Galapagos NV (Q1 2025)
April 24, 2025

Corporate Speakers:

- Glenn Schulman; Galapagos NV; Head of Investor Relations
- Paulus Stoffels; Galapagos NV; Chair and Chief Executive Officer
- Thad Huston; Galapagos NV; Chief Operating and Chief Financial Officer
- Omotayo Fasan; Galapagos NV; Clinical Program Head, Oncology
- Wulf Böcher; Galapagos NV; Head of Immunology Therapeutic Area
- John Mellors; Galapagos NV; Head of Cell Therapy Discovery
- Valeria Cnossen; Galapagos NV; Executive Vice President and General Counsel

Participants:

- Brian Abrahams; RBC Capital Markets; Analyst
- Philip Nadeau; TD Cowen; Analyst
- Sebastiaan van der Schoot; Van Lanschot Kempen; Analyst
- Manos Mastorakis; Deutsche Bank; Analyst
- Faisal Khurshid; Leerink Partners; Analyst
- Judah Frommer; Morgan Stanley; Analyst
- Jacob Mekhael; KBC Securities; Analyst
- Sean McCutcheon; Raymond James; Analyst
- David Seynnaeve; Degroof Petercam; Analyst

PRESENTATION

Operator: Good day. Thank you for standing by. Welcome to the Galapagos first quarter 2025 Financial Results and Business Update. (Operator Instructions) Please be advised, today's conference is being recorded.

I'd now like to hand the conference over to your first speaker today, Glenn Schulman, Head of Investor Relations. Please go ahead.

Glenn Schulman: Thank you, Operator. Thank you all for joining us for Galapagos' first quarter 2025 financial results and business update conference call. Last evening we issued a press release outlining these results. This 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. These forward-looking statements include remarks concerning future developments of our company and our pipeline and possible changes in the industry and competitive environment. Actual results may differ materially from those indicated by these statements, and are accurate only as of the date of this recording, April 24, 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 of the company. We are also joined by Dr. John Mellors, Head of Cell Therapy Discovery, Wulf Bocher, Head of Immunology, and Omotayo Fasan, Clinical Program Head, Oncology. They'll be available during the Q&A session.

With that, let me now turn the call over to Paul.

Paulus Stoffels: Thank you, Glenn. Before starting the Q1 financial update, I want to provide some color on the recently communicated executive leadership changes. We are very pleased with the appointment of Henry Gosebruch as the founding CEO of SpinCo. This is an important milestone in the planned separation of SpinCo as announced earlier this year. Henry has deep experience in M&A, business development and capital allocation to his past roles as President and CEO of Neumora; Executive VP and Chief Strategy Officer at AbbVie; and M&A co-head at JPMorgan.

We welcome Henry into his new role, and we look forward to introducing him to you in the coming weeks.

I would like to provide some color on my intent to retire from my role as CEO of Galapagos in the next 12 months, once the successor has been appointed. I want to underscore that I'm fully committed to supporting Galapagos as its CEO and Chair of the Board. Upon the CEO successor being appointed, my intention is to serve as Nonexecutive Chair of the Board of Galapagos, continue to provide strategic guidance and support.

Galapagos has strong foundations in place to create value for all its stakeholders. We have built a strong company with top talent in Europe, the U.S. and China as we continue to attract experts in cell therapy. Together, we are transforming Galapagos into a focused cell therapy company that is offering real hope to people facing cancer.

I also want to thank Thad for his contribution to Galapagos as CFO and COO. He supported the transformation of Galapagos into the dedicated cell therapy company that we are today. He will remain with the company until August One, to ensure a smooth transition and handover of responsibilities.

Let's now move to our Q1 financial results and business update. We continued to make meaningful progress advancing our clinical pipeline and expanding global access for our innovative manufacturing platform and decentralized manufacturing units or DMUs. As we announced in our press release last night, we are particularly pleased that we have dosed our first U.S. patient in the ATALANTA-1 study of GLPG5101, where in combination with our ongoing European sites, we are evaluating our novel CD19 CAR-T candidate in eight hematological malignancies with high unmet medical needs.

In addition, we completed enrollment of the indolent NHL cohort, added the diffuse large B-cell rate transformation cohort and are in the process of adding the CLL cohort to the

study. All other cohorts are open and enrolling. Importantly, we have selected MCL as a lead indication to take forward in a pivotal trial and are very optimistic for our prospects with this indication, which I will discuss in greater detail in a moment. We made great progress with our earlier-stage discovery programs and expect to initiate clinical development of a novel CAR-T candidate and to select at least one program for IND-enabling studies this year. In 2026, the pipeline is expected to be further expanded with at least one additional next-generation program.

Throughout the first quarter, we continued to make platform and process improvements to support pivotal studies and commercial readiness by expanding our decentralized manufacturing network in the U.S. and Europe, giving patients direct access to our therapies and limiting logistical constraints. In collaboration with our partner, Adaptimmune, we also advanced the preparation to develop uza-cel for solid tumors, such as head and neck cancer, and plan to initiate proof-of-concept studies in 2026.

Finally, we are working towards separation, and as I mentioned at the beginning of the call we recently announced the appointment of the founding CEO of SpinCo, Mr. Henry Gosebruch. Thad will talk about SpinCo in greater detail later on today's call. We have as well advanced the two Phase III enabling studies in SLE and dermatomyositis with our TYK2 inhibitor, GLPG3667, and are actively seeking partners to acquire the program.

Core to our strategy to build a leadership position in cell therapy in oncology is a decentralized manufacturing that was designed to overcome the limitations of current cell therapy manufacturing, which is centralized, and bears high-cost burdens with longer production and delivery times that require cryopreserving cells and the need for bridging therapy. A 7-day vein-to-vein time is designed to provide fresh stem-like cells, which we believe enhance the therapeutic profile by producing highly potent cells that are less exhausted, less toxic and persist longer.

In addition to logistical advantages, our DMUs are designed to enable scalable and consistent products near the clinic. We believe this approach will be more cost-effective and provide greater access to these potentially life-saving cell therapies. We are unlocking the broad-reaching potential of this decentralized cell therapy manufacturing platform as we advance our robust cell therapy pipeline. GLPG5101 is our most advanced CAR-T asset that is in clinical development in the U.S. and Europe in the ATALANTA-1 Phase I/II clinical study in eight hematological malignancies.

As I mentioned earlier, we initiated dosing of patients in the U.S. and expect enrollment to accelerate as more sites are activated. We fully enrolled the indolent NHL cohort and expect to present these top line data at a medical meeting in mid-25. Enrollment continues well in the mantle cell lymphoma or MCL cohort, which we have selected as a lead indication to take into pivotal studies.

Our plan is to start pivotal development in 2026 with an anticipated approval in 2028. We're progressing the enrollment of patients in the Phase I/II PAPILIO study of GLPG5301, or BCMA CAR-T, as a treatment for relapsed/refractory multiple myeloma.

Here, we expect to have top line data in 2026. These data will direct our development plan for this product candidate.

As noted earlier, we continue to build value by strengthening and advancing our early-stage pipeline of next-generation, multi-targeting armed cell therapies for hematological and solid tumors. We believe that the combination of fresh, fast and fit cells has the potential for transformative impact. We can see that from the data recently presented at ASH, which demonstrated 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 and efficacy results were available for 45 patients and 42 patients, respectively. As you can see, we observed high overall response and complete response rates. Here, we show 100% of patients with relapsed/refractory mantle cell lymphoma, 95% of patients with relapsed/refractory follicle and marginal zone lymphoma and 54% of patients with relapsed/refractory DLBCL achieved a CR. Of evaluable patients achieving CR, 80% were MRD negative and remains in CR at the time of data cutoff.

Of note, strong and consistent in vivo CAR-T expansion levels and products consisting of stem-like early memory phenotype cells were observed in all doses tested, further supporting our innovative platform technology. We are seeing these compelling results with very reassuring safety data with low levels of ICANS. This translates to less time in the ICU in hospital and more time at home with family.

Importantly, the eight hematological malignancies we are evaluating have created a EUR 2 billion in peak sales potential in the U.S. and the EU5 alone. We are excited to move forward with MCL as a lead indication for pivotal studies. We made the determination based on a number of factors including the high unmet medical need, strong initial data from this patient cohort and the fact that MCL accounts for approximately 6% of all NHL cases in the U.S. All combining make this an attractive lead indication for GLPG5101. Patient enrollment in this cohort of ATALANTA-1 is going well and we expect to present new data from this cohort at a medical meeting in the second half of this year.

Our strategic focus on MCL, supported by strong data and significant unmet medical need, positions us for pivotal development in 2026 and potential first approval in 2028, marking a major step forward to provide greater access to new medicines for patients in need.

Our mission is also grounded in providing greater access to these new methods via our DMUs, which requires securing the capacity for clinical studies and commercial readiness. Our efforts here are supported by strong collaborations with Lonza for the Cocoon platform and Thermo Fisher Scientific for the development of an ultrarapid PCR sterility test together with miDiagnostics.

We are also expanding our network of DMU with our collaborations with Catalent for the New York, New Jersey and Pennsylvania area, Moffitt Cancer Center in Florida region and NecstGen in the Benelux region. Collectively, these networks target nearly 250 million patients.

Additional DMUs will be integrated into the company's network in the U.S. and Europe to ensure sufficient capacity for clinical and future commercial supply in key regions. Most recently, and as announced in our press release, we have established operations in China that enable us to leverage our unique manufacturing platform and to accelerate the development and value creation of our next-generation cell therapy pipeline.

With that overview of our cell therapy business, let me turn the call over to my colleague, Thad Huston, for a review of our financial and progress on the intended separation. Thad?

Thad Huston: Thank you, Paul. Now turning to some of the financial highlights from the quarter, which as you would imagine, were impacted by our ongoing implementation of the restructuring and the SpinCo separation. Total net revenues for the first quarter of 2025 were EUR 75 million, which includes EUR 14 million of supply revenues related to Jyseleca and EUR 61 million in collaboration revenues.

Increases to operating expenses were driven by our clinical expansion in oncology CAR-T in the build-out of our DMU network as well as EUR 111 million of restructuring costs. These include severance costs, the early termination of collaborations, impairment on small molecule assets as well as deal costs related to the planned separation.

Looking to our balance sheet. We reported a cash balance of EUR 3.3 billion at the end of the first quarter of 2025. Important to note here is the timing difference of the effective payouts related to the reorganization, which is not represented in our cash balance. Upon separation, SpinCo will have approximately EUR 2.45 billion to execute its strategy for transformative transactions. Following this planned transaction, Galapagos expects the normalized annual cash burn to be between EUR 175 million and EUR 225 million, excluding restructuring costs. Upon separation, Galapagos will have approximately EUR 500 million in cash to accelerate the cell therapy pipeline, and expects to have runway to fund operations to 2028.

Turning now to the value proposition for Galapagos and SpinCo. We remain very excited by the opportunities we can create by separating Galapagos into two entities. Following the separation, Galapagos will be focused on accelerating the development of our flagship CD19 CAR-T program through our innovative decentralized manufacturing platform.

As noted, our aim is to start pivotal development in 2026 and first approval in 2028. We will continue to build value by developing next-gen cell therapy programs in hematological and solid tumors. Importantly, we will have the autonomy to partner our decentralized manufacturing platform and network as well as our differentiated cell

therapy pipeline. We also streamlined the organization to realign our footprint and reduce cash burn. As I just mentioned, upon separation, Galapagos will have EUR 500 million in cash to execute this focused strategy.

Turning to the opportunities we have by creating SpinCo. We are excited that Henry has joined as the founding CEO of SpinCo. Henry will be hiring the remainder of SpinCo's leadership team in the coming period. The Board of SpinCo will comprise a majority of independent directors. SpinCo will be focusing on building a pipeline of innovative medicines through transformational transactions. The company will have sufficient resource to pursue high-quality assets, fund development and to invest in its portfolio, which is expected to focus on oncology, immunology and virology.

If Gilead decides to opt in to SpinCo programs under the collaboration agreement, then SpinCo would be able to leverage Gilead's strong expertise and late-stage development and commercial capabilities in key therapeutic areas. Importantly, all Galapagos shareholders will receive shares of SpinCo on a pro rata basis based on the number of Galapagos shares that they owned as the record date to be established.

And with that, I'll hand it over to Paul, who will walk us through our new near-term catalysts.

Paulus Stoffels: Thanks, Thad. As you can see on this slide, we have an exciting year ahead with the potential to achieve a number of value-driving catalysts. Our clinical programs have a number of key inflection points including new top line data from the indolent NHL cohort to be presented at a medical conference in the second quarter of 2025, new data from the NCL cohort at a medical meeting in the second half of 2025 and an end of Phase II meeting for MCL that will align our pivotal trial design with global regulatory authorities and position us for pivotal development start in 2026.

Advances with our innovative discovery engine will allow us to dose the first patients with our armed bispecific CAR-T candidate in 2025, and we will select at least one next-gen candidate to take forward to the clinic by year-end. For the planned separation of SpinCo, we expect to announce additional management and Board appointments and to obtain shareholder approval for the separation by midyear.

In summary, 2025 is set to be a transformative year for Galapagos. With pivotal clinical milestones, groundbreaking advancements in our discovery engine and the strategic separation of SpinCo, we are well positioned to drive significant value for our stakeholders. We look forward to sharing our progress and achieving this ambitious goal. Thank you for your continued support and confidence in our vision.

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

Operator: (Operator Instructions)

Glenn Schulman: Thanks, Sara. While you compile the list, I just also want to mention that we have Valeria Cnossen, our Executive and General Counsel with us as well today for the Q&A period.

QUESTIONS AND ANSWERS

Operator: We'll now take our first question. This is from Brian Abrahams from RBC Capital Markets.

Brian Abrahams: Best wishes to Paul and Thad on the transition out of the company and retirement, and congrats on the hiring of Henry for SpinCo. I guess now that it seems like there's a path that's even better defined for 5101, I was wondering if you could give us a better sense of your latest thinking on the registrational requirements in MCL. What a pivotal could look like and what data you might need to show there? Then if you could also talk a little bit about your expectations for the time cushion between when this pivotal data could read out and your cash runway?

Paulus Stoffels: Yes. First, the choice of MCL is based on very good results. It's a very high unmet medical need, which we have been able to address with our CAR-T in a very positive way very high cure rates as you have seen in the complete response rates, as you have seen in the slide, as well as very good safety data and it’s still in high unmet medical need with people who have a very high -- or a short life expectancy. And maybe our clinical lead, Tayo, may give some further comments on that on when and how we will get to a pivotal design.

Omotayo Fasan: Yes. This is Omotayo, the clinical program head for 5101. So MCL is the right choice for the first indication for 5101 because like Paul said, there is a high unmet medical need. The population we're targeting, the relapsed/refractory population, with non-CAR-T therapy, have usually less than a 12-month event-free survival or progression-free survival with whatever therapy they get.

So given this, there is a pathway for a novel therapy like a CAR-T to pursue an indication using a single-arm trial design. But we also understand that with every single arm trial design, you need to have a confirmatory study lined up. Our initial thinking is that this would be a randomized controlled study to confirm the findings of the clinical benefit from the SAT.

Thad Huston: Yes. And just to address, Brian, the question about the cash runway. We did intentionally align our capital allocation between SpinCo and Galapagos to address that pivotal readout and to align it with MCL. We say that the cash will take us into 2028, which is roughly the timing that we're anticipating for that.

Operator: We'll now take our next question. This is from Phil Nadeau from TD Cowen.

Philip Nadeau: Let us add our thanks to Paul and Thad for all your work over the years. A follow-up question to Brian's from us, and that's on manufacturing. Can you talk a bit

more about your understanding or expectations for the manufacturing requirements that you'll need to file in the U.S. and Europe? How well defined are those with the regulatory agencies? And is there more work to do to understand those requirements? And maybe a second part of the question would be how many DMUs do you think you would need in the U.S. and Europe to fully satisfy the market?

Paulus Stoffels: With regard to the requirements for the manufacturing process and equipment, we are in continuous discussion with the authorities. And each of the steps have been very well defined from where we are now both with EMA and the FDA to starting pivotal -- additional steps are taken on quality release, et cetera.

Then what needs to be done by commercial. We have a whole development part in place for that with all the elements in place to be able to have our pivotal studies running as precommercial because we need to have the final formulation, final setup, and then confirming that with additional validation throughout our pivotal study development.

So that is very well understood. We have had multiple with the authorities, and we have a clear path for that with all in place to meet the 2028 date for commercial availability.

Thad Huston: Thanks, Phil, for the question. To address the point about the number of DMUs and sites. It has been evolving. I think initially, when we first acquired CellPoint, it was more about point of care, and we thought that, that would be like near the hospital. I think it's been evolving more towards decentralized manufacturing hubs. Where, again like we recently signed with Moffitt collaboration to cover the Southeast.

So we think that we'll need fewer DMUs, but have more of a regional coverage model. That's still under development for commercial, but we're still in the clinical phase at this point. But as it evolves, I think it will be more regional. And also having regional hubs as well covering the Benelux, of course U.K. and key markets throughout Europe.

Operator: We'll now take the next question. This is from Sebastiaan van der Schoot from Van Lanschot Kempen.

Sebastiaan van der Schoot: Sad to see Paul and Thad go. I think that you mentioned partnership opportunity for Galapagos after the split has been finalized. Are you also interested in partnering on the Cocoon approach with other partners for the development of cell therapies? And if so, can you describe how such partnerships would look like? Then maybe can you also provide some insight on the focus of the next-generation CAR-T?

Paulus Stoffels: Well Sebastiaan, first, I want to say I'm not yet gone. I've committed to stay for the next 12 months to make sure at first as CEO and then continuous chair. So I will stay with Galapagos for the long time. So that is -- that's my mission.

On -- yes, the partnerships. Yes. We will be -- we have a lot of interest in people who look at our manufacturing platform to be participating in that. The first, the collaboration

we did was with Adaptimmune, where we saw that -- where we actively studied uza-cel in the Cocoon and we're able to show that we could make the TCRT also in seven days with very good quality cells. That enables us now to bring that into the clinic in '26 with a study most likely in head and neck. That is the goal.

More interest is there. But at the moment, we have a single focus on making sure we bring our own platform and our own product forward to commercial. Eventually, yes, there will be opportunities to partner on the platform itself. The DMU is a very -- it's an exceptional unique approach, bringing CAR-Ts close to people and also the ability to bring them global including Asia, South America, all the rest of the world is accessible by this principle. So we'll foresee definitely collaborations as we go forward, but with a focus on making sure our own products reach the market first.

Thad Huston: I think it's a really exciting time for us. So as we do the separation to have this platform, as Paul mentioned, develop our own pipeline but also to develop next-generation assets, which John can talk more about.

Paul Stoffels: John?

John Mellors: Yes. John Mellors, Head of Discovery. I'm happy to talk about our next-generation assets. They will address high unmet medical need in both liquid and solid tumors. The approach is to take validated targets and combine them, potentially with new targets through multi-targeting strategy and also arming the cells to expand and persist and not be inhibited by the tumor microenvironment and to engage the endogenous non-CAR-T immune system to attack the tumor.

And we're targeting non-Hodgkin's lymphoma that is refractory even after first generation CAR-T therapy, but we'll move into earlier lines of therapy as data emerge, particularly in DLBCL, where there's high unmet medical need, and also refractory multiple myeloma after BCMA bispecific or CAR-T therapy.

The largest unmet medical need is in solid tumors, and we have identified three programs to hit various forms of lung cancer and gynecologic cancer. And as was mentioned earlier, we'll nominate our first candidate for IND this year for hematologic cancer, which will be advanced over existing therapies, and we will move into early clinical development through our recently established headquarters in Shanghai, China.

Operator: And we'll take our next question. This is from Manos Mastorakis from Deutsche Bank.

Manos Mastorakis: So a little bit more color on the M&A strategy, the modalities, the collaboration versus straight out acquisitions would be much appreciated as well as whether SpinCo will be completely independent in the development of its new portfolio or whether GLPG resources will be tapped into? And what are the sort of timelines for starting to see some of those deals executed by SpinCo?

Thad Huston: Yes, SpinCo will be an independent company and obviously now with having -- Henry is the Head of the -- CEO, we'll really focus on bringing in and acquiring new assets. So it's not limited to a particular area that's of strategic interest to Galapagos. It's really up to Henry and the independent Board and the management team to do those deals. We will provide, obviously the support to initially set up the SpinCo and the entity and provide any support like IT or finance or just those kind of general G&A support. But yes, they'll be an independent team.

Paulus Stoffels: And for the timing of the first deal, as we are approaching midyear, most likely, there will be no deal done before the spin is actually done. So that is -- but it will be very active on much activity ongoing to prepare for potential opportunities.

Operator: We'll now take our next question. This is from Faisal Khurshid from Leerink Partners.

Faisal Khurshid: Just -- can you provide some context on expectations for the MCL data update coming in the second half of this year? Curious if you can kind of say anything on like numbers of patients and extent of follow-up compared to the data that we saw last year?

Paulus Stoffels: Tayo, can you give a short update on what to be expected?

Omotayo Fasan: Yes. So last ASH, ASH 2024, we had eight MCL patients in that data set. That's from April 2024, exactly a year ago. We have continued to enroll and the numbers have increased, and we will be updating and releasing data second half of this year.

Faisal Khurshid: Yes. Can you say anything on how many patients and how much follow-up?

Omotayo Fasan: So the median follow-up at ASH for that cohort was about three to four months. And like I said, we'll be at least one year on. So that's about the follow-up you will expect. The numbers are more than we've reported and we're not ready to disclose at this time.

Paulus Stoffels: Well let me add in general, what we are doing is in the eight indications which we are studying, we have a Phase I/II Phase I part and a Phase II part and the Phase I part in the dose find in the Phase II part in the expansion cohorts. We typically go up to around 20 patients, might be more, but that is the range we will report on multiple of our indications in the future.

So you have seen the list on the slides on the different indications. All the indications are recruiting except for the Richter transformation in CLL, which still need to kick off, Richter's transformation is ready to go. CLL, the protocol is being finalized with the authorities and hopefully, in the next few months, we'll be able to recruit there too. So it's

a very active program. It will -- but each of the indications will be going up to a certain number in the range of 20 to confirm efficacy and safety.

Faisal Khurshid: Got it. That's very helpful, Paul. Then if I can just ask a follow-up here. What is the target profile that you think you need to achieve in MCL to kind of differentiate from the two approved CAR-T options?

Paulus Stoffels: Tayo?

Omotayo Fasan: Yes. So the two CAR-Ts you referenced, one of them is known for its efficacy, the other for its safety. We believe our profile will match -- should match the efficacy and the safety, as I just explained. So we think we will merge the best of both worlds.

Paulus Stoffels: Well in addition to that, we'll have the opportunity to have a product which can -- a cell therapy product, which can be administered in a 7-day vein to vein. So people with life expectancy of one month, you still can get therapy. That is a very important feature for what we see now in the clinics. They have relapsed patients who come back to the clinic with relapsed/refractory mantle cell lymphoma with very short life expectancies, and those are specifically people where our product can be very, very differentiated to still give a solution for that patient.

Omotayo Fasan: And I will just add on to what Paul said. One of the things we know from prior CAR-T data in MCL is that as a percentage of patients drop out between [luciferase] and infusion. The strength of our platform is that within seven days, that number is much reduced. So we believe that this is additional value 5101 will be able to bring to this high unmet medical need.

Operator: We'll take our next question. This is from Judah Frommer from Morgan Stanley.

Judah Frommer: Congrats on the progress. Just a couple of follow-ups. I guess first, maybe just in reference to expanding the collaboration agreements in the U.S. Just curious if kind of new partners are indicating that it's supply, that's an issue for them or that they're interested in expanding for CAR-Ts and their centers? Or is it the efficacy of the program that's resonating more? Then just on SpinCo, we've gotten the question. Is there any chance, given Henry's recent background, that neurology could be an area of focus going forward?

Thad Huston: Yes. So I think on the separation, I mean clearly, we see a lot of interest in our platform with cell therapy, the decentralized manufacturing. But I think where it gets really exciting is what Paul mentioned with Adaptimmune, when we test cells on the Cocoon in seven days, we see better cell quality and better outcomes.

So there has been interest, I think post separation, for us to partner with many different types of companies, both big and small, depending on whether they need a manufacturing

platform or whether they want to see even better efficacy for their products that's in their pipeline. And I think related to the SpinCo, it's -- I think our areas of interest that we've outlined has been oncology, immunology and virology which, again were areas of interest for Gilead. But I think it's always possible depending on the deal.

Paulus Stoffels: With regard to the partnerships on the DMUs, the hospitals and interest. There is significant interest. We are building up DMU by DMU as we need to validate and cost validate and with these -- the production as biological production sites. Sometimes that takes certain times, and that's where we are building up very steadily. But in between now and the year-end, we'll have multiple of the DMUs up and running, preparing for the pivotal.

So that is ongoing. Lots of interest on hospitals, and we select the DMUs where we can manufacturing close in regions with access to multiple large hospitals and within a few hours drive range so that we can deliver the fresh cells in the same day. Cells come from our manufacturing system in the morning. They need a few hours for quality release and they typically are administered in the afternoon to patients. So that is the way we operate in close to large cities with multiple hospitals today.

Operator: We'll now take our next question. This is from Jacob Mekhael from KBC Securities.

Jacob Mekhael: With the recent changes happening at the FDA, how do you think this could impact how the agency looks at point of care CAR-T? And could there be a change to how open they are to new ways and manufacturing and delivering cell therapies now that they're working with less people?

Paulus Stoffels: Well that's to be expected, I think well to be expected to be looked for on what the change is going to be. But one thing I can say if we work on and we have the recent experience in the past few weeks with the FDA working on a very high unmet medical need still gets priority, still gets support, still gets the help of the people at the FDA. But even more -- Rome cell and gene therapy conference last week in Rome and the senior regulators from Europe and the U.K. were there.

They see this also as an opportunity now Europe and the U.K. and to stand up and drive the innovation. I think we'll get support all over the world, especially because you bring a product for a very high unmet medical need, which can help many patients. So I expect, yes, there might be some hiccups. But so far, we have not yet seen that.

Operator: We'll now take our next question. This is from Chi Fong from Bank of America.

Chi Fong: This is Chi on for Jason Gerberry at Bank of America. I have a question on 5301. So if you currently has a hypothesis that Parkinsonism is a class effect and not the molecule or construct-specific effect is that you can minimize Parkinsonism by some prophylactic steroid treatment. I'm curious what's your view on that? And can you remind

us what the mitigation strategy you have implemented in the amended Phase I protocol? Are you giving patients prophylactic dexamethasone or a similar approach? And have you seen any Parkinsonism case since you have resumed the study?

Paulus Stoffels: So Tayo or John, can you step in here?

Omotayo Fasan: Yes. So I'll go and then maybe John can add as well. The mitigation strategies we put in place are strategies that have been published in the literature. When the Parkinsonism associated with BCMA therapy first hit the headlines, I think this gave us a surprise. When the data was reviewed, certain risk factors were identified, such as patients with high tumor volume was a risk factor, and patients with rapidly rising lymphocyte count. So what we've done in our protocol is to try to mitigate at least two of these or both of these issues, and we have elements in the protocol to protect patients. Since restarting the study, we have been able to manage all the patients that have been enrolled, and haven't seen any further occurrences.

Paulus Stoffels: So as you said earlier, one comment more is that we are still in the Phase I/II study phase, closing on the dose finding and then we'll further expand and we'll have -- we'll be able to report on this study in '26 because, yes, it takes time and the spacing of the dose finding and the safety event we had, we got some delay but now we are back on track, and we'll look forward to that. Based on those data, we'll decide what development path we take for our PCMA product.

Operator: (Operator Instructions) We'll now take our next question. This is from Sean McCutcheon from Raymond James.

Raymond James Analyst: Congrats on the progress. This is [Yang] on for Sean from Raymond James. We have a question regarding the U.S. clinical trial, especially for Atlantic. Now you have dosed your first patient. And could you provide some color on the degree of availability you have seen from a per patient basis or a per site basis, especially given your previous experience that for some patients, the product may be below the target dose. What's your thinking and strategy for the protocol action in that case?

Paul Stoffels: Tayo?

Omotayo Fasan: Yes. So specifically, we just began enrolling patients in the U.S. If your question was about the patients in the U.S. versus Europe. So we're still gathering data, and so I can't answer that question specifically. However what I can say in general terms is that even in cases where the doses may not be the dose as intended, when those patients have been infused, we have seen encouraging safety data and efficacy data. And an investigation and process improvements were put in place. Since then, the dosing has been more consistent at the desired dose.

Unidentified Participant: Okay. Maybe I can do a follow-up for the ATALANTA-1. We noticed that you did not mention DLBCL. Could you give us your thoughts on this cohort and what you're thinking for the defining the go-forward dose?

Paulus Stoffels: Tayo? Yes.

Omotayo Fasan: Okay. So ATALANTA has seven cohorts right now. And like Paul mentioned earlier, we're adding an eighth cohort for chronic lymphocytic leukemia. MCL is the first cohort that's going forth to pivotal. The other cohorts continue to enroll, we continue to gather data, analyze the data. And as the data matures, we intend to progress those cohorts to pivotal as well. DLBCL is one of those cohorts, it's still open, and it's enrolling patients.

Operator: We'll take our next question. This is from David Seynnaeve from Degroof Petercam.

David Seynnaeve: Just wondering, at the speed it's going now when you expect the PAPILIO-1 patient enrollment to be completed and based around if it's going to be more likely H1 or H2 2026 when you share the top line results or at least when you expect to be able to provide more detailed guidance on that?

Paulus Stoffels: I think at the moment, we are still, as I said, recruiting in the Phase I part of that. Soon, the Phase II will start. We can't give further guidance on when we'll be able to report top line data, but it will be '26, and in one of the next calls, we'll provide more detail on that, where we will land in the course of 2026.

Operator: Now there are no further questions at this time. So I will now hand the conference back to Glenn Schulman for any closing comments.

Glenn Schulman: Thanks, Sara. Thank you, everyone, for joining us today on our first quarter 2025 results conference call. On behalf of the team, I want to thank you for your attention. Also to let you know that we will be attending -- the team will be presenting at the Jefferies Conference coming up in June, and we'll be reporting our next webcast of first half financial results, July 23, followed by the webcast on July 24. So I hope everyone has a great day and be well.

Operator: Thank you. This concludes today's conference call. Thank you for participating. And you may now disconnect. Speakers, please stand by.