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Coloplast A/S (CLPBY.DK)

Q2 2024 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by. Welcome and thank you for joining Coloplast Interim Financial Statements for H1 2023/2024 Conference Call. Throughout today's recorded presentation, all participants will be in the listen-only mode. The presentation will be followed by a question-and-answer session. [Operator Instructions]

I would now like to turn the conference over to Kristian Villumsen, President and CEO. Please go ahead.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

Thank you very much, operator. Good morning, everybody, and welcome to our half year 2023/2024 conference call. My name is Kristian Villumsen. I'm the CEO of Coloplast, and I'm joined by our CFO, Anders Lonning-Skovgaard; and our Investor Relations team. We'll start like we usually do with a short presentation by Anders and myself, and then we will open up for questions.

Please turn to slide number 3. We delivered 8% organic growth and a reported EBIT margin before special items of 27% in the second quarter. Return on invested capital after tax and before special items was 15%, reflecting impacts from the acquisition of Kerecis. I'm satisfied with our performance. We continue to broadly outgrow the market and, more importantly, we continue to help more people who live with intimate healthcare needs. At the same time, we also continue with our year of launches.

Today, we announced four new launches in our Chronic Care businesses. One of the new products that we're launching is Heylo. This is the world's first digital ostomy leakage notification system, and it has now received national reimbursement in the UK as of the 1st of July. And while this is a launch in only one market for now, it confirms the need for innovative and clinically relevant solutions in our category. This is how we continue to lead our categories by raising the bar and bringing differentiated technologies to the market.

Before going into our usual half year strategic update and the details of today's results, I'd like to provide our thoughts on the proposed local coverage determination policy for skin substitute grafts that was published on the 25th of April and is relevant for the newest member of the Coloplast Group, Kerecis.

Please turn to slide number 4. Let me start with the facts. On the 25th of April, seven medical administered contractors brought forward a draft, Local Coverage Determination policy in which two coverage qualifications for skin substitute grafts were introduced. The first qualification relates to a technical requirement which Kerecis meets. The second qualification relates to a clinical requirement which, based on the assessment, Kerecis does not meet and therefore Kerecis is not included in the draft coverage policy.

The draft policy covers the Medicare portion of outpatient sales which includes both physician offices and hospital outpatient departments, and it affects around 20% of Kerecis revenue. A majority of the remaining 80% of sales are related to in-hospital sales covered by DRG codes where the reimbursement environment is stable.

The process from here is the following. Until the 8th of June, there's a consultation period in which affected parties can provide their comments to the draft policy, as is the norm. After the consultation period, there will be a final policy typically published at least 45 days before implementation date. The implementation date has not been

announced. We expect that it will be up to half a year after the consultation period, ending with a final decision to be published and implemented.

My perspective on this draft policy is that, this is a quality document. It sets out a sensible set of objectives for the category that are founded in good clinical practice. It explicitly reviews the clinical evidence for every single product in the category as a basis for recommendation to either include or exclude the product from the covered list. The decision to exclude Kerecis from the covered list is rational on the basis of the clinical evidence that is reviewed in the draft policy.

Now, and this is important, the clinical evidence on Kerecis which was reviewed in the draft policy, does not include a randomized controlled clinical study from 2023 by Lantis. We strongly believe that this study fully satisfied the LCD requirement for quality evidence that demonstrates the product safety, effectiveness and positive clinical outcomes in the function as a graft with diabetic foot ulcers.

A 2023 Lantis study on chronic diabetic foot ulcers is a randomized controlled clinical trial, with a sample size of 102 patients. And it provides high-quality evidence with a low risk of bias demonstrating the safety, effectiveness and positive clinical outcomes of the Kerecis fish skin graft compared to standard of care in the treatment of chronic diabetic foot ulcers. The study found significantly higher rates of complete wound closure at 12 weeks with Kerecis compared to standard of care.

The study also found a greater mean percent wound care – or wound area reduction at 12 weeks with Kerecis compared to standard of care. The average number of applications to use to achieve closure was 5.9, and the study also had up to one-year follow-up period. Since its publication, this study has been used to obtain commercial coverage from almost 50 payers, which has resulted in more than 100 million added lives in the US.

Following the announcement of the draft policy, we have conducted a review of the studies behind products that were included on the covered lists, and we found that our 2023 study from Lantis is not only on par, but in many cases also superior to the clinical evidence that substantiates coverage in the draft policy. The process that I described earlier is designed to rectify potential errors. This is why there is a consultation period during which we will submit our 2023 clinical study which has been omitted from the review. Mistakes happen. We will submit evidence to rectify this.

Of course, we cannot exclude some level of short-term disruption in the market as a result of the draft policy. But given the feedback that we received during last week from our customers and our field force, we feel confident that there won't be significant impact on our sales in the second half of the financial year. And therefore, we also maintain our financial assumptions on Kerecis.

In summary, we welcome this introduction of clinical qualification for obtaining coverage. We perceive this as a positive development which will benefit patients, and we also believe in the process outlined by the authorities, both fair and reasonable. And we strongly believe that we have the right clinical evidence to prove the strength of Kerecis' fish skin and to get us back on the covered list.

With that, let's turn to our half year strategic update, please turn to slide number 5. First on growth. With our Strive25 strategy, we set out to actively pursue M&A opportunities to build growth and value creation options for the mid and long term. The two most significant investments we made, Atos Medical and Kerecis, are both performing in line with our expectations, with a strong future outlook.

Atos Medical has performed consistently in line with our guidance of 8% to 10% growth and an EBITDA margin in the mid-30s level since becoming part of the Coloplast Group, now almost two years ago. Integration is also tracking well and we expect to deliver the up to DKK 100 million in operational synergies. In both categories in which Atos Medical is present, laryngectomy and tracheostomy, we see significant whitespace. This, coupled with a strong commercial model and a strong team, gives us confidence that Atos Medical will continue to be a good growth contributor and value creator in the long term.

The performance of Kerecis in the first six months is in line with our business case. The strategic fit has been confirmed. And despite the short-term noise which the draft Local Coverage Determination policy has created, we remain convinced about the strength and clinical differentiation of the fish skin technology. With the strong commercial execution from the Kerecis team, we're confident that the business will continue a strong double-digit growth trajectory and become the category leader in biologics over time.

Next, let's turn to innovation. This is a big year for us with several significant launches that will support our growth during Strive25, but also beyond the strategic period. With Luja, a new intermittent catheter with a Micro-hole Zone Technology, we're setting a new standard in intermittent catheterization with a technology that enables full bladder emptying in one free flow, and it addresses key risk factors related to urinary tract infections. Luja is now available to male users in 13 key markets.

And here in May, we've initiated the launch of Luja for women with Denmark and Italy as first launch markets and other key markets will follow over the next 12 months as we obtain reimbursement. In Ostomy Care, we're very pleased with the news on Heylo which, as I mentioned earlier, has been granted national reimbursement in the UK as of the 1st of July at the expected reimbursement level. Work to obtain reimbursement in the second focus market, Germany, is ongoing; and we expect to receive a decision from the authorities in the coming months.

In May, we've also initiated two launches that strengthened our biggest brand in Ostomy Care, SenSura Mio. The first launch represents a significant expansion of the SenSura Mio portfolio with black bag variants, which will provide more choice for people with a stoma. And the second launch is a variant of the SenSura Mio Convex, which strengthens our position in the 2Ps and Convex segments of the Ostomy Care market.

On sustainability, we continue to make good progress across all our initiatives. I'd like to call out the latest results of our Employee Engagement Survey, where we maintain a solid score of 8.1, ahead of the industry benchmark of 7.8, which I'm pleased with. Finally, we're off to a good start with our Global Operations Plan 6, a process to establish a new manufacturing site in Portugal, which will be the largest site for Coloplast to date, is on track, and the site is expected to be operational in 2026. In addition, the procurement program we launched as part of the Global Operations Plan 6 is also making good progress and is expected to deliver savings that will support our long-term EBIT margin guidance, up more than 30%.

Now, let's take a closer look at today's result. Please turn to slide number 6. In Ostomy Care, organic growth was 7% for the first six months and growth in Danish krone was 4%. In Q2, organic growth was 7% with growth in Danish krone up 4%. Our SenSura Mio portfolio continues to be the main growth driver, followed by the Brava-supporting products, and our SenSura and Assura/Alterna portfolios continue to post solid growth in Emerging markets.

From a geographical perspective, growth in the quarter was driven by broad-based growth in Emerging markets led by China and LatAm. Europe also made a good contribution to growth, driven by the UK and Germany. The US had a soft quarter with continued impact from order phasing, and the underlying demand in the US Ostomy

Care market continues to be strong, and we now expect growth in the US Ostomy Care business to be second half weighted.

In Continence Care, organic growth was 8% for the first six months, and growth in Danish krone was 5%. In Q2, organic growth was 8% and growth in Danish krone was 5%. Growth in the quarter was driven by solid momentum in intermittent catheters across the SpeediCath portfolio, with good contribution from compact, standard and flexible catheters. Luja, our new male intermittent catheter, also contributed to growth in Q2.

Our Bowel Care business also made a solid contribution to growth, driven by Peristeen Plus in Europe. From a geographical perspective, growth was broad-based across regions led by Europe, in particular, the UK and France. Markets where reimbursement has been recently established or improved such as Poland, continued to perform well and grew double digit. Voice and Respiratory Care posted 10% organic growth for the first six months, with growth in Danish krone of 8%.

In Q2, organic growth was 13%, and growth in Danish krone was 10%. Reported revenue includes negative impact from product rationalization of 1% in the first six months of the year and 2% in Q2. Growth in laryngectomy in Q2 was double digit, driven by an increase in the number of patients served in existing and new markets, as well as an increase in patient value driven by the Provox Life portfolio. Growth in tracheostomy in Q2 was also double digit and driven by continued solid demand and positive impact from forward integration. From a geographical perspective, all regions contributed to growth led by Europe as well as solid contribution from the US.

In Advanced Wound Care, organic growth was 8% for the first six months, and growth in Danish krone was 38%. In Q2, organic growth was 8% and growth in Danish krone was 36%. Reported growth for the period includes impact from the acquisition of Kerecis. The Advanced Wound Dressings business grew 8% organically in the quarter and also 8% in the first six months. The Biatain Silicone portfolio was the main growth contributor from a product perspective; while from a geographical perspective, growth was broad based across regions.

Kerecis' revenue amounted to DKK 461 million in the first six months and DKK 232 million Danish krone in Q2. The underlying revenue growth was around 35% in both H1 and Q2. The inpatient channel and surgical wounds were the main growth contributors. Kerecis' operating profit margin, excluding PPA amortization, was around 10% in both periods. And in Interventional Urology, organic growth was 5% for the first six months, and growth in Danish krone was 4%. In Q2, both organic growth and reported growth in Danish krone was 5%. Growth in both periods was against the high baseline last year.

The Men's Health business in the US was the main growth contributor in the quarter, followed by the Endourology portfolio, including solid contributions from our first laser equipment, the Thulium Fiber Laser Drive. The Women's Health business detracted from growth in the quarter, impacted by competitive pressure. We expect continued softer momentum in the Women's Health business. And therefore, we now expect growth in the Interventional Urology business to remain at mid-single digit level in the second half of this year. From a geographical perspective, the US was the main growth contributor in Q2. It was followed by Europe, most notably France.

With this, I'd now hand over to Anders, who will take you through the financials and outlook in more detail. Please turn to slide 7.

Anders Lonning-Skovgaard

Chief Financial Officer & Executive Vice President, Coloplast A/S

Thank you, Kristian; and good morning, everyone. Reported revenue for the first six months increased by DKK 1 billion or 8% compared to last year. Organic growth contributed DKK 950 million or around 8% to reported revenue. Acquired revenue from the Kerecis acquisition contributed with DKK 461 million to reported revenue in the first half of the year, reflecting six months impact. Acquired revenue contributed around 4% to reported revenue in the first six months. Foreign exchange rates had a negative impact of DKK 341 million on reported revenue or around 3%, mainly due to the depreciation of the US dollar and the Argentinian peso against the Danish krone.

Please turn to slide 8. Gross profit for the first six months amounted to DKK 9 billion, corresponding to a gross margin of 68% against 67% last year. The gross margin was positively impacted by the inclusion of Kerecis, which contributed around 100 basis points. In addition, lower freight rates and energy cost price increases and the benefit – or baseline benefit of around 40 basis points from the Italian pay-back reform also had a positive impact on the gross margin.

The positive development in the abovementioned factors was partly offset by raw material price increases, double-digit wage inflation in Hungary and ramp-up costs at our manufacturing sites in Costa Rica. The gross margin also included negative impact from currencies of around 90 basis points. Operating expenses for the first six months amounted to DKK 5.4 billion. The like-for-like increase in operating expenses, excluding inorganic impact from Kerecis was DKK 194 million or 4% compared to last year.

The increase includes impact from company-wide salary increases as of January 1. Kerecis contributed DKK 447 million to operating expenses, of which DKK 51 million were related to the PPA amortization included under distribution costs. The distribution to sales ratio for the first six months was 32%, compared with 31% last year; and includes impact from Kerecis and related PPA amortization costs as well as increased level of commercial activities.

The admin-to-sales ratio for the first six months was 5% compared to 4% last year, primarily impacted by the inclusion of Kerecis. The R&D-to-sales ratio for the first six months was 3% of sales, on par with last year. Overall, this resulted in an increase in operating profit before special items of 5% for the first six months, corresponding to an EBIT margin before special items of 27% compared to 28% last year. The EBIT margin in the first six months included negative impact of around 100 basis points from the inclusion of Kerecis, including PPA amortization costs.

Currencies also had a negative impact on the reported margin of around 110 basis points, mostly related to the depreciation of the US dollar and the Argentinian peso against the Danish krone, as well as appreciation of the Hungarian forint against the Danish krone. Financial items in the first six months were a net expense of DKK 418 million compared to a net expense of DKK 524 million last year, driven mostly by interest expenses related to the financing of the Atos Medical acquisition, as well as losses on balance sheet items denominated in mostly Argentinian peso.

The tax expense in the first six months was DKK 697 million, with a tax rate of 22% compared to a tax rate of 21% last year. As a result, net profit before special items for the first half of the year increased by 8% compared to last year. Diluted earnings per share before special items increased by 2% to DKK 11.08 and include impact from the equity raise in August 2023.

Please turn to slide 9. Operating cash flow for the first six months was an outflow of DKK 772 million, compared to an inflow of DKK 1.2 billion last year. The development in cash flows was driven by higher income tax paid in the second quarter related to the Atos Medical Intellectual Property transfer, with a negative impact of DKK 2.5 billion.

The tax payment will be offset by reduced tax payments in the following years, starting from 2023/2024. The tax payment was only partly offset by improvement in changes in working capital and an increase in operating profit of 5%.

Cash flow from investing activities was an outflow of DKK 554 million, compared to an outflow of DKK 381 million last year. CapEx in the first six months amounted to 4% of sales, compared to 5% of sales in the same period last year. As a result, the free cash flow for the first six months was an outflow of DKK 1.3 billion, compared to an inflow of DKK 795 million last year. Excluding impact from the extraordinary tax payment of DKK 2.5 billion, the adjusted free cash flow in the first six months of 2023/2024 was an inflow of DKK 1.2 billion.

The trailing 12-month cash conversion was 87%. Net working capital amounted to around 26% of sales, on par with last year. We continue to expect net working capital to be around 25% in 2023/2024 and return to our long-term expectations of around 24% at the end of the strategic period. Lastly, the Board of Directors approved the half year interim dividend of DKK 5 per share, corresponding to a total interim dividend payout of approximately DKK 1.1 billion.

Before we move to the financial guidance, I want to provide an update on the earnout for Kerecis. The earnout level for Kerecis has been adjusted to 20% of the total earnout potential. The adjustment has been set off against goodwill. I'd like to note, as we did at the time of the acquisition, that the earnout was based on a very aggressive management growth case. The business is delivering in line with expectations to the Coloplast case which is included in our financial guidance, and we are satisfied with the progress made so far.

Now, let's look at the financial guidance for the year. Please turn to slide 10. The financial guidance on organic growth and EBIT margin for 2023/2024 are largely unchanged and most assumptions laid out in November still hold. We continue to expect organic revenue growth of around 8% for the full year, with the following assumptions. Continued good momentum during the year in Chronic Care for our European and Emerging markets businesses. China Chronic Care is still expected to grow at a mid-single digit level.

Growth in the US Chronic Care business is now expected to be second half weighted due to the order purchasing patterns impacting the US Ostomy Care business in the first half. Advanced Wound Care still expected to deliver growth above the market. Voice and Respiratory Care is still expected to grow at a level of 8% to 10%. Finally, one change since our guidance in February is our Interventional Urology business, where we now expect growth in the mid-single digit level from previously high-single digit level, impacted by softer momentum in our Women's Health business.

We are adjusting our reported revenue growth in Danish krone to 10% to 11% from previously around 11% impacted by currencies. Kerecis is still expected to contribute around 4 percentage points to reported revenue growth. We continue to expect the reported EBIT margin before special items of 27% to 28%, which assumes a gross margin of around 68%, prudent management of operating expenses, negative impact from Kerecis of around 100 basis points, including around DKK 100 million in amortization charges and, finally, negative impact from currencies of around 50 basis points.

For 2023/2024, I still expect around DKK 50 million in special items related to the ongoing integration of Atos Medical. The net financial expenses for 2023/2024 are still expected to be around minus DKK 750 million, mostly related to interest expenses related to the Atos Medical financing. I'd also like to share that we have secured the refinancing of the two-year bond related to the financing of Atos Medical acquisition expiring 19th of May. The impact of the refinancing is included in the net financial expenses mentioned earlier. No changes to our assumptions on effective tax rate and CapEx. It's expected to be around 22% and DKK 1.4 billion, respectively.

We're off to a good start. We are significantly outgrowing the market in Chronic Care and in our Advanced Wound Dressings businesses. Our newest members of the family, Atos Medical and Kerecis, are both delivering double-digit growth. We are continuing our year of launches with the introduction of new products in Chronic Care, which will support our long-term growth. And we are looking at inflationary pressure across cost categories coming down.

Overall, we are on track to deliver another solid year with organic growth of around 8% and an EBIT margin of 27% to 28%. And I feel confident about our long-term financial guidance with growth of 8% to 10% and returning to an EBIT margin of 30% by the end of this strategic period, excluding Kerecis; and an EBIT margin of more than 30% long term.

Finally, before we move to Q&A, I would like to remind you that we will host and Meet the Management event here in Denmark on June 6 this year. We look forward to seeing many of you in person in June. Thank you very much, operator. We are now ready to take questions.

QUESTION AND ANSWER SECTION

Operator: Thank you. Ladies and gentlemen, at this time we will begin the question-and-answer session. [Operator Instructions] One moment for the first question, please. The first question is from the line of Anchal Verma from JPMorgan. Please go ahead.

Anchal Verma

Analyst, JPMorgan Securities Plc

Q

Hi. Good morning. I have two questions, please. One on margins. How should we be thinking about phasing for the full year? You've previously indicated that you expect equal phasing H1 and H2, and that's despite a more H2-weighted top line growth. So, were there any costs in H2 that we should be aware of that would prevent an acceleration in H2 margins? Just trying to understand a bit more on phasing.

And then the second question is on the LCD draft proposal. You mentioned that the 2023 clinical study wasn't included by the [ph] Max (00:28:01). Just trying to understand, was there a reason that the [ph] Max (00:28:03) didn't consider [ph] or remit (00:28:05) the study at the first instance itself, while drafting the proposal?

Anders Lonning-Skovgaard

Chief Financial Officer & Executive Vice President, Coloplast A/S

A

All right. Thanks for your questions. Let me start with the first one around the phasing of our margin. So as we have said since we started the year, we expect to deliver a full-year margin between 27% and 28%. We are expecting phasing in the second half to be similar as to the first half. I am also optimistic about our input costs. And so, raw material costs are starting to come down and I'm expecting that to continue into second half and specifically into next year.

And then, I also just would like to call out the FX. We had quite an impact from FX in the first half. And my expectation is that that will ease in the second half. So for the full year, we'll sit with the impact from FX of around 50 basis points. So I would say, those are the two main ones I would call out into the second half. Our underlying operating expenses, I still expect those two to develop at a lower growth rate than the top line growth.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

And to your question on the LCD, we don't fully know. We know that the methodology and the document very clearly states what clinical data has been taken into consideration for every single product that's been reviewed. We are speculating that this may have been related to the time of the publication of our clinical data, even the time of the – if you will, indexing of the related articles in relevant search engine tools that we've simply not come up in the search that's been done for the people doing the lit review. But we're speculating.

But the most important fact is that, we have the clinical evidence to support the efficacy of the technology that we're going to submit it in the hearing period. And we will, of course, be present at the hearing. And I'm also very confident that our customers who are using the product today will make sure that the LCDs understand this.

Anchal Verma

Analyst, JPMorgan Securities Plc

Q

Perfect. Thank you. That's clear.

Operator: Thank you. The next question is from the line of Jack Reynolds-Clark with RBC Capital Markets. Please go ahead.

Jack Reynolds-Clark

Analyst, RBC Capital Markets

Q

Hi, there. Thank you for taking the questions. Two for me also, please. The first on Continence Care. I was just wondering, could you run through how you're kind of trying to approach the launch of Luja Women, and kind of other synergies with the male version and how quickly are you kind of expecting many progress contributions there.

And then on Heylo, again, how you're approaching this launch in the UK? And can you update us on expectations to reimbursement in Germany and any other geographies that you're in dialogues in at the moment? Thank you.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Yeah. Thank you, Jack. Good questions. So on Luja, remember, the male version of the product has already been in market now for a good time. The male segment is about two-thirds of the market. So, now making the female version available is that's been a natural ask from day one from every customer. So, when are we going to have an offering with the same technology for women, and we have that now.

I'm expecting that we're going to be rolled out in the main markets over the course of the next roughly 12 months, and that we're going to see an equally positive reception. We've got a lot of clinicians excited about this and a lot of patients on the male product with the stories of improvement in their daily lives that we are also picking up and sharing. Reimbursement goal is to get a premium to the existing product. And so far, so good. We're following the plan just like we've been doing for the male product.

On Heylo, this has been a major milestone for us. It's been a product that's been underway for a long time. And it is quite different than the launch that we have with Luja, and that this is not just new to Coloplast; it's new to the world. There's no such category out there today. So we are, in effect, building the segment of the market. And I think that comes with responsibility that we take this technology to market with a lot of discipline.

So the focus initially would be, engaging with clinicians that they are familiar with the product, that they're familiar with the patient initiation process that patients get initiated in a good manner. We get them rolled on and connected to the service that's related to the product. And I'm expecting it to basically have a type of profile that looks like when we also initiated the Concave category. So, this is a slow build over time. So, you should not expect that this is a category that "explodes" from one day to the next. But it will contribute both to growth in the category and, of course, be a significant value upgrade.

We have received the reimbursement in the UK that we have asked for. I can't comment on the absolute level on that until it's public, but it will be 1st of July. But I'll just say that we're very satisfied with this. Now the process with the Germans is still ongoing, and everything has been submitted. So, really we are not expecting that we're going to have to submit more data. The authorities have gotten everything that they need. We are expecting that we would get a decision from them within the next month or two.

Jack Reynolds-Clark

Analyst, RBC Capital Markets



Great. Thanks very much.

Operator: Thank you. The next question is from the line of Martin Parkhøi from SEB. Please go ahead.

Martin Parkhøi

Analyst, Skandinaviska Enskilda Banken AB (Denmark)



Yes. Good morning. Martin Parkhøi from SEB. Two, maybe [ph] slash (00:34:49) three questions. Firstly on the Continence Care franchise, 8% organic growth in the first half, have you assumed accelerating growth in the second half based on the continued rollout of Luja?

And then second question, just to be a little bit prerogative on the Kerecis deal, now we have seen a reduction of the earnout, we have seen the risk on the new draft LCD policy. Have you been a little bit naïve with respect to the risk in this business that you have acquired? And Anders was very firm on sticking to the long-term targets, but I guess that assumes that you will be able to reverse the draft policy. In case it will not be reversed, how would that impact your long-term targets?

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S



Thank you, Martin. Two good questions. We're not guiding specifically for Continence on the quarters and second half. I'm expecting the good momentum to continue. As the rollout of Luja takes hold, I'll just reiterate that everything that we're doing in these Chronic Care categories, they're long hauls, so to speak, getting the product into the hands of clinicians and they start to initiate patients on them. You've seen some element of acceleration on Continence Care, and I'm just – I'd say, at this stage I'm expecting the good momentum to hold.

On Kerecis and the LCD and whether we're being naïve, you know, Martin – I'll just reiterate, 80% of this business is in acute with very stable reimbursement and the very strong performance. Kerecis continues to be, by a significant margin, the fastest-growing biologics player out there. Now, there's a hiccup on 20% of the business with the LCD coverage. I'm actually feeling quite confident about this, I have to say, with the way that this – the clinical data that we have that we can present.

If you read the document from the Medicare Administrative Contract, it is – like I said in my opening remarks, it's a rational document. It's a document that sets out the clinical evidence that has been reviewed for every single product. And the intent is to, if you will, clean up the category, so it's driven by technology that has clinical evidence.

I cannot expect anyone to make decisions based on data that they haven't seen. So, the process is structured in a way that you can make your voice heard and you can present the evidence that you have. And of course, we're going to do that. I have full confidence that that is going to work, and that the people behind this are making rational decisions, having produced this rational document.

In the event that it's not rational, remember that this is just beginning. So, we're nowhere near the full buildout of the Kerecis footprint. So, the people that we now have dedicated to work in this part of the market, we have plenty of opportunity of redirecting them to places in the market where there is coverage or in the inpatient setting, whether there is payment. So, yes, there's a hiccup. I don't think we're being naïve, Martin. This is a category that we feel strongly about, the technology that we feel strongly about; and we're not changing an iota around our conviction.

Martin Parkhøj

Analyst, Skandinaviska Enskilda Banken AB (Denmark)



Thank you very much.

Operator: Thank you. The next question is from the line of Christian Ryom from Danske Bank. Please go ahead.

Christian Sørup Ryom

Analyst, Danske Bank A/S



Yes. Good morning. I have two questions as well. The first on Kerecis as well. So, going back to Q1 where you also reported 35% organic growth for the business, I understood that you were expecting growth to pick up or to accelerate from that level later in the year. Is there any change to that expectation, and how might this uncertainty we have around the LCDs impact that?

And then the second question is on the Women's Health franchise within Interventional Urology. If you can shed a bit more light on the dynamics that you're seeing there and the outlook maybe also going into next year for that franchise. Thank you.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S



Yeah. Thank you. Thank you, Christian. Good questions. So, Kerecis is at a stage and with performance that's in line with our case. And so, all the work now is around expansion of sales force. That's ongoing. And like I've talked to you guys about, it does take some time to onboard new employees and get them up to become effective.

Now, the adjustment to the provision is against the very aggressive management case like we also talked to at the time of the acquisition. The Coloplast case is still fully intact, which is also why we're not changing what we think is going to be the contribution around the business. I expect continued strong performance in line with plan in the coming quarters. But of course, now with the change in LCD acceleration beyond the plan, I'll be a little careful.

We'll see how it plays out over the next quarter and then we'll probably be smarter around the potential impact in Q3. But we feel very good about the outlook for the year. And like I said to the previous question, should this not pan out in our favor? There is plenty of opportunity to redirect this part of the sales force to parts of the market where there is both payment and coverage.

Now, to Women's Health, we had a negative development here in Q2. And so, this is really related to the sling portion of the Women's Health business. You should think of that as it's roughly 50/50. The Women's Health business divided between meshes and slings. And we are seeing a new development in the US that the slings procedures are going down, and they – our competitive technology in the market is gaining some share. It's not something that I expect to be resolved short term. We'll need to see how this plays out. But the bulking agent category is gaining traction at the expense of the slings category.

Next year [ph] of that, (00:42:09) I'd say, too early to say. Bear in mind that the difference between the slings procedure and the bulking agent procedure is the slings is up. It's a permanent solution. So definitely, there will be clinicians that prefer that; the patients that prefer that versus a bulking agent solution where you have to come back to the doctor with a certain frequency. But this will be a topic when we get to you here in June, and we'll also be wiser in the coming quarters how this will play out. For now, we're taking a slightly more cautious stand on the outlook for IU for this year that it's going to continue to grow at the current level.

Christian Sørup Ryom

Analyst, Danske Bank A/S

Q

Perfect. Thank you. That's very clear.

Operator: Thank you. The next question is from the line of Maja Stephanie Pataki from Kepler. Please go ahead.

Maja Stephanie Pataki

Analyst, Kepler Cheuvreux SA (Switzerland)

Q

Yes. Good morning. Two questions for my side as well, please. Anders, I was wondering if you could quantify a bit when you say that raw material prices have started to come down. Would you give us a bit of a reference what you've seen from Q1 going into Q2, and how you think this is going to develop throughout the rest of the year?

And then, coming back to your commentary about US Chronic Care and calling out that it's going to be more H2 weighted. Have there been any orders that have been shifted, or what makes you confident that momentum is going to accelerate in the second half of the year? Thank you very much.

Anders Lonning-Skovgaard

Chief Financial Officer & Executive Vice President, Coloplast A/S

A

Yeah. So, let me start with the first question, Maja, around the raw materials. So as we have said, since we started the year, we are expecting raw materials to increase around mid-single digit at a higher level here in Q1 and Q2. And then, it will start to ease towards the Q3 and Q4. Please also remember, there is some time lag that is impacting our inventories. So, that is also included. But I'm expecting, as I said earlier, that the raw materials are starting to ease further into Q3 and Q4. So, for this full year I'm still expecting around a mid-single digit. So, that's how I see it.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

And Maja, to your question on after the US where we call out an element of order phasing, there's also a bit of inventory reduction in there. I'm looking at a number of different data points to form judgment on this. The first is, what does the patient inflow look like and does – is it increasing month-on-month? And the answer is, yes. I'm looking at what does the volume growth in the acute channel and into home health, what does that look like? And we are growing double digit in both of those channels.

And then finally, I look at the actual sales out. So the demand reported by distributors, that's actually a part of the selling that continues at high-single digit growth. Had I've been looking at different data, I would have been talking to this differently. But the data points around demand and growth are pointing in this direction. And so, I'm convinced that we're going to see high-single digit in the second half.

Maja Stephanie Pataki

Analyst, Kepler Cheuvreux SA (Switzerland)

Q

Thank you.

Operator: Thank you. The next question is from the line of Shubhangi Gupta from HSBC. Please go ahead.

Shubhangi Gupta

Analyst, HSBC Securities & Capital Markets (India) Pvt Ltd.

Q

Hi. Thanks for taking my question. Just follow up on the LCD thing. So according to the draft, the proposed policy statement, most of the clinical trials have been conducted for a period of 12 weeks. There have been no studies beyond the 12 weeks, and application average use was, I guess, four times. So could you please comment on Kerecis product? What is the application and have you conducted longer duration studies to see the product efficacy and safety?

And second, right now Kerecis [indiscernible] (00:46:20) not covered under the document, while some of the challenges – the peers' products are. So, what do you think differentiates Kerecis product from the others that are already covered? And also, right now you say 20% of your revenues would be impacted by this. So, do you expect this policy – the conclusion of this policy would extend to other like the 80% of your business as well?

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Thank you. Thank you for the questions. I may need some help on just restating the second part of your question, I'm not sure I got all of that. So the review, it's a quite – it's a technical review. So, there are some technical reviews, technical requirements around the product where there's an assessment and that it's quite binary whether you meet them or not. And we meet them. And equally, there is a [ph] final (00:47:22) review on clinical evidence. It's not clearly specified exactly what criteria to assess clinical performance are necessary.

But when we look at the products that have been included, we look at their study size, we look at their treatment results, we look at their risk of bias. Kerecis compares favorably to many of them. So either on par or better with most of the products that are already on that list. And we also have, of course, a one-year follow-up on the patients that were included in the 2023 study. The risk of spillover from this type of review to the acute setting is zero. So, this part of the – that the hospital part of the market works on DoD codes. It's very stable. And so, this review here pertains to Medicare, and it's the outpatient setting.

And like I said earlier, if contrary to our expectations that we were not included on this, we have opportunities to redirect our resources to parts of the market where there is both coverage and payment. But I am absolutely

convinced that given the clauses in the document that's been laid out, that we have a study that completely fulfills the requirement and that the evaluators will put us back on the list. There's a process for that, and we participate in that process. And look forward to getting the results. Of course, it's unfortunate that we've got a hiccup like this, but things happen.

Did I miss a part of your question?

Shubhangi Gupta

Analyst, HSBC Securities & Capital Markets (India) Pvt Ltd.

Q

Oh, I think I had asked that most of – in the review, so they had said that the median usage they saw was four times only in a duration of 12 weeks. So, what are the corresponding numbers for Kerecis? Like, I think they have mentioned that if you distribute beyond 12 weeks, then you have to provide a good rationale. Yeah.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Yeah. So, I think if you look at the average, the median use of Kerecis products, I would say, on the portfolio as a whole and not in the study, it's less than 4. If you look at the study, it's 5.9. But the language of the policy, you read that carefully, the language of the policy around the four applications basically says that if you're not seeing progress after the four applications, you should stop.

I mean, who could disagree with that, that if you're doing a treatment and the technology is not showing progress, I mean you should stop. That's not a good use of taxpayer money. And the key thing and the key language of the document is that this is a clinical evaluation. So if there's a clinical need, of course, you should continue treatment. And by the way, this is not part of the evaluation to be part of the inclusion or to be part of the coverage. I hope that clarifies.

Next question, please.

Operator: Thank you. The next question is from the line of Martin Brenøe from Nordea. Please go ahead.

Martin Brenøe

Analyst, Nordea Bank Abp (Denmark)

Q

Hi. Thank you very much for taking my questions. I have two, if I may. The first one is surprise, surprise also on the Kerecis. The first question would be, if you are getting any feedback from any medical doctors or your salespeople, whether this is already having an impact of the perception of Kerecis out there. That would be the first question. Thank you.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

So, the answer is that both field force and clinicians are confident that the product will be reinstated. I was at [indiscernible] (00:51:41) last week in London and had a chance to engage with a lot of customers and key opinion leaders. Lot of people are using the product day-to-day and are confident that with the clinical study that we have that we are going to get back on. Our field force is also confident.

Martin Brenøe

Analyst, Nordea Bank Abp (Denmark)

Q

Okay. Thank you. Thank you, Kristian. Just a quick follow up on it. I guess that that is a little bit up to discussion. So, it sounds like you got your argument straight, but I guess that when we see these regulations coming down, part of it is also potentially that the regulators are looking at price versus outcome. So, is there a scenario where you might be accepted, but you need to do something about the prices that you have, which are significantly higher than the standard of care today?

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Well, look at the products that are already approved. So, I think that's the data point that you need to look at. And if you look at our pricing compared to the products that are already approved, we're middle of the road. So, that's not my concern. This to me is a process thing. So if you read the – if you read the policy document, it really is a good document. The people who made it have thought about it, and they walk through analytically product by product, whether they're included or excluded, and the evidence that they look at to form judgment.

And so, if you exclude the most important study that we have around diabetic foot ulcers, of course, I can't expect the people who are forming judgment to reach a conclusion that takes that data into consideration. We have to put it in front of them. So, I'm not concerned about the pricing question, Martin.

Martin Brenøe

Analyst, Nordea Bank Abp (Denmark)

Q

Okay. Thank you, Kristian. Just a quick follow up to Anders. This earnout write-down, does that have any impact on the P&L?

Anders Lonning-Skovgaard

Chief Financial Officer & Executive Vice President, Coloplast A/S

A

No. It does not have any impact on the P&L. It's only an impact on the balance sheet. It's against the goodwill.

Martin Brenøe

Analyst, Nordea Bank Abp (Denmark)

Q

Okay. Thank you. Thank you very much for taking my questions, both of you guys. Thank you.

Operator: Thank you. The next question is from the line of Marianne Bulot with Bank of America. Please go ahead.

Marianne Bulot

Analyst, BofA Securities

Q

Thank you very much. Good morning. Just a quick question on Luja and female launch. Do you expect as well to get a premium pricing as you did for the male version? And are we going to see any pricing benefits from the male version coming into H2?

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Thank you. So, I think we've said previously depending on market for – for the male version, some market's low, some market's mid, some market's high-single digit, depending on market and, of course, the local pricing situation. And I'll say the same thing for female, but probably more of a way to mid-single digits.

And to your question on whether you're going to see the pricing benefit in the second half. We're really not guiding down to that level. This is all part of driving a Continence Care category with good momentum. We've got good momentum. Now, you should expect that momentum to continue.

Operator: Thank you. The next question is from the line of Veronika Dubajova with Citi. Please go ahead.

Veronika Dubajova

Analyst, Citigroup Global Markets Ltd.

Q

Hi, guys. Good morning and thank you for taking my questions. Apologies, I'm also going to start off with Kerecis. Just kind of a bigger picture question for you, Kristian. Obviously, I think the LCD decision or proposal was a huge signal from CMS that they have concerns longer term about the value these products offer.

And sort of a provocative question, and apology if it's been asked, but I want to ask it very directly. Look, even if you get on the list, how do you assess the risk that the longer-term growth potential of this market is just substantially impaired? Because the part of the value proposition here was, one, you get to play in the market [ph] to offer (00:55:59) that the market would continue to grow. And I'm just wondering about that. So, that's kind of my first question. I'll let you answer that, and then I had a follow up after that. But maybe you start off there.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Yeah. So, I'll start with a blunt observation. The technology works, Veronika. It really works. And I wish you guys would come to some of the customer events that we hold and see the patients' stories. This works and it delivers really, really amazing results. And when I read the policy document, I am reading a document from people who think rationally about what they want to achieve. They want to put their money – the taxpayer money against technology that works. I mean, how can you – I would do the same thing if I was writing that document.

So, these things happen. But I think what it demonstrates is the importance of clinical evidence, the importance of running a super professional organization, the importance of investing in market access and government affairs and all that. But at the core, this is about whether the technology works and that's also what the document says; we're willing to spend money on technology that works and has clinical evidence. And of course, we're going to prove that.

Now, having said that, remember, Veronika, 80% of what we're doing is in acute, right. 80% of what we're doing is in acute, and it's growing. And so, this is just a portion of the market – the inpatient portion of the market. It's paid through DoD codes. I am optimistic. And the reason we made this acquisition was, it started with a really raw and in-depth assessment on whether this works. It works. And from there, everything else flows.

So, I would be way more concerned about this if we had had a process where I didn't have a team that had produced a good clinical work and clinical results to submit. But that's not the case. That's not the case. So, at least the CEO was optimistic about the category and about the technology. But of course, there's going to be bumps in the road. Here's a bump in the road, and we're dealing with it.

Veronika Dubajova

Analyst, Citigroup Global Markets Ltd.

Q

Okay. Okay. Thank you. And fine, that's helpful. So I guess, if I summarize it, your view is the longer-term growth potential of this market is really not altered even if this LCD goes ahead as is proposed?

[indiscernible] (00:58:51)

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Maybe even the opposite, Veronika, that what's going to happen as a result of this is, all the smaller players that have gone into the category without the clinical work and without the evidence, will be thrown out. And as taxpayers, we should welcome that certainly as a company preoccupied with doing a real innovation. We certainly welcome that.

Veronika Dubajova

Analyst, Citigroup Global Markets Ltd.

Q

Okay. Okay. That's helpful. And then, apologies. My second question is just on Heylo, and I might have missed this in your prepared remarks as I was late to the call, but just curious where you are in Germany and your degree of confidence that you can obtain coverage there as well as in the UK. And maybe I don't know if you're able to share that the financial impact of the coverage that you have gotten in the UK for you in terms of how much revenue is adding per user per day. Thank you.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

So, I can't talk to the actual reimbursement level in the UK. We basically received what we asked for, Veronika. And this will be public information come July 1, but we've been asked to not comment on it prior to the actual go-live date. It does represent a substantial value upgrade opportunity.

But you need to think of it as how we work with the Concave category. It will be a segment of the market that we develop. And we will be very disciplined about how we go to market. This is not something that we're going to throw on a million people day one. We will work with clinicians that they understand how the product works. They understand the value of the product. They understand how to initiate patients. So, it's going to be a gradual build.

Now to your question on Germany, of course, having external endorsement in the UK makes me more optimistic that the Germans will come to the same judgment. But in the end, I need to see the decision. It should be just around the corner.

Veronika Dubajova

Analyst, Citigroup Global Markets Ltd.

Q

Excellent. That was it for me. Thanks, guys.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Thanks, Veronika.

Operator: Thank you. The next question is from the line of Graham from UBS. Please go ahead.

Graham Doyle

Analyst, UBS AG (London Branch)

Q

Good morning, guys. Thanks a lot for taking my questions. And just one on Wound and then one follow up on Heylo as well. In terms of the document that Kristian obviously described as a very rationally [ph] laid-out

(01:01:27) document. But one of the potentially irrational things is, you have the removal of a lot of products as it stands today.

And would you have to give us any context as to what sort of pressure this might put on the market in terms of the availability of actual product, if FDA rules were to go in place across the market? And I suppose, alongside that, the feedback you're getting from physicians because to your point earlier, these products probably do work. And certainly, there's no clinical data out there to justify that.

And then secondly, just on Heylo. What sort of central cost and central functions should we be thinking about for this product to work? And when we think about launches, what viable economic model do you need to launch across three, four, five, six, seven countries before this becomes profitable? Or is it done on a country-by-country basis, and some won't make sense and some will? Thank you.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

I just want to make sure, Graham, I'm getting your first question correct. Is the question, whether we are going to have volume enough to supply in the event that all these other products are removed or how many products we're talking about with us? Could you just restate that first part of the question?

Graham Doyle

Analyst, UBS AG (London Branch)

Q

Yeah. So as it stands today, there is a huge amount of products that would be no longer reimbursed...

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Correct.

Graham Doyle

Analyst, UBS AG (London Branch)

Q

... [indiscernible] (01:02:48). And it looks to me like that actually leaves like interesting choice, very little choice for physicians. But potentially from a supply chain perspective, if you think the entire industry just it might be tight to actually service what is a very kind of severe chronic disease and obviously a big potential risk down the road in terms of what'll happen next. So, that [indiscernible] (01:03:10).

Do you think that's something that the – that Medicare have actually thought about, number one. And [ph] of course (01:03:16) number two, in relation to that is, do you think that will change how they go about introducing any changes? So, could we see a period whereby...

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Yeah.

Graham Doyle

Analyst, UBS AG (London Branch)

Q

...maybe Medicare says, you've got a year to get us this data?

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Yeah, potentially. So I would say, clearly if you remove about 200 products from the market, they'll be more room to play for the products that are in market. That's clear. Now, a couple of things to bear in mind right now. This is a draft policy, so there's no change right now and there will be no change until the implementation date. So of course, there's going to be some noise in the market. But until the new policy is implemented, the products that are currently being sold can still be sold.

Now, we have plenty of capacity, so we can actually scale up significantly to meet demand. But whether Medicare would, in effect, basically look at this and have a longer transition period, I don't know. They probably solicit some input from the products that remain on list as to whether they can continue to supply. That's probably the best answer I can give at this stage. But right now, we are not capacity constrained.

So, on your second question on Heylo, we think that this is a long build. It's definitely a case that lends itself to volume like most of the work that we do. So, the more markets we get on, the more patients we get on, the happier we get. So, we will have scalability on what's, if you will, central cost and the cost that we have around the IT data setup and the app that is scalable. We've already made – we've made that investment.

But we are – the ambition is clearly to get this into Germany, also get it off the ground in both these markets and shortly thereafter begin the work on getting the product into the next markets. So, it'll be – because it's new, it will be a longer build and a longer launch sequence than what you're looking at with Luja and Mio and things like that with the categories already established. But it clearly lends itself to scale.

Graham Doyle

Analyst, UBS AG (London Branch)

Q

Thanks a lot. Appreciate it with the answers. Thank you.

Operator: Thank you. The next question is from the line of Robert with Davies (sic) [Davies with Morgan Stanley] (01:05:59). Please go ahead.

Robert J. Davies

Analyst, Morgan Stanley & Co. International Plc

Q

Yes, morning. Thanks for taking my questions. I had three. One was just around the [indiscernible] (01:06:08) kind of requirements and any additional studies that would be needed to be sort of added. Are you sort of able to sort of budget or get a sense of what would be required from a financial standpoint and timing-wise, to get any requisite studies done that you don't have in place? Just wondered if that was something you'd considered or kind of quantified internally so far.

The second question was just, I guess sort of the discretionary spend in China, something you've called out on some of the previous sort of calls because you're seeing some headwinds. Just wondered if there's any changes in the dynamics you're seeing from those customers.

And then the final one was just around energy costs. Perhaps you can just give us – you may have touched on it early on; I might have missed it. But just where are we in terms of energy costs and the lock-ins you had before? How long before that tails off?

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Thank you, Robert. Good questions. So on the first one around clinical studies, so I'll reiterate. Our clear conviction is that we have a clinical study that will meet and/or exceed the requirements that have been stated in the policy. We have a number of things in review already. So studies that have already been done, but not published that will further strengthen our position. But my view is that the Lantis study is plenty of documentation that we have a very potent technology that that's highly relevant and that should be covered.

To your second question on consumer sentiment in China, I'll say, I spent a week in China a little earlier, a few weeks back. We've got really good momentum in hospital. Hospital activity is back, patient inflow is back, but consumer spending is still subdued compared to where we were pre-COVID. So for now, no change on that.

Anders Lonning-Skovgaard

Chief Financial Officer & Executive Vice President, Coloplast A/S

A

And then on your final question around our energy hedges. So, this year we have hedged at a level of €150 per megawatt hour. And into next year, I'm expecting quite a tailwind when I look at the current forward rates and the current spot rates. So, that will give us some tailwind into 2024/2025.

Robert J. Davies

Analyst, Morgan Stanley & Co. International Plc

Q

Thank you. Maybe you can just squeeze in one follow up just around this consultation period on the LCD. If you present your case and it sort of doesn't go in your favor, is there an appeals process or is there any way to sort of get a sort of second crack at it? Thank you.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

I think this is it. So the consultation process, you will be heard. There'll be a number of meetings that's quite formal. We will have people at those meetings. There will be a solicitation of customer and clinical feedback. And on the basis of that, the reviewers will basically form process. There can be an appeals process before the final policy is implemented. But the exact mechanics of that, I'd have to get back on. But you need to put your best foot forward, of course, in the process where you're supposed to be heard, and we will do that.

Robert J. Davies

Analyst, Morgan Stanley & Co. International Plc

Q

Understood. Thank you very much.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

A

Thank you. Operator?

Operator: Thank you. There are no further questions at this time. I hand back to Kristian Villumsen for closing comments.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

Right. Just a thank you to everybody who has joined our call today. Thank you for your interest in the company. Should you have any additional questions, please feel free to contact our Investor Relations team, and also we look forward to seeing you on the road.

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