innovative medicines through transformational transactions.

We are forming SpinCo with sufficient resources to pursue high-quality assets, fund development and to invest in its portfolio. If Gilead decides to opt in to SpinCo programs under the OLCA, then SpinCo will be able to leverage Gilead's strong expertise and late-stage development and commercial capabilities in key therapeutic areas. The SpinCo Board will have a majority of independent directors and will be led by an experienced executive leadership team.

Importantly, Gilead has committed to negotiating in good faith amendments to the OLCA on a transaction-by-transaction basis to achieve positive value for SpinCo and all of its shareholders. We have an exciting year ahead as we advance our clinical programs and early-stage pipeline of next-generation cell therapies in a number of important cancer indications and with the launch of our newly created SpinCo. Throughout the coming

year, we expect to achieve a number of value-creating milestones that will further our commitment to transforming patient outcomes through life-changing science and innovation.

Thank you, once again for your time today and for your continued interest and support of our mission.

Operator, we are now ready to open the call for questions.

QUESTIONS AND ANSWERS

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

Xian Deng: This is regarding to 5101 and also 5201. Thank you very much for the very useful data review for 5101 and make sense of why you want to expand that. But just wondering, given you're also deprioritizing 5201, just wondering if you could remind us what's the difference between the two CD19 contract for those two CAR-Ts. I'm just wondering why are you -- if you could maybe elaborate a bit more why you are deprioritizing 5201?

Paul Stoffels: Paul Stoffels here. Let me explain. We were running 5201 and 5101 in parallel for clinical trials in Phase I/II. We saw excellent efficacy and safety for both of them. We think and we believe very much that this is driven by fresh cells, high-content memory cells, which do the job there to make that kind of outcome. But the main reasoning then is for us to simplify is that building a DMU, decentralized manufacturing network in the world for running two CD19s is quite steep.

So by not duplicating the product transfer and validation about all the DMUs we're setting up, we could focus much more on accelerating our pipeline on our main assets. And so adding the CLL and Richter transformation to the 5101 will accelerate the two indications most likely to the market. That's why reprioritizing the two indications on the 5101, we have already the agreement of the FDA on the Richter transformation, that's already done. We are completing our work on the CLL to also include that in the IND to kick that off as soon as possible in the U.S. So it is really accelerating by simplifying and really believing that the fresh cells do the job in making the difference in the CD19 space.

Operator: Now we're going to take the next question. The question comes from the line of Phil Nadeau from TD Cowen.

Phil Nadeau: Just a follow-up on the last one and then another question on the separation. Just in terms of 5101 versus 5201, were there any differences in terms of manufacturing process or characteristics between the two programs? That's the first question. Then second, in terms of the separation transaction, what is rate limiting at this point? Is it hiring of the management team? Or are there other logistical or legal steps that are really gating?

Jeevan Shetty: Jeevan Shetty, oncology. In answer to your first question, in terms of the issues regarding manufacturing, they are the same, the fundamentals of fresh cells in fresh product out 7-day vein to vein resulting in a superior product. The vectors are different. But however the basis of our decision was made on the very significant and compelling data from 5101 and the issue regarding complexity.

With regard to the second question, Thad?

Thad Huston: Yes. Thad Huston here. I think clearly, we are in the process of a number of different elements related to the separation, Valeria could also add to that, including the hiring of a management team, and that process is underway. Obviously there's a number of different legal steps as well.

Valeria Cnossen: This is Valeria. So I think as with any listing on NASDAQ and on Euronext, we're preparing diligently for the listing, and that will be subject to the review of FSMA and SEC. In addition, prior to the spin-off, the spin and the separation will be subject to the shareholders' approval at an extraordinary general meeting of shareholders that will take place at midyear with required approval being obtained, we can be listing a few days thereafter.

Paul Stoffels: For the fact that the noncore of the Galapagos Board is working very hard to recruit seasoned CEO and several executives as well as an independent nonexecutive director team for the Board. So that is actually ongoing, and we plan to have several people on board by the time we spin off.

Operator: Now we're going to take our next question. The question comes from the line of Brian Abrahams from RBC Capital Markets.

Brian Abrahams: Maybe another one on 5201. Can you just help us understand, I guess how far along you guys were on the IND filing process when you made the decision to prioritize 5101? And I guess what gives you the most confidence that 5101 will look similar to the promising data you've generated from 5201 in CLL? Then secondly, just wondering if you could give us the latest update on the types of assets that the SpinCo may be looking for?

Paul Stoffels: Yes. While we are confident that the 5201 and 5101 are pretty similar, we see similar efficacy safety activity, also the expansion if we do the manufacturing and then the administration in the expansion, we see a very significant expansion happening in the patients similar to the 5101 and with the 5201.

So that's where we don't think the vector is doing the drive of the difference, the vector we won't make the difference. We are comfortable that the way we make the cells is going to drive the difference. And the main reason to do this is to, as I said earlier, is to align on a simplification of the DMU network. We are required by the authorities to do a validation and doing equivalent studies between all of the DMU sites in the world. If you

do that, it's a cumbersome and very work-intensive process. Running two processes next to each other in the same DMUs, means we have to double that and that would delay the overall progress of our company if we had to parallel process those at this moment in time in a significant way across the world.

We are running in Europe two already in parallel, that is the 5101 and the 5301, the BCMA target in Europe, adding a third one to the network would be a very significant challenge to really bring that into pivotal studies as we want to start those next year. And that's why we concluded to offer optimization and efficiency, let's focus on one key CD19 than do the BCMA in early stage and learn whether it is a competitive product.

But then third, also start focusing on our next generation assets, which are in progress, and maybe John can talk a little bit more about that, just to highlight a few things about that because that's also important in our portfolio, why we make this prioritization.

John?

John Mellors: Thanks, Paul. My name is John Mellors. I'm the Head of Cell Therapy Discovery and Early Development at Galapagos. I'm pleased to let the audience know that we are working very hard around the clock to develop next-generation CAR-T cell therapies that include multi-targeting of cancer-associated antigens and arming to prevent suppression of CAR-T cells by the cancer microenvironment.

We have four main objectives in NHL, in myeloma, in lung cancer and in ovarian cancer. And our first product has been approved for clinical development and will enter proof-of-concept studies by the end of the year, and that's a multi-targeting CAR-T for NHL and ALL.

For myeloma, we intend to target the space that follows BCMA targeting therapy. And for lung cancer, we are targeting a validated clinical target plus an additional target and for ovarian cancer two targets in combination. And let me just emphasize that each of these indications are high unmet medical needs, and we believe we can have an impact and by impact, I mean more frequent responses, deeper responses and longer duration of response with our arming and multi-targeting strategy.

Paul Stoffels: And just confirming here that the first asset is internally ready to get into clinical trials, and that is being prepared, as John was saying, before the year-end. So I think that's also one of the big objectives for the year is progressing the first asset of our next generation into the clinic.

Thad Huston: Yes. Brian, let me take this, Thad here, the SpinCo question. First of all, I want to say that we're really excited about the creation of SpinCo. SpinCo will clearly have greater flexibility and access to acquire assets with significant potential without having the need to fit in the Galapagos strategy. So there's a lot more broad opportunities to do deals. And of course partnering with Gilead and working closely with them with

well-capitalized organization, they can really compete for the highest quality targets across the biotech space.

The types of assets, I think we're identifying are clearly to find a pipeline of innovative medicines that really have the potential to treat diseases with significant unmet need across any different types of indications with a focus on virology, immunology and oncology.

Operator: Now we're going to take our next question, and it comes from line of Faisal Khurshid from Leerink Partners.

Faisal Khurshid: I just want to ask, as you're kind of preparing for pivotal development on 5101, can you talk a little bit about what the potential indication and kind of trial strategy looks like there? Then also as a potential approval could be a few years away now what is the U.S.-based manufacturing footprint look like? And what is your progress towards getting that into place?

Jeevan Shetty: Thank you very much. Jeevan Shetty, again. With regard to the indications that we have planned, you know that we've shared data at ASH regarding the ATALANTA study in the indications of mantle cell mantle zone lymphoma as well as NHL. We intend to expand that into a number of other indications: Burkitt's lymphoma, in particular, primary CNS lymphoma as well as high-risk diffuse large B-cell lymphoma. So areas where the unmet need is significant and where the 7-day vein-to-vein time fresh cells in fresh product out have significant contributions to the outcome for patients. We will be led by the data that we see in our Phase II. And clearly, we will communicate more comprehensively as the data emerges. But our tenants are really significant unmet need that benefit from our platform.

Thad Huston: And on the manufacturing side, we have obviously the decentralized manufacturing structure. So it's a model where, of course we want to have validated sites, like we have our initial site with Landmark Bio in the Boston area, so it can cover the Boston area, major hospitals, which we're also partnering with. But we're also looking to have regional sites in kind of high density areas throughout the U.S., East Coast, West Coast, south and north of the U.S.

So trying to get the right coverage as we go adding sites by site. Like we said, Paul in his remarks, we had Blood Centers of America, for example, with the West Coast coverage as one site and continuing to add those over time.

Paul Stoffels: To start with, first of all, we did target on the high -- where the high density of oncologists are in these very specialty areas. Then for commercial, we'll broaden out into other sites as we want to cover the whole of the U.S. But we, at this moment, all of our DMUs are focused on getting the maximum number of patients in the indications we are looking for. So there is like a two-step where complete the studies, these sites are ready for commercial when we can start, but we'll work further over the year to determine where other sites will be.

Faisal Khurshid: Got it. And are the regulatory requirements different between having these manufacturing sites with the clinical trial as opposed to commercial use?

Paul Stoffels: Well there are some additional requirements for pivotal, which we are preparing for, and we are comfortable that we are ready for that by next year when we start the clinical trials. Today it's a very high standard we have to meet, of course, because we provide biologicals and human cells. So there is not much difference, but it all has to do in the end with also further automating the quality release testing and further demonstrating comparability and equivalents across the different sites. So as we go, we will strengthen that. But today we already meet a fairly high level of requirement close to commercial.

Operator: (Operator Instructions) And now we're going to take our next question. The question comes from the line of Judah Frommer from Morgan Stanley.

Judah Frommer: Just curious if you could share any indication of interest from potential external partners for manufacturing on the decentralized manufacturing units at this point? Or is that something that you haven't necessarily have conversations on yet?

Paul Stoffels: Yes. We have inbound questions from external partners to get on our platform. Of course we are making sure that we are first build up ready to go with our clinical trials. But for example, the collaboration with Adaptimmune started on -- with the interest on our platform. We validated that TCR-T, if you produce on our platform, has a similar kind of features as when we do with the CAR-Ts for the hematological testing. There we are progressing with Adaptimmune to next stage and starting clinicals, I think 18, 24 months from now. But that is one of the examples, but we have multiple others, which we are evaluating.

There are two things there for us. It's one, we can partner on the platform, but we can also strategically partner on co-development with partners. That would be our main interest is looking at people who are interested to have to where we can access, where we can strategically partner on the drug, on the cell therapy combined with the platform. So -- and our teams are very active in having those discussions.

Jeevan Shetty: And just wanted to add, in addition to this is the fact that as a cell therapy leader, we lead also hematology and oncology in these partnerships. For example, Adaptimmune is a head and neck indication, solid tumor indication with significant unmet need, and that is the form of the collaborations that we're having as well.

Thad Huston: Yes. I think it's really exciting for us to also look at this post separation and have the flexibility to partner with many different types of companies that have maybe manufacturing limitations or just capacity constraints or don't have the capital to potentially invest in having a unique differentiated platform that we have.

Paul Stoffels: And there's one particular region in the world, which is very underserved, and that's Asia. So there, we get requests from governments as well on CDMOs to partner on the platform to provide access in those regions. That's somewhat further off, but you see the fact that we have a scalable decentralize manufacturing capacity or capability with Cocoons and good results, it is very attractive for other parts of the world including those regions who don't have access and still have very high medical need in this space.

Operator: Now we'll proceed with the next question. It comes from the line of Jason Gerberry from Bank of America Securities.

Unidentified Participant: This is Chi, on for Jason. I have a question on 5301. So based on the press release, it looks to me that you're taking a harder look at whether you want to advance 5301 further in development in multiple myeloma. Is it because of the competitive dynamics in the BCMA CAR-T space or complexity of setting up a DMU network for a second CAR-T or a bit of both? Maybe, can you talk about the analysis that you're specifically looking at in the Phase I study on the PAPILIO study? And what criteria you want to see 5301 meet in order for you to advance the asset in the pivotal trial? And if I may ask a quick follow-up on the indication pursuit plan for 5101, are you prioritizing one or two lead indications as you think about capital preservation in 2026 and beyond?

Jeevan Shetty: Thank you very much, Jeevan Shetty, again. I'll take the first part of the question. With regard to the PAPILIO study, it is very clear what the competitive environment actually looks like with regard to the incumbents. So we know what parameters we need to beat or be equivalent to in both safety and efficacy. So that is very clear. And really, our determination will be based on the benefit risk ratio and the safety and efficacy, in particular.

I have to add that we are making very good progress with the PAPILIO study. Clearly, we're recruiting well, and we will share data at an upcoming hematology conference. The internal determination will be based on how competitive we are with the incumbent. But progress overall is good.

Paul Stoffels: Yes. We'll wait to determine for the DMUs there on where the first data are and the expansion of that and the expansion to other parts of the world. For 5101, you asked on the prioritization. What is remarkable is that with the KOLs we talk in the clinics, and they see this high unmet medical need NHL indications, all of the indications we are listed, the majority of them are interested to all of the KOLs we work with today. And that is -- that's where we don't prioritize at the moment, the indications. We give access to the physicians to participate with the patients in these expansion cohorts, which we are making, and that gives us the insight later this year on what are -- what will you take as priorities going into the pivotal studies for registration. But so far, these indications we list on our slide you have seen during the presentation, those are all open or one by one, they will all be open for inclusion. There are specialty centers, but most of the people are interested in the majority of the ones we have there.

Operator: Now we're going to take our next question, and the question comes line of Sean McCutcheon from Raymond James.

Sean McCutcheon: For the 2028 cash runway guidance, can you speak to maybe what milestones, programs and potentially further efficiency measures are contemplated within that guidance?

Thad Huston: Yes. This is Thad here. Good question. So we look ahead, obviously we're going through a pretty significant restructuring of the business that Paul mentioned as well reducing our overall head count by about 40%, focusing in cell therapy, and we brought our burn rate down, excluding business development, from EUR 293 million in 2024 to a range where we're saying of about EUR 175 million to EUR 225 million per year. We can certainly work towards the lower end of that range depending on some of the choices. We're initially investing to build out the DMU network, that investment will kind of move down over time but then we'll have the clinical investment that will pick up. And so that's why I would give kind of this range. We're saying the range is kind of taking us to 2028 because that's assuming midyear with approximately $500 million at separation. So we do see that we'll have runway there.

We also have a number of milestones and key inflection points, obviously going into pivotal in 2026. Obviously completing the pivotal studies for 5101. We'll also see the readout from 5301, we'll have 5701, and as also mentioned, we'll have some of our internal next-generation platforms going into the clinic, and we anticipate that we'll have a multiple number of programs between now and 2028 that will enter to the clinic. And, in addition, we're also looking to do potentially partnership deals on the platform, and we see tremendous opportunity there. So there's a number of key milestones and a number of really exciting things that will help us get to that 2028 first launch, hopefully.

Operator: Now we're going to take our next question. The question comes from line of Jacob Mekhael from KBC Securities.

Jacob Mekhael: I just had one on the ATALANTA one study in the U.S. When do you expect to dose the first patient? And maybe can you please provide some insight behind this small delay there?

Jeevan Shetty: Yes. Jeevan here, again. Thank you very much for the question. In Europe, the patient recruitment is ongoing with the U.S. clearly with the FDA IND application secured and also the inclusion of the leading cancer centers in Boston being engaged. We're working pretty hard towards enrolling the first patient into the study. So we're very confident that we will be able to recruit the patient imminently. There are clearly some procedural and operational components in the final stages of starting the trial that we are working towards, but we're very confident that we will have our first patient very soon.

Operator: (Operator Instructions) And now we're going to take our next question. The question comes from the line of Sebastiaan van der Schoot from Van Lanschot Kempen.

Sebastiaan van der Schoot: I was hoping that you could expand on the differences between the decentralized and centralized manufacturing. But then from the standpoint of the regulator compared to previous CAR-T trials in the registrational setting, do you expect any differences in terms of patient number or follow-up to demonstrate consistency between the different number of the DMUs?

Paul Stoffels: I'll start with your last remark. Because we run our comparative and validation trials on the different DMUs, we come with the same product out of that manufacturing site like large companies do, we do the same type of validation where large companies do that centrally in their sites. We do that across sites. We follow the principle of split samples where we validate that across different DMUs and validate that all of these DMUs function the same. So we have to comply with the high standards of central manufacturing in order to deliver these CAR-T cells. And that's where we don't assume any different indications from different regions in the world. We go for indication by indication, combining U.S. and European patients.

Thad Huston: Yes. I'd just add, generally, though, I mean we have significant benefits for our decentralized manufacturing model. That's where we think that, again the regulatory pathway that Paul mentioned has to be applied. But I think the delivery of fresh cells we obviously see this unique clinical benefit, but there's also a number of logistical benefits and cost benefits that we also see with our delivery and our model.

Sebastiaan van der Schoot: Okay. If I may just one more question regarding the deal in terms of uza-cel. Can you remind us of those deal terms? Then you also mentioned that you are looking for similar partnerships in the future, can you expand on that?

Thad Huston: Yes. So we did the uza-cel deal, where we essentially have an option agreement on uza-cel. We're doing head and neck cancer as an initial indication. It was, I believe, $100 million option, at least initial payment, but we have the option to go up to three different indications including ovarian and some others, and where essentially we're testing the product on the Cocoon and the platform, and then where we could opt in and basically take over the commercialization and development rights.

Operator: There are no further questions for today. I would now like to hand the conference over to your speaker, Sri Ramaswami, for any closing remarks.

Srikant Ramaswami: Again thank you all for joining us today. The team will be in Boston presenting at the TD Cowen Healthcare Conference on Tuesday, March 4th, at 1:50 p.m. Eastern Time. The following week, we'll be in Miami, participating at the Barclays Healthcare Conference. Please reach out if you're interested in connecting with us in person at these events. Have a wonderful day. And we look forward to seeing some of you in March.