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Coloplast A/S (CLPBY.DK)

Q3 2024 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

Morning everybody, and welcome to our Nine Months 2023-2024 Conference Call. I'm Kristian Villumsen, the CEO of Coloplast and I'm joined by our CFO, Anders Lonning-Skovgaard, and our Investor Relations team. We'll start with a short presentation by Anders and myself and then open up for questions like we usually do.

Please turn to slide number 3. We delivered 8% organic growth and a reported EBIT margin before special items of 27% in our third quarter. Return on invested capital after tax and before special items was 15%, reflecting impact from the acquisition of Kerecis. I'm satisfied with our performance. We continue to broadly outgrow the market and we're delivering solid growth in absolute profits. More importantly, we also continue to help a lot more people who live with intimate healthcare needs.

Let me start today's call with a few highlights. First, innovation. This is a year with several significant product launches that will support growth both during Strive 25, but also beyond the strategic period. One of these products is Luja, our new intermittent catheter with micro-hole zone technology. Well, Luja was setting a new standard in intermittent catheterization with a unique technology that enables full bladder emptying in one free flow and, therefore, addressing key risk factors related to urinary tract infections. And we are already seeing significant contribution to Continence Care growth from the male Luja catheter, which is available to users in now 13 markets. The launch of the female catheter is ongoing, and the product is currently available in 4 markets where it's received very positive customer feedback.

Another important highlight relevant for our US intermittent catheters business is the publication of a final coding decision for intermittent urinary catheters by the CMS late last week. With this final decision, the existing coding structure for intermittent catheters in the US is updated to include three new codes and, with that, differentiate between hydrophilic and non-hydrophilic catheters. The new coding structure will be implemented as of January 1, 2026.

Let me remind you that under the existing coding setup, both hydrophilic and older generations of catheters are covered by the same codes, which means that patients don't always get access to the latest technology despite there being good evidence that hydrophilic catheters lead to better clinical outcomes. We consider this change, first and foremost, to be a win for patients. Patients will now be guaranteed access to hydrophilic catheters. We also consider it to be a win for innovation.

Coloplast has been on the forefront of upgrading the US intermittent catheters market toward hydrophilic technology for many years. And today, more than 70% of our US intermittent catheter sales come from hydrophilic catheters. Still, many more patients remain that should have access to better technology, and we will continue to focus on upgrading the market, both to hydrophilic catheters and, of course, also to our micro-hole zone technology, which sets a new standard in intermittent catheterization.

Next, I'd like to turn to Kerecis. The business continues to grow at a strong double-digit growth rate of around 35% and continues to take market share in the Biologics segment of the Advanced Wound Care market. Performance and integration are both on track. So far, there's been limited impact on sales and operations from the draft Local Coverage Determination policy announced earlier this year where Kerecis was not included on the draft list of covered products.

As part of the LCD consultation period in June, we submitted comprehensive documentation to support Kerecis in getting back on the list of covered products. Our position is unchanged. We welcome the introduction of a clinical qualification for obtaining coverage, and we perceive it as a positive development which will benefit patients. We continue to 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.

We continue also to expect that final LCD policy to be announced sometime in the second half of 2024. At the same time, we also continue to develop additional clinical evidence on Kerecis. A new randomized controlled clinical study comparing the performance of Kerecis fish skin to standard of care in the treatment of complex diabetic foot ulcers is pending publication. This is the largest Kerecis study to date with a sample size of more than 250 patients, and we look forward to sharing the results very soon.

Before I move on to the details by business area, let me provide a brief update on our newly established distribution center in the US. During Q3, Coloplast established a new distribution hub to serve its Chronic Care, Advanced Wound Dressings and Skin Care businesses in the US. The US is a strategic focus market for us, and given the expansion that Coloplast has experienced in the US over the last years, there was a need to consolidate our distribution operations previously located in two centers.

The new setup is expected to drive scale benefits, while supporting future growth. This new setup has, however, resulted in short-term supply disruptions during Q3, mostly impacting the Chronic Care business, and it has detracted around 20 basis points from the group's organic growth in the quarter. It's also resulted in extraordinary costs in the quarter, which are expected to persist into Q4. We are working hard on resolving these short-term challenges and we expect to be back to normal operations in the US by the end of Q4.

Please turn to slide number 4. In Ostomy Care, organic growth was 7% for the first nine months and growth in Danish krone was 6%. Organic growth in Q3 was 8%, and growth in Danish krone was also 8%. Our SenSura Mio portfolio continues to be the main growth driver, followed by the Brava range of supporting products. Our SenSura and Assura/Alterna portfolios also continue to post solid growth in emerging markets.

From a geographical perspective, all regions contributed to growth in the quarter with broad-based contribution across emerging markets and Europe, driven by the UK. In the US, growth in the quarter improved, however, below our expectations and included impact from the establishment of the new Coloplast distribution center that I explained earlier.

Continence Care organic growth was 8% for the first nine months and growth in Danish krone was 6%. In Q3, organic growth was 8% and growth in Danish krone was 9%. Growth in the quarter was driven by good momentum in intermittent catheters across the SpeediCath portfolio and the male Luja intermittent catheter, which made a strong contribution to growth in our third quarter.

Our Bowel Care business also contributed to growth, driven by Peristeen Plus in Europe as well as the US. From a geographical perspective, growth was broad based across regions, led by Europe, especially France and the UK. Markets where reimbursement has been recently established or improved, such as Poland, continued to perform well and grew double digit. In the US, growth in the quarter was impacted by the establishment of the new Coloplast distribution center.

Voice and Respiratory Care posted 10% organic growth for the first nine months, with growth in Danish krone of 8%. In Q3, organic growth was 11% and growth in Danish krone was 9%. Reported revenue includes negative impact from product rationalization of 1% in the first nine months of the year and 2% in Q3. I am very satisfied with this performance, which continues to be at the upper end of our guidance range for Voice and Respiratory Care, and it's driven by broad-based contributions from both Laryngectomy and Tracheostomy.

Growth in Laryngectomy in Q3 was high-single digit, driven by an increase in the number of patients served in both existing and new markets as well as an increase in patient value, which is driven by the Provox Life portfolio. Growth in Tracheostomy in the quarter was double digit, 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 10% for the first nine months, and growth in Danish krone was 42%. Organic growth in Q3 was 13%, and growth in Danish krone was 51%. Reported growth for the period includes impact from the acquisition of Kerecis. The Advanced Wound Dressings business grew 10% organically in the first nine months, and Q3 organic growth in Advanced Wound Dressings was 13%, which includes benefit from a lower baseline last year and from order phasing in Germany.

From a product perspective, the Biatain Silicone portfolio was the main growth contributor, while, from a geographical perspective, growth was driven by Europe, especially Germany, as well as a solid contribution from emerging markets. Revenue from Kerecis amounted to DKK 730 million in the first nine months and DKK 269 million in Q3. The underlying revenue growth was around 35% in both periods. The in-patient channel and surgical wounds were the main contributors to growth. Kerecis operating profit margin, excluding PPA amortization, was around 10% in both periods, in line with our expectations.

In Interventional Urology, organic growth was 4% for the first nine months and growth in Danish krone was 3%. In Q3, both organic growth and reported growth in Danish krone were 2%. The Men's Health business in the US was the main growth contributor in the quarter, while both Women's Health and the Bladder Health and Surgery businesses detracted from growth.

The Women's Health business continued to be impacted by competitive pressure. The Bladder Health and Surgery business was negatively impacted by backorders, which emerged as a result of constrained supplier capacity. We are already seeing an improvement in the backorder situation here in our fourth quarter and, as a result, we expect growth in Interventional Urology to return to mid-single digit in Q4. From a geographical perspective, the US was the main growth contributor in Q3.

With this, I will now hand over to Anders who will take you through the financials and outlook in more detail. Please now turn to slide number 5.

Anders Lonning-Skovgaard

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

Thank you, Kristian, and good morning everyone. Reported revenue for the first nine months of the year increased by DKK 1.8 billion or 10% compared to last year. Organic growth contributed DKK 1.4 billion or around 8% to reported revenue. Acquired revenue from Kerecis acquisition contributed with DKK 730 million to reported revenue in the first nine months of the year, reflecting nine months of impact.

Acquired revenue contributed around 4% to reported revenue in the first nine months. Foreign exchange rate had a negative impact of DKK 305 million on reported revenue or around 2% related to the depreciation of the US dollar, the Japanese yen, and a basket of emerging markets currencies against the Danish krone, most notably the Argentinian peso.

Please turn to slide number 6. Gross profit for the first nine months amounted to DKK 13.6 billion, corresponding to a gross margin of 68%, compared to 67% last year. The gross margin was positively impacted by the inclusion of Kerecis, which contributed around 100 basis points. In addition, favorable development in input cost, price increases, and a baseline benefit of around 40 basis points from the Italian payback reform also had a positive impact on the gross margin. The positive development in the above-mentioned factors was partly offset by double-digit wage inflation in Hungary and ramp-up cost at our manufacturing sites in Costa Rica. The gross margin also included negative impact from currencies of around 80 basis points.

I would also like to share that here in July, we hedged around 70% of the expected electricity consumption in Hungary for 2025 at a price of around €100 per megawatt hour compared to €150 per megawatt hour, which is in the price we hedged here in 2024. Operating expenses for the first nine months amounted to DKK 8.1 billion. The like-for-like increase in operating expenses, excluding inorganic impact from Kerecis, was DKK 383 million or 5% compared to last year, in line with expectations. Kerecis contributed with DKK 698 million to operating expenses, of which DKK 77 million were related to the PPA amortization included under distribution cost.

The distribution-to-sales ratio for the first nine months was 33% compared to 31% last year and includes impact from Kerecis and related PPA amortization costs as well as increased level of commercial activities, including activities related to product launches here in Q3. Distribution costs in Q3 also included extraordinary costs related to the newly established US distribution center. These extraordinary costs are expected to continue into Q4.

The admin-to-sales ratio for the first nine months was 5%, on par with last year, primarily impacted by the inclusion of Kerecis. The R&D-to-sales ratio for the first nine months was 3% of sales compared to 4% last year. Overall, this resulted in an increase in operating profit before special items of 7% for the first nine months, corresponding to an EBIT margin before special items of 27% compared with 28% last year. The EBIT margin in the first nine months included negative impact of around 100 basis points from the inclusion of Kerecis, including the PPA amortization costs.

Currencies also had a negative impact on the reported EBIT margin of around 100 basis points, mostly related to the depreciation of the US dollar and a basket of emerging market currencies against the Danish krone, as well as the appreciation of the Hungarian forint against the Danish krone. Financial items in the first nine months were at a net expense of DKK 621 million, compared to a net expense of DKK 628 million last year, driven mostly by interest expenses related to the financing of the Atos Medical acquisition.

The tax expense in the first nine months was DKK 1 billion 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 nine months of the year increased by 7% compared to last year. Diluted earnings per share before special items increased by 1% to DKK 16.87 and include impact from the equity raise in August 2023.

Please turn to slide 7. Operating cash flow for the first nine months was an inflow of DKK 718 million, compared to an inflow of DKK 2.3 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 this financial year. The tax payment was also partly offset by an increase in operating profit and an improvement in changes in working capital.

Cash flow from investing activities was an outflow of DKK 904 million, compared to an outflow of DKK 655 million last year. CapEx in the first nine months amounted to around 5% of sales, on par with last year. As a result, the free cash flow for the first nine months was an outflow of DKK 186 million, compared to an inflow of DKK 1.7 billion. Excluding impact from the extraordinary tax payment of DKK 2.5 billion, the adjusted free cash flow in the first nine months of 2023-2024 was an inflow of DKK 2.3 billion. The trailing 12 months cash conversion was 82%.

Net working capital amounted to around 27% of sales, compared to 26% last year, impacted by timing and country sales mix. We now expect the net working capital to be around 26% for this financial year. The long-term expectation of net working capital-to-sales ratio of around 24% are still unchanged. At the same time, we also adjusted the full year 2023-2024 guidance on CapEx now expected around DKK 1.3 billion from previously around DKK 1.4 billion.

Now, let's look at the financial guidance for the year. Please turn to slide 8. Our financial guidance for 2023-2024 financial year is largely unchanged. We are on track to deliver a good year with growth above the market and a significant growth in absolute profit. The organic revenue growth for the year is still expected around 8% and the underlying assumptions on the performance by business area and geographies are unchanged.

Our reported revenue growth in Danish krone is still expected to be between 10% and 11% and continues to assume around 4 percentage points contribution from Kerecis and between 1 to 2 percentage points negative impact from currencies. We continue to expect a reported EBIT margin before special items of 27% to 28% with unchanged underlying assumptions of a gross margin of around 68%, prudent management of operating expenses and a negative impact from Kerecis of around 100 basis points, including around DKK 100 million in amortization charges.

I now expect negative impact from currencies of around 70 basis points from previously around 50 basis points. For 2023-2024, I expect around DKK 80 million in special items related to the ongoing integration of Atos. The net financial expenses for 2023-2024, I now expect around minus DKK 850 million impacted by interest expenses. No changes to our assumptions on effective tax rates, expected at around 22%.

Thank you very much. Operator, we are now ready to take questions.

QUESTION AND ANSWER SECTION

Operator: We will now begin the question-and-answer session. [Operator Instructions] The first question comes from the line of Jack Reynolds, RBC Capital Markets. Please go ahead.

Jack Reynolds-Clark
Analyst, RBC Capital Markets

Q

Hi there. Thank you for taking the questions. I had three, please. The first is on commercial costs. So, I'm just wondering where these are focused. Were they focused on Luja women or other products? And were they higher than expected and kind of how do you expect these costs to progress through Q4?

The next question was on the distribution center. Could you indicate the rough kind of size of the cost headwind here and how much you expect these costs to continue in Q4? And then, of course, whether you expect a rebound in kind of the lost Chronic Care revenues once these issues are sorted.

And then the third question is on guidance. So, given the higher costs in Q3, do you think that the low end of the margin guidance feels realistic? Thank you.

Anders Lonning-Skovgaard
Chief Financial Officer & Executive Vice President, Coloplast A/S

A

Yeah. So, thank you for the questions. Let me dive into it. So, our operating expenses for the third quarter, yes, we invested quite a bit into commercial activities to launch our products, and that was also included in Q3 and it's a bit more than we also included in the first half of the year. On top of that, as we have talked about, we have also included the cost related to the new distribution center in the US. So, in the quarter we included something around extra DKK 15 million and we are now expecting it will be around DKK 50 million for the year. So, it will increase to around DKK 35 million extra in Q4.

In terms of our guidance, so we are expecting to deliver within our guidance for the year, the level of 27% to 28% on the EBIT margin and delivering an organic growth of around 8%. So, that's what we are going to deliver.

Jack Reynolds-Clark
Analyst, RBC Capital Markets

Q

Okay, fair enough. Can I just follow up on the US Chronic Care? So, are you expecting a rebound in sales once these issues are sorted?

Anders Lonning-Skovgaard
Chief Financial Officer & Executive Vice President, Coloplast A/S

A

Yeah. So, what we've said previously was Chronic Care US is now in the second half of the year going to be sitting at around high-single digit from previously around double digit.

Jack Reynolds-Clark
Analyst, RBC Capital Markets

Q

Okay, great. Thank you.

Operator: The next question comes from the line of Anchal Verma, JPMorgan. Please go ahead.

Anchal Verma
Analyst, JPMorgan Securities Plc

Q

Hi, good morning. I have two questions, please. The first one is on the CMS decision for new codes for hydrophilic catheters, the fee schedule remains unchanged. I was wondering, were you expecting to achieve some premium pricing? And if so, are there any reasons why CMS hasn't offered a pricing benefit? So, is it fair to assume the tailwind will come from easier prescription and hence a potential volume uplift?

And then the second question would just be a bit more around your cost structure for next year, please. Can you provide some more color on the magnitude of improvements around COGS inflation you've seen thus far? And how should we be thinking about it going into next year? Are there any offsets we need to be mindful of?

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

Thank you for those. Let me speak to the CMS decision, and then Anders can speak to your question on COGS. So, we were really not expecting a change in the fee schedule. Of course, had there been a change, that would have been a double good news. But the draft didn't propose a change in fee schedule. So, for us, really the big news here is that CMS finally recognizes that technology matters. And this is just really good news for patients. It's really good news for anyone who cares about innovation.

And if you look at the – if you look back since reimbursement was established for intermittent catheters in the US, the fee schedule didn't make that distinction. And so, you've had really, what I'd call, a perversity in the US market where a lot of players were incentivized to basically offer patients [ph] all (00:24:44) technology that we would see in Third World countries. And this decision is a chance to change that. So, it rewards innovation, and it rewards companies that are concerned with that and not companies that are concerned with and preoccupied with selling cheap products.

Now, it's not a silver bullet. So, the code change and the reason that the CMS has proposed an implementation date of January 1 is that they recognize that this is not just going to happen, need to happen, if you will. For Medicare, this will need quite a bit of change across a very large number of commercial payers. So, there'll be a lot of work associated with that. But we will, of course, be focused hard on helping make this happen and that this becomes a reality and that the intent behind the policy also comes to fruition. So, net-net very positive news. We still have very large volumes of patients in the US market that are on uncoded products, and they really shouldn't be.

Anders Lonning-Skovgaard
Chief Financial Officer & Executive Vice President, Coloplast A/S

A

Yeah. So, thanks, Kristian. Then to your second question around, you can say, cost development into the next financial year, so I would say that the moving parts that we talked about at the Meet the Management early June still stands. So, I'm still looking into raw material prices are coming down as a result of lower inflation levels. As I said, we have also now hedged electricity prices at a lower level for next year compared to this year. And we will also continue to be prudent in terms of our spending across the organization.

We will continue to ramp up cost in Costa Rica. We will also see, you can say, negative impact from Kerecis as a result of their lower margin. And basically, the new thing compared to what we talked about back in early June, that is FX. FX is giving us more headwind also into Q4 than we saw earlier this year and especially driven by the

US dollar and some selected emerging markets currencies. But in general, the main drivers that we're looking into from this year into next year, as we described early June, still stands.

Anchal Verma Q
Analyst, JPMorgan Securities Plc

Thank you. And just a follow-up while we're on the topic of costs, please, on the OpEx side, should we continue to expect higher commercialization costs and are the extraordinary costs related to the new distribution center in the US expected to continue into next year as well?

Anders Lonning-Skovgaard A
Chief Financial Officer & Executive Vice President, Coloplast A/S

So, my expectation, as I just said earlier, we are expecting something around DKK 50 million extraordinary cost split between Q3 and Q4 for this year. Moving into next year, we expect the challenges we are currently having at the distribution center to be solved, and we will not have any extraordinary cost. That's my current expectation.

Anchal Verma Q
Analyst, JPMorgan Securities Plc

Perfect. Thank you.

Operator: The next question comes from the line of Maja Pataki, Kepler Cheuvreux. Please go ahead.

Maja Stephanie Pataki Q
Analyst, Kepler Cheuvreux SA (Switzerland)

Yes, good morning. Thanks for taking my questions. I have two as well. And, first, I would like to get back to your growth, particularly looking at the Continence Care growth, which is very solid with the 8% growth. But following your very optimistic commentary at the Meet the Management and all the divisional heads, we're super excited about the reception of it, I'm a bit puzzled that we don't start to see the positive feedback being reflected in organic growth. Could you maybe give us an indication when you do anticipate or when you do expect to see an acceleration in Continence Care growth coming through because of the rollout of Luja? That would be my first question.

And then looking at – the second question will be around China. Could you give us just a bit of an update on what is happening in the market and whether you've got a bit of a better feeling for when that market could start to recover? Thank you.

Kristian Villumsen A
President & Chief Executive Officer, Coloplast A/S

Thank you, Maja. Two good questions. I'll say on Luja, I am still very optimistic. If you look at Continence Care last year, it grew 7%. The underlying continence category consists of three product areas for us. Intermittent catheters, which is the main category. It's the bowel category. And then it's a category of collecting devices. If you look at the underlying growth of the catheter business, it is sitting very well. And that's also why the entire category is up a full point compared to last year.

The male catheter is in 13 markets. It is right now shaping up to be the strongest launch we've ever done in Continence Care. And the female product is by now only in 4 markets. Remember, Maja, it's a chronic category. So, we're starting to wind up the flywheel. And this is the first point. But, of course, we're pushing hard that the product gets into as many customers' hands as possible. We are ahead of the launch plan that we have pretty consistently across all the markets that we're in, meaning that customers are voting in favor of Luja and the technology. So, this will, of course, continue into next year and the next strategic period.

On China, unfortunately, not much news to report. I'd say surgical activity levels are still robust across the different provinces in China. We're seeing decent patient enrollment coming into the business, but the spend levels and the patient values are still depressed compared to pre-COVID. And I've now taken the stance that I'm not going to get more positive until I can actually see it in our numbers. So, I'm still looking at a Chinese business that's sitting around mid-single digit for this year. And then once we get to the end of the year, we'll start talking about guidance for next year. But right now, I'm not seeing a lot of reasons to be more optimistic.

Maja Stephanie Pataki
Analyst, Kepler Cheuvreux SA (Switzerland)

Q

Okay. Kristian, maybe a quick follow-up on that, because you've also highlighted that you have three different kind of businesses in Continence Care. Maybe I'm wrong, but my recollection was that last year's numbers was negatively impacted due to some backorders on collecting devices. So, we're really lacking the comparable numbers. Could you give us a bit of an indication of what the underlying real Continence Care, so catheter sales growth was doing this year versus last year? Is it comparably up 50 bps or anything that we can actually really try to figure out what's going on? Thank you.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

No, so catheters are – they're meaningfully up, Maja, which is also why the entire category, the entire continence category is up by a full point. Catheters are growing fast and collecting devices that is also a relatively significant share of the category still is, of course, a drag on growth. It's about 15% of the total category with very limited growth in it. So, if you know that, I think you can back what we're saying about catheters.

Maja Stephanie Pataki
Analyst, Kepler Cheuvreux SA (Switzerland)

Q

Thank you.

Operator: The next question comes from the line of Niels Granholm, Carnegie. Please go ahead.

Niels Granholm-Leth
Analyst, Carnegie Investment Bank AB (Denmark)

Q

Thank you for taking my questions. First question on the CMS decision. Can you talk about the degree of switching which takes place between the hospital and home care? So, what proportion of patients would you estimate [ph] are still being (00:33:19) switched back to uncoded as they return to home care?

My second question is just a kind of housekeeping question on the calculation on your organic growth. Is it correctly understood that you exclude product rationalization from the calculation of your organic growth? Thank you.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

Thank you. Thank you, Niels. If you look at the market now in the US, you still probably have about 60% of volumes that are uncoded. I don't have accurate data because on the switching, that takes place because we don't run those businesses. We just know that it's happening. And you can also see from the fact that a large number of the distribution players have had a focus on driving uncoded technology and uncoded brands. I don't know the exact amount of what that is. We just know it's significant.

And about the whole, if you will, strategic opening that's coming now is that once the market is educated on these new codes that this, in effect, becomes impossible. So, the net-net impact of that, we don't know what it is yet, but we will, of course, invest heavily with the commercial muscle that we have to drive the conversion also to the new codes. Yeah, Niels, yeah.

Niels Granholm-Leth Q
Analyst, Carnegie Investment Bank AB (Denmark)

But would you expect the distributors to absorb the entire margin compression that they would experience when more patients move to coded going forward?

Kristian Villumsen A
President & Chief Executive Officer, Coloplast A/S

Well, if you decide to serve the demand, I mean, you're going to have to. So, of course, and, Niels, this then becomes a question on what will happen with the distribution landscape. And I think there you will see some level of consolidation on how many people will participate in that game. But that notwithstanding the companies or the distributors that have partnered with us and have had good growth with us also have profitable growth, even if you will, the hydrophilic margin that they get.

Niels Granholm-Leth Q
Analyst, Carnegie Investment Bank AB (Denmark)

Okay.

Anders Lonning-Skovgaard A
Chief Financial Officer & Executive Vice President, Coloplast A/S

All right. Niels, then to your second question around the product rationalization now beyond the Voice and Respiratory Care, it's related to the divestment of a small company we did end of Q1 called MC Europe that is reflected here.

Niels Granholm-Leth Q
Analyst, Carnegie Investment Bank AB (Denmark)

Okay. Thank you.

Operator: The next question comes from the line of Veronika Dubajova from Citi. Please go ahead.

Veronika Dubajova Q
Analyst, Citi

Yeah. Hi guys. Good morning, and thank you for taking my questions. I have three, please. Just wanted to circle back, Kristian, to kind of how quickly you think this reimbursement change can translate into that change in the prescription paradigm. And I guess how much investment in education will you need to do on the physician level to ensure that the scripts are written for the correct codes and that physicians understand the value of the hydrophilic category? So, apologies, it's just sort of a multi-part, but if you could talk through what you specifically as Coloplast and as industry need to do to do that and how long you think that might take, and how much investment that might necessitate, that would be helpful as a starting point.

And then sort of related to that, I guess, obviously your catheter business is both a wholesale and a distribution business. And so, maybe from that hat of a distributor, if you can talk through whether you think there might be some backlash from some of the distributors towards your product, given that you are the player who's most actively pushed for this change, that will be a detriment to their profitability. So, that's my second question.

And then my third question is on Kerecis and the 35% growth rate. I think when we started at the beginning of the year, your ambition had been to grow a bit more than that for the year. Just curious if you think there's anything you can do to get that growth to accelerate as we move into the fourth quarter and into next year, or this is it and given the changes in the market, we should be more anchoring towards a slightly lower growth rate here going forward. Thanks.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S
A

Yeah. So, Veronika, thank you for three good questions. I'll say on the catheter opportunity related to the CMS decision, we still need to work this through with our team on exactly how we're going to go – how exactly we're going to go about it. I'm not imagining that this would trigger a significant increase, if you will, in cost to do this.

We have a very sizable setup and a very sizable muscle in the US that for a long time has been driving the conversion to hydrophilic. And, of course, now we are now getting the tailwind from the authorities actually recognizing the distinction in technology that we've been talking about for, I think, the original reimbursement got introduced in 2008 or 2009, something like that.

So, we've been driving this for a long time. But it's not a – like I said in my opening remarks, it's not a silver bullet, right? So, the education needs to happen and you need to cover thousands of customers. You need to work through a very large number of payers. So, of course, it will be a prolonged push. But I think net-net, good news for patients, good news for people who believe in the technology.

To the second part of your catheter questions related to whether there's a backlash, remember that the work here has now been led by – it is a coalition of manufacturers. And I would say – I also think the distributors should be concerned that patients actually get on good technology. And this is also what CMS is basically spelling out now, that there is evidence that this hydrophilic technology does make a difference for a large number of patients. And, therefore, it deserves separate codes. But, of course, they are more expensive products, so they will put some pressure on margin.

On Kerecis, we're still on plan. We are seeing that on the LCD that it's a bit harder to initiate new accounts in the outside hospital setting. But we're still on plan. Acceleration on the business will come from, of course, a decision, hopefully a positive decision on LCD and then the continued commercial expansion as we get people up the productivity curve.

Veronika Dubajova
Analyst, Citi
Q

That's helpful. Thanks, Kristian. And do you think – can I just – going back to that first question, I mean, I guess the way to ensure that you get the right script written is, I mean, my question's really sort of, you are going to have to educate a different customer, right? I mean, I think you've been focusing your education on the patient. Are you going to have to focus more on the physician to make sure that they're writing the correct script, or you think...

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

We've been doing both...

Veronika Dubajova
Analyst, Citi

Q

...you can do that for patients? Okay.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

We've been doing both, Veronika, also historically. So, our strategy has always been, if you will, against or with a headwind from, if you will, a dealer incentive to vote for an uncoded product, the recipe has always been to drive demand, clinical demand and consumer demand. So, we've been focused on educating clinicians for many years and we will continue that process.

Veronika Dubajova
Analyst, Citi

Q

Okay. Thanks. And sorry, one final one quick reminder, what proportion of scripts are product-specific in the US market at the moment?

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

Very low.

Veronika Dubajova
Analyst, Citi

Q

Very low. Okay.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

[ph] We don't know (00:42:03).

Veronika Dubajova
Analyst, Citi

Q

Okay. Thank, guys, so much.

Operator: The next question comes from the line of Graham Doyle from UBS. Please go ahead.

Graham Doyle
Analyst, UBS AG (London Branch)

Q

Morning. Thanks, guys. Just a couple on – just following up from Veronika's questions there. In terms of your exposure in continence or in catheters, roughly how much is via Medicare versus, say, commercial insurers, presumably the vast majority? And then in terms of the mechanism under this new reimbursement, when it comes to the actual prescription, so it gets written for, let's call it, the correct code now, presumably there's still that sort of discretion – narrower, but still discretion in terms of which manufacturer the distributor then chooses, [ph] it's difficult (00:42:51) to know how specific that can get.

And then one quick one, given how speedy the proposal and update was, it's different but for this, say, versus the wound LCD, and we've seen some other LCDs withdrawn last week in other categories. Have you any sense as to when we might get an answer on that? Has there been any more discussion around it? And are physicians expecting a delay given we're already into late August now? Thank you very much.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S
A

Yeah. Thank you, Graham. So, the short answer on, if you will, the, payer distribution of the market is that we don't have a strong data on that. I can't look internally on all the plants that our distributor partners serve, but I would imagine that it probably follows the broader population distribution. And, of course, we still have to win. We still have to win with the brand.

But we have been winning with the brand for more than a decade. And this will now happen on the back of a Luja launch that our belief is that this will set a new standard in the category also in the US. And I'll just reiterate what I said earlier that the Luja launch is by now the most successful or fastest uptake that we've ever had in the catheter category. So, we feel optimistic about our position, and we'll make it tough to compete. On the LCD, we have no news to report. I'm still expecting that we get a decision sometime in the fall.

Graham Doyle
Analyst, UBS AG (London Branch)
Q

Right. Thank you very much. It was super helpful. Thanks, guys.

Operator: The next question comes 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'll just take one for now since most of my questions have been answered. Just on the supply disruption, can you maybe just elaborate a little bit on exactly what happened here? And just how sure are you that this will be fixed in Q4?

And just from an observation from one of your peers, they've been saying that they've taken market shares in the US in Ostomy Care. Is that also a part of the explanation why you might have seen a little bit of a weaker growth compared to your expectations here? That's my question. Thank you.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S
A

Thanks, Martin. Yes. So, the effort to consolidate two distribution centers into one, we've run into some, what I'll call, just operational snags. Of course, I'm not satisfied with this. We didn't plan for this. And whenever a customer places an order with us and we're not able to fulfill it, we're not living up to the basic promise that the company is making.

Yeah, I can assure you that the people who are responsible for this know that we are not satisfied with this. But we have a lot of people working on bringing productivity back up and we're already seeing productivity improve, and we are still expecting with everything that we know there that by the end of the quarter, we will be out of the woods and have a good performance again. I'm not seeing this related to the Ostomy sales in the US. I still see underlying good demand, yeah.

Martin Brenøe
Analyst, Nordea Bank Abp (Denmark)

Q

Okay. Thank you. Maybe just one quick follow-up.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

So, maybe, Martin, I'll just say maybe we just reiterate, we still see double-digit volume growth in our bags and plates business in the acute channel in the US, but this basically means that a lot of patients are coming out on a Coloplast product.

Martin Brenøe
Analyst, Nordea Bank Abp (Denmark)

Q

Okay, makes a ton of sense. Maybe just one quick question, also just reflecting on Anders' comment on FX and now we see a little bit of, let's call it, some unlucky event, and now you're reaching this EBIT margin of 27%, around that level, a little bit above, but still around 27%, that's a bit far away from 30%. That's my first sort of observation, that's quite obvious. But can you maybe just help us a little bit of how the trajectory of the EBIT margin expansion should look like back to the 30% also with flagging a little bit of some headwinds going into the next fiscal year? That would be super helpful. Thank you.

Anders Lonning-Skovgaard
Chief Financial Officer & Executive Vice President, Coloplast A/S

A

Yeah. So, Martin, let me take your question around that. So, I think I talked to some of the moving parts into next year earlier, and also at the Meet the Management back in June. So, it's clear that we are expecting that our margin will improve as a result of some of these moving parts, especially raw materials price levels are coming down, inflation levels are coming down. We continue to be prudent on costs and we expect that also to continue into the following years.

And then on top of that, we will also expect that the Kerecis underlying margin will improve. We have an ambition that the Kerecis business will grow on an average of 30% over a three-year period. And at the same time, we will improve the margin until 2025-2026 to 20%. So, those are some of the moving parts. But, of course, everything starts with the growth, and we are committed to deliver growth in the level of 8% to 10%. So, scalability across our P&L will also contribute to the margin. And so, we deliver the 30% into the next strategic period.

Martin Brenøe
Analyst, Nordea Bank Abp (Denmark)

Q

Got it. Very clear. Thank you so much, Anders and Kristian, for this.

Operator: The next question comes from the line of Aisyah Noor, Morgan Stanley. Please go ahead.

Aisyah Noor
Analyst, Morgan Stanley & Co. International Plc

Q

Hi, good morning. Thanks for taking my question. Just standing in for Rob Davies. One question I had was on the Women's Health business. Do you observe any changes in patient behavior based on your commercial efforts so far? And based on the demand trends you're seeing, could this business continue to be in decline in 2025?

And then second question is a really quick one on SenSura Mio Black. When do you plan to launch this in the US and have you been able to charge a premium for this product so far?

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

So, let me take those questions. The first one on Women's Health, I'm not really seeing a significant change in the dynamics in the category. The whole category is still depressed. It is a little too early. We have a large number of initiatives in motion, both on the sales force side, on the marketing side, on the education side. And, of course, I'm expecting that to also reap some results, but it's too early to judge.

But this will also impact the urology business moving into next year. So, the growth that we've seen historically from urology will not be as strong as it has been. But on the other hand, the 2% that we have in this quarter, we also believe it clearly is the trough. We were impacted also by backorders in this quarter and we're coming out of that.

To your question on SenSura Mio Black, could you just repeat the question again?

Aisyah Noor
Analyst, Morgan Stanley & Co. International Plc

Q

When do you plan to launch in the US for this product? And have you been able to charge a premium so far?

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

So, I will have to just – let me just check that. I think that we still have a couple quarters to go before we're launching in the US.

Aisyah Noor
Analyst, Morgan Stanley & Co. International Plc

Q

Okay, thank you.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

But I'll just revert with an accurate date, so you have it, you should not expect that the product comes with the [ph] premier launches and to (00:51:20) existing price structure.

Aisyah Noor
Analyst, Morgan Stanley & Co. International Plc

Q

Okay, thank you.

Operator: The next question comes from the line of Marianne Bulot, Bank of America. Please go ahead.

Marianne Bulot
Analyst, BofA Securities Europe SA

Q

Yes. Good morning. Thank you for taking my question. Maybe two question. The first one on Heylo. Wondering how has been the feedback since the launch in the UK and if you had any update regarding Germany.

And second question on Wound Care, if we look at the Advanced Wound Dressing side, so where you had the 10% organically, just wondering if there is any specific region that was stronger that led to this 10% growth. And maybe if you had a feedback as well on the US launch of the Silicone Fit franchise. Thank you.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

Thank you, Marianne. So, quickly on Heylo, early days. Remember this is going to be a long category build. So, we're deep in the education effort of both patients and healthcare professionals in the UK. We're tracking well in the UK. Still no answer from the German authorities who are delayed in their response. So, we don't know where this will land in Germany yet.

On Wound Care, as you'll recall from my opening remarks, the quarter is a little skewed by order patterns in Germany, ahead of a price increase in Germany. We're also getting good growth from emerging markets. So, you shouldn't expect as strong a quarter in Q4. I'm looking at a Q4 that's sitting at the mid- to high-single-digit type of range.

The launch of the Biatain Silicone Fit product in the US, still early days, but a good level of activity, good opportunity pipeline.

Operator: The next question comes from the line of Christian Ryom, Danske Bank. Please go ahead.

Christian Sørup Ryom
Analyst, Danske Bank A/S

Q

Hi. Hello, Kristian and Anders. Thank you for taking my questions. I have two as well. The first is to the CMS coding update. And given that this is first implemented on 1st of January, is there an opportunity that we might actually see a differentiation in the fees for the different categories when the fee schedule for that year is announced in, I would imagine, about a year's time?

Yeah. And maybe as a tag on to that, I would think from the discussion that we've already had on this call, that we could expect some lobbying from distributors, arguing that they should have – get a higher reimbursement level for the coded categories. So, is that a sort of a possible outcome? That's the first question.

And then the second question is to the gross margin. So, when I try to back out the acquisitions of Atos and Kerecis from the gross margin in the quarter, the gross margin is still below 66%, whereas if we go back to the period prior to these two acquisitions, it was sort of comfortably in the range of 67% to 69%, so 1 to 3 percentage points higher. Anders, can you talk about what's the main delta versus where you were at that time and how plausible the pathway back for the, say, old Coloplast excluding Atos and Kerecis to that gross margin level? Thank you.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S
A

Thank you, Christian. Two really good questions. Yeah. So, the – I think the reason that the CMS has put in place now an implementation period for Jan 1, 2026 is that they recognize that the change here in coding will affect a lot of commercial payers also. I don't have at this stage an indication that we're going to be looking at a different fee schedule. Of course, I'd welcome that.

But I don't have an indication that that will happen. In fact, the CMS document quite explicitly says that there's no change to the fee schedule. So, if that happens, it will be, of course, a welcome development on our part, either through an increase in hydrophilic reimbursement or, if you will, a decrease in non-coded.

I think the rational system, of course, would pay more for modern technology than it would for old technology. Our view has always been, Christian, that the current reimbursement levels were adequate to support modern technology, and that the perversity of the US system was that it didn't distinguish between modern and old technology. And that comes in now and that I think is also what will drive the change, that it will be significantly more challenging to drive this switching behavior. But, of course, this assumes that we can educate the market, physicians and consumers still.

Anders Lonning-Skovgaard
Chief Financial Officer & Executive Vice President, Coloplast A/S
A

Yeah. And, Christian, let me take your second question around the gross margin. And, yes, before acquisitions of Atos, Kerecis, our gross margin for the remaining part of the business is down in the level of 2 percentage points. And it is really driven by the significant higher input costs that we have seen over the last couple of years, higher energy, high inflation in Hungary, and also the ramp-up of cost at Costa Rica. So, that has really impacted our gross margin for our, you can say, main business.

And when we look ahead, that's also why we are becoming optimistic that the inflation levels are coming down, energy are coming down, and also the salary levels. I also have an expectation that it will come down to lower levels into 2025. So, that's how we see it. And the price increases we have actually experienced over the last couple of years have not been able to compensate for these significant price increases on the input cost.

Christian Sørup Ryom
Analyst, Danske Bank A/S
Q

Great. That makes sense. Thank you very much.

Operator: The next question comes from the line of Shubhangi Gupta, HSBC. Please go ahead.

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

Hi, thanks for taking my question. My first question is on Continence Care. So, could you give us a split of volume versus price increase in Continence for Q3? Was there any increase in reimbursement prices? And also regarding the new policy on catheters, you have mentioned that 70% of your catheter revenues is from hydrophilic, and some of your peers have mentioned about 60%. So, when it is already the predominant type of catheter, so what really is the advantage from this policy? It's just the volume increase from prescription.

And second on your midterm margin targets, for Kerecis, you're expecting over 20% in 2025-2026. So, how much of that is dependent on the top line growth?

And third on China Ostomy Care business, which has been weak for quite a while now. So, is there some loss of market share? Could you help understand what exactly is happening there? Thank you.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

Thank you. Let me see if I remember all of what you've asked for. So, if you look at the Continence Care growth, it's driven by growth across the SpeediCath portfolio, but mostly by the new launches. So, this is Luja and it's the recent [ph] Set (00:59:45) launch that we have. And in addition also really good growth from the SpeediCath portfolio in emerging markets.

We have, and I'll remind you that, of course, we have higher pricing on Luja. So, there is a mix effect in the growth also. But the – when I look at the launch performance, we are well ahead on value, we are well ahead on volume.

If I look at the – I think the second question was to the distribution of volume and value of our business in the US. When we say [ph] IC or (01:00:24) coded technology in the US, 70% of our business is on that, but that's not volume. That's a value number. I'd say if I look at the market today, our assessment, about 60% of that market still needs to be converted. So, there are a lot of patients who are on old technology, and there's been a lot of people in that market who've invested in driving old technology.

So, of course, this should change. And more than anything, I think it will be driven by a change in volume. So, more patients will, in effect, come onto hydrophilic technology. It will be much, much more difficult to switch people away just given the dedicated codes.

And then the final question you had on Ostomy China, is so, like I said to an earlier question, a pretty good activity if I look at surgeries and the inflow of patients, much more cost conscious consumers, a way more challenging consumer channel, where some of the local low-cost players are picking up some share. And so, that is part of the game now when Chinese consumers are where they are. And I'm really not willing to become more positive until I can see it in the actual behavior by the Chinese consumers. So, this is still a business that's sitting at mid-single digit, mid-single digit plus for now.

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

Q

And the one on your midterm Kerecis margin, how much of that is dependent on top line, especially if there is a possibility that the product might not be covered under Medicare?

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

A

I'm sorry, I'm not getting that question. What's the question?

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

Q

So, you have mentioned you are expecting 20% operating margin for Kerecis in 2025-2026. So, how much of this is dependent on top line? Yeah.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S
A

Well, of course, the business needs to continue to grow. And so, we need to continue to grow at a CAGR of 30%. We need to deliver that. This is a business that starts with a very favorable gross margin position. So, it also – it scales very favorably, but we need the growth. It's not a cost exercise. Yes.

Operator: The last question comes from the line of Marco Cox from Barclays. Please go ahead.

Marco Pires-Cox
Analyst, Barclays Capital Securities Ltd.
Q

Hi there. Marco from Barclays speaking on behalf of Hassan Al-Wakeel. And most of my questions have already been asked, but I just had one follow-up question on Kerecis. So, you mentioned the fact that you're seeing it harder to initiate new accounts outside of the hospital setting. I was just wondering to what extent do you see this. Is it only minute or are you starting to see it slow down at a faster rate?

And following on from that, how strong do you think Kerecis is in other indications such as vascular and pressure ulcers? And has there been any change in your thinking about how you can use your sales force to increase sales in other indications away from [ph] DFUs and DLUs (01:04:09)?

And further to that, one of your peers talked about actually launching outside of the US with their biologics portfolio as early as H2 this year. So, I was wondering if there was any change in your thinking there as well on the timeline to launching outside the US, given a potential drag in the US we could see from the reimbursement changes. Thank you.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S
A

Yeah, so good questions. So, when I look at the account by account performance in the outside hospital setting, we're not losing accounts. So, the accounts that we're doing business with already are staying with Kerecis. We have good relationship there and good performance there. But we have had a couple instances where potential new accounts are basically awaiting a final decision on LCD. This doesn't, for now at least, materially impact the business.

Remember, this is just 20% of the current Kerecis business. The footprint is mainly in the acute setting. And it will also continue to be mainly in the acute setting. I am seeing a number of accounts in dermatology pick up, but we still continue to serve existing customers. Now, the product is indicated for all types of wounds and we have, I think, good clinical evidence to support it also in other indications. And I'm still seeing very strong inpatient demand in surgical wounds. Otherwise, we couldn't be growing at the rates that we're growing.

Marco Pires-Cox
Analyst, Barclays Capital Securities Ltd.
Q

And in terms of...

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S
A

Oh, OUS, you had a question on OUS. Yeah, so I think this is, of course, mostly relevant for people who have most of their business in the outpatient setting. We are doing some activities outside of the US, but our overwhelming focus is on succeeding in the US. And it will continue to be so.

Building up the next, if you will, the next portfolio of markets is going to be a pretty significant effort. We don't want to put the technology into the market if we don't have the appropriate pricing. And so, there will be a fair amount of clinical and market access work that need to go into play that it becomes an attractive category in Europe and potentially in some markets in Asia-Pac. But that's more for medium and long term when we look at it.

Marco Pires-Cox
Analyst, Barclays Capital Securities Ltd.

Q

Great. Thank you.

Kristian Villumsen
President & Chief Executive Officer, Coloplast A/S

Thank you, operator. This concludes the session, and thank you everybody for joining our call.