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Half Year 2023 Ucb SA Earnings Call

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PRESENTATION

Antje Witte ***UCB SA - Head of IR***

Hello. Welcome to the UCB Half Year 2023 Capital Market Call. My name is Antje, and I'm the Head of Investor Relations at UCB.

Before I introduce you to the agenda and hand over to the speakers today, I'd like to make some remarks. This video conference is being recorded. This presentation and the following Q&A session are covered by the disclaimer and safe harbor statement as stated on Slide 2 of the slide deck. Please kindly read this carefully.

You can find the presentation in our Download Center if you dial-in by phone. The presentation and the following Q&A session are intended for institutional capital market participants. If you're not, please disconnect now. Following your feedback, we implemented some changes. We have shortened the presentation, and reduced the number of speakers to have more time for Q&A., and you have been invited to ask your questions live.

With this, I'd like to introduce to you our speakers for today: Jean-Christophe Tellier, our CFO -- our CEO; and Sandrine Dufour, our CFO. In the Q&A session, not only Jean-Christophe and Sandrine, but also our Chief Medical Officer, Iris Loew-Friedrich; Emmanuel Caeymaex, Head of Immunology and U.S. are here to answer your questions.

And as Charl van Zyl, our former Head of Neurology has recently left the company to join Lundbeck as a CEO, we have asked 2 members of his leadership team to join the Q&A panel. So it's my pleasure to introduce to you Kim Moran, Head of U.S. Rare Diseases; and Mike Davis, Head of Global Epilepsy. Kim is launching with the team RYSTIGGO as we speak; and Mike is managing our evolving epilepsy portfolio.

With this, Jean-Christophe, over to you.

Jean-Christophe Tellier ***UCB SA - CEO & Executive Director***

Thank you very much, Antje. Good morning, and good afternoon, good evening, everyone. It's a pleasure to welcome you to our half year results. Maybe I can go directly to the slide after the agenda, please. And so get the next one, please.

So as you see in this slide, we are at an inflation point now. And I think at the end of the first half of '23 mark this moment, which is an important one for UCB, which is a moment where we can leave behind the absorptions that the necessary decline of our product after the loss of exclusivity and start to build a new phase of growth for the company, build on current growth drivers as well as new assets. And actually, we are today in this new period -- starting this new period of growth, thanks to a few elements.

The first one is the good resistance performance and resilience of our current growth drivers. And I would like to mention CIMZIA, but

also, of course, Briviact and EVENITY. The second element is the fact that we incorporate -- we are incorporating in our portfolio, new assets, thanks to the success that we have had in our development portfolio. And here, of course, I have in mind BIMZELX, FINTEPLA and RYSTIGGO.

Last also, but not least, we're able to enter into this new phase because we are doing a rigorous and disciplined allocations of our resource, so that we can make sure that we provide sufficient investments behind the preparation and the executions of the launches as well as managing the tail of our products.

Next slide, please. And so because of all of that, I think we can qualify in the first half of 2023 as a solid performance for UCB. And you can look at this slide from different lenses. That is one lenses, which is the classical one, which is revenue or the net sales. And here, you are still observing a decline of our revenue or net sales. But as I said, it's because of the last period where we have the loss of exclusivity, and we need to absorb. But because we are starting a new phase, we can have starting this new growth. Actually, if I put on the side the loss of exclusivity of VIMPAT, we are currently growing already by 8%.

The second lenses that you can look at the first half is what has been achieved during the first half in terms of new patient population. Because by adding new patients' populations, be able to provide access to these new patient populations, it is, of course, new source of growth for the company.

And during the first half of 2023, we achieved approval of FINTEPLA for Lennox-Gastaut syndrome in Europe. We have also in Europe achieved the ability to launch BIMZELX in PsA, psoriatic arthritis and, AS axial for arthritis. And we are actually, as we speak, launching RYSTIGGO in the U.S. So new tools, new assets, new patient population that will fuel growth for the company for the future.

And then the third lenses that you can have to look at our first half performance is how confidence we are for the full year guidance. And here, you can see that we are confirming our guidance for 2023.

Next slide. And this is not the end of the journey. We are expecting in the second half of '23, 7 approvals for ongoing regulatory reviews in various geographies. So first, as you know, we are waiting the actions of the FDA for bimekizumab in psoriasis in the U.S. for the third quarter of this year. But we are also on top of that, waiting for axSpA and PsA approval in Japan from bimekizumab.

We are waiting for the rozanolixizumab approbation for generalized myasthenia gravis in Japan. And we are also expecting for zilucoplan, our next new asset approval for generalized myasthenia gravis in the U.S. and in EU, as well as additional filing that we get approval later on. So you see the journey of bringing new assets, new territories, new patient populations into the UCB portfolio is just starting now.

Next slide, please. So, I would like to now quickly zoom in on 3 of our key growth drivers: epilepsy, generalized myasthenia gravis and immunology. Epilepsy reached the inflection point because if we are today in this junction before the loss of exclusivity and the new growth, epilepsy portfolio is for us the perfect illustrations of that because of the loss of E KEPPRA in Japan and VIMPAT in Europe and in the U.S.

But as you can see, we can build growth, thanks to the very good growth and accelerations of growth actually of Briviact globally; as well as FINTEPLA we have reached already more than EUR 100 million during the first half of the year; and NAYZILAM.

Next slide, please. The new and second pillar of growth that I would like to illustrate is UCB starting the journey in generalized myasthenia gravis. And here, our objective is, of course, to elevate the standard of care and to maximize patient outcomes because it is our purpose in all different areas we are evolving.

Now with RYSTIGGO, you see on the left-hand side, the patient population that we think could be addressed and could be treated with our portfolio. With RYSTIGGO, our anti-FcRn antibody, we are the first and only targeted therapy, which is able to treat patients who are either acetylcholine receptor positive or MuSK positive in general myasthenia gravis.

And later with zilucoplan, our complement C5 inhibitor, we will have in our hands the first self-administration targeted therapy that inhibit the complement cascade. So altogether, we will have a portfolio to treat broadly all patient population from different angle, and we will be able to satisfy patients who want to be treated at home, who want to be treated in a hospital, want to continue to go with an infusion and also the diversity from a physician standpoint.

Next slide, please. Last but not least, our third pillar of growth with also 3 growth drivers today is immunology. I mentioned the resilience and the performance of CIMZIA. 15 years after the launch, we were the fifth anti-TNF in the marketplace, and we continue to gain market share, thanks to the diversification and the differentiation that we have been able to build and to provide for patients. You see here 2% of growth, but in fact, if the underlying volume growth of the product was 8%. The difference is mainly due to difference in inventory.

The second growth driver is BIMZELX that we are starting to launch in a lot of different geographies. We have already been approved in 10 different -- by 10 different regulatory agencies, and we have been approved in 36 new different countries there. I will comment BIMZELX on a specific slide.

EVENITY, please, I also would like you to remember that the contribution of EVENITY to our growth come from 2 sides. One, we are booking the revenue directly in Europe, and that's the numbers that you see here, and we are already enjoying a very successful launch in the bone builder markets in a lot of different geographies; but two, we are also gaining a net contribution from Amgen, which is a significant growth of plus 44% for the first half of the year.

Next slide, please. And so when you look at the performance of EVENITY globally, you can see on the right-hand side, the impressive growth that the success of the product has, which is translated here, in the next contribution from Amgen to UCB P&L. And you see on the left-hand side that we are already reaching 485,000 patients across the globe and with 30% of market share in the building -- in the bone builder market we are gaining the leadership that we wanted to achieve.

And last but, of course, not least, I would like to close before handing over to Sandrine with BIMZELX. So on the last slide, you will see the BIMZELX leadership build-up that we are strengthening month after month. On the left-hand side, we are currently pleased with the fact that more than 10,000 of patients are currently benefiting from BIMZELX across the different geographies.

And on the right-hand side, you can see here that on the 3 main regions that today we have launched the product, in Japan, Europe and Canada, we have reached already more than 35% of dynamic market share, meaning the ability of the new patients to be treated by BIMZELX today is more than 1 out of 3. So quickly after the launch of the product, which is a remarkable performance.

So as you can see, a great first half of the year. Solid performance, an ability to build -- continue to build on the growth of our growth drivers, which demonstrate resilience during the first half of the year; two, a portfolio that continues to evolve with new assets, new territories, new patient populations coming in, success of the launches where we have been already able to implement them. And I'm sure that RYSTIGGO in the U.S. will be also a confirmation of this ability to execute; and three, a solid discipline and rigorous allocation of resource and cost management that allow us to deliver the result that Sandrine will now further comment. Thank you.

Sandrine Dufour ***UCB SA - Executive VP & CFO***

Thank you, Jean-Christophe. And good morning, good afternoon, everyone. Let me present this robust first half results as well as the confirmation of our guidance. I will directly go to the next page to give the key highlights.

And as expected, the first half results reflect the impact of the loss of exclusivity of impact. You heard Jean-Christophe explaining that excluding this impact, we have an underlying net sales growth of 8%. And if I look at the trends of the last months of the semester, I can say that the negative impact of the loss of exclusivity are now mostly behind us, and this is what gives us the comfort to talk about an inflection point as we enter the second part of the year.

Now from a resource allocation point of view, we have continued to be very disciplined to make sure that we adequately fund the multiple launches in terms of products, new indications and geographies. Our Focus For Growth, transversal program is yielding very positive results. We will have achieved a run rate of about EUR 200 million of sustainable cost efficiency by year-end by closely managing

all our cost categories, and this contributes to fund the increase of investments behind the launches as well has absorbed the inflation impact, which year-over-year is not insignificant.

As committed, Zogenix is becoming earnings accretive as of 2023. And finally, the profile of margin between the first half and the second half will be different as we accelerate investments to support the launches. And I, of course, will come back on that.

So if we move now to the next page, I will look at the full P&L, and I will start with the net sales. So the total net sales reached EUR 2.4 billion. It's a 12% decrease, 14% at constant rate. And as I said, adjusted for VIMPAT growth at constant rate was 8%, and this was supported by solid volume growth.

Next to the net sales, revenues achieved EUR 2.6 billion. It's a decrease of 11%. I would like to mention that the other revenues include a onetime milestone payment of EUR 70 million linked to our partnership in Japan for VIMPAT. But as a reminder, we also had a similar amount of EUR 70 million for the sale of intellectual property rights for olokizumab last year in the first half. So year-over-year, this is neutral.

Adjusted gross profit was EUR 2 billion, with a decrease in line with revenues and a stable adjusted gross margin of 77%. Total OpEx decreased by 15% to EUR 1.3 billion, reflecting lower expenses and higher other operating income.

And if I start with marketing and selling expenses, they grew by 3% to EUR 753 million, driven by the launches, the prelaunch activities. We have the ongoing launch activities of FINTEPLA, BIMZELX and the global launch preparations for BIMZELX in the U.S., RYSTIGGO and zilucoplan in generalized myasthenia gravis.

R&D expenses decreased by 5% to EUR 759 million. This is reflecting the investments in the late-stage pipeline as well as the earlier-stage activities. The R&D ratio increased from 27% to 29%, and this is a function of the net sales decrease.

G&A decreased by 9%, and the other operating income increased significantly to EUR 350 million. So first, this is the result of the net contribution from Amgen in the commercialization of EVENITY, which grew by more than 40% from EUR 108 million to EUR 156 million. And second, as we had mentioned back in February, we sold a portfolio of established brands in Europe for EUR 145 million.

And so in total, adjusted EBITDA reached EUR 801 million after EUR 814 million in the first half of last year. It's a decrease of 2% and a decrease of 9% at constant rates. This is reflecting the lower revenues, the lower operating expenses, and it corresponds to a 31% margin after the 28% margin in the first half of last year. And even if you exclude the contribution of the sales of the established brand products, this is a solid 25%.

Moving to profits. Profit amounted to EUR 311 million, it's a 22% decrease versus last year. And if I look at the conversion from EBITDA to profit, we had higher amortization of intangibles in the first half of '23, this is linked to the Zogenix acquisition. We had lower other expenses versus '22, as the first half last year was impacted by Zogenix acquisition.

Financial expenses were higher at EUR 79 million, not just because of higher net debt linked to the Zogenix acquisition and higher interest rates, but also due to a nonrecurring positive currency impact in '22. We had EUR 25 million positive, while the nonrecurring currency impact this first half is a EUR 9 million negative.

And effective tax rate ended up at 22%. That compares to 17% in H1 last year, and the increase in tax rate is explained by the expected drop in profit before tax compared to last year, where the tax charge remains stable and a one-off reversal of a deferred tax liability in 2022. And finally, the core EPS was EUR 2.63 per share. This is a decrease of 16% versus last year.

So in summary, we delivered healthy financial results for the first half. We see the inflection point in the net sales performance, leaving the loss of exclusivity impact behind us. And we were able to decrease OpEx and to significantly improve other operating income, both with the increase of EVENITY contribution and the sale of products. So all of that puts us in a comfortable position to invest behind our ongoing and upcoming launches in the second half of the year.

So that takes me to the next page, where we confirmed the '23 guidance. Revenue is expected in the range of EUR 5.15 million to EUR 5.35 billion, adjusted EBITDA margin in the range of 22.5% to 23.5% of revenue, core EPS in the range of EUR 3.40 to EUR 3.80 per share. We expect a different top line trajectory in the second half versus the first half as the loss of exclusivity impact is expected to diminish significantly in the second half, and we expect also higher contribution from the launches.

On the other side, the EBITDA margin is expected at a significantly lower level in H2 versus H1. This was already the case in previous years. But beyond that, we will increase in the second half our marketing and sales investments to support the launches of BIMZELX, of RYSTIGGO of zilucoplan. And we expect as well to see higher R&D in H2 versus H1 with the progress of our clinical program. And last, the benefit of the sale of the 5 established brands product, which was, as indicated in February, reflected in the guidance will not be repeated in the second half.

We confirm our peak sales guidance for Briviact and FINTEPLA, knowing that CIMZIA peak sales of more than EUR 2 billion was already achieved last year, and our guidance of 2025 is unchanged. And as you know, it's largely a function of BIMZELX as well as other growth drivers such as Briviact, FINTEPLA, EVENITY and the future launches of RYSTIGGO and zilucoplan, which will all contribute to the top line growth as well as margin expansion.

So with this, let me thank you and hand over back to Jean-Christophe.

Jean-Christophe Tellier ***UCB SA - CEO & Executive Director***

Thank you, Sandrine. And I just would like to close this first part of the call before opening the Q&A with this headline that I would like you to keep in your mind that we have a strong growth ahead.

Next slide, please. As we have reached an inflection point. And so we are currently, of course, managing the last part of the loss of exclusivity. We are delivering on our pipeline. We are launching a new product that can help us to bring new treatment options for new patient populations. And with this, we will continue to create value for shareholders and all stakeholders now and in the future.

So this is -- with this inflection point that I would like to close the first part of the call, and now I would like to thank you for your attention and open the floor to questions. Thank you.

Antje Witte ***UCB SA - Head of IR***

Thank you, Jean-Christophe. Thank you, Sandrine.

QUESTIONS AND ANSWERS

Antje Witte ***UCB SA - Head of IR***

So we will now start the Q&A session. (Operator Instructions) So let's go to the questions. The first on the line is Jeroen Van den Bossche from KBC. And while we are unmuting him, the second on the line will be Stacy Ku from Cowen.

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

I'll just have one question so to give some time. One of the things that I'm personally struggling with is looking at RYSTIGGO and zilucoplan with terms of positioning. Will you -- when will you first of all, review the pricing on RYSTIGGO? And then could you present us with the physicians you, why they would choose either/or RYSTIGGO or zilucoplan over efgartigimod today?

Kimberly Moran ***Head of US Rare Diseases***

First question on pricing. So pricing, we have published for the U.S. specifically. The current price is $6,050 per vial. What we need to really be aware of with RYSTIGGO is that it is a cyclical therapy. So dependent upon the patient's weight as well as the number of cycles the patient needs, the total cost per year is quite variable. And at that price point, from a WAC perspective, it is at parity with Vyvgart.

And now in terms of copositioning, we have such an advantage in terms of bringing 2 products almost simultaneously to market. With

RYSTIGGO, we're looking at patients that often want the direct support of a health care provider, allowing for that in-office administration. Additionally, with RYSTIGGO, we have a broader population given the novel and first and only indication for MuSK-positive patients.

Next, if you look at zilucoplan pending approval, it will be the first and only self-administration. This allows a lot of flexibility for physicians. Patients want individualized choices. If you look at young women, which are predominantly a MuSK patient, they want flexibility in terms of how they're treated.

If you look at older males, another part of our population, they may want to interact with their health care provider and have an infusion. Having this individualized flexibility for in-office or at-home allows us to meet the individual needs of patients with generalized myasthenia gravis.

Antje Witte ***UCB SA - Head of IR***

Thank you. So the next question is coming from Stacy Ku from Cowen. And thereafter, I will read the question from Peter Verdult. Stacy, please go ahead.

Stacy Ku ***TD Cowen, Research Division - VP***

Hopefully, you guys can hear me okay.

Antje Witte ***UCB SA - Head of IR***

Very well.

Stacy Ku ***TD Cowen, Research Division - VP***

Wonderful. So the first question is regarding BIMZELX, just wanted to know if there's any update on the FDA interactions. Are there any remaining gating items for the Q3 FDA action date?

And then the second question is a follow-up on RYSTIGGO. So just given the successful Argenx launch of Vyvgart, can you set expectations for the early launch and provide more details on the potential reimbursement dynamics? Just help us set some expectations given ongoing payer discussions and potential timing of favorable policies.

Iris Loew-Friedrich ***UCB SA - Executive VP, Chief Medical Officer and Head of Development & Medical Patient Value Practices***

Yes. Stacy, thanks very much for the question on BIMZELX and the ongoing review by FDA. So I'm not in a position to give you an update. We have confirmed to you that the active review is ongoing. You know our policy that we are not commenting with any further detail on that. I ask for your understanding. You know that we have updated you when things changed a few weeks ago. We'll do so. But at this stage, we expect action by the FDA during the third quarter. Thank you.

Kimberly Moran ***Head of US Rare Diseases***

And Stacy, happy to answer the second component in terms of reimbursement dynamics. So we expect the majority of U.S. payers to continue to update their policies throughout now and the end of the year. We're expecting to have similar acetycholine antibody positive policies to Vyvgart, and then possibly just a rider for MuSK indications, but actively engaging with our regional level payers.

Antje Witte ***UCB SA - Head of IR***

Okay. Thank you so much, Kim. So I'm now asking a question for Peter Verdult from Citi. He had to jump to another call. The first one seems to be for Sandrine. The first half EBITDA margin below 23% if we adjust for the considerable product disposal gain and VIMPAT Japan milestone. As we look ballpark into 2024, how should we think about cost trends? Will R&D and G&A continue to be directionally down with selling and marketing spend rising? He wants to get a handle on whether total OpEx will go up or stay flattish?

Sandrine Dufour ***UCB SA - Executive VP & CFO***

Shall I -- do you have other questions, Antje or shall I answer, yes?

Antje Witte ***UCB SA - Head of IR***

No, go ahead. Go ahead.

Sandrine Dufour ***UCB SA - Executive VP & CFO***

Okay. Well, thanks, Peter, for the questions. I mean as you know, Peter, we only give the guidance on '24 in February next year. But overall, '24 will be a year of strong investments. We will support the launches. And at the same time, we will benefit from the growth of our portfolio. So we'll come back on that more directly the trends when we are in February, but that's the overall framework.

Antje Witte ***UCB SA - Head of IR***

Thank you, Sandrine. And Kim, the next question is from Peter. It's also for you. Any early feedback you can share on the RYSTIGGO launch and how you can use the fatigue data given it was not included in the label? This is what he's saying. Kim?

Kimberly Moran ***Head of US Rare Diseases***

Excellent. So early indicators. We are actively having patients enroll in our patient services program, which is under the ONWARD branding label. In addition, fingers crossed, we will hopefully have our first patient infused today.

In terms of the MGS-PRO, really amazing scale. It's a patient-reported outcome that was created with patients and for patients. If you look at the types of information that is measured in there, well, not in the USPI, it is consistent with our primary and secondary endpoints.

Antje Witte ***UCB SA - Head of IR***

Thank you. So the next question is coming from Graham Parry from Bank of America, and he will be followed thereafter by Florent Cespedes from Societe Generale. Graham, over to you. Graham?

Graham Glyn Charles Parry ***BofA Securities, Research Division - MD and Head of Healthcare Equity Research***

Can you hear me now?

Antje Witte ***UCB SA - Head of IR***

Yes, I can hear you now.

Graham Glyn Charles Parry ***BofA Securities, Research Division - MD and Head of Healthcare Equity Research***

Great. Yes. So follow-on for Peter's question actually. Just I know you don't want to give 2024 guidance, but you do have 2025 guidance. So I guess what we're trying to establish is obviously if you have a heavy launch investment year in 2024 the shape of the margin recovery of about 700 to 800 basis points between 2023 and 2025. Is that going to be more back end loaded into 2025? Or do you still expect to see some margin expansion in 2024? Does the 2025 guidance assume any milestone payments or divestment gains similar to those that you've been seeing this year?

And then a question for Iris. Does the Argenx CIDP result make you reconsider investing in CIDP Phase III for RYSTIGGO given the apparent success of their studies there?

Sandrine Dufour ***UCB SA - Executive VP & CFO***

So let me start with '25. And Graham, I think we've always said that the margin expansion in '25 would be more back-end loaded. So in that sense, that's really the effect of the operating leverage benefiting from the growth of revenue and absorbing, of course, then seeing the ratio of marketing and sales and R&D decreasing as a percentage of revenue.

And then to your question whether we've built in this guidance on milestones, I mean, we -- I think what I can say is that this type of milestones are typical of our industry. We have them almost every year. So I would consider this as part of our business, but we have not baked in the guidance in '25 anything related to that.

Iris Loew-Friedrich ***UCB SA - Executive VP, Chief Medical Officer and Head of Development & Medical Patient Value Practices***

And Graham, regarding our strategy and decision-making for CIDP as an indication. As you know, we have decided in 2021 that we would not pursue CIDP with rozanolixizumab. The decision was driven by the clear understanding that CIDP has a very heterogeneous disease pathology. We know that there is cellular immunity, T cells, B cells, macrophages involved, we know that autoantibodies play a role in certain patients, but they have only been identified in about 10% of the CIDP population as the causal underlying disease biology.

And with this very heterogeneous picture, we have decided to focus on autoantibody-mediated diseases, where autoantibodies are known or where there is promising evidence that they are the underlying reasons. That's why we are currently focusing on diseases like MOGAD, autoimmune disease like autoimmune encephalitis and as of recently, fibromyalgia.

And the ADHERE study that you quote does not change our assessment of the CIDP disease biology because you see very clearly that you need a highly enriched, highly selective study design that focuses on responders to therapy to have a successful study outcome. So no reason to change our strategy. Thank you.

Antje Witte ***UCB SA - Head of IR***

Thank you, Iris. So the next question is coming from Florent Cespedes, Societe Generale. And he will be followed by Charles Pitman from Barclays. Florent, please go ahead.

Florent Cespedes ***Societe Generale Cross Asset Research - Senior Equity Analyst***

Two quick ones. First on BIMZELX following the approvals in Europe for the R indications, PsA and axSpA, should we see kind of an inflection point in the second half of the year on sales for these products, knowing that on the IL17 R indications are the main drivers? And if you could give us some comments on the recent launch?

And second a question on inorganic growth. Are you still looking to acquire products or companies to strengthen your portfolio? Or are you fully focused on product launches? If you could give us some color on that point, would be great, notably in terms of areas and eventually in terms of size of the potential products and companies that you could look for to strengthen the portfolio?

Emmanuel Caeymaex ***UCB SA - Executive VP of Immunology Solutions & Head of US***

Yes. Florent, thank you very much for your question. So indeed, BIMZELX is now approved in the European Union for PsA and for axSpA. And as you know, countries open up for those launches one by one, right? So currently, we're launching in Germany, and we've seen a nice uptick in our sales starting second half of June when the product became commercially available. But of course, it is one country amongst the whole of Europe now where we have 85% access in psoriasis.

So I would say that at the level of a region, it will support accelerated growth, but I think the full impact will really be seen in next year and maybe even in the second half of next year, when all the countries that take longer for reimbursing new indications will come online.

But clearly, the results in psoriatic arthritis in axSpa are very positive. The differentiation is well understood. And the early signs of the launch in Germany are very promising and really in line with what we're expecting. And of course, you know that UCB is established in rheumatology since a long time. So we really are able to build on our existing footprint and reputation.

Jean-Christophe Tellier ***UCB SA - CEO & Executive Director***

And maybe, Florent, for the second question that you had. I think you have a part of the answer in the way you formulated the question and particularly in the latter part, right? I mean, I think you see clearly that we have a very strong agenda from an execution standpoint and from a launch standpoint. So yes, the focus of the company right now is making sure that we are delivering on these launches and the execution is doing as much as possible just focusing on that, and we would like to avoid distractions by inorganic program or agenda.

Having said that, we are looking in an opportunistic way, and just for you to keep in mind the 2 maybe streams that we have looked at in the past and that you have seen illustrations of that. One is ability to strengthen our pillars of expertise and the patient populations we are already in, in order not to complexify or add infrastructure, but complement what we have.

You can see that, for example, with the acquisitions of FINTEPLA in epilepsy and/or Ra Pharma and zilucoplan in complement of RYSTIGGO. And the other pillar is early stage, early asset candidates because we always, from a focus of innovation that we have, looking at pathways where we think we are expert in. So that's basically the 2 things that classically where you looking at, but don't expect something in the near future because the near future will be fully dedicated to executions and focus and don't distract the organization.

Antje Witte ***UCB SA - Head of IR***

Thank you. Next question from Charles Pitman from Barclays, and he will be followed by Yifeng Liu from HSBC.

Charles Pitman ***Barclays Bank PLC, Research Division - Research Analyst***

Two from me. Firstly, on CIMZIA, that it's good to see kind of sales holding up well there in the face of Humira biosimilars. I was wondering if you could speak partly to the kind of pricing pressure, you're seeing in that area in the face of launch of adalimumab biosimilars, and maybe also just touching on the -- any market intelligence you might have on the development of a CIMZIA biosimilar?

And then secondly, just in terms of what the kind of neurology strategy looks like for UCB. I mean there's also an exciting pipeline of products that aren't necessarily part of the conversation we're having right now reading out in 2024, how will Charl Van Zyl's departure impact your expectations?

Emmanuel Caeymaex ***UCB SA - Executive VP of Immunology Solutions & Head of US***

Thank you, Charles. So on -- let me start with the CIMZIA biosimilar. So our -- what we're understanding right now is that there is a single agent that is about to start the early clinical work. And so therefore, we don't see an approval of the CIMZIA biosimilar in the first markets worldwide before the end of 2026. So that gives us a bit of a runway with CIMZIA.

And in terms of the dynamics with the entry of multiple adalimumab biosimilars in the U.S., from a pricing point of view, it's not obvious that there will be a big impact just because of how the U.S. market works with the PBMs. And so far, we haven't really perceived a trend for special demands linked to these entries.

And I think on the contrary, CIMZIA is well established. We're growing by more than 10% in both rheumatology and dermatology. There's erosion in Crohn's, which is why the overall volume growth is 7% for CIMZIA in the U.S. That might erode by kind of low single-digit percentage points with the entry of adalimumab biosimilars.

It's kind of hard to forecast, but I can refer you to Europe and the rest of the world where we have continued to grow in mid-single digits or even in international markets, double digits after the entry of both Enbrel and Humira biosimilars. So I think that the volume growth will most likely continue to be robust. And from a pricing point of view, perhaps some impact that we haven't seen it yet. Thank you.

Jean-Christophe Tellier ***UCB SA - CEO & Executive Director***

And Charles, for your second question, first of all, let me tell you that the departure of Charl is, of course, something that we have seen with a certain emotion because it's always sad to see people that were in your team, and who have joined the organizations to leave. But on the other side, we are happy for him. It's a great recognition of the value of UCB and our ability to develop talent and make sure that this talent are recognized. So of course, we wish him all of the best in his new adventure.

In terms of strategy, my main comment will be, look, please see the strategy as a UCB strategy. And it's not really UCB that you can divide by pillar or by therapeutic areas. Each of these different pillar needs to fuel and to build the overall UCB strategy. And the UCB strategy always have been towards innovations and making sure that we are building excellence in areas where we feel that we can have a better chance than competition to find differentiated medicines.

So the expertise in science in terms of modality, in terms of pathways are critical. And it's true for neurology as well as for neuroinflammation, or neurodegenerations, or for immunology, and this is really how we are looking at this in the future. So my

conclusion will be please keep in mind, our objective is to continue to deliver differentiated patient products to patients suffering from clinic disease, and particularly in areas where we know quite well the pathways, and we can have an element of differentiation from a modality standpoint in areas where we can lead.

Antje Witte ***UCB SA - Head of IR***

Thank you. Next question is coming from Yifeng Liu from HSBC. And thereafter, I will read questions from which I got via the e-mail. Yifeng, please go ahead.

Yifeng Liu ***HSBC, Research Division - Analyst of Healthcare Research***

Two questions, please. First one is we've noticed that you are spending some CapEx on manufacturing, biologic, a new biologic unit and the new -- in cell and gene new units. Could you give us some color on how we should think about your strategy for manufacturing on the biologics side going forward in terms of outsourcing and the manufacturing in-house?

The second one would be on the U.S. Inflation Reduction Act. How much of an impact do you think that's going to have on UCB, particularly for small molecules and BIMZELX in the future?

Jean-Christophe Tellier ***UCB SA - CEO & Executive Director***

Thank you for the question. And maybe we'll start with the first one, and Emmanuel will leave you for the second one about the U.S.

So in terms of manufacturing, strategy and investment, 2 main elements that you need to have in mind. First, we want to develop internal expertise in areas of growth for the future. So when we see areas where we want to invest, this is where in the future we want to keep the expertise internally. And this is the reason why we have investing for Inflexio, for example, or in mammalian manufacturing to make sure that on BIMZELX and rozanolixizumab in the future will not be dependent only from external partners.

The second element is we always want to have a network and for critical and strategic product, develop a strategy where we have backup or second source. And then finally, for all of the rest, we are mainly dealing with partners and CMOs. And so overall, we are building and leveraging for 70% of our manufacturing capabilities with external partners. So external partnerships, dual sourcing and building and strengthening internal expertise for strategic assets.

Emmanuel Caeymaex ***UCB SA - Executive VP of Immunology Solutions & Head of US***

Thank you. And on the Inflation Reduction Act, I would say that the -- we're still trying to really understand what it means longer term. But I could say that short to medium term, we see the impact as being modest. There's going to be some additional use in Medicare Part D that will be more than compensated for by some price erosion. In terms of BIMZELX, we don't really see an impact before the next decade. So there will probably be some indirect effects at some point but really, we don't see that in the next 5 or 6 years.

And in terms of our pipeline, as you know, we are heavily geared towards antibodies as a company. Of course, we are concerned with the limitations that the Inflation Reduction Act may pose on the life cycle development in products indicated for rare diseases, where the kind of protection or the exclusivity doesn't extend currently beyond the first indication. And so for a company in that space, it's something we are watching closely. But overall, I would say that it doesn't represent a sea change for us.

Antje Witte ***UCB SA - Head of IR***

Okay. Thank you. And I will now read questions from Xian Deng from UBS. The first one is on BIMZELX, asking if we would file BIMZELX for PsA, axSpA, etc while we are waiting for PSO for psoriasis, if we would consider using vouchers or something like this to speed up the other indications and when there could be the launches?

And the second question is could you elaborate about the erosion pattern for VIMPAT and KEPPRA in the first half and your expectations for the second half, please? I would say the first one is for Iris.

Iris Loew-Friedrich ***UCB SA - Executive VP, Chief Medical Officer and Head of Development & Medical Patient Value Practices***

Yes. Thank you, Antje. So of course, you can imagine that we have the supplemental biologics license applications for psoriatic arthritis and axSpA and now also HS sitting ready. We currently believe that the fastest path for these indications to be approved in the U.S. is to submit them immediately after or shortly after the approval of the original biologics license application for psoriasis. So that's the current plan.

We currently have no plans to use vouchers to accelerate the review process. A clinical supplement would be on 10-month review period, and that's what we are currently calculating. I would not feel comfortable to go ahead and give you an approval or launch date for the additional indications. As you know, we always take it one step after the other. So first milestone will be the action of FDA on the psoriasis BLA in the U.S.

Antje Witte ***UCB SA - Head of IR***

Thank you. And I think the question about the erosion patterns for VIMPAT and KEPPRA is for Mike.

Mike Davis ***Head of Global Epilepsy***

Excuse me. Sorry about that. Thanks for the question. First, let me reiterate JC's and Sandrine's point that the journey and the erosion rates for KEPPRA and VIMPAT are mostly behind us. I think that's a good inflection point for growth. Second, after a slightly anticipated erosion rate, we see a much more predictable and stabilizing of the erosion rate as we go forward to second half. We definitely see VIMPAT and KEPPRA in the second half, mostly predictable and stable.

One thing to add to that is we do see great solid growth rates in Japan and China for VIMPAT around 20%. So again, erosions behind us, stable in the future and good growth in the international markets in Japan and China for VIMPAT.

Antje Witte ***UCB SA - Head of IR***

Thank you so much, Mike. Next question is from Dominic Lunn from Credit Suisse. Asking on the NEUPRO U.S. generics. UCB lost the patent appeal in April, but sales are up in the first half with no apparent generic entry as of yet. So could you just update us on your current assumptions for timing of a generic entry and how this is reflected in the guidance?

Jean-Christophe Tellier ***UCB SA - CEO & Executive Director***

I can take this one. On the NEUPRO generics, you're absolutely right. The patent -- I mean NEUPRO is today currently out of patent. So we can have a generic coming in, in the near future. We have integrated that into the update of the guidance for this year. The point of attention of Neupro, I would say, is that despite the loss of exclusivity, it is a patch. It is a transdermal system, which is not that easy to produce and to manufacture, and that's the reason why there is a certain uncertainty about the date of the arrival of the generic.

Antje Witte ***UCB SA - Head of IR***

Thank you. Another question of Dominic, you asked about CIMZIA biosimilars, but I think Emmanuel has answered this one. So in the interest of time, I'm moving to the next question from Gary Steventon from BNP Paribas Exane. Can you confirm that there are no extensions to the PDUFA date for the FDA's review of BIMZELX and PSO and that you don't currently have an expected target date for a decision? Iris, please.

Iris Loew-Friedrich ***UCB SA - Executive VP, Chief Medical Officer and Head of Development & Medical Patient Value Practices***

Yes, I can confirm that there has been no extension of the PDUFA date and that we currently do not have an action date by FDA. Our estimate of the third quarter action that we have shared with you is based on our knowledge and experience of the process and the dynamics of the interaction with the agency, but there has not been any official action by the agency. Thank you.

Antje Witte ***UCB SA - Head of IR***

Thank you. Next live question from David Evans from Kepler followed by another question from Charles Pitman. David, please.

David Paul Evans ***Kepler Cheuvreux, Research Division - Senior Equity Research Analyst***

Yes. So another question on margins, please, for Sandrine. So the underlying margin in H1 was actually quite good, I thought even with minimal VIMPAT sales, which is reassuring. But for H2, I was wondering if you could give any more color on what the increased investment really is going on and also going forward. I mean you talked about increased spend on marketing and sales, but also R&D. But could you elaborate, is that any further headcount? Is this U.S. investment? Or is it ex U.S.? Ultimately, is it -- or is it more variable event driven kind of one-off costs?

And then also on the -- you didn't mention gross margin in terms of kind of pressures in H2, and I can't really see reasons for any further gross margin pressure? But is there any reason to issue -- assuming gross margin deteriorate in H2 or beyond?

Sandrine Dufour ***UCB SA - Executive VP & CFO***

Thank you, David, for your question. So on the margin -- the expected margin in H2 indeed what I said is that we expect to see some increase in the second half of the marketing and sales investments. And think of it this way, I mean as we're going to launch BIMZELX in the U.S., there are significant variable investments. I think we have referred in the past with Emmanuel, plan to do DTC, and this comes with quite substantial cost that we didn't have in the first half. But as we also build infrastructure or have built infrastructure for RYSTIGGO, there's also a ramp-up effect for both RYSTIGGO and zilucoplan, which you've not seen in the first half. So that's definitely the line, which is expected to increase versus H1.

Now what I said to in regard R&D as well is that we expect to see higher R&D in H2 versus H1. I mean but it's not different from our initial forecast. We had said that we were expecting for the full year R&D to be in line in absolute level versus last year about I would say this is not a difference. Now as to the gross margin, I don't see either expected pressure in second half. So you're right on this one.

Antje Witte ***UCB SA - Head of IR***

Thank you. Next question -- short question from Charles Pitman.

Charles Pitman ***Barclays Bank PLC, Research Division - Research Analyst***

I just wanted to come back to BIMZELX and just ask if you can provide any insight Emmanuel into how you're thinking about the commercial opportunity by indication?

Emmanuel Caeymaex ***UCB SA - Executive VP of Immunology Solutions & Head of US***

Yes. So we -- clearly, the psoriasis market is huge. And you've seen that we are really on our way to leading the IL17 segment in dynamic share in psoriasis. And typically, that segment is 25% to 30% of the market for new and switch patients. So we see psoriasis as the largest indication with BIMZELX. We recognize there's competition there, but I think that where we are today, where we are launched, we really are able to take share, and we see that growth continuing.

Next may well be HS. Clearly, it's not a large market today, but it's a market where that will expand rapidly and where we'll have only 3 players for the next 5 years or so. So we would see a high share in a fast-expanding market. And axSpA and PsA taken together should be around the level of HS maybe a little larger if you put them together.

Antje Witte ***UCB SA - Head of IR***

Thank you, Emmanuel. Please stay on because I have a question from Kerry Holford, Berenberg. For CIMZIA, she says, I think you referenced an inventory impact on CIMZIA in Q2. Can you define this amount?

Emmanuel Caeymaex ***UCB SA - Executive VP of Immunology Solutions & Head of US***

Yes. Thank you. So it represents the majority of the difference between the volume growth of 8% and the value growth of 2%. It's really a kind of first half '23 effect that's driven by both the U.S. and Japan. In Japan, we have a partner. In the U.S., it's just a little higher inventory at the end and a little lower now.

So it's transitioning. But if you think about the whole year, I think we're going to maintain a gap between value growth and volume growth as has been the case in the past. And some of it will be net price erosion, maybe also to complement the question that Charles

asked earlier. The ASP price in the U.S. for the LYO formulation continues to erode. I mean that's just mechanical, and so that's going to cost us a little bit continuously as we look forward.

But hopefully, that detail helps you with the modelling. Thank you.

Antje Witte ***UCB SA - Head of IR***

Sandrine, very last question from Kerry from Berenberg. On the '25 outlook, how -- when BIMZELX is not approved in the U.S. in Q3, what would happen to the guidance in '25?

Sandrine Dufour ***UCB SA - Executive VP & CFO***

Well, thanks for the question. So the guidance that we have -- which is unchanged for '25 is with the expectation of FDA action in Q3. We have always said that our guidance was built on a series of different scenarios with potential different timing of launches, different launch trajectories.

Now of course, if the question is, are there scenarios where the guidance in '25 would not be supported anymore, the answer is, of course, yes. But that's not the case, and that's why it's unchanged as we expect the FDA action this quarter.

Antje Witte ***UCB SA - Head of IR***

Thank you very much. It's at the top of the hour. So I respect everybody's time on a very busy day, and we have come to the end, at least of all new questions. So Graham, I'm happy to connect after the call with you. And I'm thanking everybody for your time, your interest, your questions, your answers, and wish you a great day and a good summer. Take care.