

03-Nov-2020

# Coloplast A/S (CLPBY.DK)

Q4 2020 Earnings Call

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*President & Chief Executive Officer, Coloplast A/S*

**Anders Lonning-Skovgaard**

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

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## OTHER PARTICIPANTS

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*Analyst, Goldman Sachs International*

**Christian Ryom**

*Analyst, Nordea Bank Abp*

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## MANAGEMENT DISCUSSION SECTION

**Operator:** Hello, and welcome to Coloplast's Full-Year Financial Results 2019 to 2020 Conference Call. The call has an expected duration of one hour.

I will now hand over to President and CEO of Coloplast, Kristian Villumsen. Please begin.

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**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

Thank you, operator; and good afternoon, and welcome to our full-year 2019/2020 conference call. I'm here joined by our CFO, Anders Lonning-Skovgaard; and our Investor Relations team. And we will start with a short presentation by Anders and myself, and then open up for questions.

Please turn to slide number 3. This year has been one of the most challenging years in our company's history. Few anticipated the severity and speed with which COVID-19 impacted the global population in early 2020. Through a strong global crisis management, we swiftly put all necessary measures in place to keep our people safe, continue to serve our customers and maintain business operations. Our teams across the world have managed the situation locally. And I would like to sincerely thank everyone in the company for assuming this responsibility and for approaching this complex situation in an innovative way to deliver on our priorities. I'd also like to take this opportunity to thank our clinician partners for their commitment to serving patients throughout this very difficult time.

Our full-year results were negatively impacted by the cancellation of elective procedures in our Interventional Urology business, as well as the negative impact from the pandemic on our Wound & Skin Care business in China and on our Chronic Care business in Europe, in particular, in the UK. We continue to adapt our business to the challenging situation, and we're encouraged by the largely stable underlying growth in the US and in our Emerging Markets. We delivered 4% organic growth, and EBIT margin of 32% and a return on invested capital of 46%, a solid set of results, I believe, in a year which has been unlike any other in the history of our company.

We've seen lower growth in new patients in Ostomy and Continence Care as a result of the COVID-19 outbreak. Broadly speaking, across markets, surgeries and procedures have picked up again; and in our key markets, new patient levels are normalizing. Our challenge is currently in Europe, and we're unfortunately seeing what can probably best be described as a second wave of the virus. We do not know what the second wave will look like.

In Q4, we saw a flat growth in several countries in Europe due to limited growth in new patients. And in the UK, due to the extended lockdown and measures put in place by the NHS to handle the COVID-19 crisis, there's been a significant decline in screening, referrals and operations. The situation in the UK has improved and new patients discharge is now around 80% to 90% of pre-COVID levels, up from an April low of around 60% of pre-COVID levels. Anders will speak more about guidance later, but we are seeing a more challenged European business as we move into 2021, also bearing baseline in mind.

As we navigate the crisis, we're adapting our business and commercial activities and continuously rebalancing our go-to-market model. In many of our markets our sales forces are still working from home, and in response, we've accelerated our digital investments. We continue to build stronger capabilities in virtual education, remote support and digital sales with tools now deployed globally. As we continue to mitigate the pandemic and focus on business continuity, we're also working to ensure that we emerge stronger from the crisis. As the year draws to a close, I feel optimistic about our future,, which holds many opportunities for growth.

We hosted our Capital Markets Day at the end of September and to recap, the core of the new Strive25 strategy is all about innovation and growth in our two core geographies, US and China. The strategy will be supported by key growth enablers, including our efficiency agenda, our people and culture agenda, and our sustainability agenda. We expect to deliver 7% to 9% organic growth per annum and more than 30% EBIT margin. The work is well underway. We remain confident in our long-term guidance and the underlying market growth and potential for growth in the segments we serve.

Today, the Board of Directors approved an ordinary dividend of DKK 13, 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 18 per share compared to DKK 17 last year. Our guidance for 2021 is an organic revenue growth of 7% to 8% and a reported growth in Danish kroner of 4% to 5%. The reported EBIT margin in Danish kroner is expected to be 31% to 32%. In 2021, we will continue to prioritize investing for growth and invest up to 2% of revenues in incremental growth initiatives focused in particular on Asia, Interventional Urology, and digital initiatives.

Before we take a closer look at today's results, I'd like to spend a few minutes on the acquisition of Nine Continents Medical that we announced today. Please turn to slide number 4. At our Capital Markets Day in September, we spoke about pursuing acquisitions within adjacent markets in our Interventional Urology business. Today, I'm very pleased to announce that we've completed the acquisition of Nine Continents Medical, an early-stage company pioneering urological over-active bladder treatment with tibial nerve stimulation.

Globally, around 80 million people suffer from over-active bladder, which is a condition that causes a frequent and sudden urge to urinate. The condition impacts a person's ability to work and socialize and the overall quality of life. Many of these people suffer in silence. So-called first-line therapies, including behavioral and lifestyle changes often yield poor results. And second-line therapies including a variety of pharmacological options are often associated with negative side effects. Patients who fail first and second-line treatments maybe offered more invasive treatment options, so-called third-line therapies, such as Botox injections, Percutaneous Tibial Nerve Stimulation and Sacral Nerve Stimulation.

Of the 80 million people globally that suffer from over-active bladder, approximately 40% seek treatment. And of those, about 3 million patients globally are candidates for third-line therapy. Today, less than 10% of these patients are actually treated. And the market is around \$1 billion in size, growing around mid-single digit.

The company that we've acquired, Nine Continents, have developed an innovative third-line therapy that is not on the market today to compete with the treatments that I mentioned before. The device is an implantable tibial nerve stimulator. It's a miniaturized, self-powered unit placed in the lower leg under local anesthesia during a short, minimally invasive procedure. The solution requires no patient activation, no recharging, nor any recurring doctor visits. And it builds on the clinically proven mode of action from percutaneous tibial nerve stimulation, which is an over-active bladder treatment available in the market today.

The feasibility data that we have so far is promising and the next step will be to design and execute the pivotal study, which is expected to begin during 2021 and continue until 2023, 2024. I'm very excited about this acquisition. It represents a long-term growth opportunity for Coloplast in a large underserved market. The technology's exciting and it is the type of opportunity we wish to pursue. It's a minimally invasive procedure that takes place outside of the operating theater and a device that, if successful, can make people basically forget about their condition and live a normal life. This fits perfectly with Coloplast's mission. As the adoption of Implantable Tibial Nerve Stimulation increases, and if the Nine Continents product is successful, we are looking at a very large growth opportunity for our Interventional Urology business.

Now, with that, let's take a closer look at today's results. Please turn to slide number 5. In Q4, we got back into positive organic growth territory and posted 2% organic growth. The quarter was impacted by challenges due to the COVID-19 outbreak as we had expected, but there were also positives.

In Ostomy Care, organic growth was 6% for the full year and growth in Danish kroner was 5%. In Q4, organic growth was 3% and growth in Danish kroner was flat. From a product perspective, growth continues to be driven by our SenSura Mio and Brava supporting products in larger markets like the UK, US and Germany. SenSura Mio Convex continues to be the main contributor to growth, driven by both Europe and the US. Brava supporting products delivered double-digit growth for the year, driven by growth in the US, China and the UK. Our SenSura and Assura/Alterna portfolio growth was driven by China, Latin America and tender deliveries in Russia.

In Q4, China and the US were the key contributors to growth. And growth in Europe, and in particular, in the UK, was challenged by lower growth in new patients due to COVID-19. Phasing of tender deliveries in Russia last year impacted growth negatively due to a very tough comparison period.

Across the Ostomy Care business, growth in new patients has been negatively impacted as only the most acute ostomy surgeries have taken place, following the COVID-19 outbreak. The impact has been the largest in Europe, in particular, in the UK, which is Coloplast's largest market in Europe. Growth in new patients continues to improve, albeit at a slower pace in Europe and is still too early to fully assess the impact of the second wave of COVID-19.

In Continence Care, organic growth was 6% for the full-year and growth in Danish kroner was likewise 6%. In Q4, organic growth was 4% and growth in Danish kroner was 2%. From a product perspective, the SpeediCath ready-to-use intermittent catheters continued to drive growth. The SpeediCath Flex contributed positively to growth, especially in the US and across the European markets. SpeediCath Compact catheters continue to drive growth in countries like the UK and France. And sales growth for Peristeen products remains satisfactory, driven by France, the US and the UK. From a country perspective, the US, Argentina, Germany and Italy were the main contributors to growth in Q4. And growth in Europe and mainly the UK was challenged by lower growth in new patients due to COVID-19.

Across the Continence Care business growth in new patients has been negatively impacted due to the COVID-19 outbreak as only the most acute patient groups, such as spinal cord injuries have been treated, whereas other patient groups, including multiple sclerosis and the BPH patients have often postponed their treatment. The impact has been the largest in Europe, and in particular, in the UK. And growth in patients now continues to improve albeit at a slower pace in Europe.

In Interventional Urology, organic growth was down 7% for the full year and growth in Danish kroner was also down 7%. In Q4, organic growth was flat and growth in Danish kroner was down 3%. The negative growth for the full year was mainly due to the decline in sales of Titan penile implants and Altis single incision slings due to the cancellation of elective surgeries in the US within Men's and Women's Health.

Elective procedures in the European business were also negatively impacted, resulting in lower sales of disposable surgical products. Elective procedures recovered during the second half of the year at an encouraging pace. And despite the surge in COVID-19 cases in several key revenue states in the US, the recovery in our Men's and Women's Health business has continued. We delivered flat growth for the fourth quarter, but in October, the business returned to growth, driven by Men's Health in the US. We continue to invest in commercial initiatives, including the launch of the Endourology portfolio the US.

In Wound & Skin Care, organic growth for the full year was 1% and growth in Danish kroner was flat. Organic growth for Wound Care in isolation was flat. In Q4, Wound & Skin Care delivered negative 3% organic growth, and Wound Care in isolation delivered 1% organic growth. The Biatain Silicone portfolio was the main contributor to growth, driven by the US and Germany. Growth in Biatain Silicone was offset by a decline in revenues in the Biatain and Comfeel product portfolios, primarily in China, which has seen a significant decline in hospital activity on the Wound Care side due to COVID-19.

The European Wound Care business improved significantly in Q4 compared to Q3, in part driven by a good contribution from the recently launched Biatain Fiber portfolio. Biatain Fiber has now been launched across seven markets and continues to be well-received. China and the wider Emerging Markets region contributed negatively the growth in Q4 due to a decline in hospital activity and sales related to COVID-19.

The Skin Care business reported double-digit organic growth in Q4 due to increased demand for InterDry and EasiCleanse products, which is correlated with an increase in non-COVID hospital admissions in the US. The Compeed contract manufacturing business contracted some growth in Q4 impacted by lower demand due to the COVID-19 pandemic.

On a separate note, before I hand over to Anders, I'm pleased to release our new Sustainability Report. A few noteworthy achievements this year include: A further reduction in occupational injuries; 41% of our production wastes now recycled, up from 32% last year; and 67% of our production now runs on renewable energy. As part

of our new strategy, we've launched several new ambitious targets to reduce emissions and improve our products and packaging. And I look forward to reporting on our progress.

With this, I'll now hand over to Anders, who will take you through the financials and outlook in more detail. Please turn to slide 6.

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## Anders Lonning-Skovgaard

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

Thank you, Kristian; and good afternoon, everyone. Reported revenue for the full year increased by around DKK 600 million or 3% compared to last year. Most of the growth was driven by organic growth, which contributed around DKK 700 million or 4% to reported revenue.

Foreign exchange rate had a negative impact of DKK 132 million or minus 1% on reported revenue. A positive effect from a favorable development in the US dollar and the British pound against the Danish kroner was offset by a significant decrease in the value of Argentinian pesos and Brazilian real against the Danish kroner.

Please turn to slide 7. Gross profit was up by 4% for the full year to around DKK 12.6 billion. This equals a gross margin of 68% on par with last year. The gross margin was possibly impacted by operating leverage driven by revenue growth, as well as savings from the GOP4 program, including the closure of the c factory in Denmark in 2019. The gross margin was also positively impacted by restructuring costs of DKK 43 million in the comparison period last year.

The gross margin was negatively impacted by product mix due to decline in US sales and in Interventional Urology. Increasing costs in Hungary due to salary inflation and labor shortages also weighed on the gross margin. There was a further negative impact on the gross margin from extraordinary costs related to the COVID-19 outbreak. The gross margin includes a positive impact from currencies of around 30 basis points. In Q4 the gross margin was 69% on par with last year.

The distribution to sales ratio for the full year came in at 29%, on par with last year. The 2% increase reflects increased investments in sales and marketing activities across multiple markets and business areas, for example, in China, the US and the UK. The impact from these investments was offset by lower travel and sales and marketing expenses due to the COVID-19 situation. In Q4 the distribution cost decreased by 1% compared to last year, reflecting strong cost control as well as sustained investments.

The admin-to-sales ratio for the full year and Q4 came in at 4% of sales, on par with last year. The R&D-to-sales ratio for the full year ending Q4 came in at 4% of sales, in line with last year. Overall, this resulted in an increase in operating profit of 5% for the full year, corresponding to an EBIT margin of 32% compared to 31% last year. The EBIT margin contains a positive impact from currencies of 20 basis points. The EBIT margin was possibly impacted by cost-saving initiatives and lower spending following the COVID-19 outbreak.

Please turn to slide 8. Operating cash flow for the full year amounted to around DKK 4.8 billion compared with around DKK 4.4 billion last year, and includes a positive impact of DKK 197 million related to a reclassification of lease payments following the adoption of IFRS 16. The positive development in cash flows was mainly due to an increase in operating profit of DKK 298 million.

Cash flow from investing activities was impacted by investments in automatization, IT and the new factory in Costa Rica. CapEx investments amounted to DKK 931 million for the full year, up DKK 295 million compared to last year. As a result, CapEx accounted for 5% of revenues compared to 4% last year. As a result, the free cash

flow for the full year was an inflow of DKK 3.9 billion against DKK 3.8 billion last year. Adjusted for the DKK 197 million positive impact from the IFRS 16, the free cash flow was down by 3%. Our cash conversion for the full year was 90%.

Net working capital for the full year amounted to 23% of sales compared to 24% last year. Inventories increased by around DKK 300 million due to an increase in inventories of strategic products. Trade receivables decreased by around DKK 200 million due to an increased focus on payment terms in primarily Emerging Markets. Due to the COVID-19 outbreak, I continue to monitor trade receivables closely. We also continue to pay smaller suppliers earlier.

In Q2, a new share buyback program was launched totaling DKK 500 million, and it was completed during our Q4. Full-year return on invested capital after tax before special items was 46% against 48% last year. Excluding the impact from IFRS 16, return on invested capital would have been 48% and on par with last year.

Please turn to slide 9. For 2021, we expect revenues to grow 7% to 8% organically and 4% to 5% in Danish kroner. Phasing of growth is expected to be back-end loaded with low single-digit growth in the first half of the year and double-digit growth in the second half of the year.

The organic growth guidance is based on four key assumptions. First, Intervention Urology will be positively impacted by the comparison period in 2019/2020. Second, there is an uncertainty around growth in new patients across chronic care in the UK and other markets, especially in Europe. In addition to a tough comparison period, the lower growth in new patients will lead to weaker growth in the Chronic business in the first half of the year. Underlying growth in the US and Emerging Markets is expected to be largely stable.

Third, there's an uncertainty around the resumption of hospital activity impacting Wound & Skin Care. This is partly offset by the comparison period in China and France in 2019/2020, as well as the full-year impact of the Biatain Fiber launch. Fourth, we have no current knowledge of any significant health care reforms, whereas last year, we saw a large negative impact from the French health care reform. Finally, the guidance also assumes a stable supply and distribution of products across the company.

Due to the depreciation of the US dollar, British pound, Brazilian real and the Argentinian peso against Danish kroner, reported growth in Danish kroner is expected to be 4% to 5%. The currency impact is based on spot rates as of November 2. For 2021, we expect a reported EBIT margin in Danish kroner of 31% to 32%. The reported margin in Danish kroner is expected to be positively impacted by the Hungarian HUF. But this is offset by depreciation of the US dollar, Brazilian real, Argentinian peso against the Danish kroner.

As a result of the COVID-19 outbreak, we have exercised strong cost control. And we have also seen a natural reduction in cost due to lower travel costs and sales and marketing spend. We expect this natural cost reduction to continue into the first half of 2021. To ensure that we emerge strongly from this crisis, we continue to invest for growth and invest up to 2% of sales in incremental investments into innovation and sales and marketing initiatives. For 2021, the bulk of investments will go into Interventional Urology, Asia and consumer and digital investments. We announced the acquisition of Nine Continents Medical today. And during 2021, we will primarily invest into R&D, including clinical trials.

The gross margin will be positively impacted by operating leverage and the Global Operations Plans 4 and 5. The positive impact is expected to be partly offset by [ph] cost price (00:23:17) in Hungary from wage inflation and labor shortages, as well as transfer costs related to the transfer of machines to new factory in Costa Rica.

Sustainability investments will also impact the gross margin. Overall, the expectation is that the gross margin for 2021 will be in line with 2019/2020, factoring in a positive impact from currency.

We expect our net financials to end the financial-year 2021 at around zero. This is primarily due to hedging gains on the US dollar and British pound against the Danish kroner, offset by losses on balance sheet items denominated in a number of foreign currencies, including the Argentinian peso.

CapEx guidance for 2021 is expected to be around DKK 1.1 billion and is driven by investments in automatization initiatives as part of GOP5, the [ph] mixed (00:24:10) factory expansion in Costa Rica, more capacity for new and existing products, as well as IT and sustainability investments. Our first volume of factory in Costa Rica will be operational at the start of 2021. Next year, it will be an important transfer year that we will see the transfer of around 15 machines to Costa Rica. Finally, our effective tax rate is expected to be around 23%.

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

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## QUESTION AND ANSWER SECTION

**Operator:** [Operator Instructions] Our first question comes from the line of Lisa Clive from Bernstein. Please, go ahead.

**Lisa Bedell Clive**

*Analyst, Sanford C. Bernstein Ltd.*

Q

Hi. Thanks very much. Just have two questions on the guidance. First of all, could you be fairly specific around what your assumptions are around the second wave for COVID and the potential for disruptions of elective procedures, which obviously would have an effect on Urology, but as well as your Wound division?

And then, second, I know you don't typically do this, but could you give us some indication of what your guidance on the top line is by division? I suppose just because it's much more important this year, given the COVID variables. Thank you.

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

Thank you, Lisa. Good questions. We're not going to guide by division. I'll put some color to each of the businesses. Regarding your first questions related to COVID, we're not assuming, I'll be explicit about that, another, if you will, fundamental lockdown of elective procedures.

So, we are seeing, in the US, that elective procedures are continuing. We're seeing that also in Europe. I'd say our view is – and this is also what gets back to us from our markets – is that the health care systems are in a very different shape now than they were back in March. There are processes in place, PPE in place, ventilators in place. So, we think that's a sensible base case.

On impact by division, we're not giving specific guidance when it comes to growth rates, but for Chronic it will be, like Andrew said, a weaker first half, basically driven by both a baseline effect from last year and, if you will, a somewhat lower growth in the new patients in the period from March and onwards, primarily in Europe.



On Wound Care, we are seeing, I think, good performance in Europe. We're also seeing good impact from the Biatain Fiber launch. We're also seeing good performance in North America. Really, the challenge has been more in China and EM [Emerging Markets]. And I am expecting that we're going to get back to growth in this year – good growth in Wound Care in China.

And the Interventional Urology, as you can imagine of course since that led to the revision of guidance back in March and had clearly the largest impact from COVID. We'll have a significant impact the other way this year driven by baseline.

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**Lisa Bedell Clive**

*Analyst, Sanford C. Bernstein Ltd.*

Q

Thanks.

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**Operator:** And the next question comes from the line of Veronika Dubajova from Goldman Sachs. Please, go ahead.

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**Veronika Dubajova**

*Analyst, Goldman Sachs International*

Q

Hey, guys. Good afternoon. Thank you for taking my questions. I'll keep it to two, please. One, just would love to understand which markets outside of the UK you're seeing a slowdown in new patient kind of generation, if I can call it that, for Chronic Care? And I guess, kind of what your thoughts are on, one, duration of that?

And two, do you think these are patients that are disappearing from the system altogether due to things like mortality, or do you think we will see a pent-up demand at some point in time in the future? Just would love to get your thoughts on that.

And I guess related to that, I seem to remember that when we talked at Q3, your guidance was for the UK to be flat. Clearly given that Europe was flat in fourth quarter, suspect the UK was either worse, or you had a lot of other markets that were flat. So, if you can get some granularity on that, that would be great?

And then my second question is just the competitive environment in Ostomy. And I know you get asked this question every quarter, but if I look at the kind of divergence between your growth rate and the growth rate of your closest publicly listed peer, the gap has been narrowing pretty substantially over the past six to seven quarters. And I know you're saying you're not seeing any change, but would just love to get an update, and how you're thinking about the narrowing of that gap? Is there something we should be reading into that or not at this stage? Thanks, guys.

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**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

Thank you, Veronika. I'm not sure I took note of all the questions. So, Anders will supplement me here. Let me start from the top on which countries that we've seen negatively impacted in Europe. UK is at the top of the list because of its size. We've also seen significant negative impact in a number of the smaller markets in Europe. It's typically highly correlated with incidents of COVID. We've seen good performance from Southern Europe and from Germany. So, I hope that gives a bit of color. So, it's mostly UK and the number of the smaller markets in Europe.

So, European markets posted zero percent growth in the quarter, but IU was positive, Wound Care was positive. And the flat growth in Chronic was principally the UK, plus a number of smaller markets like I talked about. But IU positive and Wound Care positive for Europe.

What was the second question? Maybe I'd just address the Ostomy competitiveness. So, we've grown 6% on the year for Ostomy Care, which is still significantly above market, 3% for the quarter. And still, our read is above competition. Ostomy Care is a long play, Veronika. And I wouldn't read too much into quarterly figures. I'd be looking at moving annual totals. But of course, we also play close attention to activities from competition.

Anders, anything you want to add? I missed the question after your first one.

**Veronika Dubajova**

*Analyst, Goldman Sachs International*

Q

Yeah, my second question was just the patients that you are not seeing in the Chronic Care segment. Do you think this is a temporary delay? And if so, how long until it gets better, or is there risk that there's an element of mortality in here, which means there might be some duration to the kind of depressed growth rate, if I can call it that?

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

Yeah. So, I think the truth is a bit in between. So, for some of the patients, it will be literally just a postponement. But I'm also painfully aware that a number of the health care systems are projecting higher mortality rates from colon cancer, simply because some of the screening programs are not operating at full capacity or not operating at all. And objectively, the surgery levels had been depressed. So, I think you are going to see some level of excess mortality, particularly on the colon cancer side.

**Veronika Dubajova**

*Analyst, Goldman Sachs International*

Q

Okay. And can I just confirm, I think you had said in Q3 that you expected the UK to be flat. It sounds like it was not flat, that it was down. Is that fair?

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

It was flat.

**Veronika Dubajova**

*Analyst, Goldman Sachs International*

Q

It was flat, okay. Understood. Okay. Excellent. Thanks, guys.

**Operator:** And the next question comes from the line of Christian Ryom from Nordea Markets. Please, go ahead.

**Christian Ryom**

*Analyst, Nordea Bank Abp*

Q

Hi. Good afternoon, and thank you for taking my questions. I have two as well. So, my first question is also on the NPD inflow. And maybe whether you could talk to sort of when – for how long you potentially foresee this having

an impact on your growth rates. Because as I understand your business, your cost benefit from an accumulating base of uses and the slower inflow does risk having some knock-on effects in the next quarters? Can you maybe help us a little bit with just how to think about that dynamic? And then, my second question is to the OpEx growth for next year, whether we should also expect that to be back-end loaded? Thank you.

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**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

If I start, Christian, with your first question. So, really it is going to depend on how that the virus plays out and how quickly health care systems get, if you will, fully normalized. But please, also bear in mind that we have a couple of very significant baseline effects on the year. Also for Europe, the first two quarters last year were very strong, in particular, second quarter was an exceptionally strong quarter for Europe. So, there is also a baseline effect in there. But there is an uncertainty there that I don't think I can accurately predict when we will be fully out of it. It's going to depend on how the virus pans out. But the good thing is that we know that it is going to pan out. The question is the profile and how fast.

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**Anders Lonning-Skovgaard**

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

A

And Christian, in terms of your question related to the OpEx growth, yes, you should also expect that to be back-end loaded. I am assuming that the global travel ban – the prudence that we have in terms of our cost will continue throughout this quarter and into the second quarter. When that is said, we have initiated the investments into the Urology business.

As you might recall, we put quite a few of the activities within you Urology on hold during our second and third quarter last year. But we have initiated those activities again throughout the fourth quarter. And as a consequence of the acquisition of Nine Continents, we are also starting up investments into that area over the next couple of quarters. But overall, I'm expecting the OpEx growth to be back-end loaded as well.

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**Christian Ryom**

*Analyst, Nordea Bank Abp*

Q

Okay. Thank you very much.

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**Operator:** And the next question comes from the line of Michael Jüngling from Morgan Stanley. Please, go ahead.

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**Michael K. Jüngling**

*Analyst, Morgan Stanley*

Q

Great. Thank you. Good afternoon. Three questions, please. Firstly, on the 2021 guidance, what would the margin guidance have been if you did not acquire Nine Continents, or perhaps you can do the other way around and say what the dilution would be from the acquisition?

Question number two is also on the 2021 guidance. I'm not quite sure what you mean by the assumptions that you've made on page 17 for this year's guidance with respect to the uncertainty around growth in new patients across Chronic Care. Is it included or is it not included? What I mean by that is if the COVID crisis continue at a higher rate as we're seeing now, are we including that in the guidance or not?

And then question number three is the Nine Continents Medical product, can you sell this through your existing sales force or do you need to build a specialized sales force that can cater for these new devices? Thank you.

**Anders Lonning-Skovgaard**

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

A

So, thanks for the questions, Michael. Let me start with the question around the investments we will do into the acquisition we just made. So, the guidance of an EBIT margin of 31% and 32% would not have changed, if we have not done this. When that is said, we have committed ourselves to invest up to 2% of revenue into new activities to drive growth. And this is one of the key initiatives into 2021. And we are going to increase our R&D spent within IU. And we will also invest into a team to run the clinical studies.

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

And Michael, on your second question, when it comes to guidance around new patients. So, we are if you will – on the negative side, we're not assuming a complete lockdown. I mean, that will be a change to our outlook similar to what we saw in March or a significant disruption of elective procedure. We are assuming that the current level that we have in Europe is going to continue for at least the next couple of quarters.

When it comes to your question around Nine Continents and the sales force, the product will fit nicely within our existing sales force. But of course, once – and I will also emphasize that the first job now is to do the clinical work and get us through pivotal and get the product reimbursed. Assuming that, that happens and depending on the strength of the product, I mean, we will also be of course willing to invest more heavily, if we think that, that is what is required to maximize the potential.

**Michael K. Jüngling**

*Analyst, Morgan Stanley*

Q

Great. Can I just follow up on the uncertainty around growth in new patients. If I understand this correctly, for the next sort of two quarters, the expectations are for not a lot of new patient growth, but then to improve in the remaining two quarters of the year. Broadly speaking, that's what your guidance is suggesting. Is that right?

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

Broadly speaking, continuing at the current level, Michael.

**Michael K. Jüngling**

*Analyst, Morgan Stanley*

Q

Great. Thank you.

**Operator:** And the next question comes from the line of Kit Lee from Jefferies. Please, go ahead.

**Kit Lee**

*Analyst, Jefferies International Ltd.*

Q

Thank you. I have two questions, please. Firstly, I just want to get some color on your US Chronic Care performance in 4Q? What is that? Was it back to double-digit growth, or was it running in the lower level?

And then my second question is just to get your latest thoughts on the digital channel. Do you now see a more permanent shift to budget sales and marketing going forward, which might potentially make your cost base more efficient as well? Thank you.

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

Thanks. Good questions. US Chronic Care performance has continued to be strong here in Q4. And we're delivering both a quarter and a year with double-digit growth. We're very satisfied with that and really strong performance on the ground from our US team. We've also launched a new member to the SpeediCath family, a new product that fits into the [ph] 5-1 (00:40:51) category in the US called, SpeediCath Soft, which we think is going to be a nice addition to the portfolio in the US.

To your question on the digital channel, to me this – we have certainly expanded significantly on the digital front. We've deployed a number of tools and made an investment into both training our people and deploying the tools globally. I suspect that these are going to be at least a semi-permanent mix of the go-to-market model. And at the very least, you're going to find, I think, a large number of customers [ph] who you are actually (00:41:32) going to better serve through these types of channels going forward.

But my base scenario is not that COVID is going to continue. My base scenario is it will at, some point, stop, right. And we are going to get back to something that looks a lot like what we used to have with much better access. And we know from customers that there's a real thirst for getting back together. And we're talking about doing training. We're talking about doing in-servicing of accounts. I mean, these are what you might call, [ph] a contact sport (00:42:13). And there's lot of hunger in the market to get back to that. So, I don't envision that it's going to fundamentally change the cost structure of the commercial organization. If anything, it's going to expand its reach.

**Kit Lee**

*Analyst, Jefferies International Ltd.*

Q

That's great. Thank you.

**Operator:** And the next question comes from the line of Scott Bardo from Berenberg. Please, go ahead.

**Scott Bardo**

*Analyst, Joh. Berenberg, Gossler & Co. KG (United Kingdom)*

Q

Hi, guys. Thanks for taking my questions. Yeah, first question, please. I wonder if you could just give a little bit more color on Oliver Johansen's departure. Obviously, only a few weeks ago, he was giving us an innovation update of the company, and now he's left. I'm not sure if that's performance related or anything connected with the Ambu issues. If you could just give us a little bit more understanding there, that would be helpful, please.

Second question, sorry if I missed this, but did you call out what you are seeing with respect to new patient kind of growth in the fourth quarter and for the full year, both for Ostomy and Continence? Any feeling for how those patient numbers look like, that would be very helpful, please.

And lastly, on the Nine Continents acquisition, yeah, it looks to be an interesting little pre-revenue technology company. \$145 million is obviously a meaningful sum, given that revenues aren't expected for four, five years or so. So, I wonder if you could help us understand, please, how you've gone about valuing these startups, or what is the sort of opportunity for this product if it comes to market? Thanks.

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

Thanks, Scott. Lots of meat on at least two of those three questions. Let me start from the top with your question about Oliver Johansen. Please don't read anything into that. Our innovation projects are continuing just as we presented them. As you know, we changed the structure of the company just recently in connection with the Strive25 strategy.

And Nicolai Buhl Andersen now heads up the Innovation area. Nicolai is basically reconfiguring his team for what he thinks is the job at hand. So, please don't read anything into this. That's related to neither performance nor Ambu. This is Nicolai setting his team.

When it comes to the inflow of new patients for Q4 and the full year this year, as you know, we had the bulk or, if you will, the most dramatic impact to the business back in the March, April and May timeframe, when health care systems were also most badly hit. And we have basically seen the patient inflow starting to pick up from that timeframe throughout the months. Until this year, it's been at a slower pace in the UK. And like we said earlier, the UK is sitting at around 80% or 90% to pre-COVID levels. So, it's certainly not gone, but it's not back to growth from pre-COVID levels.

When it comes to Nine Continents, well, a good question. As you heard from our presentation of the strategy, we are adamant that this should become a significant growth contributor to the group. That is going to require that we expand beyond the segments that we're in. We've done a very serious piece of work when it comes to scanning literally many hundreds of companies and ranking them pretty much based on the strength of the technology team, et cetera. And for a number of the segments that we're in, we've developed what you might call a target list.

For over-active bladder, where Nine Continents medical are developing a product, this was a company at the top of the list, from our view. It went up for sale a bit earlier than we had expected. But the valuation reflects that the size of the underlying medical need is very significant. It reflects that the existing alternatives to patients, or the existing treatment options really should be improved and can be improved and the strength of what we believe is the technology here so. Of course, you model out different scenarios for what kind of pickup and what type of share that you could get. You also model up different scenarios even if you might fail. And that's how you get to a perspective on value. And then of course, there's a negotiation with the selling side. And this is where we came out.

In my mind Scott, this is a strategic play on behalf of the company. Over-active bladder is a – it's a big segment. It's got a lot of people suffering from this condition. And they really deserve better treatment options than they have today. And so, I'm pretty excited about it, but also humble that we need to show clinical results and reimbursement before we can really start talking about how it's going to contribute to the company. But in the scenario that we get through that with good results, this will be very important to the group.

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**Scott Bardo**

*Analyst, Joh. Berenberg, Gossler & Co. KG (United Kingdom)*



Yeah, brilliant. Thanks for the answers. And maybe just a quick follow-up, please. I think at the Capital Markets Day, you outlined, there's quite a lot of innovation programs going on at Coloplast and you still expected to sort of maintain this 4% R&D ratio. I mean, does that still hold despite this Nine Continents acquisition? I would imagine running a Class III device clinical study is not going to be cheap, a product that has a big market potential. I just wonder if that guidance is still – encompasses this acquisition. Thanks.

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**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*



It does. It does, Scott.

**Scott Bardo**

*Analyst, Joh. Berenberg, Gossler & Co. KG (United Kingdom)*

Q

Okay, perfect. Thanks.

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

We can manage within this guidance. And we think that we are going to – well, we are going to make a very serious effort on this device.

**Scott Bardo**

*Analyst, Joh. Berenberg, Gossler & Co. KG (United Kingdom)*

Q

All right. Thanks for the questions.

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

**Maja Pataki**

*Analyst, Kepler Cheuvreux SA (Switzerland)*

Q

Hi. Good afternoon. Also two questions from my side, please. The first one is a question around guidance. You have talked a lot about the baseline that you have coming out of this year, which is understandable, in favor. But I was wondering, how do you think about pent-up demand when it comes to Interventional Urology? Is this something that you believe is existing and is that baked into your guidance?

And then, my second question relates to the acquisition of Nine Continents. You point out what the current third generation – or third-line therapies are. Could you give us a bit more indication on which of the products is actually leading? And can you tell us also, if it is possible, in a short answer, what the shortcomings are of the current third-line therapies? Thank you very much.

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

Great questions. Just when it comes to the question on pent-up demand and Interventional Urology, we believe that there is not that much a pent-up demand. The growth that we're seeing now is, if you will, clean. There may be some level of that, but separating out how much it is, I'd say, it's almost unknowable. The team's view – our team's view is that it is quite limited.

When it comes to the question around Nine Continents, let me see if I capture all of the sub-questions that you had. So, the prevailing treatments out there in third line, so one is Botox injections. And clearly, there's both a couple questions related to that: One is the actual efficacy of this treatment working; and the other one is that you actually have to go back for Botox injection at regular intervals.

The more invasive option is the Sacral Nerve Stimulation, which is a market that was invented by Medtronic and that Axonics has now recently launched a product into. Of course, these are very invasive procedures, where people have to undergo, in some cases, multiple surgeries to get to results. And of course, that is going to be something that everybody will think about before they undergo that type of treatment.

The alternative that we're talking about here is Tibial Nerve Stimulation. And there are solutions to that in the market today, but they require you to go to the doctor to go through treatment. The implant that we're talking

about here would be less invasive. It's basically a miniaturized version of an implant, be done in the outpatient setting, and you wouldn't have to go to the doctor. It's basically a – it's a one time procedure and something that you could be using for years, if you are responding to treatment.

I think you had some question around guidance. Was there that I missed. What was that?

**Maja Pataki**

*Analyst, Kepler Cheuvreux SA (Switzerland)*

Q

No, that's perfectly fine. Just to understand, is Botox the most common third-line therapy because it's not invasive? I'm just trying to understand how the market for third-line therapies is roughly split. No numbers, just magnitude.

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

So, the Botox market today is about a \$300 million market. If you look at the PTNS market, so the Percutaneous Tibial Nerve Stimulation, that's around a \$60 million market today. But of course, that is very correlated also with the types of solutions that are out there. The bulk of the market now sits in a Sacral Nerve Stimulation with Medtronic as the market leader and Axonics as the runner up. That's a market of about several million US dollars today. So, that's how it breaks down.

**Maja Pataki**

*Analyst, Kepler Cheuvreux SA (Switzerland)*

Q

Thank you very much.

**Operator:** And the next question comes from the line of Martin Parkhøi from Danske Bank. Please, go ahead.

**Martin Parkhøi**

*Analyst, Danske Bank A/S*

Q

Martin Parkhøi, Danske Bank. Just coming back to the acquisition question [indiscernible] (00:54:13) it's a pivotal trial starting next year. What are the normal attrition rates in a pivotal trial like that? I'm just trying to see what kind of risk there is. And then, secondly, can you speak a little bit about the cost that you could be likely to incur, if this will be a marketed product? Because, I guess, the \$145 million are only a one-off – upfront payment.

And then, final question, just like anecdotal stories, can you talk about how you – I think I know it's been difficult after you have won the huge GPO contract in US, but have you been able to gain some traction?

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

Thank you, Martin. I'm going to have to take a pass on the attrition rate and pivotal trials, but I promise you, I'll do some investigation for when we meet each other next. To your question on cost, as I understood it, was related to the total cost of the acquisition and subsequent milestone?

**Martin Parkhøi**

*Analyst, Danske Bank A/S*

Q

Yes.



**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

We aren't disclosing the size of what it is. I'll say, also, we have to get to the milestone first. It's related to, of course, us getting successfully through the clinical work and getting FDA approval. But I can say, it's significantly less than the upfront – significantly less.

And then, anecdotally, on Ostomy Care. We have built a strong pipeline for accounts within the GPO. And we have seen the first conversions. But access on the OC side Martin is more restricted than it is on the Continence side. So, it has acted as a bit of a damper on progress. But I'm still very satisfied that the business is posting double-digit growth. And both Ostomy and Continence are pulling their weight.

**Martin Parkhøj**

*Analyst, Danske Bank A/S*

Q

And then, just a follow-up question. It's probably actually completely new question. Just on the contract manufacturing, on the Compeed, is this completely neutralized? Because you have both growth in Wound Care and Skin Care in the quarter, but the division is minus 3%. How should I look at that with the comparison base in the coming quarters?

**Anders Lonning-Skovgaard**

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

A

Yeah. Martin, let me take that one. So, our contract manufacturing of Compeed is around 15% of our total Wound & Skin franchise and it is true that in our fourth quarter last year, we had a significant impact from the COVID. So, it has a negative growth – a quite significant negative growth. And that's actually also our assumption into 2021 that, due to the COVID situation and the low activity levels in the society, it is impacting our contract manufacturing business.

**Martin Parkhøj**

*Analyst, Danske Bank A/S*

Q

Okay. Thank you.

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

**Niels Granholm-Leth**

*Analyst, Carnegie Investment Bank AB (Denmark)*

Q

Good afternoon. My first question is kind of a housekeeping question. So, one, when would you expect to initiate amortizations related to the Nine Medical [Nine Continents Medical] acquisition, and how many years would you amortize the acquisition price over?

And my second question is when it comes to your acquisition strategy, would you consider to enter the [ph] urologic endoscope (00:58:13) market through acquisitions? You mentioned that you have an interest to enter this space on your Capital Market Day. Thank you.

**Anders Lonning-Skovgaard**

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

A

So, Niels, let me take the first one. In terms of our amortization assumptions, we will start the amortization in the year when we launch the product. And my assumption for now is it will be amortized over 15 years.

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

And Niels, when it comes to your question regarding scope, the work that we're doing right now is focused on distribution agreements. And that's our focus.

**Niels Granholm-Leth**

*Analyst, Carnegie Investment Bank AB (Denmark)*

Q

Okay. Thank you.

**Operator:** And the next question comes from the line of Annette Lykke from Handelsbanken. Please, go ahead.

**Annette Lykke**

*Analyst, Svenska Handelsbanken AB (Denmark)*

Q

Thank you so much. My first question would be if you could maybe say little bit about the growth trends in the quarter for the division that has – in relation to elective surgery, has it been sort of the same recovery, or have you seen some sort of slowdown in association with the second COVID wave?

And then, just some housekeeping question, net finance, what to expect for the full year? Could you give some kind of indication here? And then the net negative effects of around 3%, should we assume more or less the same for all the four segments? Thank you.

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

So, Annette, just a point of clarification, your question on elective surgery, if that is related to Interventional Urology.

**Annette Lykke**

*Analyst, Svenska Handelsbanken AB (Denmark)*

Q

Yeah.

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

The trend that we've seen through the quarter has been improving, and it's also – the improvement has continued into the month of October, we have pretty good visibility on the surgery levels. We have not seen any impact from a second wave of COVID on the IU surgery levels.

**Annette Lykke**

*Analyst, Svenska Handelsbanken AB (Denmark)*

Q

And neither for the Wound Care division or?

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

A

So, Wound Care, it has played out differently depending on market. Skin in the US has come through the quarter well. Wound Care Europe has come through the quarter quite well. The challenge has really been Wound Care in Emerging Markets and China.

**Annette Lykke**

*Analyst, Svenska Handelsbanken AB (Denmark)*

Okay. Thank you.

Q

**Anders Lonning-Skovgaard**

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

And then in terms of your – what you said the household questions.

A

**Annette Lykke**

*Analyst, Svenska Handelsbanken AB (Denmark)*

Yes.

Q

**Anders Lonning-Skovgaard**

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

So, financial items for 2021, I'm expecting a level of around zero. And the other – the last question you had, that was around the currency effect, right?

A

**Annette Lykke**

*Analyst, Svenska Handelsbanken AB (Denmark)*

Yeah.

Q

**Anders Lonning-Skovgaard**

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

Yeah. So, overall, for 2021, I'm expecting a negative currency effect of around 3%. So, we are expecting a reported growth of 4% to 5%. And my current view is that it's more or less equally split across our franchises.

A

**Annette Lykke**

*Analyst, Svenska Handelsbanken AB (Denmark)*

Okay. Great. Thank you for taking my questions.

Q

**Kristian Villumsen**

*President & Chief Executive Officer, Coloplast A/S*

Okay. Operator, this is as far as we are going to get today. I just want one wrap-up comment to Martin Parkhøi's question about attrition rate in these types of trials. We would say now from having gotten the input, that typically, this would be quite low and under 10%. But here doing COVID times, attrition rates have been high up, but more to come on that front, Martin, when we see each other.

From our side, thank you all of you for dialing in, and for your interest in the company. Continue to stay safe. Thank you very much.

**Operator:** This now concludes the conference call. Thank you all for attending. You may now disconnect your lines.

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