04-Sep-2023

Coloplast A/S (CLPBY.DK)

Business Update Call

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MANAGEMENT DISCUSSION SECTION

Operator: Ladies and gentlemen, thank you for standing by. Welcome and thank you for joining the Coloplast Conference Call on the Closing of the Acquisition of Kerecis. Throughout today's recorded presentation, all participants will be in a listen-only mode. The presentation will be followed by a question-question-and-answer session. [Operator Instructions]

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

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

Good afternoon, everyone, and welcome to this conference call on the completion of the acquisition of Kerecis. I'm Kristian Villumsen, the CEO of Coloplast and today I have the distinct pleasure to introduce to you Fertram Sigurjonsson, the CEO and Founder of Kerecis. Fertram will speak about the unique fish-skin technology that Kerecis has developed and the great work done by the team in bringing the technology to the market and already helping tens of thousands of patients. As usual, I'm also joined by our CFO, Anders Lonning-Skovgaard, and our Investor Relations team. We'll start with a short presentation and then open up for questions like we usually do. Please turn to slide number 3.

I'm excited to share that on August 31, we finalized the acquisition of Kerecis after receiving approval from all relevant authorities, as well as reaching a shareholder acceptance level of 100%. Let me start by officially

welcoming the Kerecis team into the Coloplast family. I truly look forward to continuing the strong growth and profitability expansion journey that Kerecis is on as we build the category leader in the biologics wound care segment together.

Our companies are a strong fit. We have a shared mission of making life easier for people with intimate health care needs. We are rooted in Nordic origins and culture and we are both sustainability leaders. We have a complementary geographical footprint and complementary product portfolios with Kerecis' presence in the biologics wound care segment in the US and Coloplast's presence in the advanced wound care dressing segment in mostly Europe and emerging markets. Importantly, we both lead or aspire to lead our categories through a strong business model, which has innovation and clinically differentiated technologies at its core.

If I reflect for a moment on our success in Ostomy Care and Continence Care, the key to our category leadership in these segments is our business model centered around technology and innovation. We've been bringing differentiated technologies to these segments for decades and we continue to do so. It all starts with the technology. And around that technology, we've built a model that creates user preference through services and clinical and payer preference through evidence. Last but not least, this model is, of course, also enabled by excellent commercial execution and a purpose-driven organization.

When I look at Kerecis and their unique fish-skin technology, as well as the compelling clinical evidence and strength of their organization, I have a strong conviction that this is the emerging category leader. Kerecis has grown to become the fifth largest company in the US biologics wound care segment in a short period of time. And, for me, this is a strong testament to the strength of their business model, and not least, the differentiation of their technology. The fish-skin technology developed by Kerecis is gently processed.

It's scalable, sustainable, and not least, clinically differentiated. And it's already winning in the biologics segment. With Kerecis, we believe that we found a unique asset that will strategically transform our presence in the Advanced Wound Care market. Kerecis has a strong growth outlook and a high gross margin profile through a cost-efficient production setup, which translates into a strong profitability expansion potential through continued growth and scalability. And thus Kerecis is well-positioned for long-term value creation, supported by Coloplast's industry-leading infrastructure and geographical footprint.

Finally, today we confirmed the updated long-term guidance announced on July 7. As a result of the acquisition, we raised our long-term organic growth guidance to 8% to 10% from previously 7% to 9%. This assumes around 1 percentage point growth contribution from Kerecis to the Coloplast's group organic growth as of our 2024/2025 financial year. On the EBIT margin, we maintained our long-term guidance of more than 30% but expect short-term dilution of around 100 basis points per annum from the acquisition.

With that, I will now hand over to Fertram, who will share more details about the origins of the company, the unique fish-skin technology and the commercial success of Kerecis. Please turn to slide number 4.

Gudmundur Fertram Sigurjonsson

Chairman, President & Chief Executive Officer, Kerecis

Thank you, Kristian, and good afternoon, everyone. I am Fertram Sigurjonsson, and I'm the Founder and CEO of Kerecis. Let me start with a brief introduction. I'm an entrepreneur and an investor, and I have extensive experience from several medical device companies and the prosthetic industry. Seeing the devastating impact that amputations have on patients' lives, my mission was to reduce amputations by identifying a sustainable material but these are similar to human skin as possible that could be used to support the body's own ability to

heal. The more similar the material is to the tissue that you're trying to heal, the more likely it is that the wound healing and tissue regeneration process will be successful.

Now, I found this material in skin from cold water cod fish. The story of Kerecis started in 2009 in Isafjordur, a fishing town in the North-West of Iceland when I realized that codfish skin can be used for treatment of wounds and human tissue trauma. I will speak about the advantages of our fish-skin technology in the next page. But at the high-level, the structure and the properties of cod fish skin are very similar to human skin. And as there is no known viral disease transmission risk from cold water fish to human, the fish-skin can therefore be gently processed, which preserves the natural structural components of the fish-skin, resulting in improved wound healing.

Finally, the fish-skin used in our products is derived from Atlantic cod, which is a wild fish and as such not exposed to an antibiotic or vaccines like fish from fish farms. Iceland is a well-known -fishing nation and a leader in sustainable and responsible fisheries. The cod fish skin used in our products is caught in the pristine cold waters of the Atlantic Ocean close to the Arctic Circle, and is a byproduct of local fisheries. The rationale for setting up of manufacturing in Isafjordur was strong, as the fresh, daily supply of cod fish year-round and also an abundant supply.

As of today, we use less than 1% of the Icelandic Isafjordur cod fish. Kerecis products are also produced with 100% green energy. After several years of development and clinical trials, our intact fish-skin technology was approved by the FDA in late 2014 for wound treatment and received reimbursement in late 2015. In 2016, we launched the technology in the US and reached sales of around DKK 7 million and started expanding our organization rapidly.

Since then, we have grown to more than DKK 500 million in sales in the 2021-2022 financial year. We have expanded the Kerecis organization to account for more than 500 employees, and most importantly we have since helped tens of thousands of patients with our fish-skin technology.

The biologic wound care segment in which we compete is around DKK 15 billion, concentrated just in the US. The segment is characterized by several big competitors and many smaller competitors, with most of the competing technologies derived either from human tissue or other mammalian tissues such as porcine or bovine. Kerecis is the only-approved manufacturer of fish-skin technology for wound healing.

Today, Kerecis is the fifth largest and the fastest growing company in the US biologics wound care market. We continue to make market share and reach many more patients. I have a similar view as Kristian for what has driven our success: It all starts with the strength and differentiation of our fish-skin technology, which is supported by compelling clinical data as well as a strong commercial execution enabled by a purpose-driven organization.

Now, let's take a closer look at our fish-skin technology and its advantages. Please turn to slide number 5. I already mentioned that for a successful wound healing, the material used in the treatment needs to be as similar as possible to the tissue you're trying to heal. I also mentioned that there is no known viral disease transmission risk from cold water fish to human, allowing for the fish-skin to be gently processed. This preserves the natural structure and components of the fish-skin.

The result is a product, which closely resembles human skin and allows for improved wound healing, which also is backed by compelling clinical evidence. For comparison, all the tissue-based products are based on tissues of mammalian origin. In the case of human-based tissue, there are strict requirements of screening and handling; and in the case of animal tissue, there are strict requirements on viral deactivation, which means that the tissue is

harshly processed. This harsh processing removes the natural components and denaturalizes the material, making it more dissimilar to human skin than our gently processed fish-skin.

Let's take a closer look at the Kerecis fish-skin and how it compares to human skin. The similarity is striking. First, the Kerecis fish-skin has the same natural three-dimensional structure as human skin, characterized by epidermis, dermis and subcutaneous layer. It also has the same thickness, same elasticity and same porosity as human skin.

Next, fish-skin has natural mechanical properties such as robustness and flexibility that closely resembles human skin. This also means that the Kerecis fish-skin products can be easily handled, sutured or stapled without being destroyed in the process. Third, the chemical complexity of the natural molecules and polymers in the fish-skin remains intact in the manufacturing process. Finally, the natural organization of the fish-skin with proteins, elastin, glycans and lipid structures all found in human skin remain intact in the Kerecis fish-skin, which is another enabler of improved wound healing.

Turning to the manufacturing process itself, in a very simplified manner, we prepare the fish-skin products by removing the scales and the cells from the skin, which leaves tiny holes where the cells used to be. Next step is to remove the liquid from the skin. And as the final step, the products are sterilized. When healthcare professionals apply the fish-skin products onto a wound, the human cells begin to proliferate into the fish-skin, laying the new tissue.

The holes that used to be populated by fish cells become populated by the patient's own cells, which start to divide and proliferate and make new tissue. Over time, the fish-skin is completely replaced by human tissue. The performance of the fish-skin technology is documented by a portfolio of more than 40 publications, including a number of randomized controlled studies. The clinical evidence shows improved outcomes compared to both the standard-of-care and market-leading competitors. Treatment with the fish-skin results in a reduction of treatment time and reduction of treatment costs.

Beyond the improved clinical performance, the fish-skin technology is also characterized by a more cost-efficient production compared to competing biologic technologies. This cost efficiency is achieved through the simple supply chain and production. The fish-skin is a byproduct from Icelandic fisheries and, therefore, inexpensive to procure and gently processed. Another benefit of the fish-skin technology is simple logistics. The products can be stored at room temperature and have a long shelf-life of three years. In addition, the technology platform is scalable as the full product portfolio is made from the same processed skin with differences in form factor to address the different wounds types.

So, let's turn to slide 6. Now, let's take a closer look at our product portfolio footprint and commercial strategy. Our product portfolio is adapted to wound types and care settings and with that also to different reimbursement codes and categories. They believe that the depth of our portfolio is an important competitive advantage.

All of the products that you see on this page are [indiscernible] (00:12:53) first generation of products and subject to strong patent protection. It covers fish-skin from all species and their manufacturing methods. The patent protection of the first generation of products is expiring around a decade. And to counter any potential impacts from patent expiration, we are already working on the second and third generation of products which will be covered by new patent protection.

Now, turning to a split of our revenues. Around 50% of the sales today come from surgical applications; around 40% from chronic wounds, which cover diabetic foot ulcers, venous leg ulcers and so on; and the remaining 10%

is derived from burn wounds. By care setting, around 80% of sales originate from the hospital setting with the remaining 20% from the private office setting.

In the hospital setting, we are typically covered by Tier 3 codes and we see the pricing environment as a staple. In the private office setting, the coverage is product-specific and here we see a more dynamic pricing environment. However, given our efficient production setup and limited exposure to the private office setting, we are well positioned to absorb any potential price pressure.

Since our product launch in 2016, we have been growing strongly and we expect to continue to grow across the different wound types and care settings. A significant share of growth is expected to come from our proven commercial model in the hospital setting. We continue to see many opportunities to bring our fish-skin technology to even more patients by continuing to increase the penetration in existing accounts, by expanding into new territories, as well as continuing to expand our product range within wound care.

For the medium and long term, we see potential to apply our fish-skin technology to other indications. From a geographical perspective, we are predominantly a US business where we have around 98% of our revenues. The US remain a key growth driver and focus market in the years to come. Over time, for the medium and long term, we see an opportunity to expand Kerecis' presence in markets outside of the US and leverage Coloplast's footprint in the wound care market in Europe and emerging markets.

Please turn to slide number 7. As the Founder of Kerecis, the decision to sell the business is not one that I took lightly. I have spent the last 14 years on bringing the unique fish-skin technology to life, hiring the best talent, establishing a strong company culture and building a world-class sales organization. I think of Kerecis as a long-term business. Our fish-skin technology has an incredible potential to transform the lives of many more people globally.

So when considering a new owner for Kerecis, three things were decisive. One, it had to be a long-term thinking owner that understands the type of work and commitment it takes to be a category leader. Two, it had to be an owner who shares the same mission and culture as Kerecis and our employees. And three, it had to be someone who has a complementary footprint and strong infrastructure that can help bring the Kerecis technology to more patients worldwide and preferably all around the globe.

I believe that Coloplast checks all of these boxes. Coloplast is a category leader in chronic care markets and has been committed to the category for more than 65 years. We have a similar understanding of what makes a market leader and the role technology and innovation play in this as well as the type of commitment needed to become a brand of choice for healthcare professionals and users. Both companies have Nordic origins and we share very similar mission and culture built on values of compassion, curiosity and integrity.

We also both have strong focus on building a sustainable business, both financially and environmentally. Finally, Coloplast possesses some industry-leading infrastructure, which is key to enabling continued growth and sale of Kerecis. At the same time, Coloplast has a highly complementary geographical exposure to the European market and emerging markets. The industry-leading infrastructure and geographical complementarity will be key to bring our fish-skin technologies to many more patients globally over the medium- and long-term.

Before I hand over to Coloplast's CFO, Anders Lonning-Skovgaard, I would like to thank all my colleagues at Kerecis for the great work and impressive results so far. I look forward to continuing the growth journey together, now as part of the Coloplast family.

Anders Lonning-Skovgaard

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

And please turn to slide number 8. Thank you, Fertram. Before I dive into the numbers, I would also like to officially welcome all of Kerecis employees to Coloplast. I look forward to working with you and supporting your strong performance.

Now, turning to the numbers the financial assumptions that we laid out in the announcement from July 7 are unchanged. We expect continued strong revenue growth trajectory for Kerecis, with around 50% growth in 2022/2023 financial year and an estimated three-year CAGR of around 30% until 2025/2026 financial year. Kerecis is expected to deliver an EBIT margin of around 10% this financial year and around 20% in 2025/2026. Beyond 2025/2026, I expect Kerecis' profitability to continue improving with an EBIT margin expected to be in-line with Coloplast's long-term guidance of more than 30%.

As a result of the acquisition, we adjusted our long-term guidance as Kristian also explained earlier. We expect long-term organic growth of 8% to 10% and an unchanged long-term EBIT margin guidance of above 30%. During the Strive25 strategic period, the EBIT margin is expected to remain below 30% with around 100 basis points of impact from Kerecis, including PPA amortization. EBIT margin for Coloplast, excluding Kerecis, is still expected to be around 30% in the Strive25 period.

The remaining assumptions on long-term CapEx-to-sales and net working capital-to-sales ratio as well as our tax rate are unchanged. For this financial year 2022/2023, Kerecis will be included in the financials with one month of impact. Growth will be treated as acquired growth and included under our Wound Skin Care business area, which, going forward, will be called Advanced Wound Care. Finally, all assumptions under transaction and our capital allocation policy are unchanged.

On August 30, we finalize the equity raise related to the financing of the acquisition. This was a big moment for Coloplast as it was only the second time since we became a listed company in 1983 that we have used the stock market to raise capital. Thank you to all investors for your support and strong interest in our company.

With that, I will hand over to Kristian for closing remarks.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

Please turn to slide number 9, ladies and gentlemen. Thank you, Anders. And I just wanted to say that we're very, very excited to start working closely with Fertram and his team. With the acquisition of Kerecis, we believe that we found a unique asset that will strategically transform our presence in the advanced would care market and a business that is both strategically and financially aligned with the Coloplast investment case as summarized on this slide.

With Kerecis, we add a long-term growth business with a proven growth track record, a high gross margin profile driven by cost efficient production setup, which we expect will drive both long-term growth and significant shareholder value creation, also enabled by Coloplast's industry-leading infrastructure.

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

QUESTION AND ANSWER SECTION

Operator: Ladies and gentlemen, at this time, we will begin to question-and-answer session. [Operator Instructions] One moment for first question, please. And the first question comes from the line of Maja Pataki from Kepler Cheuvreux. Please go ahead.

Maja Pataki
Analyst, Kepler Cheuvreux SA (Switzerland)

Q

Yes. Good afternoon. Thanks for taking my question. My first question is relating to the setup of Kerecis in the US from a sales force perspective and what kind of investments are needed to support the growth CAGR that you are giving to the market?

And then the second question was really related to the split of the Kerecis revenues with surgical amounting to quite a fair bit of revenues. Could you talk to the different kind of growth dynamics that we're seeing from that perspective? Thank you.

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

A

Fertram, please go ahead.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Well, we are successfully targeting hospital accounts with incumbent biologic players. We are not the – we will continue to make investments in our sales organization to ensure continued growth. We continue to invest in and creating improved better clinical evidence and continue the growth journey that we are on.

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

A

Maybe we should say Maja, from the point of view of the investment case, everything that we have laid out in the assumption is included. You should think of the growth trajectory over the next three to five years is going to be a number of successive sales force expansion, basically on the same model that Kerecis has been on, but it's baked into the existing assumptions.

And then you had a second question on the split of sales team across the different – across the different...

Maja Pataki
Analyst, Kepler Cheuvreux SA (Switzerland)

Q

...wound types.

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

A

...wound settings. Yeah.

Maja Pataki
Analyst, Kepler Cheuvreux SA (Switzerland)

Q

Yeah.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Yeah. Exactly. Yeah. So, we don't comment on the split between our sales force. We have a dedicated sales force for the hospitals and we have a dedicated sales force for the private office and we continue to invest and build those sales forces but we don't comment on the split between them.

Maja Pataki
Analyst, Kepler Cheuvreux SA (Switzerland)

Q

Okay. Thank you.

Operator: And the next question comes from the line of Lisa Clive from Bernstein. Please go ahead.

Lisa Bedell Clive
Analyst, Bernstein Autonomous LLP

Q

Hi. Thanks very much for the presentation today. Just a few questions in terms of the reimbursement. You mentioned that your portfolio has several different price points that can sort of be competitive in different segments. My understanding is at least within the hospital setting, the reimbursement changed a few years ago so that any skin substitutes were included in the DRG. So, I just wanted to get a little bit more granularity in terms of how your portfolio is positioned from a price point versus competitors, whether cost is an advantage or whether it's really more around just selling on the clinical data? That's my first question.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

That's a very good question. So, about 80% of our sales are to hospitals mostly covered by DRG codes and about 20% is the sales to the private office. We have four different brands: One for the burn segment, another one for the operating room; and then two brands for the outpatient segment. They all have different price profiles and offers different parts of the market. We price the product in the middle of the range. It's not the cheapest product and it's not the most expensive product. As was commented on earlier, we have a very attractive manufacturing cost profile, which makes it possible for us to respond very well to any price pressure that might occur in the market.

Lisa Bedell Clive
Analyst, Bernstein Autonomous LLP

Q

Okay. And then two follow-up questions. What sort of storage does it require? Is it sort of fridge temperature? Is it – doesn't need to be frozen? That would just be helping to understand the sort of supply chain and the convenience factor for clinicians.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Yeah. No. It's room temperature. Three years of shelf-life. The material is very light. It's easy to transport and very accessible by the healthcare providers.

Lisa Bedell Clive
Analyst, Bernstein Autonomous LLP

Q

Okay. That's good to know. And then lastly, just on the data. One of the things that's been so complex about the biologics market is that it's been really hard to get good quality clinical data that really proves that these products work. And it seems like that's kind of why this is really a US-only market because most ex-US healthcare systems just are not convinced enough by the data to warrant sort of paying for these products. So, just how do you, as a sort of industry I guess, how do you get around that or how do you overcome that and why do you believe that Kerecis' data is quite compelling when I think others have sort of largely failed on that – or not failed but it hasn't been quite as convincing?

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Yeah. Well, we have over 40 studies and then then randomized controlled studies and we continue to invest in clinical work. The reason why we have this traction in the US is because of the clinical data that we have, and of course the investments we made in building the sales force. I think our data and is actually what's needed in the marketplace.

I expect that we will increase the number of covered lives in the US in the future and the matter in Europe and overseas market is different. So, it's the national payers, you need to go from country-to-country to get coverage. In those countries, you also need regulatory clearance on a country-by-country basis. And that's of course a lot of work. We have been a small company. We have been growing very fast in the US [ph] from (00:27:18) 2016 and really have had our hands full to take on that growth.

Now, we are part of a bigger organization with sales in 140 markets around the world and we would be better placed not to take advantage of our existing clinical data to get coverage in those overseas market. Also, our material, as I mentioned before, is cost-efficient to make. We can vary the cost to some extent. We have great clinical data that shows the reduced treatment cost and better performance than competitive products. Also, there are no cultural barriers for the fish-skin and it can be applied to wounds and to patients all around the globe in the long-term.

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

A

So, can I just have a follow-up comment from my side, Lisa. So, the financials that we have attached to the case are based on US and a US case, and successive expansions on existing technology and portfolio. But of course we will do real work to get the technology into the world and get it approved. We believe that the fish-skin technology has just inherent advantages.

If you look at the supply chain of competing products and analyze what it would take to get mammalian-based products into the European markets or even human-based or human tissue-based products into the European markets, it would be significantly more costly than to do it with the fish-skin technology, just from an analysis of how this supply chain will be set up. So, in effect, companies that base themselves on that type of technology would be at a disadvantage going in. So we will start that work also, but it will of course have some lead time.

Lisa Bedell Clive
Analyst, Bernstein Autonomous LLP

Q

Great. Thanks for that. Congratulations on the deal. It sounds very interesting.

Operator: And the next question comes from Shubhangi Gupta from HSBC. Please go ahead.

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

Q

Hi. Thanks for taking my question. I have one. The CMS has released a new guidance, according to which some of the skin substitutes [ph] would lure (00:29:45) coverage, which are being used for diabetic foot ulcers and other leg ulcers, and this would be effective mid-September. So can you just provide some color if any of your products would be impacted by this recent change? Companies like Organogenesis have already flagged they have been impacted by this.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Okay. So our products are not affected by these changes. So, the fact is that three Medicare Administrative Contracts thus recently have updated their local coverage determination for biologics. They all affected private office setting. So the change takes effect now in September and includes a maximum limit of 4 applications from previous 10 applications in 12 weeks and the exclusion of [indiscernible] (00:30:32) products as covered.

So these MACs that have made those changes, they cover 13 million lives out of the total 65 million Medicare, Medicaid covered lives. So it is 13 million out of 65 million Medicare covered lives. So the Kerecis products are covered by about 150 million lives in the US and including those 65 million. So the impact of this to Kerecis is going to be very limited because it touches only a small part of our business. And for example, this maximum limit of four applications is not detrimental for us.

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

Q

Thank you.

Operator: And the next question comes from Veronika Dubajova from Citi. Please go ahead.

Veronika Dubajova
Analyst, Citigroup Global Markets Ltd.

Q

Hi, guys. Good afternoon. Thank you for taking questions. I have three, please. First one, it's just – if you look at the growth trajectory that you have and the broad assumptions that you have in US, I'm just curious to what proportion that growth is driven by new products versus the sales force expansion that, Fertram, you touched upon if you can give us a little bit of flavor. And I guess, is there anything in the pipeline, either in terms of the shape or indications that we should be looking out for that's key for the growth? That's my first question.

My second question...

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Okay. So, let me address your first question if that's okay.

Veronika Dubajova
Analyst, Citigroup Global Markets Ltd.

Q

Go ahead.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

So, our plan in the US is based on the current portfolio and it's about continuing the coverage in the US. So we don't have salespeople in all of the US. Yeah. We are continuing to hire salespeople. That's number one. And number two, then we have a subscale amount of existing accounts in the US and we want to get people in those accounts and get a bigger market share in the accounts that we are already serving. And number three, as I mentioned just before, then we are now covered by 155 million lives in the US. We believe that we have clinical data that can bring us up to the complete 291 million covered lives. And that's basically those three things that are driving our growth in the short term.

Veronika Dubajova
Analyst, Citigroup Global Markets Ltd.

Q

Understood. That's helpful. So, maybe kind of a slightly provocative question, Fertram, but it's our first opportunity to talk to you. So, you have a great product, you have a growth trajectory that you are on already before being acquired, why selling the business now? And I guess I know you gave us three reasons for why Coloplast is the right partner, but I'm just stuck a little bit. The playbook you have here for growing is fairly straightforward. I'm kind of curious why does it make sense to partner with someone like Coloplast today.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Well, Coloplast is of course a great company and has been around since 1955 (sic) [1957] and made a substantial impact on people all around the globe. Whereas, our impact is to date mostly in the US. They are a category leader in the categories that they currently serve. We have made a very good stint in the US and things look really good there.

But the world is complicated. To get on the overseas market, there is registration needed in every market. You need to talk to the payment authorities. And maybe most importantly, the category of biologics doesn't really exist outside of the US, so you need to change doctor behaviors. You need to teach the doctors that there is need for a biologic to treat the patients. And that's a very daunting task in [ph] 148 (00:34:21) countries around the world. Whereas in the US, other companies have created awareness of the segment for us. So, we are really a fast follower in the US with a superior product that's better priced.

So, I think that's especially the situation and where the timing was right. And also maybe – I mean we have been around for over 10 years. We have shareholders that have been invested in the company since the seed stage. The company has been going up substantially in value in the last equity rounds. The D round, for example, last summer, it's currently invested in and there is [ph] wishful (00:34:59) liquidity for some of our shareholders and we wanted to get that liquidity through an IPO. The IPO markets are not looking good. But when Coloplast approached us earlier in the year and we put together all the pros and cons, this was the decision of the shareholders, which I strongly support.

Veronika Dubajova
Analyst, Citigroup Global Markets Ltd.

Q

Okay. That's helpful. And again a provocative question, but I'm going to ask it nonetheless, obviously. Coloplast are a fantastic company, but wound care has not historically been one of their stronger businesses. Did you think

about the merits of partnering with someone who is a stronger, bigger player in wound care versus Coloplast with their slightly smaller market share?

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis
A

Well, of course, I'm going to change that. So, Coloplast will become the category leader in wound care. But we did not consider other alternatives, no.

Veronika Dubajova
Analyst, Citigroup Global Markets Ltd.
Q

Okay. Okay. Helpful. And then final question. I promise you, this is a very quick one. Just on the DRG reimbursement, just curious what's the average price for your product versus the entirety of the DRG. Just kind of what's the proportion of the cost that you're accounting for in terms of the procedure.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis
A

Yeah. Exactly. So I cannot go into any details there. But I just want to repeat what I said earlier: We are not the cheapest product by far and we are not the most expensive product.

Veronika Dubajova
Analyst, Citigroup Global Markets Ltd.
Q

Okay. Okay. Excellent. I had to try. Thanks so much.

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

Thanks, Veronika.

Operator: And the next question comes from the line of Niels Granholm-Leth from Carnegie. Please go ahead.

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

Thanks for taking my questions. So, in the category of fish-skin biologics, who would you mention as being your most – or your closest competitors? I know there are a number of start-up companies in this space and which of them would you say have reached the farthest and would be closest to you?

And secondly, could you talk about if there has been any discussions about creating a specific reimbursement code for fish-skin technology in the US? Thank you.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis
A

Okay. Well, I'm not aware of any companies that are close to getting any commercial traction in terms of fish-skin. So, our key competitors are Integra, Organogenesis, MIMEDX and Smith+Nephew. And those are the companies that we are meeting every day in the marketplace. In terms of special reimbursement categories for our products, I'm not going to go into any details here in our reimbursement strategy or quoting strategy.

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

Q

Okay. And then finally, I was surprised to see the proportion of your products that are being used for surgical procedures and – which obviously leaves a lot of potential in in the chronic space. And – so could you talk about which products that you are replacing in the surgical space and which type of chronic wounds that your technology is mostly used on? Thank you.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Yes. So, in the hospital setting in surgical wounds, we are talking about all sorts of wounds, ranging from chronic ones or to reconstructive surgery and then we also a portion of our revenue from burn wounds and we have a several brands that support this in the hospital setting and we have strong growth in the hospital setting, which is a very big market in the US with over 50,000 operating rooms and that's a very good market to be in.

And then in the outpatient market, we have the private power office business, which is about 20% of our business, and those are mostly diabetic wounds, venous leg ulcers and vascular wounds and so on. And our growth, we are growing above these segments and we haven't finished building out our national footprint in neither of them.

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

Q

So, would there be any limitation to the size of the wound when using your technology?

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

No. Not really. But the diabetic wounds and the wounds that are serviced in the private office, they tend to be smaller and the price per square centimeter higher. And the wounds that are treated or injury that's treated in the hospitals, they tend to be bigger and the price per centimeter lower.

In terms of whom we are competing with and products, we are displacing them. But also just the products from companies that I have mentioned before, Integra, Organogenesis, MIMEDX, Smith+Nephew, and people like the fish-skin. We have it in all sorts of shapes and forms and we recently launched the new product called Shield, which we issued a press release on recently, which is the product combined with a silicon packing and we received very good first reactions to that product, with several million lives already covered after only a few months in the market.

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

Q

Great. Thank you. And then just finally, would you be willing to share with you – with us, what proportion of Kerecis that you owned personally? Thank you.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

No. Unfortunately not.

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

Q

Okay. Thank you.

Operator: And the next question comes from Christian Ryom from Danske Bank. Please go ahead.

Christian Sørup Ryom
Analyst, Danske Bank

Q

Yes. Good morning. Good afternoon, sorry, and thank you for taking my question. So, first one is on, say, this idea about the product portfolios being complementary between the Kerecis portfolio and the existing Coloplast portfolio. Can you talk a bit about how often you would use the Kerecis product with a foam dressing or with another product in Coloplast's portfolio?

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Yeah. Exactly. That's a good, good, good question. So, when the product is used, basically we ship it to the medical facility. And the patient comes in, the wound is debrided. So, the doctor has a knife or a debridement tool and he cuts away all that tissue in the wound at maximum bleeding. Then he cuts the fish-skin to shape [indiscernible] (00:41:38) the product and then he puts the fish-skin into the wound bed.

What will happen then is that the cells and the blood will seep into the fish-skin and the human cells, the healthy human cells from the wound perimeter, they will start to crawl into the fish-skin and seek to occupy the holes that used to be occupied by the fish cells that we had removed. So, on top of the fish-skin, we put a contact layer, and on top of that we put a wound dressing.

And often those are good – these can be products from different vendors including Coloplast. And cross-selling can be done. But sometimes, the hospitals, they have their own preference on wound dressings and we will just need to understand better what's the right strategy here and how to work with the existing product portfolio of both divisions.

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

A

So, Christian, you should not assume that this has material impact on the case. The absolute core of the case is the existing portfolio. This cross-sell of wound dressings would be sugar on top for the dressings business.

Christian Sørup Ryom
Analyst, Danske Bank

Q

That makes sense. Thank you. And the second question is then also to this revenue split between surgical, chronic and burn. So, just comparing to the presentation you had on when you announced the transaction, I believe the revenue split that you showed there was probably for last year's numbers. But it seems like surgical accounts for a significantly greater percentage of sales in this year's numbers, almost suggesting that all of growth over the last year has been carried mainly by surgical applications. Is that a correct interpretation? Yeah. That's the question.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Yeah. Exactly. Well, it's a little bit tricky because sometimes we talk about the wound type that's being treated and sometimes we talk about the care setting where the product is being used in. So, first, on the chronic wounds, we

are treating chronic wounds through our sales force that is selling in the private office. But they're also treating chronic wounds through the OR sales force. So, that needs to be – you need to take a look at this, both of these things. But we have a proven commercial model in the hospital channel where we have the most significant growth coming from. We also have good growth in the wound area. But I would not say that there is a material difference between those.

Christian Sørup Ryom
Analyst, Danske Bank

Q

Great. That makes sense. And then final question. Can you provide us some insights into the stages for your manufacturing expansion? So, when we should expect, say, the next leg of the manufacturing expansion to be fully in place?

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Yeah. So, we are, of course, experiencing substantial growth. And our facility, we have two facilities in Isafjordur in North-West Iceland and they are about 25% utilized currently. But we are growing fast. So, we are preparing for the third site to be constructed and those plans are being discussed. The thoughts there would be to start constructions in 2024 and then bring in equipment in 2025 and then commissioning at 2026. The costs that, look, maybe Anders, I'm not the one to comment on. So, we have very low capital requirement.

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

A

Yeah. As we have said several times, we are expecting Kerecis to run a CapEx level less than the existing Coloplast CapEx-to-sales ratio.

Christian Sørup Ryom
Analyst, Danske Bank

Q

Okay. Great. Thank you very much.

Operator: And the next question comes from Robert Davies from Morgan Stanley. Please go ahead.

Robert J. Davies
Analyst, Morgan Stanley & Co. International Plc

Q

Yes. Thank you for taking my questions. I had a few. The first one was just on why would a doctor would not use this product? So what are the alternatives? Is it typically that they're picking a competitive product, is it that they don't pick the product at all or something else? That was my first question.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Yeah. Okay. So that's different. And the difference between care setting. So, when you're in a private office, the doctor makes his own decision largely than in a big hospital. And there is a list of approved products that they can just choose from. But doctors are – they are used to certain products and there are people habits. And they need to be convinced that clinical data and benefits to change and switch to new products and we've been very successful in talking about that over the past years.

So, the reason not to use our product, I mean there are products in the market that's cheaper than ours. And our product might not be on the list of approved lists of products in that hospitals. We are on a lot of the IDMs in the US currently but we are not on all of them. And also it might just be that the doctors use a certain product, has been using it for the past 10 or 20 years, and he just wants to continue to use what he's used to use.

Robert J. Davies
Analyst, Morgan Stanley & Co. International Plc

Q

And then – thank you. My second question was just following up on our comment around sort of your manufacturing footprint. I'm just curious, obviously you're kind of using Icelandic fish. What's the scope for broadening into using other types of fish categories? I mean are you basically planning to serve the global market all from your manufacturing sites in Iceland? Would you sort of over the medium- to long-term as you enter new markets open up local manufacturing in those regions too? Thank you.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Let me tell you there's a lot of fish in Iceland and the oceans around Iceland, so there is actually an abundance in terms of fish. And we're using less than 1% of the fish skins that are available in Iceland. And actually we could have 100% market share just by using a small, tiny portion of the fish-skins that are available in Iceland. So, we use cold water fish. It needs to be cold water fish. That's very important because there's no viral disease transferred from cold water fish to humans.

We have to use then cod fish because it's readily available all around Iceland. It's sustainably and certified as being sustainable, harvested and the fishing stock is sustainable-certified. It's not farmed. So there is no exposure to antibiotics or medicines that we need to take account within our manufacturing and manufacturing validations. Of course, we have a lot of very exciting R&D programs that are kind of going through in that sense but we are open to use other types of fish-skin. So, that would be then for some other benefits that the current fish-skin doesn't have other applications, other indications.

Robert J. Davies
Analyst, Morgan Stanley & Co. International Plc

Q

I see. Thank you. And then my last question was just around the profitability expectations for the business over the next years. I remember the initial announcement. You obviously laid out some impressive sort of growth forecast for the business. But I just wondered how you were thinking about balancing some of these new opportunities about pushing into new markets or expanding your sales force versus the kind of expected trajectory of margins over maybe a three- to five-year period. Thank you.

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

A

So, let me take that question. And so, as we have said several times, the numbers we have put forward is related to the US. So we have not included the expansion into Europe or Asia-Pac or other regions. So it's a US-only numbers we have included in our case. Yeah. Was that answer to your question? Yeah. And the current...

Robert J. Davies
Analyst, Morgan Stanley & Co. International Plc

Q

Yes. I guess effectively, should we be baking in some sort of assumptions for potential dilution for entering those new markets? Or is it just a working assumption at the moment, just the focus on the US and the other regions are going to be sort of non-meaningful on a sort of three- to five-year view?

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

So, our focus is to deliver on the US case and that is the case we have put forward. And that's what we are going to work on.

Robert J. Davies
Analyst, Morgan Stanley & Co. International Plc
Q

Okay. Okay. Thank you. That was all my questions.

Operator: And the next question comes from Mattias Häggblom from Handelsbanken. Please go ahead.

Mattias Häggblom
Analyst, Svenska Handelsbanken AB
Q

Yeah. Good afternoon. Thank you so much for taking my question. I have a two-part question. To better understand some previous targets provided by Mr. Sigurjonsson in conjunction with Kerecis' AGM in February 2023 and quoted in Icelandic media at the time, including sales of $110 million to $130 million for 2022/2023 compared to Coloplast target that I think translates into $110 million.

And secondly, the ambition to reach $500 million in sales within three to five years, which implies a much higher sales CAGR than the targets provided by Coloplast. So with more resources at Coloplast, I'm curious to understand if things have changed in February or it seems to be Coloplast has decided to take a more conservative stance compared to those previous targets.

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

So thanks a lot for that question, Mattias. Let me just comment on that. And so, we have put forward numbers that we believe in. We mentioned that the 7th of July and we are basically confirming those. You can see financials of going around 30% over the coming three years and improving the EBIT margin of around 10% this year to around 20% in 2025/2026. And, over time, we believe also we can bring the Kerecis' EBIT margin to around the 30% level. That's the numbers we are aiming at. And as I said earlier, this is focusing on the US. So, these are what we are focusing on.

Mattias Häggblom
Analyst, Svenska Handelsbanken AB
Q

The follow-up would be, is it fair to assume that you have discounted some of the previous [indiscernible] (00:52:18) assumptions?

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

So I can only say what I'm saying. We have done a lot of work around this. These are the numbers we believe in, Mattias, and that we are going forward in the coming years.

Mattias Häggblom
Analyst, Svenska Handelsbanken AB
Q

That's very clear. Thank you so much.

Operator: The next question comes from Maja Pataki from Kepler Cheuvreux. Please go ahead.

Maja Pataki
Analyst, Kepler Cheuvreux SA (Switzerland)

Q

Yeah. Thanks. Just a quick follow-up question on the targets that you've put into slide 8. Just to be on the safe side that I get it right. When you talk about the long-term targets that you're providing to the market now, like the 8% to 10% and then the more than 30% EBIT margin, that is on a reported basis. It's not pre-PP&A (sic) [pre-PPA] for Kerecis or any other deal?

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

A

You're correct, Maja. That is reflecting amortizations, less PPAs, in connection with the deal.

Maja Pataki
Analyst, Kepler Cheuvreux SA (Switzerland)

Q

Right. And the target for Kerecis stand-alone is pre-PP&A (sic) [pre-PPA]?

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

A

Yeah. Correct.

Maja Pataki
Analyst, Kepler Cheuvreux SA (Switzerland)

Q

And, Anders, I don't know whether you can share some light on how you're thinking about the whole situation. But when you talk about the accretion impact from the deal, increasingly accretive by 2026/2027. On your Coloplast stand-alone pre-integration margin, were you assuming an ongoing margin improvement on a stand-alone basis?

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

A

Yeah. So, we have now put some numbers into the market and we are committed to deliver, you can see, the 8% to 10% organic growth, including Kerecis. And we are committed in total getting back to the 30% EBIT margin guidance. And that, of course, includes a number of assumptions, also ex-Kerecis that we have put into the market. I will not speak to how I see the EBIT margin development year-over-year over this period, but we are committed to deliver on the EBIT margin long-term financial guidance that we have given to the market.

Maja Pataki
Analyst, Kepler Cheuvreux SA (Switzerland)

Q

Great. Thank you very much.

Operator: The next question comes from Davide Marchesin from Equita. Please go ahead.

Davide Marchesin
Analyst, Equita SIM SpA

Q

Hi everybody. Thank you for taking my questions. I have a few. First of all, I understand your 30% revenue CAGR over the next years is based on just increasing penetration in the US. Do you expect to start selling your products also in European markets or Asian markets over the next, let's say, 18 months?

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

A

So, no, the case is based on US. So, my comment from earlier is that of course over time, the idea is that this isn't just a US business. It becomes a global category, but it will require both clinical and regulatory work, which has some lead time. So, you should think of the performance as US performance now.

Davide Marchesin
Analyst, Equita SIM SpA

Q

Okay. Thank you. And as a follow-up, if at some point in time you will start selling the product also in some European or Asian markets, this will be, EBIT margin-wise, accretive or dilutive? Because I assume that when you start selling the products in a new market, the EBIT margin you are making out of it is pretty low. So, the 20% target in fiscal year 2025-2026 maybe could face some headwinds in case you start selling the products as well?

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

A

So, let me take that one. As Kristian said and as we have mentioned many times now, this case is based on US and we need to do the work in terms of Europe and Asia-Pac and we don't even know what are the price points. So, we need to do some work before we can start to speak to how we see the product portfolio if we are to move into Europe or when we have to move into Europe or Asia-Pac. So, it's too early to discuss financials.

Davide Marchesin
Analyst, Equita SIM SpA

Q

Understood. Good. Then third question regards what the Kerecis is focused on because it's focus in wound care. Can you tell us briefly the difference between wound and skin care. And if you see a room for increasing or expansion of Kerecis into skin care as well?

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Okay. So, we – I mean, skin care is this application in intact skin; wound care is application on the fish-skin. We are only in the market on treatment of fish-skin and also on implantable use of the market – implantable use of the product. So that's where that stands.

Davide Marchesin
Analyst, Equita SIM SpA

Q

Thank you. And, finally, Kerecis is selling now mainly in the US. Is it fair to assume that Kerecis is running with a rather high FX transaction risk? In the sense that if the US dollar appreciate, this would be margin-accretive and the other way around?

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

A

So, now, it's true that they are selling of course in US as it is a US business. So that would just be part of our total US dollar exposure for the group. And as you all are aware, we are hedging our US dollar for the group.

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

A

But, of course, if that exposure goes up, we aim to build a big business.

Davide Marchesin
Analyst, Equita SIM SpA

Q

Okay. Okay. Thank you very much.

Operator: And the next question comes from Martin Parkhøi from SEB. Please go ahead.

Martin Parkhøi
Analyst, Skandinaviska Enskilda Banken AB

Q

Yes. Good afternoon, Martin Parkhøi, SEB, and two questions for Fertram. Just back to a lot of the numbers on the guidance, Coloplast guidance and your guidance. So the questions maybe a little bit going back. If you look over the last couple of years, how predictable has the growth actually been in Kerecis? When you started the year, how exactly have you precisely will be able to predict the growth?

And then secondly, you mentioned yourself that the IPO market was closed. So, there was not an option for you, which in my books, it sounds like you have considered one. So, if there should have been an IPO, what will be the three main bullets of a risk section on IPO of Kerecis?

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Yeah. These are good questions. So, I don't think I can comment on the IPO risks. And...

Martin Parkhøi
Analyst, Skandinaviska Enskilda Banken AB

Q

No? Then just the general company risk. It was just a neat way to ask the question. So, forget about the IPO, just mentioned three main risks.

Gudmundur Fertram Sigurjonsson
Chairman, President & Chief Executive Officer, Kerecis

A

Exactly. Well, we started selling in 2016 and then we have $0 and you know from the documentation about the revenue was last year and we've sustained very, very good growth. We continued to grow through COVID. And we are very upbeat about the business case and the outlook for the business.

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

A

So, I'd say Martin, from us having looked at it, relatively good predictability. I think the only time that the business has really faced headwinds was in the early stages of COVID. So, it reflects really strong work by the team. In our book, the main risk is associated with our ability to retain a good team that's doing really great work. We're completely convinced on the technology. But it's also taken a fantastic sales team to get this thing off the ground in the US and we really need to maintain that culture and continue to expand that team.

Martin Parkhøi

Analyst, Skandinaviska Enskilda Banken AB

Q

Okay. Thank you.

Kristian Villumsen

President & Chief Executive Officer, Coloplast A/S

All right. I think that concludes all that concludes all the questions. So, thank you to everybody for dialing in and please reach out to the Investor Relations team if you have any follow-up question to today's call. Otherwise, we'll see you around. Take care.