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COLO B.CO - Q4 2019 Coloplast A/S Earnings Call

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PRESENTATION

Operator

Ladies and gentlemen, thank you for holding, and welcome to today's financial statements for the full year 2018- '19 and annual report 2018- '19 conference call. (Operator Instructions) I must advise you that this conference is being recorded today, on Tuesday, the 5th of November 2019.

And I would now like to hand the conference over to your first speaker today, Kristian Villumsen, CEO of Coloplast. Please go ahead, sir.

Kristian Villumsen - Coloplast A/S - President & CEO

Thank you very much, operator, and good afternoon, and welcome all to our full year '18- '19 conference call. I'm joined here by our CFO, Anders Lonning-Skovgaard and our Investor Relations team, and we will start up with a short presentation by Anders and myself, and then as we usually do, open up for questions.

Please turn to Slide #3. '18- '19 was yet another strong year with strong financial results with organic revenue growth of 8% in a market that's growing 4% to 5%. Coloplast maintains its position as one of the most profitable med-tech companies in the world, reporting an EBIT margin of 31% before special items and a return on invested capital of 48% before special items.

Expressed differently, we continue to make life easier for millions of people with intimate med health care needs and our growth means that we will continue to grow that number significantly again this year.

Our results also speak to the solid underlying performance across the business and our ability to consistently take share. Growth continues to be driven by innovative products like SenSura Mio Convex, SenSura Mio Concave, SpeediCath Flex and the SpeediCath Compact catheters as well as Titan penile implants, the Biatain Silicone portfolio and, of course, strong commercial execution throughout our organization.

From a regional perspective, Europe continues to perform strongly. The U.S. delivered double-digit growth and emerging markets came in at 12% growth. Going forward, given the high investment levels, we expect to see strong growth in the U.S. and emerging markets. In '19- '20, we will continue to prioritize investing for growth and invest up to 2% of revenues in incremental growth initiatives focusing, in particular, on China, the U.S. and the U.K. We will continue our efforts within the clinical performance program in Ostomy Care and Continence Care.



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We've now begun the strategy process leading up to the announcement of our new strategy in June next year. This is a very exciting process for myself and for the company, and we're aiming for a good balance of continuity and renewal. Today, the Board of Directors approved an ordinary dividend of DKK 12. In addition to the dividend of DKK 5 paid in connection with our half year results, this brings the total dividend for the year to DKK 17 per share compared to DKK 16 last year.

Our guidance for '19- '20 is an organic revenue growth and a reported growth in Danish kroner of 7% to 8% and an EBIT margin of around 31% in fixed currencies and Danish kroner.

Before we dive into the results, I'd like to walk you through the important decision that we've announced today regarding our Interventional Urology business. Please turn to Slide #4. Following a thorough strategic review of the Interventional Urology business, the management team, together with the Board, have decided that Interventional Urology, both fits well with the Coloplast's mission to help make life easier for people with intimate health care needs and the long-term aspirations of the group to create value through profitable growth in attractive growth markets.

Coloplast has proven to be a strong steward of the Interventional Urology business. And our belief is that the decision to keep the business is the best outcome for Coloplast and the Interventional Urology business. Our objective is to continue to invest into the business to derive even greater long-term value.

Taking a closer look at the strategic review, 4 key considerations led us to the conclusion. I'll touch on each of these in turn.

First, Interventional Urology is a large and rapidly growing market characterized by real unmet clinical needs. The underlying drivers of the market growth are demographics, the aging population and increasing demand for minimally invasive procedures. Coloplast is currently a market-leading player in 4 critical segments: Men's Health, Women's Health, Endourology and Specialty Interventions. We see significant longer-term growth opportunities within existing segments for continued innovation, treatment penetration and geographical expansion. Similarly to the situation in chronic care, we see demand from consumers and surgeons for less invasive solutions that are easy to use and reduce costs, and we see a similar need for physician education and patient awareness.

Today, within Men's Health and Women's Health, only a very small fraction of people suffering from conditions such as erectile dysfunction, stress urinary incontinence and pelvic organ prolapse are treated. The segment also affords opportunities to expand into adjacent Interventional Urology markets based on indications that are significant unmet opportunities. In other words, we're talking about strong clinical needs and, therefore, also lots of opportunity.

Second, the business has an attractive financial profile of high-growth and margin as well as return on invested capital, which currently sits above the group average. We have consistently outgrown the market, growing at 2 to 2.5x the market over the last 5 years, and we've steadily grown earnings. This is testament to a solid performance track record, which is a strong outset from which to develop the business further. We've made large commercial investments into the U.S. business over the past years, and the team has done excellent work translating these investments into growth. This year, we will initiate another wave of investments into innovation and commercial initiatives. In other words, this is already a great business, and therefore, a great platform for expansion.

Third, Interventional Urology is led by a strong experienced management team with extensive industry experience. The management team has elevated the business substantially over the past years, and the business has a deep bench with financial and operating discipline. As part of the strategic review, we've decided that it's the right time to make a leadership change to prepare the business for the next chapter. Last week, Steve Blum took over the role of Senior Vice President of the Interventional Urology business. Steve has been with our company for 3 years, delivering strong growth rates in North America as Head of North America Sales. He led our investments into North America with great results. Prior to joining Coloplast, Steve has 20 years experience in the medical device industry from Boston Scientific and AMS, both in global roles. I believe that Steve has what it takes to take our Interventional Urology business to the next level. In other words, this is a strong organization and leadership bench. And on behalf of executive management and myself, I'd like to thank, Steffen Hovard, for his contributions to the IU business through the years.

Now #4, with respect to the conclusion of the strategic review, having owned the business now for more than a decade, we have a clear understanding of the risks involved and the business has matured significantly from both the commercial, financial, organizational and risk perspective. Due to



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the different class of products, the business has different regulatory and clinical requirements, and we are committed to ensuring and investing for full compliance with these requirements. For example, significant investments are being made to ensure compliance with the new EU medical device regulation. As a result of the mesh litigation over the last 8 years, it is our view that the women's health business has been largely derisked. Having owned the business for 10-plus years, Coloplast has a clear understanding of the risks involved in this business and the understanding has matured significantly. The mass tort litigation is behind us, and there's very limited inflow of new cases in the women's health business. And in addition, we see limited litigation in the other Interventional Urology segments.

Within Women's Health, we see a large future strategic opportunity. After a period of low market growth, the women's health market has returned to mid single-digit growth in a largely underserved patient population that needs treatment options. Today, for example, less than 2% of women suffering from stress urinary incontinence are treated. Coloplast is well positioned in the market with a modern portfolio in a favorable competitive landscape with only one major U.S. competitor. Coloplast is focused heavily in physician training and a more robust patient consent process is in place compared to the past.

Regulatory requirements have increased. We've seen up-classification of certain products by the FDA, and there is a significant demand for clinical documentation. We are investing in 522 studies, premarket approvals and MDR compliance to meet regulatory requirements and the increased demand for clinical documentation. Now that the strategic review has been concluded, the path forward for our Interventional Urology business is to execute on the current strategy, which is centered around innovating to solve clinical needs, driving growth in existing segments, geographical expansion and the pursuit of adjacencies through business development and M&A.

Let me put a few words to that. Compared to recent years, we will increase the level of investment into R&D, and we will innovate for clinical impact with the aim of reducing the total cost of care.

In North America, we will continue to invest in patient awareness and physician education within Men's Health and Women's Health to grow the market and continue to take share. A key initiative in the U.S. over the next many years will be to develop a long-term competitive position for Endourology. We're currently on track to having 80% of the Endourology portfolio available in the U.S. in 2020.

In Europe, our strategy is focused on expanding and continuing to grow share in existing strongholds, such as France, Germany, U.K., Spain and Italy. In emerging markets, Interventional Urology has a broad reach today based on a distributor network and the strategy is to prioritize Tier 1 and 2 high-growth markets.

Overall, the outlook for the Interventional Urology business is strong and consistent with the excellent track record of historical performance. The business is set to deliver attractive growth and sustained profitability, and we're excited by the opportunities ahead of us. To sum it up, Interventional Urology is core to our mission and value creation.

Let's take a closer look at today's results now. Please turn to Slide 5. For the full year, our revenues grew 8% organically and 9% in Danish kroner and amounted to DKK 17.9 billion. In Ostomy Care, organic growth was 7% for the full year, and growth in Danish kroner was 8%. For Q4, organic growth was 7%.

Growth continues to be driven by our SenSura Mio and Brava supporting

products in larger markets like the U.K., Germany and U.S. SenSura Mio Convex continues to be the main contributor to growth driven by Europe. SenSura Mio Concave is now available in 16 markets and the portfolio continues to increase its contribution to the overall Ostomy growth. Our SenSura and Assura portfolio growth was driven by satisfactory performance in markets like China and Brazil.

Growth in Q4 was negatively impacted by the French price reform and a slowdown in demand in North Africa as well as weaker demand in Greece. In Continence Care, organic growth was 8% for the full year, and growth in Danish kroner was 9%. For Q4, organic growth was 7%.

The SpeediCath ready-to-use intermittent catheters continue to drive growth and especially, the compact versions performed well in countries such as the U.S. and the U.K. SpeediCath Flex contributed to the positive development, driven mainly by Europe and the U.S. SpeediCath Navi, our



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new hydrophilic catheters, specifically designed for emerging markets and lower price developed markets, has been launched in 4 markets. Our Conveen collecting device portfolio posted positive growth, driven by France and the U.S. And finally, sales growth for Peristeen products remains satisfactory, driven by France, Italy and the U.K.

In Interventional Urology, organic growth was 10% for the full year and

growth in Danish kroner was 13%. For Q4, organic growth was 11%. The growth was primarily driven by sales of Titan penile implants, the Axis Biologics portfolio and Altis single incision slings in the U.S. We continue to see an attractive return on the commercial investments that have been made in the U.S. over the last 2 years.

Our Endourology business saw satisfactory growth in Europe, driven primarily by sales of J.J. stents and ReTrace access sheaths.

Within Specialty Interventions, the biggest growth driver is our Elefant

suction and irrigation device for laparoscopy.

In Wound & Skin Care, organic growth was 8% for the full year, and growth in Danish kroner was 10%. Organic growth for Wound Care in isolation was 8% for the full year. For Q4, organic growth for the total business area was 6% and for Wound Care in isolation was 7%. The growth in Wound Care was driven by the Biatain Silicone portfolio in Europe, in particular in France and the U.K., and the Biatain Silicone Sizes & Shapes portfolio also contributed meaningfully to growth. Contract manufacturing of Compeed and the Skin Care business also contributed to growth.

Turning to our geographical segments. We saw organic growth of 6% for the full year and 5% in Q4 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 11% for the full year and 11% in Q4. The U.S. Chronic Care business posted double-digit growth for the full year, driven by new product launches and the continued upgrade of the capital market to hydrophilics. Growth in Q4 was positively impacted by a strong quarter for Interventional Urology. Growth rates in Japan and Australia remain satisfactory.

Now revenue in emerging markets grew organically by 12% for the full year and 11% in Q4. Markets like China, Argentina, Brazil and Russia continued to deliver very satisfactory performance. Growth for the full year was negatively impacted by weaker demand in the North Africa region and weaker demand in Greece following the reform last year.

On a separate note, before I hand over to Anders, I'm pleased to release our latest corporate responsibility report. A few noteworthy achievements this year include reducing occupational injuries by 30% to our all-time low. We also renewed our commitment to inclusion and diversity and broadened our definition of diversity. It's more than gender. It's also about generation and nationality. Today, only 50% of our teams live up to the diverse team definition and our goal is year-on-year improvement until we reach 75%. Our ambition is to raise the level of diverse teams year-on-year through natural turnover.

And finally, I'm proud that this year marks the first year we're using 100% renewable electricity at all our production sites. This is part of our continued efforts to minimize our environmental footprint. Going forward, we'll strive to do even more.

And with this, I will now hand over to Anders. Please turn to Slide 6.

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

Thank you, Christian, and good afternoon, everyone. Reported revenue for the full year increased by around DKK 1.5 billion or 9% compared to the same period last year. Most of the growth was driven by organic growth, which contributed DKK 1.3 billion or 8% to reported revenue. Foreign exchange rate had a positive impact of DKK 158 million or 1% on reported revenue, primarily due to the appreciation of the U.S. dollar against the Danish kroner. The parts of -- development was partly offset by the depreciation of the Argentinian peso against the Danish kroner.

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Please turn to Slide 7. Gross profit was up by 10% for the full year to around DKK 12 billion. This equals a gross margin of 68% compared to 67% last year. The gross margin was positively impacted by operating leverage, driven by revenue growth and improvement in production efficiency through the GOP4 program. The gross margin was negatively impacted by product mix and high single-digit rates inflation in Hungary. Restructuring costs amounted to DKK 43 million compared to DKK 50 million last year. The full year impact from currency was neutral. In Q4, the gross margin was positively impacted by the closure of the factory in Thisted in Denmark in June this year.

The distribution-to-sales ratio came in at 29%, which was on par with last year. The 10% increase reflects an increase in investments in sales and marketing activities across a number of markets in Chronic Care, Wound Care and Interventional Urology. Overall, the majority of the new investments remain on track. In Q4, we made additional commercial investments into Interventional Urology business in the U.S.

The admin-to-sales ratio came in at 4% of sales, on par with the recent trend. The 16% increase in admin costs relates to an increase in cost within IT and legal as well as DKK 15 million related to the strategic review of the Interventional Urology business.

The RD-to-sales ratio came in at 4% of sales, in line with last year. The 8% increase in R&D cost reflects a higher general activity level to drive the clinical performance program and investments into MDR preparations.

Net other operating income amounted to DKK 58 million compared to DKK 39 million last year. The increase was mainly due to a DKK 16 million gain on sale of former production facilities in Denmark.

Today, we announce that the provision for the mesh litigation has been increased by DKK 400 million. The mesh litigation is in its final phase, and we have settled more than 95% of the known cases. But it is taking longer time to resolve outstanding cases, which has led to an increase in cost and legal spend. It is very important to emphasize that the increase in the provision is not driven by large inflow of new cases. The number of filed cases is stable and inflow is limited. The DKK 400 million increase in provision is booked in Q4 as special items. The total provision now amounts to DKK 5.65 billion, and it's our current best estimate of the costs associated with resolving all the lawsuits.

For the full year, our operating profit before special item increased by 9% corresponding to an EBIT margin before special items of 31%, on par with last year.

Operating cash flow amounted to around DKK 4.4 billion, which was on par with last year. The flat development was mainly due to an increase in tax payments due to lower tax deductions this year in connection with the U.S. mesh litigation. Cash flow from investing activities includes capacity expansion in machines to produce new and existing products. CapEx investments amounted to DKK 636 million, down DKK 33 million compared to last year. CapEx to sales amounted to 4%. As a result, the free cash flow was an inflow of DKK 3.8 billion, up 10% from DKK 3.4 billion last year. Our cash conversion for the full year was 98%.

Net working capital amounted to 24% of sales on par with the start of the year.

With respect to the mesh litigation in the U.S., total mesh payments for the full year amounted to DKK 0.4 billion. Total mesh payments to date amounted to DKK 5.1 billion.

Full year return on invested capital after tax before special items was 48% against 44% last year.

Please turn to Slide 8. For '19- '20, we expect revenues to grow 7% to 8% organically and 7% to 8% in Danish kroner. Our guidance assumes stable growth trends across our regions as well as continued positive impact from new product launches and commercial investments. Our guidance assume an annual price pressure of up to minus 1 percentage point. We expect price pressure to be closer to the full 1 percentage point for '19-'20 due to the French price reform within Ostomy Care and Continence Care, which was implemented in July. We have successfully mitigated half of the impact from the 9% price cut. We're also seeing price pressure from smaller reforms in Switzerland and Holland. The guidance in Danish kroner reflects a positive impact from the appreciation of the U.S. dollar and British pound against the Danish kroner, which is partly offset by the depreciation of the Argentinian peso and the Brazilian real against the Danish kroner. The currency impact is based on spot rates as of November 4, 2019.



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For '19- '20, we expect an EBIT margin of around 31% in fixed currencies and in Danish kroner. On our operating expenses, we expect broadly stable trends into next year. We continue to invest for growth and invest up to 2% of sales in incremental investments into innovation and sales and marketing initiatives in, for example, China Ostomy Care, U.S. Continence Care, Interventional Urology and the U.K. The gross margin will be positively impacted by operating leverage and the global operations plan for, which is on track to deliver 100 basis points EBIT margin improvement in 1920. The positive impact is expected to be partly offset by cost pressure in Hungary. We continue to see high single-digit rates inflation in Hungary. And given labor shortage in Hungary, we have hired a large number of production employees from Ukraine, which has put pressure on cost. We will not incur any restructuring costs in '19- '20 compared to DKK 43 million in '18- '19.

Overall, the expectation is still that the gross margin will improve in '19- '20 compared to '18- '19. We expect our net financials to end the financial year '19- '20, at minus DKK 100 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 '19- '20 is expected to be around DKK 850 million and is driven by investments in more capacity for new and existing products as well as the factory expansion in Costa Rica, optimization initiatives and IT investments into digitalization. Finally, our effective tax rate is expected to be around 23%.

This concludes our presentation. Thank you very much. Operator, Kristian and I are now ready to take questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from the line of Patrick -- sorry, of Sebastian Walker of UBS.

Sebastian Walker - UBS Investment Bank, Research Division - Associate Analyst

I've got 2, if I could. First, just on growth, so does the 7% to 8% between '19- '20 assume improving momentum in the rest of the world region, I think, Kristian, you mentioned expectations of improving growth. What gives you confidence that we'll see that come through?

And then secondly on margin guidance, I'm kind of surprised that you don't expect an improvement in EBIT margins given the manufacturing and restructuring costs are largely complete and we should see those GOP benefits falling through. So how large, I guess, are these Interventional Urology investments that you're planning on making?

Kristian Villumsen - Coloplast A/S - President & CEO

Sebastian, why don't I talk a bit to your question on growth, and then Anders will comment on the question on margin. It is correct that we expect that our emerging markets region should improve next year. There's actually quite a lot that's going well for us in EM. The China business is doing very well. Our Latin America business is doing very well. Our Eastern European and Russia businesses are doing very well. But we've had the headwinds like that we've talked about in North Africa and to some extent, also Greece that we've talked about. So we expect that we will continue to give momentum in the regions that I've talked to and that the work that we've done in (inaudible) will result in better performance next year. And of course, mathematically, we also expect that if you work in (inaudible) and have the baseline from this year, you will show better numbers next year. I hope that clarifies. Anders?

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

Yes. So in terms of our margin assumptions for '19- '20, so we are expecting to deliver an EBIT margin of around 31%. And as we are expecting to grow between 7% and 8% organically, we are also expecting leverage effect throughout our P&L. I'm also expecting, as I said earlier, that the Global



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Operations Plan 4 will contribute to the margin development. We actually already saw a bit of contribution in our fourth quarter. But some of that contribution from our Global Operation Plan will be offset by a negative impact from the wage inflation in Hungary, and so we are currently looking at a wage inflation in Hungary of around 10%. And we are also looking at labor shortages in Hungary. So therefore, we have hired people from Ukraine to support our production in Hungary. We have also decided to continue our investment program. So we will invest up to 2% of revenue also in '19- '20. We will continue to invest into most of our geographies. So in Europe, it's going to be in the U.K., U.S. and also selected emerging markets and especially China. And then we have -- as we have also talked to quite a lot of the French health care reform, that is impacting through the P&L. So that's the main drivers for our margin in '19- '20. So we will deliver an EBIT margin of around 31%.

Sebastian Walker - *UBS Investment Bank, Research Division - Associate Analyst*

Just quickly, if I could follow-up. So thanks for both of those. In terms of a potential GPO contract win, is there anything included in guidance either on top line or on bottom line from that?

Kristian Villumsen - *Coloplast A/S - President & CEO*

No, that's not, Sebastian. We hope that we'll get an announcement from Premier before the end of the calendar year, and we'll, of course, keep you informed as soon as we know something.

Operator

And your next question comes from the line of Patrick Wood of Bank of America.

Patrick Andrew Robert Wood - *BofA Merrill Lynch, Research Division - Director in Equity Research and Head of the EMEA MedTech & Services Team*

I feel a bit like the Buzz Aldrin of this conference call. I have a few questions, please, if I could. The gross margin in Q4 was a bit better than I was actually expecting given the price reforms and things you've been having, but I was interested to hear that the product mix was a bit of a headwind on that side of things. So I'm kind of curious, is that a function of the divisional growth rates with urology obviously growing a bit faster? Or is there something else going on within the subdivisions, I would have expected Concave and Convex to sort of help on the gross margin side? So that's one bit.

And then the second one, I appreciate, it may be difficult for you guys to comment, do we know if the Premier GPO contract is still open or have the negotiations on that closed?

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

So thanks, Patrick, for your questions. If I start with the gross margin. So in Q4, our gross margin was positively impacted by scale. It was also impacted by the closure of the Thisted factory that we have been speaking to for some time. We had also a positive impact from the restructuring costs. So as you might recall, we included restructuring cost of around DKK 43 million up until end of the Q3. In our Q4, we did not include any restructuring costs, but we did that last year. So we had some positive impacts on our gross margin in Q4, as I just mentioned. And that meant that we had for the year, an improvement in gross margin compared to '17- '18.

Kristian Villumsen - *Coloplast A/S - President & CEO*

And if I should comment on your question on the GPO, we don't have any final news. And what I've learned from history is that we don't comment on it until it's final. So I'll -- what we've heard last, Patrick, is that we will have an announcement before the end of the year.

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Patrick Andrew Robert Wood - *BofA Merrill Lynch, Research Division - Director in Equity Research and Head of the EMEA MedTech & Services Team*

Totally understandable. And just a follow-up on the mix side. So you feel confident about the mix platform for different products going forward for next year as Concave and Convex and Flex Pro and everything continue to drive, that should help the gross margin a little bit, right?

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

Yes. So into '19- '20 and that's also part of the expectations in our Global Operations Plan 4, as a consequence of closing our factory in Denmark in Thisted, we have moved our production of Concave to Hungary. We have also finalized the move of our Convex production to Hungary. And that is part of the 100 basis points improvement that we are expecting going forward. But when -- that is said, we're also seeing high wage inflation in Hungary. And as I also said earlier, we're also seeing quite a challenge in terms of labor shortages where we have Ukrainians employed now in Hungary. And that is giving us some headwind.

Operator

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

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

My question goes back to one of the previous questions. It seems to me like we are dealing with a, I would say, margin development top line growth like it's your game, you have had the growth over the last 5 years of 7% to 8%. And you have had strong momentum from you SenSura Mio program, Convex and Concave. You have had good momentum in SpeediCath Flex, Biatain sales, and you have also had competitors like ConvaTec and also within urology that has been with you or it has been weak. So my question is simply, is it possible for you to increase margins? And you're yet again, expecting flat margins from '18- '19 to '19- '20. So all of your efforts, for example, from GOP4 seems to be offset. Is this how we should see? Also in the next 5 years that it is hard for you to increase margins? Then this, of course, opens up for questions, when we should expect your Costa Rica facilities to be ready, as you would have lower cost in this respect. And should I see it like this that not until maybe from '21- '22, you will be able to get some margin improvements?

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

So if I start with this. Annette, thanks for your question around the EBIT margin. It's a little bit back to my comment earlier around the assumptions for the EBIT margin in '19- '20. So we are expecting to deliver an EBIT margin next year in the level of 31%. And I think I have talked to the main drivers. In terms of Costa Rica, as we have also talked to previously, we are starting to produce in Costa Rica. And we started to produce during '18- '19. And we will now, in '19- '20, start to build our own facilities and those facilities will be ready by the end of 2020. And so that's the plan in terms of Costa Rica. And we have included the costs -- part of that -- those costs in our CapEx forecast for '19- '20.

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

But if this means that in Costa Rica from, I would say, is that Q3 next year, you would be able to produce commercial volumes in Costa Rica? Or when should we expect Costa Rica to have a positive impact on your gross margin?



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

Yes. So we are already today producing in Costa Rica. But of course, the volumes are very, very low. But over the course of '21 and ongoing, we will start to see an impact. But please remember that even though the wage is at index 80 compared to the Hungarian wage levels, we have higher freight cost.

Kristian Villumsen - *Coloplast A/S - President & CEO*

If I may just add to what Anders has said. Remember, we've talked about this many times about how you think about running the company. It's very possible to run Coloplast in a way where we get more margin out, right? But we believe that at some point, you're also going to sacrifice growth. So our fundamental stance is a -- maintaining a good balance between investing for short term, medium-term and long-term growth and delivering good margins here and now. We think the balance for this year, definitely delivers on that. And then to your question on what will it be going forward, well, that's what we will update all of you on when we talk about the new strategy come next summer, right?

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

Kristian, can I then just ask simply, is it possible to grow at 7% to 8% and then still deliver some margin improvements because you've not been able to do that over the last 5 years? And if you say yes, then please explain what is different?

Kristian Villumsen - *Coloplast A/S - President & CEO*

Could you repeat the question, please?

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

The question is that over the last 5 years, you have delivered growth of 7% to 8%, but you have not been able to increase your margins. I'm just asking, is it possible for Coloplast to grow at the 7% to 8% growth level as you've done and at the same time have some margin improvements?

Kristian Villumsen - *Coloplast A/S - President & CEO*

Well, for -- it's a great question. For -- you know the guidance for this year is around around 31%. Of course, that gives some level of expansion possibility in -- just in that guidance. But whether we'll be successful doing that going forward, I think, will come down to, if you will, the level of success that we have with the investments that we make. So hard to predict, but I still feel pretty good about the numbers that we're putting out right now.

Operator

And your next question comes from the line of Michael Jungling of Morgan Stanley.

Michael Klaus Jungling - *Morgan Stanley, Research Division - MD, Head of MedTech & Services and Analyst*

Three questions, please. Firstly, on the gross margin for the fiscal year that you've just reported. How much was the gross margin headwind from the salary inflation in Hungary? Question number two, also on gross margin, the headwind to gross margins that you expect in your guidance for fiscal year '20, could you please quantify that, not just the inflation number, but the actual gross margin headwind? And then thirdly, does your guidance for your current fiscal year or the new fiscal year includes U.S. medical device tax, if indeed, it kicks off? And what would be the impact if you incur the medical device tax?



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

So again, back to the gross margin, Mike, so thanks for the question. So we are not specifying in such a detail the impact that you are asking for. So the gross margin that -- the drivers that I'm speaking to is ones that I spoke to earlier, that we, in '18- '19, seen a positive impact from operations and the plan that we have executed. So the closure of Thisted, we have seen impact from the scale. But -- and we have also had restructuring costs included but that is partly offset by wage inflation, as I said earlier, and the labor shortages in Hungary. And it's -- some of the dynamics that we also see into '19- '20. '19- '20, I have also spoken to drivers and please also remember that I'm not expecting any restructuring costs in '19- '20 as well.

In terms of the med tech -- the taxes in the U.S., so it is still not, you can say, decided. So that is still up for, I don't know, negotiations, but it's around USD 1 million to USD 2 million we are talking about.

Michael Klaus Jungling - Morgan Stanley, Research Division - MD, Head of MedTech & Services and Analyst

Great. And then maybe a follow-up on the gross margin then, do you see gross margin expansion in fiscal year '20? Will the gross margins expand?

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

That's my assumption. My assumption is that we will see an improvement in gross margin as a consequence of the execution of Global Operation Plan 4. So that is my assumption.

Operator

And your next question comes from the line of Kate Kalashnikova of Citigroup. Kate, your line is open.

Moving on to the next question from the line of Veronika Dubajova of Goldman Sachs.

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

I have 3, please. One, Kristian, I hoping you could elaborate a little bit on what drives the lower versus the upper band of the revenue growth guidance? You have 2 years under your belt of growing pretty solidly at 8%. So curious, under what conditions would you envisage that 7% growth? What would need to happen? And what's the single biggest variable that you see here? That's my first question.

My second question is on -- a quick financial one on MDR costs and what is it baked into the guidance? What are you anticipating? And then my third question is a big picture question on urology. You've alluded on number of occasions, including today, to the need to invest into the business since -- once you've made the decision to retain it as part of the portfolio. Can you help us quantify those investments, not just when you think about fiscal year '20, but also beyond? What do you need to do to realize the value that you see in this business?

Kristian Villumsen - Coloplast A/S - President & CEO

Veronika, as always, great questions. I'll take a stab at question 1 and 3, and Andres will talk MDR. So when you look at the guidance for the year that we're in between 7% and 8%. The reason that, that 7 number is in there is that we have a French health care reform as significant headwind for the year. We are operating with a base assumption that we will continue the strong growth that we have in both Europe and the U.S. and in Asia. And we also have had and also for quite a bit of time have had good performance in a number of our EM regions. And so to get to the higher end of this, we need to see the work that we've done in our Premier region and in -- and beyond actually take effect, right? So remember that French health care reform headwind is significant for us.



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Now on the big picture question for IU. The -- it's true that we've communicated that, to develop this business over time, you need to develop it. We're not specifying exactly how much yet, Veronika. That will also be part of the coming strategy. And I'll also say, therefore, all of the business unit heads in the company, they are competing for capital. But we are in the fortunate situation that IU already has a strong P&L with good leverage effect that we can invest from. So there is, I think, capacity in the business itself to also develop it going forward.

A couple of the areas that will require investment will be in R&D. We've not invested a lot in building a pipeline historically. So more money and resources will flow toward that, not just organically. I also imagine that this is a place where we'll have to do business development/M&A type work. But exactly what that pipeline looks like? That's the work that's ongoing. But I'll say this, Veronika and I'm fundamentally optimistic about the opportunity that this business represents in the platform that we have there. Anders?

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

Yes. And in terms of your second question, Veronika, in relation to the MDR cost. So we started to include costs related to the medical device regulation a couple of years back. So -- and my assumption is, into '19- '20, we will have this more or less the same cost level as we had in '18- '19, but then it will start to tail off in the years after that.

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

That's great. And Kristian, can I ask, like, kind of what's the long-term ambition for IU is? You've given us some sense for where you want to get in the other 3 businesses, either in terms of market share or growth. What's the vision you have in IU? What underpins this decision to keep the business?

Kristian Villumsen - Coloplast A/S - President & CEO

I'm going to be talking about the vision for it. But of course, you need to imagine a much bigger number than what we have now. We are talking about some numbers internally, but I'd love for that to be substantiated with you guys when we see you next year at CMD. I've said before that when we're in businesses, we are competing for market-leading positions. So we will be doing that here. We already have good performance, and we think there's potential for more, but the vision and the whole story will present to you at CMD.

Operator

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

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

This is Christian here from Nordea. A couple of questions from me. So my first question is to your Endourology business or part of your Urology business in the U.S. How long have you had your endourology products available in the U.S.? You mentioned that you expect to have 80% of your entire portfolio ready by 2020. So if you can clarify the state of your Endourology business?

And then my second question is to the OpEx, how you will allocate your OpEx investments for the next year? So -- as you've mentioned a couple of time, Anders, you're saying that you expect to see gross margin expansion next year. But at least at the midpoint, you're guiding for a flat EBIT margin, meaning that you'll increase your OpEx to sales ratio? Should we expect mainly to go into R&D or into sales investments or maybe into additional admin costs, which we saw a quite significant increase in this year? That's my questions.



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Kristian Villumsen - Coloplast A/S - President & CEO

So let me talk to your question on Endo. The Endo portfolio, we've had a process that's been running for a few years now. So you should have a base assumption that this product portfolio is becoming available between now and 2020. So it's not something that we've done a lot with until now in the U.S. It's been a substantial effort to get this portfolio registered. And as we get it registered, we'll also start to put people behind it.

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

And in terms of our investments into '19- '20, so we are looking at stable ratio. So we are expecting the distribution cost to be in the level of last year. We will allocate cost to additional investments, as I said earlier, into the U.K., into the U.S., into China and other selected emerging markets. You will also continue to invest in innovation. I also expect that the ratio we have been looking at in the last year of around 4% that, that will continue. And in terms of admin costs, yes, we had a high increase in admin cost last year, that was a consequence of additional investments into IT, legal, and then we have also done some work on the Interventional Urology strategic review. But I also expect we will invest further into IT in '19- '20 in order to support some of our work with digitalization. So that's some of our main, you can say, assumptions.

Operator

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

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

I just want to talk first of all about the strategic review in Interventional Urology. Can you discount that you didn't have any acceptable external offers for this business, which is why you've decided to keep it? And furthermore, you've had a very public review of this business. I just wonder if you could share with us what really is the key message? What you've learned apart from the fact that you like the businesses that you're already in? So (inaudible) share a little bit potentially if this is a signal for you to do more M&A in this field? So that's the first question, please. And second question just relates to Ostomy. Obviously, consistent solid performance in Ostomy, but 7% is amongst one of the weaker organic growth, I think, you posted over the last years, which is somewhat of a surprise given the discussion about Concave opening up significant addressable markets for you. So what's going wrong in Ostomy in your opinion? Or what has not lived up to the full potential? Last question, just a financial one maybe for Anders, I am sorry if I missed this, but can you give us some sense or guidance on where you expect net financials to be this year? I'm just trying to understand whether, given the FX things, which have been quite rather core of late, this is an incremental negative or positive for you?

Kristian Villumsen - Coloplast A/S - President & CEO

Scott, good questions. I'll talk to your questions on IU and on Ostomy. So yes, you're right, we did. It became a public review because there were some rumors in the market. But for me, in my first year as CEO, the review was actually a great way to get to know both the business and the underlying markets and the team around the business. So I have had tremendous benefit of us actually doing the work. And as I walked through in my intro remarks, the 4 key observations that we have, those are real, right? Those are -- so we fundamentally believe that these are attractive patient segments. These are segments that fit within the purpose of the company. The base performance of the business allows for P&L that we can invest from. And I've also met a great team. So in terms of what I've learned, in addition to looking at this, we've also, of course, spent real-time looking at the legal side of that business. And on the positive side, we have 95% of all the litigation that we've been involved in is now behind us. There is a tail of cases left that are running longer and, therefore, incur some more costs, which is reflected in the provision that we have. But the critical data point for me is that there's very, very limited inflow. So after 8 years of mass tort litigation in the U.S., we think that the cases that have been in this market that have come forward and that we now have a process to bring them to conclusion.

The other thing I'll say is, the other data point that's been very important for me is that there is a very, very little litigation in the other product segments that we're in. So if you have a business with these characteristics, of course, there are suitors for that type of performance. But we've made a choice here, Scott. We've made a choice that this is a business that we want to develop. We see it as part of the family and that we think we can take the business to a new level.



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On the Ostomy side, listen, it's 7%. I don't want to be in a position where I'm defending a 7% number because this is -- this means that we're taking share. And if you take the lid off, the 7% number and look at how we're doing across the different regions. We're doing very well in Europe. Very, very well in China. And we've actually also seen pretty decent growth in Ostomy in the U.S. But we've also talked to how we want more out of that business. So the damper on that growth rate that you're seeing is really the softening in EM, which is reflected there. This is not something where I'd say there's something structurally worrying in the Ostomy business. So the other thing I want to say about that is, if you look at the growth in North America and in Europe, it's driven by the new products. So Convex and Concave are still pulling real weight, and we're going to make the new portfolio matter also in emerging markets for the coming period. So I'm optimistic about Ostomy. Anders?

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

Yes. So Scott, the final question around net financials. So with the current exchange rates, I expect the net financials to be around minus DKK 100 million and that is primarily driven by hitting losses on the U.S. dollar against Danish kroner. So that's my current expectation.

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

So basically, bottom line growth should be broadly similar to your EBIT growth this year, if I understand correctly, broadly a similar net financial. Perhaps, last question for me, please. And just to understand, obviously, we've been talking about GPO contracts in the U.S. for many years and hopefully, you'll be successful in the pending case with Premier. But with respect to the impact on margin, if you are successful in this award and you start to serve these hospitals, will that have any bearing on your margin for Ostomy and the group at all as you look to better resource centers?

Kristian Villumsen - Coloplast A/S - President & CEO

It will be insignificant, Scott, because although you will see a price effect, that price effect will happen in the acute setting. And the acute setting takes up low single-digit volume of the Ostomy business. So we will take an initial price effect on it. But of course, our view goes much beyond that effect, right?

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

No need for significant incremental sales force or whatsoever, that's encapsulated in your expectation?

Kristian Villumsen - Coloplast A/S - President & CEO

At the moment, we think that we're invested to the extent that we want to be in Ostomy in the U.S., and we have full coverage. So I don't expect it to immediately trigger a need for further investment. No.

Operator

And your next question comes from the line of Maja Pataki of Kepler.

Maja Pataki - Kepler Cheuvreux, Research Division - Head of Med Tech Devices Sector

Two questions for me, please. Kristian, you were talking about the growth opportunities in IU and also the needed investments. What I would like to understand is, are we already seeing a step up in investments come the current business year? So in other words, is this also one of the reasons why we're not expected to see a margin improvement? And then the last question is, you're talking about the negative price impact for growth and you've been stating this roughly 1% negative price headwind for quite some time, could you give us a feeling what the headwinds were last year and what you expect it to be this year, just to have a comparison?



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Kristian Villumsen - Coloplast A/S - President & CEO

Yes. So we are investing in IU also this year. We've invested into Interventional Urology also over the last couple of years. And again, this year, we're investing up to 2% and Interventional Urology makes that list. It makes that list. So on the pricing side, I think what I'll -- the way I'll answer that question is that this year, we are closer to the full 1% negative impact of pricing pressure. We've typically said up to 1% negative price pressure and we are significantly closer to that 1% that we were last year.

Maja Pataki - Kepler Cheuvreux, Research Division - Head of Med Tech Devices Sector

Just very quickly to clarify something. I probably wasn't very clear in my question. But are we seeing a step up in investments for Interventional Urology already come this year? Is that already part of it? I know that you have been investing into growth, hence, the strong growth we've seen in the past. But is there a change in the, let's say...

Kristian Villumsen - Coloplast A/S - President & CEO

There's not a -- so thanks, Maja. There's not a change in our investment stance for IU. We've -- so we've -- I'll say, it's the continued investment on the back of good results over the last 2, 3 years.

Thank you, operator. We will now close the call.

Operator

Thank you. So ladies and gentlemen, that does conclude your conference for today. Thank you for participating, and you may now disconnect.

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