Convatec Group PLC

AGM Trading Statement Conference Call Transcript
16 May 2024

Operator^ Good day, ladies and gentlemen, and welcome to the Convatec's AGM trading update for the four months ended April 30, 2024. (Operator Instructions) I would like to remind all participants that this call is being recorded. Questions will follow after the presentation.

I will now hand over to Jonny Mason, CFO of Convatec, to start today's call.

Jonny Mason^ Good morning, everyone. Thank you for joining us today for this trading update ahead of our AGM later. I'm going to say a few words to summarize the good sales performance, and then Karim and I will answer any questions that you have.

So for the first four months of 2024, our organic sales growth was 6.5%. This represented a continuation of the good sales growth from 2023 and was broad based across four categories. In advanced wound care, organic growth was mid single digits as expected. Growth was reduced from our normal high-single-digit growth by the continuing market wide anti-bribery and corruption campaign in China, also as expected. But we continue to gain market share in China, and we expect growth to accelerate there as the year progresses.

The antimicrobials and foams portfolios continued to grow well, with good growth across North America, Europe and GEM. The launch of ConvaFoam continued to progress with a strong win rate in clinical evaluations in the USA, and we're on track to begin launching ConvaFoam in Europe later this year.

In biologics, the growth in InnovaMatrix was strong, although the rate of growth was slower than last year as it laps the higher sales base. It contributed roughly two points to wound care growth. And I'll come back to talk about the draft proposed LCD position in a moment.

In ostomy care, organic revenue growth was mid single digit as expected. The response to the Esteem Body launch in Italy in March has been strong, and we've begun launching in the US, Poland and the Czech Republic as well.

In continence care, organic growth was ahead of our expectations at high single digit. Our home services group delivered outstanding customer service and continue to see strong new patient starts, supported by a further increase in reimbursement levels in the US. Encouragingly, the performance outside of the US, although small, also contributed to

growth. And we're pleased with the positive customer reaction to the launch of GentleCath Air for women in France.

In infusion care, organic growth was mid single digit as expected, with phasing of growth weighted to the second half. We continued to see strong underlying demand for our infusion sets, both within and outside of diabetes. And the diversification of products and customers is progressing well.

Now, moving to strategy. We made further progress in launching new and differentiated products across all four categories. In particular, in infusion care, new customer pump launches across diabetes and Parkinson's is building robust and more diversified demand for our innovative infusions.

So overall for the year to date, we delivered a strong start with wound, ostomy and infusion care performing as expected, while continence care grew a bit faster than anticipated. And given this strong start, we now expect a more balanced growth between H1 and H2. And we are on track to deliver our full-year guidance of 5% to 7% organic growth.

Within that, the mix of categories may shift. The outlooks for ostomy care and infusion care are unchanged at mid single digit and high single digit, respectively. Continence care is expected to grow faster, mid to high single digits. And wound care may grow a little slower, also mid to high single digit, allowing for the new uncertainty introduced by the draft LCDs. With sales on track, we are also on track to deliver the other financial targets of adjusted operating margin at least 21% at constant currency and double-digit growth in EPS and free cash flow to equity.

Now, let me comment on the draft LCD proposals before moving on to Q&A. InnovaMatrix is an excellent product based on great technology. It delivers positive outcomes for patients, and we have seen strong support from health care professionals who appreciate and value having InnovaMatrix available to them as an innovator. It is not on the list of covered products in the current draft proposed LCDs.

And whilst it does meet the technical requirements outlined in the draft, being only two years since launch, the clinical evidence required by that current draft proposal has not yet been published. We are following the normal product development cycle under the 510(k) pathway. We have FDA clearance based on a predicate product which is on the covered list, and we are currently carrying out four clinical studies in the US which we expect to publish later this year.

In the meantime, we are participating fully in the consultation process for the draft LCDs. It is worth noting that previous draft LCDs have been modified, delayed or not implement. So

let's see how this consultation develops. We are confident in the qualities of the InnovaMatrix products and technology, and that it will be covered for reimbursement in diabetic foot ulcers and venous leg ulcers across all points of care, albeit, the timing is currently uncertain.

For now, InnovaMatrix is still covered for diabetic foot ulcers and venous leg ulcers. And remember that it is also cleared and covered for use for several other indications such as pressure and vascular ulcers or post Mohs surgery in skin cancer and through other points of care. There are good growth opportunities in these other areas.

And my final comment is that irrespective of any potential short-term disruption from the impact of the draft LCD, we remain confident of delivering our 2024 and our medium-term guidance. Our confidence is based on the broad-based global growth across attractive chronic care segments and the launching of central new and differentiated products across all of our four categories.

Thank you very much, Karim, and I will now be happy to take any questions that you have.

+++ q-and-a

Operator^ (Operator Instructions) Hassan Al-Wakeel, Barclays.

Hassan Al-Wakeel^ Hi, good morning. Can you hear me?

Karim Bitar^ We can.

Hassan Al-Wakeel^ Perfect. Thank you for taking my questions. I have three, please. Firstly, can you talk about the growth guidance? And given the anticipated acceleration in infusion care and China wound in the second half, what exactly are you baking in for the impact on biologics? Are you seeing any disruption? And if you don't, what do you think the wound care business could achieve later this year?

Secondly, in a worst case scenario, can you talk about the potential impact on a full-year basis and what this could mean for the margin trajectory over the medium term? Does it delay the profile meaningfully? Or do you see anything to mitigate the impact?

And then, finally, can you talk about the strength in continence? And I think you called out Europe after the US, and I'd love to hear about the traction that you've been having with GC Air and your conviction around growing share from what is a very low level in Europe. Thank you.

Jonny Mason^ Well, let me start, Hassan, on the H2 sales question and perhaps medium-term guidance. And then, Karim will follow up with your third. We've had a good start to the year, and are pointing now to a flatter profile of sales growth across the year. You're right that we still are confident in infusion care growing to high single digits this year. That second-half weighted, as we said previously, and we've got visibility on orders. It's based on the several customer pump new product launches which is building demand for our innovative infusion sets.

And yes, we are starting to see that the bribery and corruption campaign is working towards its end in China. Access is starting to open up, although obviously, it's had an impact on us in the early part of the year. So we do see growth in China, in wound care accelerating in the second half.

But look, we're being prudent, I think, in anticipating that these draft LCDs may lead to disruption in wound care and in InnovaMatrix sales specifically as the year goes by. They may not. We haven't seen any disruption so far. If there isn't any disruption, then we'd be comfortable saying that wound care would be high single digit. But prudently, we're taking that down because we think there may well be some disruption.

On your question of medium term, no, we don't anticipate that this is going to impact our medium-term guidance, neither the sales growth nor the margin build trajectory. When we bought InnovaMatrix or Triad Life Sciences as it was called, we knew there was some uncertainty as regards reimbursement in the biologics sector.

And therefore, that was built into our plans. And so, our plans did include a certain prudence, and that's why we're comfortable in saying that the guidance, this latest new uncertainty won't impact the guidance that we're planning to deliver.

Hassan Al-Wakeel^ Super.

Karim Bitar^ Good morning, everybody. And I'll just pick up the question around continence care. What I would just highlight is that the business in North America, particularly the US, continues to perform really well. As Jonny highlighted, the level of customer service that we're providing to both payers and to consumers is really outstanding. And as you know, we measure that in a very quantitative manner via net promoter score, loyalty measures, and they really are world class. We've introduced and rolled out that same capability now outside the United States in places like the UK and plan to further leverage that capability. And again, we're finding a way to replicate that level and quality of service.

In regard to that, Hassan, specifically to GC Air for women, I would say that the pull that we're getting both from health care professionals and consumers is very strong and robust.

What we're finding is that because we really have a third generation intermittent catheter that's ready to use, and has no coating on it, right? And so, as you know, in the US, the FDA has awarded us a superiority claim in terms of comfort because in essence, we really don't do any damage to the urethra. And you can imagine if you're using intermittent catheter four to six times per day, that's really, really important.

So the fact that it's ready to use, there is no sticky, gooey coating on it, and the fact that it really doesn't harm the urethra, and has really been designed to frankly reduce the likelihood of getting urinary tract infection seems to be very well received by consumers and health care providers. And so, we're very excited about being able to launch in other key European markets, and also the US later this year. So let's just say initial signs are encouraging.

Hassan Al-Wakeel^ Perfect. Thank you. I'll jump back in the queue.

Operator^ Graham Doyle at UBS.

Graham Doyle^ Good morning, guys. Again, hopefully you can hear me. Just with regards to InnovaMatrix, it would be good to get a sense of what data you had when you bought the business. So what actually gave you confidence that the product works? That would be the first question.

And the second question, just around the studies you talked about. Do you think the two prospective studies that you're running this year and will publish, do you think they'll be enough to justify reimbursement under the framework that we've seen at the moment?

And then, just a quick last one on infusion care, and why are you still expecting it to be H2 weighted? Is that related to any particular launches? So we could get a sense of that. Thank you.

Karim Bitar^ Sure. Maybe, what I'll do is take the two questions really tied to InnovaMatrix, and then, Jonny, if you can weigh in maybe on the IC business and why it's H2 weighted. Look, the reality is that we had analyzed and studied the biologics segment for a couple of years. And we were very thoughtful that we are making and pursuing the acquisition as to do we want to be focused on an allograft or do we want to be focused on a xenograft. And we very clearly decided to focus on xenograft, and particularly porcine.

So that was a very deliberate choice. Having looked at the fish and the cows and human tissue, et cetera, et cetera. And the rationale really was that we wanted to focus on three criteria: quality of the offering; B, speed in terms of being able to cycle through and innovate; And then, thirdly, anticipating there would be downward pressure on

reimbursement front to make sure that we had the lowest cost position. And so, frankly, InnovaMatrix ticked all three of those.

Now, your specific question was, Graham, was what kind of data will we accessing? So when we do our assessments, we'll typically look at it in terms of what is the degree of technical risk? What is the degree of commercial risk? And then, what is the ROI that we would anticipate from this acquisition?

In the arena of technical risks, we went ahead and focused on clinical performance. And also, in terms of the regulatory dossier, what we were dealing with. And what we were dealing with at the time was that we ensured that we had actually received a clearance for the product by the 510(K) process. And 80% to 90%, frankly, of Class 2 medical devices in the United States are cleared this way. This is a very normal way of doing it. So we knew that the likelihood of clearance, that risk have been taken out.

The next thing we need to focus on was from a clinical vantage point, how would clinicians respond to the utilization? And frankly, in dialoguing and engaging with a whole series of thought leaders around the United States, they've developed a whole series of case studies. We felt very encouraged by the feedback we were getting. As you know, we've been in the wound care business for several decades and are very familiar with that US marketplace. So that clinical feedback we got from the case studies was very, very encouraging.

Thirdly, we need to go out and assess what was going to happen on the reimbursement front. And on the reimbursement front, what we typically will do is look at what's happening on the coding side, what's happening on the coverage side, and ultimately, what's the level of reimbursement you get. And we ensure that the coding had been put in place and that coverage was imminent. And that was exactly what the case was.

So that's what we're dealing with at the time. And then, as you can imagine, we looked at what was the investment we're going to make relative to return, and the case was very compelling and has proven to be the case.

In regards to the two prospective studies, what I would say is that we have one for diabetic foot ulcers and one obviously for the whole pressure ulcers area -- against leg ulcer area, excuse me. I stand corrected on that. And these two studies are ongoing, and we also have two real-world evidence studies ongoing. And you may note that here in and December '23, the FDA actually has come up with draft guidance, highlighting the importance on quality and caliber, also real-world setting.

So I think the bottom line is that we need to see what happens with the draft proposal LCD. Will it be modified? Will it be delayed? How will it be implemented? And I think that will

create the basis for what level of clinical evidence is going to be required.

We've always planned on running and driving these clinical studies. And we've always plan on running randomized clinical trials in addition to these studies to go ahead and also secure reimbursement coverage beyond Medicare, but also with private payers. So we're very much tracking where we wanted to be. And obviously, we're seeing some uncertainty and downward pressure now on reimbursement front.

I'll pass the baton on to Jonny to maybe comment on infusion care, why we anticipate accelerated growth in the second half.

Jonny Mason^ Yeah. It's not based on any one particular thing, Graham, but the breadth of new product growth in the market. We've got infusion set demand growing with Beta Bionics with their iLet pump, with Ypsomed, with AbbVie, that new Parkinson's application is growing very nicely and they expect to launch in the US later this year as well. We've got Tandem Mobi and Medtronic 780G. So it's a broad base of increasing demand.

And I guess, why we are remaining confident that we will increase sales growth into the second half and hit high single digits for the year is that we have good visibility over the orders. This is a B2B business. We talk to our customers regularly. And as I say, it's across that spectrum of different things that we see demand growing.

Graham Doyle^ Great. Thanks a lot for the detailed answers, guys. Thank you.

Operator^ Kane Slutzkin, Deutsche Numis.

Kane Slutzkin^ Thank you. Morning, guys. A quick one. Sorry to come back to the draft of LCDs, but just can you just give a sense for the level of investment that has gone into that space for yourselves, whether it be sales and marketing? And in the event that these draft of LCDs were implemented, would there be a case where you would pull back on some of that investment or you'd have some of that cut out? Or would it be possible to redirect those resources to I guess other parts of the market where there's payment and coverage? And just what are the costs of some of these studies or have you reported those costs already?

And then, just finally, just on ostomy and continence. I know, Karim, I think it was in March where you -- in the last results, where you mentioned probably too early to call those two divisions getting to the mid or high single digit growth. It seems like you got there quite quickly on continence. I guess, just maybe a cheeky question. Can we expect something similar on ostomy, quicker than maybe you had alluded to in March? Thanks.

Karim Bitar^ Yeah. So look, let's start up with InnovaMatrix and the commercial

infrastructure. We clearly have a commercial infrastructure focused on the physician office. So we're talking about general surgery, typically podiatrists. But as you know, we also have a strong commercial presence in hospitals, and then also in the outpatient wound clinics. I think the reality is that today, when you look at InnovaMatrix revenues, approximately 20% are actually outside of DFU and VLU. So I think that's an important thing to highlight.

And B, I would just also highlight that all the other indications that Jonny mentioned, so things such as, say, pressure ulcers, vascular ulcers, the treatment of MOHs, right, which is a surgical method that you use to treat skin cancer, these are all outside of the current draft proposed LCD. So I think there's a significant opportunity to grow above and beyond DFU and VLU. And frankly, we're seeing rapid growth in that arena.

So is there an opportunity to redeploy our commercial resources? I think the short answer is yes. Will we need the same size and scale, quote, unquote, in a worst-case scenario short term? I think one is to evaluate and assess that, right? And so, that's what I would say there.

In terms of the cost of the studies, look, we've always factored in that we would be investing in the tunes of millions of dollars, right? So these are important investments as part of the business case. We fundamentally, as a company, are very committed to the whole concept of evidence-based medicine. Our view is that when you generate scientific evidence, clinical evidence that really helps health care providers understand how to use Convatec's solutions, right? And so, whether that's in ostomy care or continence care or wound care, infusion care, frankly, we've been ramping up our medical capabilities.

And you may have seen recently at the European Wound Care Conference, where we highlighted the completion on AQUACEL Ag Extra, the study where we were comparing ourselves to standard of care. This was a non-inferiority study, and in fact, we demonstrated superiority, right? We were able to increase the ability to heal wounds during the course of 12 weeks by over 30%, right? The likelihood of being able do that. That was a very meaningful achievement.

So I think the point I'm trying to make is, yes, there's money to be spent. We planned on doing this. But as you think about our vision of pioneering trusted medical solutions, then you think about the FISBE strategy, innovate, we've consistently contemplated making sure that the medical component of that is strong and robust in addition to product development, process development and regulatory.

On OC and CC, the question, Kane, you're posing is could those be high single digit? Look, I think I've answered the question before. Is it possible? I think the short answer is yes. Are we going to strive to do that? The short answer is yes, but I think it's frankly premature at this point to go ahead and make that call. Let's continue to work hard in continence care to

sustain the excellent service levels through the HSG group. Let's go ahead and make sure that GC Air for women is successful. Let's make sure the next 24 to 36 months, we roll out GC Air for men, right? That's something that we've spoken about briefly.

And then, in ostomy care, as you know, we have Esteem Body, our one-piece convex which is off to a good start. Let's make sure we succeed with that. And then, we need to make sure that we also introduce, frankly, a comparable version, the Natura Body, the two piece, with this tremendous baseplate technology where you basically avoid leakage. It's got the leak defense technology, and where now the pouch becomes truly discrete and has a whole series of benefits for patients.

So is it possible? Yes. I think it's premature to make that call. I'd like to see more data, more evidence of successfully launching the GC Air portfolio and the Body portfolio. And I think it will become a lot clearer to all of us during the course of the next 12 to 24 months if that's going to be feasible.

Jonny Mason^ Okay. Let me just build on Karim's first answer numerically as it were. Given we're in buildup and there is a significant operating expense investment in the InnovaMatrix area, the operating margin of that business is roughly in line with the rest of the group. So I don't think you should be expecting any disproportionate impact on profit and over and above whatever sales impact you choose to model.

And then, secondly, the cost of the trials, as Karim said, these have always been planned. So that is already in our T&I investment numbers.

Kane Slutzkin^ All right. Thanks, Guys.

Operator^ Anchal Verma, JPMorgan.

Anchal Verma^ Hi. Good morning. To start off again, apologies to stick on the LCD topic. Just one more, please. In terms of understanding when you would get the trial results from the real-world evidence study and the other two studies you are running, when can we expect these trial results to come out? And within that and comments for the draft proposal are due in June, is it fair to assume potentially, this will be helpful for the next cycle or the next round to try and get on the proposal based on these trials?

And then, on the reimbursement question as well, I think there was a wider term expectations for reimbursement pricing cuts. Is that still potentially looming in terms of a wider Medicare pricing reimbursement changed? And then, just the second question on margin phasing, given top line is now expected to be more equal weighted, how should we think about the margins from H1 to H2?

Karim Bitar^ Yeah. What I think the first two questions in regards to the LCD, the proposed draft LCD, and then, maybe Jonny can comment on margin. Look, I think we've highlighted that these four studies, we anticipate the -- basically, going ahead and publishing the results of these studies here in 2024. I think the whole draft proposal has to be -- it's very dynamic, right? And so, I think that if you look at what's happened historically, you tend to have delays, you tend to have modifications, and then there's all aspects of how it she gets implemented. And so, I think there's a fair amount of uncertainty.

Obviously, the more clinical trial data and evidence we can generate, that certainly buttresses our position and strengthens our position. So frankly, independent of the LCD situation, we're very committed to going out and generating that evidence, publishing that evidence. And then, sharing it with all the relevant authorities, is what I would say.

Is there potentially further downward pressure on reimbursement front? Look, I think that no one really knows at this point. I think it's a very dynamic situation. Obviously, CMS, the Center for Medicare and Medicaid Services has taken note of how much is being spent on these skin grafts. And so, I think that it's uncertain. I think from our vantage point, we've always anticipated that there would be downward pressure on the reimbursement front. And clearly, this draft proposal LCD moves in that direction.

But on the other hand, I would say, based on the innate technological strength of InnovaMatrix, based on the fact that physicians are very keen to have this in their armamentarium, based on the tremendous results they're seeing clinically, and based on the fact that patients are really appreciating it, and based on the fact that we're committed to ensuring that all the evidence is made available to the relevant authorities, I remain confident and optimistic about the prospects for InnnovaMatrix.

I'll pass the baton to Jonny in regards to margins.

Jonny Mason^ Yeah. Look, we're not talking about margin in detail today. This is just a trading update. But I think the general theme is that we are in an environment where inflation is abating. We've previously described how inflation last year was in the 5% to 7% zone, and we think this year, more like 3% to 5%. It takes time for lower inflation to feed through into our P&Ls. Just like the other way around, it takes time -- it did take time when we were on the other side of the curve for the higher inflation to feed through.

We do have certain hedges in place to stabilize the impact of any price changes on the P&L, and we're operating FIFO inventory accounting as well. So it takes time. And therefore, as inflation diminishes, you should expect the benefits of that to build through the year. That's just the general comment. So more benefit from lower inflation in the second half than in

the first, but we'll update you properly on margin at the half year.

Anchal Verma^ Thank you.

Operator^ Jack Reynolds-Clark, RBC.

Jack, please go ahead. It seems like Jack is having technical issues. We will then move on to our next questioner.

Veronika Dubajova, Citi.

Veronika Dubajova^ Hi, guys. Hopefully, you can hear me okay. It's Veronika here from Citi.

Karim Bitar^ Hi. We can hear you. Thank you, Veronika.

Veronika Dubajova^ Excellent. Very good. Thank you for taking my questions, please. I have three. The first one is actually on InnovaMatrix and not related to the LCD just to make it a little bit more fun. I would love to understand whether you're satisfied with the growth profile that InnovaMatrix has delivered year to date? If I look at the back half of last year, I think you called out a 4.5 percentage point contribution to the AWC growth from InnovaMatrix, then it has fallen down to 2% in the first four months of the year. I appreciate obviously, the baseline has increased.

But it does seem to me on my math, the growth has slowed down from something like 100% last year to 20% to 30% this year. So just curious, to what extent this is in line with your expectations? And is there anything that's changing here in either the market dynamics or the commercial uptake potential that you see? So that's my first question.

My second question is on the LCD, unfortunately. I'm just curious, Karim and Jonny, to get your thoughts on how you think of the MACs will think about prospective single-arm studies versus randomized clinical trials. My understanding from the document is that there's a very strong preference from the MACs for randomized clinical trials. And so, I'm just curious whether you think the studies that you have will meet the threshold? And to the extent that they're not, are there any plans to commence an RCT over time?

And then, my final question is going to be on ostomy. And I'd love to understand how you feel about the traction that you see in the US, but also in the UK. And whether we're getting any closer to the point where the headwinds in the UK are starting to dissipate. Thank you so much.

Jonny Mason^ So I'll take the first one, Karim. So on the numbers, haven't quite got the

same numbers, Veronica. So let's offline, just just check those. I think we called out 3.5 points contribution to wound care last year. The general point is right though, and we haven't got 20% is higher than that in the first quarter. But the general point is right, that the roughly 100% growth last year will diminish this year as the base increases. Obviously, so for us, for a similar dollar quantum of growth, and I think we've said prior to this new uncertainty, we were targeting roughly a similar dollar quantum of growth, that would be a lower percentage growth rate.

And are we satisfied with the growth? Yes, we are. We think we had a good start in InnovaMatrix just like in the rest of wound care. And had it not been for this new uncertainty around draft proposed LCDs, we would have been reconfirming high-single-digit growth for the year, but we want to be prudent in case the drafts lead to some uncertainty in the market.

Karim Bitar^ Yeah. Look, what I would say, Veronika, on the LCD draft proposal, I think obviously, there are some challenges in terms of how it's been drafted, right? So I don't want to get in all the technicalities now because we're obviously engaging with all the various parties. The first thing I would just say is I think it's important to highlight that we launched in 2022, many of the other products have been on the market for decades, right? And so, I think it's very important to realize that the way the regulatory environment has been set up has been to frankly have a clearance process via 510(K) process. And so, a 510(k) allows you get clearance, and therefore, to market your product.

And the US authorities, Health and Human Services, have always encouraged that there be innovation. And that's the way you'd encourage innovation, because then, Medicare, in essence, encourages innovation. And then, thereafter, typically producers that are serious and capable, develop additional clinical evidence that that is utilized with private payers.

That's always been really the standard in the United States. So it's quite interesting here that you have an LCD that tries to retrospectively change the rules of the game, not consistent and coherent with how the FDA has been approaching it for quite some time. So I think that's important to realize that this is a very atypical situation and approach.

Having said that, I think your specific question was, hey, to what degree will the prospect this study suffice? I think the reality is that the prospect of studies are important, I think real-world evidence is important, and I think our randomized clinical trials are important and they have different values and ability to give you different indications. So we are very much tracking on publishing these prospective studies for diabetic foot ulcers, for venous leg ulcers this year. We're very much on track to publish our real-world evidence this year.

And what I would say is we're very much on track to frankly go ahead and commence our

randomized clinical trial studies this year. That's exactly what we've been planning for quite some time. And so, I think it's important to realize that if you're going to go ahead and foster innovation from a regulatory environment, it's important to make sure that you afford parties the opportunity to develop and generate their evidence, to publish their evidence, and then share it.

In terms of traction in ostomy care, I'd say our US performance continues to improve. We're executing better. We have a strong support from the home service group, and so, that really bodes very, very well. And we're very excited about the opportunity to frankly launch Esteem Body in the United States. We've obviously got some encouraging initial signs from Italy, and so, that bodes well. And I would say similarly with the UK, we're in the midst of strengthening our commercial capabilities there, and we're also very excited about launching Esteem Body.

So I would say, look, let's stay tuned. But overall, I would say that the prospects for growth in ostomy care are robust as commercial execution improves, as we improve the quality of our current portfolio, and as we launch new products. So I'm cautiously optimistic that the good things are going to be happening in ostomy care.

Veronika Dubajova^ Thank you, Karim. And can I just ask a follow up? Sorry to be annoying about the LCD and the trial question. I mean, do you have indication from the MACs that if you were to conduct a randomized clinical trial and let's say that it's published one, two years from today, would they be open to revisit the coverage decision once that data is available? Or is your impression that this is set in stone once we get there?

Karim Bitar^ Yeah. I don't think it's set in stone, is the bottom line. I think that there's a strong regulatory and clinical incentive to encourage folks to generate the evidence and share the evidence. So I'll leave it at that. And you can imagine, there's a lot of dialogue and engagement occurring with a variety of parties.

Veronika Dubajova^ Okay. Thank you, guys.

Operator^ Jack Reynolds-Clark, RBC.

Jack Reynolds-Clark^ Hi, there. Thanks for taking my question. Can you hear me?

Karim Bitar^ Yes.

Jonny Mason^ We can hear you now. Thank you, Jack.

Jack Reynolds-Clark^ Perfect. Perfect. Lovely. Trying to push you a little bit on what

assumptions are baked into the wound care guidance. I mean, do you assume some destocking or what what assumptions are embedded in that? Thank you.

Jonny Mason^ Well, so two different time perspectives. First of all, for the remainder of this year, look, we've made a prudent assumption that a significant chunk of the sales of InnovaMatrix may be impacted by uncertainty in the market, and that is irrespective of whether the LCD consultation process leads to alteration, delay or implementation. We don't know how it will play out. Certainly to date, we've seen no impact whatsoever. InnovaMatrix continues to grow nicely. It's early days, I accept, but it's continuing to sell well, as are the sales to the indications outside of the scope of the draft LCDs.

So we've assumed that the sales we were anticipating for this year take a significant impact, just to be prudent. And that is what has led us to take the wound care indication of growth for this year down from high single digit to mid to high. So you can do your maths and come up with the approximate quantum. But the only reason wound care indication has come down is because of that new uncertainty with LCDs. There's nothing else contributing to that reduction.

And then, (multiple speakers) sorry, Jack. I should have said on the medium term, look, we had already got prudence in our plans for potential uncertainty in reimbursement around biologics, which we recognized right from when we made the acquisition. And so, it's because we have that prudence in our plans that this doesn't reduce our confidence in being able to hit the financial targets that we have set out in our medium-term guidance.

Jack Reynolds-Clark^ Okay. That's seems clear. Thank you. And then, just following up on the other indications. I guess, can you talk about how fast that segment is growing? And obviously, you talked about reallocation of commercial resource there potentially in a worst case scenario, but what levers do you have to really accelerate your growth in those other segments?

Karim Bitar^ Yeah. Jack, what I would just highlight is that the clearance we have from the FDA covers a whole series of indications outside of diabetic foot ulcers and venous leg ulcers. So pressure ulcers, vascular ulcers, the treatment of skin cancer by Mohs surgery. So there's really a plethora, and it's a very large and significant opportunity. Frankly, if you did the simple math in terms of scale of the opportunity, it's at least comparable to DFU and VLU sum together. And probably, one could argue, frankly larger than that, okay? Just to put things in perspective. So there's a large opportunity outside.

I think in terms of our ability to deploy resources at other points of care to, for example, let's say, the dermatology area where typically, mohs surgeries are carried out because we're talking about skin cancer. That's something that we are capable of doing, and frankly, have

been doing for some time. And that business has been growing rapidly. And if you break it down by indication, it's one of the more rapidly growing segments for us. And frankly, the clinical performance we're being able demonstrate is very, very robust.

So I think that the bottom line, what we're really focused on is making sure that we engage with all the relevant parties, whether that'd be the MACs, whether that'd be health care providers and associations, whether that'd be patient associations. And again, I think it's really important to stress the fact that this is a draft proposal. It's a very dynamic situation. And one needs to see will the draft proposal be delayed? Will it be modified? Will be implemented? So clearly, there are degrees of freedom there that are important.

Two, it's absolutely critical and important that we drive the whole aspect of the medical evidence. That's exactly what we're doing. And we anticipate being able to publish a whole series of data and scientific and clinical information later this year. And then, obviously, there is an opportunity above and beyond DFU and VLU which we have been pursuing, and we'll go and pursue vigorously. I hope that answered your question.

Jack Reynolds-Clark^ That does. Yeah. Thank you very much.

Operator^ Sam England, Berenberg.

Sam England^ Hi, guys. Thanks for taking the questions. I'll stay clear of the LCDs because it's been a lot already. So firstly, on Esteem Body. Can you just give us a bit more colour on the early success there in Italy? And is that being driven more by greater share of new patient starts or existing patients switching onto the product? And what feedback do you gained from patients and healthcare professionals so far? And then, just a quick one on wound. Is there any update on the nitric oxide platform in wound? And any timelines around product launches there?

Karim Bitar^ Sure. Yeah, look, it's early days with Esteem Body. What I would say is that the whole concept of lead defense bodes really well. We've historically really being viewed as having the gold standard in terms of avoiding leakage, not causing skin irritation, not causing infections. And I think, what we're finding is that patients, whether they'd be new patient starts, or frankly, people are using our products and going out and upgrading. Frankly, it's a balance of the two, which is really positive for us, right? There is a high degree of interest in using it in both domains in a pretty balanced manner.

And then, there's this whole aspect of the 8-shaped pouch. It's very, very discreet. It doesn't tend to go ahead and bloat and sag and bulk up. And frankly, based on its performance, we'll get feedback from consumers. We have one consumer who's been raving and ranting and basically highlighting how as a result of the bag not basically expanding and bloating,

particularly when she sleeps next to her partner, guest what? She is now being able to sleep after 14 years of not being able to sleep, period. Right?

Now, that may seem like a small element, but you can imagine that getting a good night's rest is hugely important. And that relates frankly to how we've designed our product. I don't want to get too much into how exactly we were able to achieve that, functional benefit, just from a competitive intelligence perspective. But clearly, it's a very well-thought-out design in terms of avoiding leaks, being discreet, and maybe having the kind of experience that allows you to have a, quote, unquote, normal life.

In terms of the nitric oxide technology platform, that's moving along very nicely both in Europe and the US. So we're very much tracking to go ahead and file the appropriate regulatory approvals during the course of 6 to 12 months, both in Europe and the US. And we're very committed in that technology platform. And as we've shared previously, we think that its got some significant antimicrobial properties which we've documented in randomized clinical trials studies in diabetic foot ulcers, in fact. And B, we think that it may actually have the ability to accelerate the whole wound healing process. So that bodes well in terms of clinical performance. So I would say on track and would anticipate being able to introduce the nitric oxide technology platform in that '25, '26 timeframe period.

Sam England^ Great. Thanks very much.

Operator^ Lisa Clive, Bernstein.

Lisa Clive^ Hi there. Can you hear me?

Jonny Mason^ We can.

Lisa Clive^ Okay, great. Two questions. One, just on patch pumps. Any potential -- any update on the potential to get involved in that supply chain or even potentially CGMs? And then, second question on ConvaVac. Are you still on track for a 2025 launch? And I assume, the lead time for that is around collecting data. And obviously, you've talked a lot about the importance of clinical data and clinical trials, et cetera. Is that really what you're hoping to have in the back pocket for your sales reps when that product hits the market? Thanks.

Karim Bitar^ Yeah. Lisa, what I would say is the whole area patch pumps and CGM, we're busy bunnies and we're making progress. And I'm not going to be able to say more than that, so I would just say stay tuned. But clearly, an area that we're actively exploring.

And then, at ConvaVac, again, we're very much tracking in terms of the development process and very focused on being able to introduce that new offering both in the United States and

in Europe, and potentially in global emerging markets. And again, I think we're very much on track for a '25/'26 launch. So I think we're making good progress on both fronts, and I would just say stay tuned.

Lisa Clive^ Thanks very much.

Operator^ Christian Glennie, Stifel.

Christian Glennie^ Hi, guys. Thanks for taking the questions, please. Still on the LCDs unfortunately. I suppose just to clarify, some points of clarification here around the exposure to this issue. If you talk about the $74 million of sales you did last year, you said 20% was outside the VLU. Is that essentially 80% of your current business is exposed to these issues, potential reimbursement obviously? And then, linked to that, any reasons why you can't get more into the hospital channels? Obviously, that's unaffected by DRG codes and the like.

The second one is on -- just to come back on the medium-term guidance. I mean, are you saying categorically that, say, you no longer have this channel open to you for, let's say, two, three years where you go away and do a randomized clinical trial? That scenario is still -- you'd still be on track to hit your targets in that scenario as well?

And then, finally, just to set the scene around pricing of InnovaMatrix maybe, that typically is in this channel versus some of the competition. And is pricing a potential discussion point with the MACs? Or is it just all around the clinical evidence? Thank you.

Jonny Mason^ Do you want me to take the first two, Karim?

Karim Bitar^ Yeah, that'd be great.

Jonny Mason^ So yeah, I think you've got the numbers right there, Christian. $74 million of sales last year, about 20% of that was outside the scope of the draft LCDs, so the other 80% within it. But you know, note the comments we've made, the other 20% is growing faster. There is no reason why we can't get into the hospital channels. We've already started, although it's very small still. There, we have the opportunity to benefit from synergies with the rest of our wound care sales force, which is very well established. Obviously in the USA, achieving 30% market shares in the antimicrobial sector, for example. So we'd expect that to grow faster.

And as regards to medium-term guidance, I think look, that's what we are saying, which is that there are a number of different ways that this current consultation might play out. It might well be postponed or modified. We're confident that we will have InnovaMatrix covered in all points of care. But we can't be sure of timing, because that obviously will

depend on how the consultation plays out.

But even so, that wouldn't be sufficient to knock us off being able to deliver on our medium-term guidance, because in our plans, we had built in some contingency and uncertainty regarding reimbursement in biologics anyway. So yeah, we are -- despite this new uncertainty, we're still on for that medium-term guidance.

Karim Bitar^ Yeah. Look, Christian, on that last point in regards to price and clinical, I think that both are linked, right? I mean, ultimately, clinical performance and value for your money are important considerations. And obviously, then MACs basically are part of the CMS. And so, when you think about the Center for Medicare and Medicaid Services, in essence, it really is a public reimbursement entity or a payer.

So I think, look, I think it's very dynamic right now. I think clearly, they've got a concern about the amount of spend. And there's a whole plethora frankly, of manufacturers that have tried to enter this whole skin graft area who maybe are not as focused on evidence-based medicine, investing in clinical trials, being of a certain size and scale. And so, many of them, frankly, have not pursued a 510(k) process, right?

We spoke about that. We pursued that. Work with the FDA to get that clearance, particularly on the allograft or non-xenograft front, that's what we've seen happen. So look, I think there's a desire on the regulator to manage both the robustness of the clinical evidence and how much is being invested in this area. I think on the other hand, the regulator also has a vested interest in making sure that health care professionals have the very best clinical choices to treat. And I think choice is absolutely important. And I think that as a company that is generating evidence, that is publishing evidence, and frankly, is able to add significant value to patient outcomes, I think that bodes well for us. And so, my level of confidence in terms of InnovaMatrix being a growth platform for the company is certainly remains strong.

Christian Glennie^ Thanks. Can I have a quick follow up, please, on the mention of random -- on RCT that I think you said was it was in the plan. Was that always in the plan? How progressed is that design of that trial, I guess?

And then, second, if I can on continence care. Just quantify the US reimbursement, the benefit that you've had on US reimbursement for the upgrade to continence care. Thank you.

Karim Bitar^ Okay. Maybe, I'll take the first on our expertise. And then, Johnny can comment on continence care.

Yeah. Look, we've always planned on running randomized clinical trials, right? I mean, you

see that, for example, even with AQUACEL Ag Extra. We've run randomized clinical trials. You've seen us comment about randomized clinical trials tied to the nitric oxide technology. So we always plan to do that. And we've always planned to basically start running those trials here forward.

When you go out and pursue a randomized clinical trial, frankly, it's very helpful to have prospective studies and real-world evidence to help you design those studies. What is the scale? What are the criteria you want to have? So you can imagine we'll be leveraging the current four studies that we intend to publish by -- and are expected to publish by year end with this year. And at the same time, make sure that those randomized clinical trials are well underway. So always been planned. We're on track to go out and do that, and we'll be doing that.

Jonny Mason^ And on continence care, it's a straightforward answer. CMS has granted an increase of 2.6% in this area. Now, remember that applies to approximately half of our sales in the US. So a bit is around about 1% on top line for the category.

Christian Glennie^ Okay. Thank you. That's helpful.

Jonny Mason^ Yeah, I think we're up for our time now. So I wonder if we might ask operator to hand us back.

Operator^ There are no further questions in the webinar, and I'll hand back to Karim Bitar for closing remarks.

Karim Bitar^ Super. Look, I just wanted to say thank you to everybody. I really appreciate the active participation and engagement. And yeah, I think we're encouraged by our performance in the first four months. I think we got off to a strong start. And I think as Jonny highlighted, there's a sense of optimism and confidence in our ability to go ahead and grow the business 5% to 7% on the top line to achieve the 21% plus EBIT margin this year. And then, get into the mid 20s by '26 or '27. And then, consistently make sure that we drive the EPS and free cash flow double digits.

So again, a big thank you to all of you, and look forward to reengaging with you here and in the summer.