THOMSON REUTERS STREETEVENTS **EDITED TRANSCRIPT** COLO B.CO - Q2 2019 Coloplast A/S Earnings Call

EVENT DATE/TIME: MAY 02, 2019 / 1:00PM GMT

THOMSON REUTERS STREETEVENTS | www.streetevents.com | Contact Us

©2019 Thomson Reuters. All rights reserved. Republication or redistribution of Thomson Reuters content, including by framing or similar means, is prohibited without the prior written consent of Thomson Reuters. 'Thomson Reuters' and the Thomson Reuters logo are registered trademarks of Thomson Reuters and its affiliated companies.



CORPORATE PARTICIPANTS

Anders Lonning-Skovgaard Coloplast A/S - Executive VP & CFO Kristian Villumsen Coloplast A/S - President & CEO

CONFERENCE CALL PARTICIPANTS

Annette Lykke Handelsbanken Capital Markets AB, Research Division - Medtech Analyst Carsten Lønborg Madsen SEB, Research Division - Research Analyst Christian Sørup Ryom Nordea Markets, Research Division - Senior Analyst Craig Mcdowell JP Morgan Chase & Co, Research Division - Analyst Kate Kalashnikova Citigroup Inc, Research Division - VP Nyeok Lee Jefferies LLC, Research Division - Equity Associate Romain Zana Exane BNP Paribas, Research Division - Research Analyst Scott Bardo Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst Veronika Dubajova Goldman Sachs Group Inc., Research Division - Equity Analyst Yi-Dan Wang Deutsche Bank AG, Research Division - Research Analyst

PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and thank you for standing by. Welcome to today's interim financial statements for H1 2018-2019 conference call. (Operator Instructions)

I must also advise you that this conference is being recorded today, Thursday the 2nd of May 2019. And I would now like to hand the conference over to your speaker today, Kristian Villumsen. Please go ahead.

Kristian Villumsen - Coloplast A/S - President & CEO

Thank you very much, operator. Good afternoon, and welcome to our second quarter call of 2018-'19. My name is Kristian Villumsen, I'm the CEO of Coloplast and I'm joined here by our CFO, Anders Lonning-Skovgaard and our Investor Relations team.

The agenda is that I will take you through the business highlights. Anders will take you through the financial items and outlook, and then Anders and I will take the questions that you might have.

Please turn to Slide #3. Q2 was another strong quarter for Coloplast with 8% organic growth, a 12% increase in EBIT and ROIC of 44%. A few highlights include 6% organic growth in Europe, driven by solid growth across markets. We continue to see good momentum in our strategic growth drivers: North America and China. Our new launches, including SenSura Mio Concave and SpeediCath Flex are tracking well, and we continue to receive positive feedback from both users and health care professionals.

From a divisional perspective, Continence Care, Interventional Urology and Wound Care reported strong growth. Ostomy Care growth in the quarter was driven by solid growth in Europe, U.S. and China but negatively impacted by a high baseline in Emerging Markets and lower tender activity, primarily in Russia.



For the full year, we continue to expect organic revenue growth of around 8%, and we now expect the reported growth in Danish kroner of around 9% from previously 8% to 9%. We continue to expect an EBIT margin of 30% to 31% in constant exchange rates and a reported EBIT margin of around 31% in Danish kroner. We now expect a CapEx of around DKK 700 million versus previously DKK 750 million.

In France, the reimbursement review of Ostomy Care, Continence Care and Wound Care is still ongoing and a final decision has not yet been reached. We now expect the conclusion during our third quarter. In the U.S., I'm pleased to announce that we've won another important sole-source contract, this time with Kindred at Home, the largest home health agency with more than 700 locations in 41 states and an estimated market share on ostomy of around 5%.

The U.S. home health agency is playing an important role in patient's journey from hospital to home. Patients that have undergone ostomy surgery are discharged from the hospital after 3 to 5 days. And once discharged, approximately 2/3 of all patients go through a home health episode for a period of 1 to 3 months. In this period, generalist nurses typically visit patients in their homes and provide support and advice. Home health revenues only account for approximately 5% of our total ostomy revenues but they have important spillover effects on community sales. Our current market share in home health is estimated at 10% and with the Kindred at Home win, we expect to pick up most of their estimated 5% market share.

In U.S. ostomy, it's important to be winning in the hospital, in home health and in community through direct-to-consumer efforts. Taking more share in home health has been an important part of our plan for U.S. ostomy, and we are encouraged by the progress that we're making and this will support our growth ambitions in the U.S.

We're making good progress on our commercial investments into R&D and sales and marketing. To name a few large investment cases, we're moving ahead with important clinical work for our clinical performance program. In the U.K., our investments into Charter are on track and translating into market share gains. In the U.S., the sales force expansion in Continence Care is on track. In Japan and Australia, our investments into Continence Care on the back of newly introduced reimbursement schemes are yielding good results.

Today, the Board of Directors approved a half year interim dividend of DKK 5 per share corresponding to a total interim dividend payout of approximately DKK 1 billion.

Before I move to our financial results, I'd like to mention that we're hosting a Meet the Management event in London on August 20. The event will provide an update on our progress with the LEAD20 strategy as it moves in to its final year. It will also be an opportunity to meet with the wider management team at Coloplast and we look forward to meeting many of you in person in August.

Please turn to Slide 4. Revenues for the first 6 months grew 9% in Danish kroner and amounted to DKK 8.7 billion. In Ostomy Care, organic growth and growth in Danish kroner were both 7% for the first 6 months. Q2 organic growth was 6%. Growth continues to be driven by our SenSura Mio and Brava supporting products in larger markets like the U.K., France and Germany.

SenSura Mio Convex continues to contribute solidly to growth. Our new ostomy appliance, SenSura Mio Concave, has been launched in 15 countries and continues to receive positive feedback. The new product portfolio is increasingly contributing to growth. Our new SenSura Mio Baby & Kids portfolio has been launched in 6 countries. And just like the new hospital assortment, this portfolio should improve our position when competing for tenders and contracts, in particular, in the U.S.

Our SenSura and Assura portfolio growth was driven by satisfactory performance in Emerging Markets, particularly in China and Brazil. From a geographical perspective, we continue to see solid growth in Europe, the U.S. and China. Growth in Q2 was negatively impacted by lower tender activity in Russia, softer demand in our North Africa region as well as a strong comparison period.

In Continence Care, organic growth was 8% for the first 6 months and growth in Danish kroner was 10%. Q2 organic growth was 9%. The SpeediCath ready-to-use intermittent catheters continue to drive growth, and especially the Compact catheters performed well in France, the U.K. and the U.S. SpeediCath Flex continues to contribute to growth in Europe and the U.S. We also continue to see good growth on the SpeediCath standard portfolio, in particular, in the U.S. and Emerging Markets.



The new SpeediCath Navi hydrophilic catheter, which is specifically designed for Emerging Markets and lower-price mature markets, has been launched in Japan and is being launched in Spain and South Africa. We look forward to following these launches, and early customer feedback is encouraging.

Our Conveen collecting device portfolio posted positive growth due to satisfactory growth in France and the U.S. And finally, sales growth for Peristeen products remains satisfactory, driven by France and the U.S.

In Interventional Urology, organic growth was 9% for the first 6 months and growth in Danish kroner was 12%. Q2 organic growth was 10%. The growth was driven by sales of Titan penile implants and Altis single-incision slings in the U.S. We continue to take market share in the U.S. in these segments, and we continue to invest in sales and marketing activities.

Our Endourology business saw satisfactory growth in especially France and Germany. 2 weeks ago, on April 16, we received disappointing news from the FDA and we're ordered to stop selling and distributing our Restorelle DirectFix Anterior surgical mesh product intended for transvaginal repair of pelvic organ prolapse. The decision seriously limits the treatment options for women suffering from pelvic organ prolapse. Despite the positive efficacy and performance data that was included in our premarket approval, the FDA has determined that it did not contain sufficient evidence of long-term benefit compared to native tissue repair.

Coloplast has worked closely with the FDA to develop clinical evidence through the 522 studies. However, as FDA is aware, we've not yet had sufficient time to collect long-term data. We will continue to collect data and decide on a possible resubmission in the future. Global sales of the product represent 0.2% of group revenues, meaning that the financial impact is insignificant. We're currently executing on a plan to withdraw the product from the U.S. market as well as globally and here, it's important for me to emphasize that this is not a product recall and the FDA have not, in their decision, concluded that there is any product defect. We do not expect this decision to impact the U.S. product liability case regarding transvaginal surgical mesh product since the specific product was already involved in the litigation and has been from the beginning of the mass tort, and we believe most claimants have already come forward with their claims over the past 8 years.

We've settled more than 95% of the known cases, and we still view our provision as sufficient. We continue to see the litigation mature towards conclusion and we have a very limited number of litigation cases involving women that have had a Restorelle DirectFix Anterior mesh device implant.

Also we do not see a risk that this will lead to heightened regulatory scrutiny on the rest of our women's health portfolio. The 2016 FDA final orders, which reclassified transvaginal mesh used in pelvic organ prolapse repair and required the filing of PMAs has not been brought into question.

As a company, we remain committed to women's health and to providing treatment options for pelvic organ prolapse and stress urinary incontinence, and we're helping customers transition to alternative product solutions.

In Wound & Skin Care, organic growth was 10% for the first 6 months and growth in Danish kroner was 11%. Organic growth for Wound Care in isolation was 9%. Q2 organic growth for Wound & Skin Care and Wound Care in isolation was 9%. The growth in Wound Care continues to be driven by the Biatain Silicone portfolio in Europe where we're clearly taking market share. Markets like the U.K. and France posted solid growth. The newly launched Biatain Silicone Sizes & Shapes portfolio continues to contribute meaningfully to growth. China also saw good momentum driven by the Biatain formed dressing portfolio.

The U.S. Skin Care business contributed to growth in the first 6 months. Contract Manufacturing of Compeed also contributed positively to growth, helped by low comparative numbers last year, which followed inventory reductions in connection with the sale of the Compeed brand from Johnson & Johnson to HRA Pharma.

Turning to our geographical segments. We saw organic growth of 6% for the first 6 months in our European markets. The growth continues to be satisfactory across the portfolio of countries and in particular, in key markets like the U.K. and France. Organic revenue growth in other developed markets was 10% for the first 6 months. We continue to see solid growth in the U.S., driven by new product launches and the continued upgrade of the catheter market to hydrophilics.



Growth rates in Japan, Canada and Australia remain satisfactory. Revenue in Emerging Markets grew organically by 12% for the first 6 months. Growth was driven by markets like China, Brazil and Argentina as well as several smaller markets and for example, Central and Eastern Europe. As explained earlier, growth in our second quarter was negatively impacted by lower tender activity in Russia and softer demand in our North Africa region as well as a strong baseline which primarily impacted Ostomy Care.

With this, I will now hand over to Anders. Please turn to Slide #5.

Anders Lonning-Skovgaard - Coloplast A/S - Executive VP & CFO

Thank you, Kristian, and good afternoon, everyone. Reported revenue for the first 6 months increased by 9% compared to the same period last year. Most of the growth was driven by organic growth, which contributed 8% to reported revenue. Acquisitions contributed 1% to reported revenue, resulting from acquisitions of Lilial and IncoCare in Q2 last year. Foreign exchange rate had a positive impact of less than 1% on reported revenue, primarily due to favorable development in the U.S. dollar against the Danish kroner, which was partly offset by the depreciation of the Argentinian peso against the Danish kroner.

Please turn to Slide 6. Gross profit was up by 9% to around DKK 5.9 billion. This equals a gross margin of 67%, which was in line with last year. The gross margin was positively impacted by operating leverage driven by revenue growth as well as improvements in production efficiency. The gross margin was negatively impacted by the launch of new products, where the production economy is not yet fully optimized as well as high single-digit wage inflation in Hungary, restructuring costs and acquisitions. Restructuring costs for the first 6 months amounted to DKK 27 million. In the second quarter, restructuring costs amounted to DKK 10 million. The currency impact on the gross margin was neutral.

The distribution-to-sales ratio for the first 6 months came in at 29%, which was on par with last year. The 8% increase reflects increased investments across business areas and several markets. The admin-to-sales ratio for the first 6 months came in at 4% sales, on par with the recent trend. The 22% increase was mainly related to timing expenses within IT and legal. This year, for example, we are strengthening our CRM platform.

My expectation for the full year is that the admin-to-sales ratio will be around 4%. The R&D-to-sales ratio for the first 6 months came in at 4% of sales, in line with last year. The 10% increase in R&D costs reflects a higher general activity level and investments into the MDR preparations. Other operating income and expenses amounted to a net income of DKK 41 million in the first 6 months against DKK 29 million last year. The increase was mainly related to a DKK 16 million on sale of former production facilities in Denmark.

Overall, this resulted in an increase in operating profit of 10%, corresponding to an EBIT margin of 30%. The currency impact on the EBIT margin was neutral. Operating cash flow amounted to DKK 1.2 billion compared with DKK 1.4 billion last year. The decrease is primarily explained by an increase in working capital due to increased inventories related to Brexit and timing of orders and payables between quarters as well as increase in tax payments due to lower tax deductions this year in connection with the U.S. mesh litigation.

Cash flow from investing activities was impacted by capacity expansion in machines to produce new and existing products as well as the establishment of production facilities in Costa Rica. CapEx investments amounted to DKK 273 million for the first 6 months, down DKK 54 million compared to last year due to timing of investments. As a result, the free cash flow was an inflow of DKK 1 billion against DKK 811 million last year. Our cash conversion in Q2, calculated as a 12-month trailing average, was 96%.

I'd also like to mention that the second part of the approved share buyback program of DKK 500 million was initiated in Q2 and is expected to be completed in Q4.

Please turn to Slide 7. For '18-'19, we continue to expect revenues to grow around 8% organically, and we now expect around 9% growth in Danish kroner. Acquisitions are expected to contribute 0.4% to reported growth. Our guidance assumes stable growth trends across our regions as well as continued positive impact from new product launches and commercial investments.



For the full year, we expect Emerging Markets growth to be just under 15%. This is due to the lower-than-expected demand in our North Africa region. Our expectation is that the lower tender activity in Russia that impacted Q2 negatively, will resume in the second half of the year. We continue to expect mid- to high single-digit growth for the Wound Care for the full year.

Our guidance assumes an annual negative price pressure of up to minus 1%. As Kristian explained earlier, the reimbursement revenue in France in Ostomy, Continence Care and Would Care is still ongoing. We expect an outcome during our Q3. And at this stage, we still expect an impact this financial year. We have seen a smaller reform in Switzerland and pricing pressure among health insurance companies in Holland. For '18-'19, we continue to expect an EBIT margin of 30% to 31% in constant currencies and around 31% in Danish kroner. The revenue and EBIT guidance in Danish kroner is impacted by the appreciation of the U.S. dollar against the Danish kroner. The currency impact is based on spot rates as of May 1.

On our operating expenses, we expect broadly stable trends in '18-'19. We will again invest up to 2% of sales in incremental investments into innovation and sales and marketing initiatives in the U.K., Emerging Markets and the U.S. across all business areas. Most of the incremental investments were initiated in Q1. Hence, I continue to expect a quarterly phasing of investment similar to last year.

Higher growth from our new products launches still means pressure on the gross margin. But as previously communicated, we continue to relocate manufacturing out of Denmark to Hungary, and we will close the factory in Thisted in Denmark in June and reduce the number of production workers in Denmark to approximately 200 people in '18-'19.

We expect restructuring costs of approximately DKK 35 million this year compared to DKK 50 million last year. We expect high single-digit wage inflation in Hungary in '18-'19. Overall, our expectation is that the gross margin in fixed currencies will be in line with '17-'18.

The Global Operations Plan IV is on track and is still expected to deliver an EBIT margin improvement of up to 100 basis points in '19-'20 and 150 basis points in '20-'21. After the Thisted factory closes in June, we will have 1 innovation factory in Denmark and all ramp-up production will be done in low-cost countries going forward. We now expect our net financials to end the financial year 2018-'19 at minus DKK 100 million from previously minus DKK 75 million, primarily due to hedging losses on the U.S. dollar against Danish kroner as a result of the appreciation of the U.S. dollar against Danish kroner.

CapEx guidance for '18-'19 is now expected to be around DKK 700 million from previously DKK 750 million and is driven by investments in more capacity for new and existing products as well as the factory expansion in Costa Rica and the new distribution center in the U.K. Finally, our effective tax rate is expected to be around 23%.

This concludes our presentation. Thank you very much. Operator, we're now ready to take questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And your first question comes from the line of Michael Jungling from Morgan Stanley.

There is no response from this line. We will pass to the next question. Your next question comes from the line of Kate Kalashnikova from Citi.

Kate Kalashnikova - Citigroup Inc, Research Division - VP

It's Kate Kalashnikova from Citigroup. So I've got 2 questions. One for Kristian and one for Anders. Question first, could you please tell us what gives you confidence that Coloplast can deliver its goal of double-digit growth in both Ostomy and Continence in the U.S. this year? And how successful Convex Flip launch has been? Is it fair to say that SenSuras do not immediately develop after surgery? The patients may not always know that there is a better product that they can switch to and this lack of awareness is holding up the growth little bit. And then the second question is for Anders. So Coloplast clearly has visible operational leverage benefits because of its strong organic growth and cost savings as well that you talked about.



Could you please talk about margin driver for this year and also next year? And when do you expect margin benefits to come through to the bottom line?

Kristian Villumsen - Coloplast A/S - President & CEO

Thank you, Kate. This is Kristian. To your first question about U.S. growth and our level of confidence, we have a good momentum. So the business is one that we expect to contribute double digit as our expectation. And we're now doing around high single digit in the U.S. As you know, we have now a stronger product lineup in the country than we've ever had. We've added a number of products to the ostomy lineup, most recently now with the Convex Flip product, which is the local version of -- or the local brand of our Concave product.

It's correct that this is not a -- not necessarily a discharge product. So this will be relevant for people who have often been discharged, for a period of time, have developed hernia. And, of course, it's our job to create awareness that this product is available. We create that awareness all through our traditional channels in the acute setting through the work that we do with health care professionals. But probably more importantly, all the work that we do through the care program and online and our direct-to-consumer offering is where we drive awareness of the product.

It's still early days for the launch. I'll say, globally, I'm very pleased with where Concave is at. It's contributing meaningfully to ostomy growth. And then the final thing I want to highlight for U.S. this year when it comes to momentum is also the win that we've had with Kindred.

This is particularly pleasing to me since we've -- as you all know, a while back, we also added Encompass. This is now the second win in home health. Encompass was #3 or 4 in that market, Kindred is #1. So this gives us more to play within, in the home health setting. I hope that answers your question. Anders?

Anders Lonning-Skovgaard - Coloplast A/S - Executive VP & CFO

Yes. So in terms of your second question around the EBIT margin. So if I start with '18-'19, so our EBIT margin year-to-date is 30%. This means that rest of the year, I expect an improvement in our margin in order to deliver on our guidance in standard currencies of 30% to 31%, but also to deliver reported margin of around 31%. The improvement is mainly coming from increased top line. Else I see a relatively stable cap costs or distribution costs for the remaining part of the year. So I expect to see a scale effect in the second half of the year just as we have seen in the last several years. Secondly, in terms of reported margin, I also expect that I will have a larger currency effect in the second half of the year than I had in the first half of the year based on the currency rates that we have else of the 1st of May.

In relation to next year, so '19-'20, so the outset for next year is, of course, where we will end '18-'19. So currently we're expecting that we will deliver a reported margin of around 31%. But it's also important to mention that our overall guidance is to deliver growth in the level of 7% to 9%, and we are investing for the upper end of that growth guidance. So we are willing to invest up to 2% of revenue in other extra sales-enhancing initiatives or in more innovation. But it's clear, else it has been through several years. We are seeing a scale effect throughout our P&L as you also are referring to.

On top of that, next year, we will -- I'm expecting to see impact from our Global Operations Plan IV that we've been talking to for some time. We are on track with the plan. The majority or the main contribution from that plan to our margin development is from the close down of our Thisted factory.

And as I mentioned earlier that we are on track, but I also expected to see contribution from procurement savings and also additional efficiency gains, especially across our volume sites. So I'm expecting that, that plan will contribute to [200] basis points next year and up to 150 basis points into 2021. So that's some of the main drivers for this year and also for our '19-'20.

Operator

And your next question comes from the line of Christian Ryom from Nordea Markets.

THOMSON REUTERS STREETEVENTS | www.streetevents.com | Contact Us



Christian Sørup Ryom - Nordea Markets, Research Division - Senior Analyst

I have a couple of questions. So my first is across both Ostomy, Continence and Wound & Skin. You mentioned the U.K. is a -- is one of the key drivers. And have you any clarity on to what extent growth in the U.K. may have been driven by customers, say, building up stocks ahead of Brexit? And that's my first question.

And then my second question, can you quantify the Russia impact so this delayed tenders I was talking about in the -- something in the area of 1% to the organic growth in Ostomy that you're missing out on this quarter due to the delayed tenders? And then finally, on the Restorelle withdrawal. Will there be any timing to or facing of the impact on revenue that we should be aware of across the coming year?

Kristian Villumsen - Coloplast A/S - President & CEO

I think those questions are for me. Thank you, Christian. So to the U.K. first. It's true. We're seeing good momentum from the U.K. business across business areas for the Chronic Care business, so both for OC and CC. We do not see significant changes in ordering patterns from consumer in Charter Healthcare. So we think that the momentum that we see in the Chronic Care business is driven by the initiatives that we've been doing in the product launches that we've put in place in the country. Remember, this has been one of our investment areas, in particular, into Charter. There is some level of purchases from the NHS supply chain for the Wound Care business that you will see in the number that we're reporting now, but even if you control for that, we still have a very strong underlying growth.

So the bottom line is not that much when it comes to the impact from Brexit preparations and purchasing patterns. Russia. Russia, I just want to make sure that everybody's on the same page with EM. We -- there are number regions that are actually pulling quite nicely in any -- so very good growth in LATAM, very good growth in Asia, very good growth from most of Eastern Europe. And then you've got this market in Russia where we have large tenders that move large volumes, particularly in Ostomy, where timing is pretty important.

So we expect tender volume to pickup for the remainder of the year. So we don't quantify the isolated effect of Russia, but the impact from North Africa comes on top of this. We do expect this to have EM come in and slightly below or 15% ambition this year. So there is some softness from North Africa that remains in the number. And then for Restorelle, the product is so small that the timing impact, I think, is negligible.

Operator

And your next question comes from the line of Annette Lykke from Handelsbanken.

Annette Lykke - Handelsbanken Capital Markets AB, Research Division - Medtech Analyst

I have questions in 2 areas. So first of all, in respect to the home health segment, how significant or how bigger part is this of the total U.S. market growth? And in this respect also, are there -- I mean, at least home health organizations context coming up soon? Or is it a general flow?

And do we see the same growth for this segment as for the rest of the market? And then a question to Anders on MDR. I assume that you have intense investments right now preparing for the deadline, May 2020. And should we expect that to sort of level off from, yes, May next year?

Anders Lonning-Skovgaard - Coloplast A/S - Executive VP & CFO

All right. Why don't I start with the question around the home health. Thank you, Annette. So home health is about 5% of the market in value in Ostomy Care. This growth in that part of the market of mid-single digits overall, that's home health overall. So you could say, the importance of winning presence in this channel is for the spillover effect into community, where much like you have to win in the hospital setting to win the NPD, you have to retain that NPD into the home health setting to ensure that the patient remains on your product until their home and on a good routine.



The momentum or the timing around contracts, so this is more of a commercial push-type thing. So these are opportunities that we've worked on for a long time. As you'll recall, we won Encompass a while back. And now Kindred is another important win, but it's through commercial work of maturing an opportunity to completion.

Annette Lykke - Handelsbanken Capital Markets AB, Research Division - Medtech Analyst

Okay.

Anders Lonning-Skovgaard - Coloplast A/S - Executive VP & CFO

And Annette, in terms of your second question around the MDR program, yes, we are investing in order to ensure compliance with the Medical Device Regulation. And we are investing and we initiated this investment last year and then they have moved into this year.

The majority of the cost that we have included is the proof in R&D. And the majority of the activities we're doing is within our urology space, but also, to some extent, within the Wound Care. And into '20 -- or '19-'20, I expect that it will start to be reduced, yes, as of May the next year.

Annette Lykke - Handelsbanken Capital Markets AB, Research Division - Medtech Analyst

Okay. Just one follow-up question to Kristian on home health. Is this home health segment also where patients are going to, he say, he has some sort of problems with leakage or in fact, he need a new type of ostomy bag.

Kristian Villumsen - Coloplast A/S - President & CEO

So the -- you have to think of this as, this is a place where a lot of different types of patients go. So the type of nursing that you meet there is not very specialized. So you have very, very few nurses in there who are ostomy specialists. So you meet generalist nurses. So this is not a -- generally a problem-solving space, if you will. For that, we provide access to the CARE program, which will then refer to specialist nurses.

Operator

And your next question comes from the line of Romain Zana from BNP Paribas.

Romain Zana - Exane BNP Paribas, Research Division - Research Analyst

Two. The first one will be on the [French] reform. I haven't seen any official proposal so far, but the media release where I'm talking about a potential 20% cuts in pricing. Is such cuts realistic scenario in your view? And if not, what could be a reasonable assumption?

And last, how would you share this pressure with distributors? Or would it be like 50-50, would be -- would it be a fair assumption? Second question is [rather] on the margin and I was wondering how impactful on gross margin could be the rollout of Mio Concave in H2? That would be great to have a bit more granularity.

Kristian Villumsen - Coloplast A/S - President & CEO

Thank you very much for the question. When it comes to the French reform, I will just say this. There is a lot of noise around that entire process and a lot of numbers floating around many participants. So until that process has reached a conclusion, we don't see much reason to speculate what the final number will be.



As soon as we have visibility on that, we will let you know. And then to the same -- in the same vein, how that impact will be shared between us and other participants in the market will also have to be determined by the impact. But naturally, we would not expect that the manufacturers would bear all the burden.

Anders Lonning-Skovgaard - Coloplast A/S - Executive VP & CFO

And your question in relation to Concave. So we are in the middle of finalizing the transfer of the Concave -- or the last Concave machines out of the -- our factory here in Denmark. And that will be completed over the next couple of months. So on our group gross margin, I'm not expecting any significant negative impact into the second half.

Operator

And your next question comes from the line of Veronika Dubajova from Goldman Sachs.

Veronika Dubajova - Goldman Sachs Group Inc., Research Division - Equity Analyst

I'd like to start with talking about Emerging Market growth. And Anders, I think, thank you for the point of clarification in terms of thinking without saying that you expect growth to be under 15%. Can you help us understand what precisely is going on in North Africa?

And I guess, what degree of visibility do you think you have on EM growth, not just this year, but more conceptually as we think about the business over the medium term? It's been an important driver of growth for the company, but it's also had a lot of volatility. So if we can start there and then I'll have a follow-up after that.

Kristian Villumsen - Coloplast A/S - President & CEO

So Veronika, this is Kristian. It was me who remarked on the less than 15% and I did it with some pain. So I would love to be able to say that I have good visibility on the political development in North Africa, but the truth is, I don't. So we, as you know, have called out EM as an investment region and a growth region and they're also a region where we understand that one of the prices -- where price that you pay to participate is the exposure to volatility.

I think we've had our fair share or -- of the volatility over the last few years. We had a very serious political situation around Brazil. A few years back, we've had the oil price decline. We've had a very significant reform in Greece, probably the biggest reform that the country has ever seen. And so now what's happening in North Africa, I don't want to overplay it, but it does affect the growth on the margin and this is primarily Algeria.

The other moving part in the quarter is Russia, where my belief is that we do have better visibility on the tender pipeline and this has one to do with the timing, rather than underlying demand. And I'd say for your question around what level of visibility we have conceptually, it depends on the market that we talk about. So I'd say for Central and Eastern Europe, in general, pretty good visibility.

When we get to the Middle East and Latin America, we have more volatility and then, of course, I mean, you've all been following Russia over the past many years. That's also -- there's a bit of volatility there. China, that's our most important market. We have a very good visibility on the Chronic Care side. And the Wound Care business, there is a little more volatile and exposed because it's more of an acute business, but that's what I'd say. I hope that answers your question.

Veronika Dubajova - Goldman Sachs Group Inc., Research Division - Equity Analyst

Yes. That's helpful. I guess my follow-up to kind of leading on from that, I look at maybe a bit of the slowdown in EM. It is obviously outside of your control, but the business is slowing down this year a little bit.



You have a bit of headwinds from Restorelle. I know your guidance is for around 8% organic revenue growth. But as you think about your ability to be in the upper half of that 7.5% To 8.5% and an interval versus the lower half, any comments on that on the back of some of these headwinds?

Kristian Villumsen - Coloplast A/S - President & CEO

Well, you want to have for us to deliver at the high end of the guidance. You have to have all the regions pulling. Right now, there are some compensation for the slowdown that we have in Europe over in Emerging Markets from Europe. We have a very strong quarter, very strong YTD in Europe. But as you look forward, you want to have double-digit growth in North America, 5% to 6% growth in Europe. Our ambition level for emerging markets is 15% to 20% and Asia, also around the 20% range. Then you'll get to the high-end of the growth range, right? And so it does require us to have, if you will, all our horses pulling the carriage.

We have some optimism though for EM over time. And one of the reasons that we have, I think, optimism for the potential of, Veronika, is that until now, this is mainly an Ostomy business. We've worked quite hard to also have this become a Continence business and establish access for reimbursement for these categories. We've been working on that in Europe for the last 30 years and this is a category that's just emerging now in Emerging Markets. So I hope that, that is also going to become a significant portion of the EM growth going forward.

Operator

And your next question comes from the line of Yi-Dan Wang from Deutsche Bank.

Yi-Dan Wang - Deutsche Bank AG, Research Division - Research Analyst

Kristian, if we could get a little bit color on the underlying Ostomy growth, excluding the effects or the volatilities that you sometimes see in the emerging markets for the quarter, will be helpful for us to see how well some of these important new products are coming through in the space. And if you could also comment on the progress that you're making in the upcoming GPO contracts in the second half of the year, that would be useful.

Kristian Villumsen - Coloplast A/S - President & CEO

Thank you, Yi-Dan. So listen, when I look at the Ostomy business, it's healthy, right? So if I look at how the business is doing in Europe, it's growing at a healthy clip. It's the new products that's helping us drive growth. So Convex continues to drive growth. Concave is also now quite a meaningful component of that growth. In the U.S., we'll continue to take share.

We're not getting quite as much growth as I would like to see, but I'm hoping this will pick up now with the Kindred, right? We're a high single digit in the U.S. And in Asia, Ostomy is growing very significantly and contributing to -- contributing well to group. So I look at the franchise and I'm quite pleased with where we are. And then we have some headwinds in North Africa and a bit of timing on Russia that affects us this quarter. So overall, healthy.

On the GPO side, well, this is a process. It's coming up this fall. We're deeply engaged in this process, and we're doing our best. We're doing our best to make sure that the process takes into consideration with the premier -- that's coming up now that the process takes into consideration the new technology that we put into the market and the share that we've gained. Concluding anything on that, I -- or projecting anything on that, I hesitate to do that. We've -- we're in a better position than we were the last time. So I'd like to think our odds are up.

Yi-Dan Wang - Deutsche Bank AG, Research Division - Research Analyst

Okay. So would you say that excluding the effects of Russia and North Africa, the underlying run rate of the Ostomy business will be similar to what we saw in the last few quarters? Or has it actually picked up a little bit more compared to those quarters?



Kristian Villumsen - Coloplast A/S - President & CEO

I'd say it's similar to the -- what we've seen in the previous quarters.

Operator

And your next question comes from the line of Scott Bardo from Berenberg.

Scott Bardo - Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst

So I just really want to follow on from your comments on Ostomy, North America, please, Kristian. And I guess, I'd make sure my question is, you've had aspirations as a company to grow double digit in Ostomy in the U.S. for many years, if I can recall and you invested very heavily on your CARE program. You've won some business with Cleveland Clinic and you also mentioned you're moving to home care.

You're still growing well, but you're not quite at that level. So I want to understand a little bit more as what is the major detractor at the moment given the investments you've already made into achieving this double-digit growth that you aspire towards?

And following on from that, please. I understand clearly you're being opportunistic with some home health collaborations. Can you please remind us, if there's any differences or any read across between your previous foray in home health in the U.S. market, which didn't end that well to my recollection? So I wonder, is there any risk that you end up jeopardizing the big -- the bigger opportunity or causing friction, as I believe, it's the price -- the case previously?

Kristian Villumsen - Coloplast A/S - President & CEO

Scott, you're going to have to clarify what your second question is about. I'm not sure I understand that.

Scott Bardo - Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst

Sorry. Yes. So you were installing medical in North America market. That didn't end well, I understand. And I know that was more of an ownership structure. But I'd like to understand the move into home health this time, and why is that different? And why -- and I know, you're confident that won't represent any risk or competitive response that could impact the forward opportunity.

Kristian Villumsen - Coloplast A/S - President & CEO

Let me take that -- let me take up your last question first because we're not -- this is not us going into home health. This is us supplying products to home health. So we are winning a -- an exclusive contract with the biggest home health agency in the U.S. to supply OC products and this is a process that's been underway. It's much like the process and the win that we have with Encompass.

It's on the back of all the work that we've done on the product side and the service side under one solution, where these home health agencies are looking to us to help standardize on a good product platform and service. So you should look at this as us getting a larger share of the products that go into home health, not us running a home health agency in any shape or form.

On the OC side, I think we've -- it's true. We've been at this for a while. And you need a number of components to fall into the right place to be successful. You know that we've invested in product and getting a full portfolio into the market. You know that we have invested to gain a largest share in the acute setting.



We also are communicating today about the importance of actually getting a foothold in home health, right? And you all know about all the investments that we made over time into CARE and DTC to also increase our share in community. The final component is GPO. And we're, of course, working hard on that. And it's not that GPO is a silver bullet, but you need to play all of these 5 areas and have progress in all of these 5 areas, we think, for the breakthrough to follow. But I do want to say that, we are growing high single digit, double digit depending on the quarter that you look at. So we're continuing to take share, but, of course, we want more.

Scott Bardo - Joh. Berenberg, Gossler & Co. KG, Research Division - Analyst

Understood. And just a follow-up question, please, on the Continence Care business. I mean, obviously pleasing performance and continued to do well in this business. I am starting to see some of the more established players coming in with competitive products to SpeediCath on the hydrophilic catheter side and also on the Compact Female catheter side. And I just wonder if you could discuss a little bit whether you're seeing any change in the competitive environment at all and -- or any change or impact to your business is requiring a bit more activity and effort.

Kristian Villumsen - Coloplast A/S - President & CEO

Well, I'll say this. It's a competitive space. And it's true that there've been a number of product launches recently, and we are following those very carefully. As you know, we have also launched a number of products. And so we -- I wouldn't say that the space has been -- has become more competitive. It's the same type of players that I think are -- who have invested in innovation that are our classical competitors. I'm quite confident in the portfolio that we have at the moment. It's never been stronger, and there's more coming.

Operator

And your next question comes from the line of Carsten Madsen from SEB.

Carsten Lønborg Madsen - SEB, Research Division - Research Analyst

2 questions. First, on the mesh litigation. For quite a long time, you had stated that more than 95% of the cases has been settled. But how long time do we have to wait until you can say close to 100% or at least communicate something else than what you think you've been looking for some time now?

And then, what has actually changed along in the last decades because they are particularly difficult or particularly expensive? How should we read this? And then again, on the French reform, not only in France. So do you feel that you have sort of a closure or better dialogue or a better grip of the situation, a better understanding of what's going on and what will happen in France than what you had before you acquired Lilial?

Anders Lonning-Skovgaard - Coloplast A/S - Executive VP & CFO

So Carsten, if I should start. It was a mesh litigation. Yes, it's true. We have been communicating that we have been settling more than 95% for some time. We are working on finalizing the whole mass tort litigation. But it is taking some time to get the final cases sought. So I still expect that it will take 1 to 2 years before we are fully having this mass tort litigation behind us. I still believe that the provision we have is sufficient to close it down.

Carsten Lønborg Madsen - SEB, Research Division - Research Analyst

Okay.



Anders Lonning-Skovgaard - Coloplast A/S - Executive VP & CFO

And in terms of the other question...

Kristian Villumsen - Coloplast A/S - President & CEO

Sorry. Maybe a comment in Lilial, and maybe one more comment to make on the mesh litigation is that we are not seeing that the cases that are left are different than the ones that we've had before. It's the -- it's simply the pace, right?

So when it comes to Lilial, yes, it's true that, that gives us a seat at the table for the industry association of the home care companies and distribution companies in France. So -- and more access, but also we benefited a lot from the strong product positions that we have in these types of dialogues, but that also gives access.

Carsten Lønborg Madsen - SEB, Research Division - Research Analyst

As just with all the rumors about the potential price cuts and stuff it -- in relation to what you're putting into your guidance that would be. Of course, nice to know how close you are to the situation.

Kristian Villumsen - Coloplast A/S - President & CEO

So this is something that we follow extremely closely. We, of course, take this extremely seriously. We -- from our past experience, these are processes that are -- there'll be lots of numbers floating around and they're -- they are not done until they're done.

And so we don't really see good point in speculating about impact until we have something final. But I can assure you, we take it extremely seriously, and we are very, very deeply involved in the process.

Operator

And your next question comes from the line of Craig McDowell from JPMorgan.

Craig Mcdowell - JP Morgan Chase & Co, Research Division - Analyst

They relate to the acquisition announced earlier today of Acelity by 3M, just few questions around that. Firstly, could you confirm whether there was any interest from Coloplast in that asset?

Secondly, did you comment on what you expect any competitive impact from that acquisition? And how it might change competitive dynamics in Wound Care?

And finally, could you comment on your M&A ambitions or strategy, both in terms of acquisitions and disposals?

Kristian Villumsen - Coloplast A/S - President & CEO

Yes. So a few remarks. We -- of course, we saw the news. This is not something that we have participated in and basically because we're not active in the negative pressure space. We made a deliberate choice some time ago to not participate in that space. We are more interested in the traditional advanced wound [addressing] space. So that's where we are.



We are very much focused on Silicone. I do think that this means if you look at the category that 3M is taking a more serious position, which we, of course, will follow very closely. And when it comes to the question about our willingness to do M&A, we've communicated, I think, consistently for some time now that we are -- we're very willing to look at that given the scale of our Wound Care business right now. So I hope that answers your question.

Operator

And your next question comes from the line of Kit Lee from Jefferies.

Nyeok Lee - Jefferies LLC, Research Division - Equity Associate

I have 2 questions, please. Firstly, on the GOP4 plan you have. Do you still have restructuring charges for next year? And then, I guess a follow up on that would be the DKK 100 million -- sorry, the 100 bps margin improvement target you have for 2019-'20 from this plan. Is that net of the restructuring charge?

Anders Lonning-Skovgaard - Coloplast A/S - Executive VP & CFO

So in terms of our Global Operations Plan IV, as I mentioned earlier, we are on track. And we are expecting that, that plan into '19-'20 will contribute with around 100 basis points and up to 150 basis points into '20-'21.

I'm not expecting any additional or I don't expect any restructuring costs into next year. I expect that we will complete the close down of the Thisted factory this year, where the majority of the restructuring costs are related. So I don't expect any restructuring costs into next year in relation to the GOP4 Plan.

Nyeok Lee - Jefferies LLC, Research Division - Equity Associate

Okay. And secondly, on new catheter, the Navi for the Emerging Markets. What sort of pricing premium are you expecting compared to the nonhydrophilic in those markets?

Kristian Villumsen - Coloplast A/S - President & CEO

So Navi is moving into the hydro category. So in the markets where we have reimbursement for hydrophilics, it's playing at the same price point. And the real benefit that you get is that the -- in most of the Emerging Markets, the bulk of the procedure or the bulk of the usage that's happening is with the soft catheters our offering with our traditional SpeediCath is more of a stiff product. So we're basically catering to a larger share of the demand in the markets with the Navi. All right. Thank you for all your questions.

Operator

And your last question comes from the line of Yi-Dan Wang from Deutsche Bank.

Yi-Dan Wang - Deutsche Bank AG, Research Division - Research Analyst

I have a few more. This is on the contract wins that you've been having success with. Just wondering how long contracts normally last for in general in the market? If you could comment on your win rates versus expectations. It seems that your pop outs want the entire solutions offering, if I may say so. I...



Kristian Villumsen - Coloplast A/S - President & CEO

Are you talking U.S. now, Yi-Dan?

Yi-Dan Wang - Deutsche Bank AG, Research Division - Research Analyst

Yes. The U.S. yes, U.S. with products and services that the total solution is helping you to win these contracts. Just wondering how successful that is. Any -- there are contracts that you go for, but you don't win them. Why are you not winning those?

And then thirdly, given the success that you've been having, what kind of responses your competitors have that you've seen from your competitors? And if your competitors were to follow your strategy, if they haven't done so already, how long do you think you have this advantage for? And then finally, who was Kindred supplied by before? And when will this contract stop for you?

Kristian Villumsen - Coloplast A/S - President & CEO

So let me start with the last question. Kindred was mainly -- was something that was basically just won. And this was a Hollister kind of tech account and there's multiple players in there. And it's now become an exclusive Coloplast account. Exclusive means around 80% of the total volume in the account.

So, Yi-Dan, this is part of the competitive gain that happens in the category. You basically try to run the business to develop a value prop that's compelling to customers. This is our take that you need a value prop that has a strong product portfolio. We, of course, think that the product portfolio offering that we have is unique. It is unique at the moment also with the way that we can talk to Concave like no one else.

And then, of course, the service competent, we've worked on for a while. We haven't seen a similar offering from our competitors. And I don't know to what extent that they're working on it. But I can say this is something that we've worked on for years. When it comes to contracts and the duration of contracts, it's not standardized. This -- it depends on the customer in question, but they're typical multiple years.

Yi-Dan Wang - Deutsche Bank AG, Research Division - Research Analyst

And your win rates?

Kristian Villumsen - Coloplast A/S - President & CEO

Our win rates? How would I know? I -- we're taking...

Yi-Dan Wang - Deutsche Bank AG, Research Division - Research Analyst

Yes. So I think that win rates should be 100%, given what you're saying about your products and your services, but that clearly is not the case right now. So why are you not winning the others?

Kristian Villumsen - Coloplast A/S - President & CEO

So I couldn't give you a standard answer for that. We're winning so much that we're continuing to take share, but the account also has to be open and available for conversion, right?



So I think this is as much as we have time for today. But thanks a lot. And I hope I'll get to see many of you in -- during the next few weeks. Thank you.

Operator

Thank you. That does conclude your conference for today. Thank you for participating. You may now disconnect.

DISCLAIMER

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2019, Thomson Reuters. All Rights Reserved.

