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RTIX.OQ - Q3 2019 RTI Surgical Holdings Inc Earnings Call

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CORPORATE PARTICIPANTS

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CONFERENCE CALL PARTICIPANTS

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David Louis Turkaly *JMP Securities LLC, Research Division - MD and Senior Research Analyst*

Lucas Grant Baranowski *Craig-Hallum Capital Group LLC, Research Division - Research Analyst*

PRESENTATION

Operator

Good morning, ladies and gentlemen, and welcome to the RTI Surgical Holdings Conference Call. (Operator Instructions) I would now like to turn the call over to Ms. Molly Poarch. Please go ahead.

Molly Poarch - *RTI Surgical Holdings, Inc. - Director of Corporate Communications*

Good morning, and thank you for joining the call to discuss RTI's Third Quarter 2019 Results. On the call today are Camille Farhat, our President and Chief Executive Officer; and Jonathon Singer, our Chief Financial and Administrative Officer.

Camille will provide a brief strategic update and discuss the quarter. Jon will then discuss the third quarter financial results. After the comments, the team will be available to take questions.

Before we start, let me make the following disclosure. The earnings and other matters we will be discussing on this conference call will involve statements that are forward-looking. These statements are based on our management's current expectations, but they are subject to various risks and uncertainties associated with our lines of business and with the economic environment in general.

Our actual results may vary from any statements concerning our expectations about future events that are made during this call. We make no guarantees as to the accuracy of these statements. Accordingly, we urge you to consider all information about the company and not to place undue reliance on these forward-looking statements.

During the call, we will also present certain financial information on a non-GAAP basis. Management believes that non-GAAP financial measures taken in conjunction with U.S. GAAP financial measures provide useful information for both management and investors by excluding certain noncash and other expenses that are not indicative of our core operating results. Management uses non-GAAP measures to compare our performance relative to forecast and strategic plans to benchmark our performance externally against competitors and for certain compensation decisions.

Reconciliations between U.S. GAAP and non-GAAP results are presented in tables accompanying our earnings release, which can be found in the Investor Relations section of our website.

Now I will turn the call over to Camille. Please go ahead.



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Camille I. Farhat - RTI Surgical Holdings, Inc. - CEO, President & Director

Thanks, Molly, and good morning, everyone. For the third quarter, we delivered revenue of approximately \$76.1 million with adjusted EBITDA of \$7.1 million or 9.3% of revenue. These results are attributable to continued strong performance in our OEM franchise and offset by lower-than-expected revenue contribution from our spine business.

Starting with our Global Spine business. We had a tough quarter in our spine franchise, and we take full responsibility for the results. That said, we continue to believe we have the right strategy of investing in differentiation and scale to drive long-term top line growth, and we have high confidence in the portfolio of products we have assembled and continue to expand upon to support that strategy. We want you to know that we are laser-focused on the progression of our Novel Therapies commercial operating model and the acceleration of our worldwide product plan in Established Therapies.

Revenue from spine established therapies softened over the prior year quarter primarily due to the slowing of growth from the annualization of the Fortilink product, which launched in 2018, and was further impacted by the loss of a key customer following hospital vendor consolidation. This reinforces the importance of scale as a key component for our growth strategy and also for our ability to maintain relevance for customers facing vendor consolidation decisions in the future.

We are working on executing our product plans and to rapidly develop new products through our R&D efforts and bring them to market, given the importance of refreshing our Established Therapies portfolio.

Among the early new product launches stemming from our reinvigorated R&D efforts, at the end of September, we fully launched the CervAlign ACP System in the U.S. As an added benefit, initial adoption of the CervAlign ACP System is driving pull-through for Fortilink-C.

Also in September, we initiated the limited market release of the Hybrid Performance System HPS 2.0 in Australia and Europe. In addition, we submitted the 510(k) application to the FDA for the Fortilink A Interbody Fusion device with TETRAfuse 3D technology, the next extension of our Fortilink family of products. This will be followed closely by the 510(K) submission for our streamlined navigation system.

As it relates to our Novel Therapies, on our last call, we described the creation of a unique commercial operating model designed to drive the adoption of our differentiated portfolio over the long run to standard of care. While we have made significant progress in building this channel, we continue to be in line with the 6-month delay we've previously shared. We have solidified the sales structure for Novel Therapies and anticipate completing hiring and training for all open seats by the end of the year.

We remain highly confident we have the right novel products to drive growth. This confidence stems from the clinical and real-world evidence supporting the safety and effectiveness of Coflex for the right patients in a large fusion-based market. Similarly, we remain confident in Smmetry's future, given the effectiveness of this therapy and the significant market opportunity among sacroiliac joint patients. Smmetry supports the fundamental principles of arthrodesis and driving fusion in orthopedic procedures.

The latest interim clinical outcomes on 148 patients at 12-month follow-up in the EVoluSlon study for Smmetry revealed that 73% of patients showed evidence of fusion at 12 months. It also showed that 71% of patients had a clinically important reduction in the pain from their baseline and 60% of the patients using opioid presurgery were opioid-free at 12 months. These interim data for Smmetry continues to be very promising for us. Taken together, there is significant opportunity for the growth of both Coflex and Smmetry as we increase adoption of these Novel Therapies.

To help develop momentum within the spine franchise and accelerate the progression of these goals, we asked Marc Viscogliosi, the former CEO of Paradigm Spine; and Fran Magee, D.V.M., the former Chief Technology Officer at Paradigm Spine, to play larger roles within our spine business. Both Marc and Fran have been serving as consultants to RTI since we closed the acquisition in March. And Marc has stepped in to run our spine franchise on the interim basis and Fran, who has been instrumental in repositioning Coflex as an alternative to fusion for the appropriate patients, will now shift his focus to help us accelerate our R&D product introduction by advancing our worldwide product plan for spine. Dr. Magee is one of the pioneers in motion-preservation spine technologies and a 30-year veteran of orthopedic and spine device development, including 10 years as Chief Technology Officer for Spine Solutions and Synthes Spine. Mark and Fran have deep knowledge of the spine space and their leadership is already making an impact among our commercial and R&D teams.



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Turning to the rest of the business. The OEM franchise delivered another strong quarter fueled by our continued emphasis on customer intimacy, operational excellence and focused innovation. Our OEM team is 2 years into their strategic transformation, and we're seeing the benefit in their enhanced predictable execution and contribution to our growth. The OEM business has progressed significantly and, today, serves a diverse set of end markets with attractive growth profiles. It is supported by a deep product pipeline and has earned a solid market position, serving leading medical technology companies under long-term, high-margin contracts. The business is further distinguished by our unique technical expertise, private label product development and track record of operational excellence. In an effort to continue the transformation, we are consolidating the OEM and Sports businesses into a single operating segment. These teams currently run with highly similar operating mechanisms and rely on many of the same team members and will operate more effectively and efficiently as a single segment. Ultimately, this shift helps reduce complexity and enables our next phase of operational excellence working as a cohesive team to further accelerate growth.

The OEM business continues to be extremely predictable and generates cash. It is an example of the positive impact of our transformation efforts to reduce complexity, drive operational excellence and accelerate growth. And just as the OEM team has benefited from consistent leadership in driving customer intimacy and commercial execution, we believe our spine business is in the early stages of a longer-term transformation that will benefit from strengthened leadership, investment in the Novel Therapies channel and the multiple product launches that we have planned for 2020.

And with that, I will hand over to Jon to outline our financial performance.

Jonathon M. Singer - RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary

Thank you, Camille. RTI's worldwide revenues for the third quarter of 2019 were \$76.1 million, a \$7.1 million or 10.2% increase compared with \$69.1 million during the same period for the prior year. Driving Q3 growth was continued strength in the OEM franchise, driven by increased demand from certain distributors, primarily in our dermis-based implants and contribution from Coflex of approximately \$8.2 million. This was partially offset from declines in the Established Therapies portion of our spine portfolio.

Gross profit for the third quarter of 2019 was \$41.5 million or 54.5% of revenue, a 10.2% increase compared to \$37.7 million or 54.5% of revenues in the third quarter of 2018. Gross profit for the third quarter of 2019 included a \$2.1 million charge for the purchase accounting step-up of Coflex inventory. Gross profit adjusted for the impact of nonrecurring charges was 57.3% of revenue from the third quarter of 2019. The nearly 300 basis point improvement in margin from last year is evidence of continued progress of our efforts to drive operational excellence in the accretive margin impact from the addition of Coflex.

Marketing, general and administrative expenses were \$37.1 million for the third quarter of 2019, an increase of \$7.4 million or 25.1% compared to \$29.7 million for the third quarter of 2018. The increase is predominantly driven by the addition of Paradigm in the investment in our sales and marketing infrastructure to create the commercial operating system to drive the growth of our Novel Therapies portfolio.

Research and development expenses were \$4.3 million in the third quarter of 2019 compared to \$3.6 million in 2018. The increase in R&D is driven by the acceleration of organic growth investments in our pipeline.

During the third quarter of 2019, we incurred \$3.2 million in nonrecurring acquisition and integration costs to support the acquisition of Paradigm and continued execution on our strategy to reduce complexity and accelerate growth.

Adjusted earnings before interest, taxes, depreciation and amortization for the third quarter of 2019 was \$7.1 million or 9.3% of revenue compared with \$9.1 million or 13.1% of revenue for the third quarter of 2018. The decline of adjusted EBITDA is driven by the investments in sales and marketing outlined earlier.

Net loss applicable to common shares was \$4.9 million or \$0.06 per fully diluted common share in the third quarter of 2019 compared to net income applicable to common shares of \$2.9 million or \$0.04 per diluted common share in the third quarter of 2018. As outlined in the reconciliation tables presented in our earnings release, excluding the impact of the various nonrecurring charges, adjusted net loss applicable to common shares was \$1 million or \$0.01 per fully diluted common share in the third quarter of 2019.



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Based upon the third quarter performance and our current business outlook, we have adjusted our financial guidance for 2019. We now expect full year revenues in the range of \$305 million to \$310 million, a reduction from the previous range of \$325 million to \$335 million, and we expect full year adjusted EBITDA to be in the range of \$30 million to \$34 million compared with the previous range of \$36 million to \$40 million.

Operator, I'd like to open the line for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from the line of Matt Hewitt from Craig-Hallum Capital.

Lucas Grant Baranowski - Craig-Hallum Capital Group LLC, Research Division - Research Analyst

This is Lucas Baranowski on for Matt Hewitt here at Craig-Hallum. Just a few questions today. I guess first off, it sounded like you lost a key customer, which is one of the things that kind of weighed on revenue, but we believe there was also maybe some weather-related disruption, particularly in the Southeast. I guess was that the case? And any commentary you can provide on maybe how much of a headwind that was?

Jonathon M. Singer - RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary

Yes, Lucas, we do believe that there was some weather-related impact. If you look at it from an operational perspective, it impacted us in 2 different ways. One is when the hurricane passed through the Florida area, we shut down Alachua for 4 days, 2 of which are normal production days. And so we did lose a couple of shipping days from Alachua. And then obviously, as the hurricane went through the Southeast and the Texas area, there was delay of surgeries. It's difficult to put a full quantification around that, but we estimate somewhere in the vicinity of \$1 million is impacted by those factors.

Lucas Grant Baranowski - Craig-Hallum Capital Group LLC, Research Division - Research Analyst

That's very helpful. And then I guess, turning to your comments around OEM and Sports getting consolidated into a single segment, I guess, is that an initiative that's more about trying to find some cost savings? Or is it more about trying to accelerate growth in those lines?

Jonathon M. Singer - RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary

Look, I think it's a continuation of the strategy around the reduction of complexity predominantly. I think there's a lot of synergy, as we indicated in the script, in the operating mechanisms. There is not what I would call a material cost reduction implication of it. It's more around what I would call management efficiency from a decision-making process and then just consistency from a strategic perspective. Because if you look at the Sports franchise, it's predominantly driven off of the tissue-based portion of the business, and about 60% of the revenue in OEM is tissue-based as well. And so there's just very good synergy. And Olivier has indirectly been managing both, anyhow. And so I think this just puts a more formalized consistent management approach from a strategic and operational perspective.

Lucas Grant Baranowski - Craig-Hallum Capital Group LLC, Research Division - Research Analyst

Okay. Great. And then just one final question and then we can move to the next person. Colflex. Just kind of any updates you can provide on reimbursement progress there? Any small wins you've had or just qualitative commentary on how the conversations with payers are going?

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Camille I. Farhat - RTI Surgical Holdings, Inc. - CEO, President & Director

Yes. Look, what I would say is the #1 thing that we have been focusing on in the conversations with payers is taking the data back to what the PMA is, which is an alternative to fusion. Our focus is helping in engaging in these conversations, and we continue to make progress, though, as we -- as you know, this is not a short-term process. The reality of the situation is the real world evidence is what people believe when you have a patient that is returning to relatively normal activity with a Coflex and we're counting in weeks, 4 to 6 weeks and then you've got to be counting on fusion in, like, 6 months. These are part of the conversations we're having. And it's really -- the majority of that is driven by where do we position the product versus the concern of the insurance companies where any compression then ends up having a Coflex in more cases than we need to have. So the focus is on the label and the appropriate patients and what we're calling the decision zone.

Now to continue with the story about are we seeing progress and where we are, I will tell you, as I mentioned in my script, in the operating model, the commercial operating system that we're putting in place is really working. We have a couple of pilot zones where we have not had disruptions, where we have the right team, where they are focused on the decision zone and where they have been really engaged with surgeons in basically identifying the right patient for these procedures. And what I will tell you is since we started that pilot in late May through where we are today in October, these 2 areas, we have seen a growth of about 33% in the cases on Coflex. So this is what gives us continued confidence that the -- when we have all the right people in place and we have them trained and they're effective, that, that model will continue to grow.

And just as a summary kind of going back to where we are in covered lives, we're close -- we're north of 50 million and maybe closer to 60 million covered lives right now. So we don't believe that, that is the biggest hurdle that we're facing, and it's more about the effectiveness of the channel and the work we're doing in setting that up as we've discussed on the last call.

Operator

Your next question comes from the line of David Turkaly of JMP Securities.

David Louis Turkaly - JMP Securities LLC, Research Division - MD and Senior Research Analyst

Congrats on bringing Marc on for a more expanded role. As we look at sort of spine and maybe even particularly legacy spine, just to get some sort of color on, what are the things you need to do or how long it might take to sort of get that back to growth? So I don't know if it's more technologies you need to add. Or do you think you have more personnel you need to swap out? Or just any color on what you think it could turn it around in the timing?

Camille I. Farhat - RTI Surgical Holdings, Inc. - CEO, President & Director

Sure. So if you go back to where we started, we have been very transparent that the pipeline was relatively dry as the new management team kind of came on board in '17. We developed a pipeline and worldwide product plans, and we started focusing the energy. You have seen the quality of the work of our R&D organization, whether it is with Fortilink and the awards that they have won, CervAlign, et cetera. So we're right now focusing on continued execution and accelerating that momentum. We -- as we have said, in late '19, we'll start getting the products out, you're seeing CervAlign, the extension of Fortilink. We're applying for navigated instruments still by the end of this year to get that on market. And we have a slew of products that we're expecting to come, part are refresh, part are gaps that we expect to have in 2020 on the biologics side and the hardware side. So for us, we know our teams can execute. We have added with the -- with Paradigm and other R&D capability, when you have seen the HPS 2.0 come out of the German team. And so with Fran back in with that team as well, and then Fran now also playing an instrumental role in accelerating our activity, I think we're set up for great success in the product introductions and what people can expect with us, but that momentum you get a big customer discontinuation of products or through consolidation of vendors, and that it's hard to kind of make up for that because you can't accelerate there on the -- that much. So Jon, I don't know if there's anything else...

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Jonathon M. Singer - RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary

Well, I think in addition, we've got a complete refresh of the biologics portfolio in process with a pretty exciting pipeline there, and we should start seeing -- some of the projects are longer term, but we should start seeing the implications of that as well from a standpoint of new product cadence. So I think we would be disappointed next year if we didn't experience double-digit launches, if not more, and that's what we're going through the planning process right now to confirm the commitments across the organization and then what are the implications in the revenue cadence.

David Louis Turkaly - JMP Securities LLC, Research Division - MD and Senior Research Analyst

Got it. And then the OEM and Sports combo. I get that there's tissue involved in both, but I would think that the sales channel and the customer base that there wouldn't be a lot of overlap. I guess any color on sort of -- I guess what will happen in terms of those 2 combining personnel wise? And again, it wouldn't logically seem to me like they would go together well, but any other color you could add would be great.

Jonathon M. Singer - RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary

Yes. They do have slightly different sales models. Obviously, the OEM business is -- an account executive who's managing a large end market user -- provider, where in the Sports, in the PRS channels, we're more direct. But one of the things that we've been doing in less on Sports side, but more on the PRS side is just moving towards master-distributor relationship. And so that's more like managing an OEM relationship because we've really simplified the channel. We don't have direct reps anymore in either of the channel. So it's all through either distributor 1099 relationships. So there is a nuance there, but Jimmy, who's historically run the sales infrastructure on the sales -- on the Sports side is now just taking on a larger role across, but most of the resources underneath him that has supported the Sports business will continue to be in place. And so from a commercial perspective, you're correct, but then once you get into the sales and operating planning, the -- we're getting into the nuance of the operation. But how many donors do we need in order to support supply? What are the cost reduction initiatives prioritized against sterilization technologies? A lot more of the back-end activity. There's a tremendous amount -- as well as leverage of R&D across end-use markets or customer bases.

Camille I. Farhat - RTI Surgical Holdings, Inc. - CEO, President & Director

Let me just kind of try to see if I can provide the framework and how to think about it. The R&D team that is doing tissue is doing tissue for both equally. And to them, a customer is a customer, whether it is an RTI Sports or it is an OEM customer. And same thing on the operations side. So when you kind of think, as Jon was telling you, on the R&D, on the quality systems, on the operation system, standing these up in a redundant way with almost similar operating mechanisms and the same people on the back-end didn't make as much sense. And so kind of gaining more internal productivity and combining both and then the ability to simplify and work better with our OPOs on the number of donors we need as well as the next phase of the operational excellence beyond 2019, what we need to do from an efficiency perspective, you get that synergy and then you treat the customers as customers in the way we go to market. We've simplified to the extent possible that Sports channel and so it just -- we're serving a different customer base from that side, but the management continues as is today.

Operator

Your next question comes from the line of Craig Bijou with Cantor Fitzgerald.

Craig William Bijou - Cantor Fitzgerald & Co., Research Division - Research Analyst

I want to start with the updated guidance. So if you look at the numbers in Q3, it looks like you missed the street by \$3 million to \$4 million for the quarter. Jon, you said that it was about \$1 million, probably due to weather, but then the guidance comes down \$20 million to \$25 million. So maybe if you guys could just reconcile kind of what assumptions are going into the revised guidance and maybe where you're pulling some of that revenue out. Obviously, legacy spine, but looks like Paradigm might have come in a little bit lower than you were expecting as well. So maybe just a little color on that would be helpful.



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Jonathon M. Singer - RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary

Yes. Let's start with -- the street miss is \$3 million to \$4 million, but the miss off of our internal projections is larger than that. So you've got a foundation that we thought would be coming. The first half of the year, we had tremendous momentum really across the board with the exception of Novel Therapies, and that underpinned our expectations going into Q3. And so the continuation of growth really across the board because growth builds upon growth. And so just the math of the progression got us to the guidance. But when you -- when we missed the quarter by somewhere between \$4 million to \$6 million and not only didn't we achieve the third quarter, but we're not growing and, in some instances, we're going backwards, so you get a bit of a multiplier effect. And then we did have a couple of OEM customers that just moved -- moved demand. It's not an implication from a standpoint of the long-term relationship. It's just a matter of delivery between Q4 and Q1 that also had a relatively large impact on the swing between expectations for the full year. So when you add it all up, we were kind of limping into the low end of the guidance range when we went into the quarter -- the back half. We felt that based upon the momentum of the base business and a belief that we would see some acceleration in Novel Therapies that we had a shot at the full year guidance, but then that progression went backwards, and it's just -- it's resulted in where we are. I don't know if that gives you enough detail, but that's kind of -- that's at a macro level. I mean, I can go franchise-by-franchise, product-by-product, but on a macro perspective, that's what's going on.

Craig William Bijou - Cantor Fitzgerald & Co., Research Division - Research Analyst

And that's helpful. And I guess maybe not to get into every single franchise, but Paradigm, you guys, I think, have had -- have provided detail on what the expected sales were for the -- or what you were expecting in 2019. So maybe just thoughts on revised numbers there or how we should think about that?

Jonathon M. Singer - RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary

Yes. So yes, bear with me. The full year expectations for Paradigm, kind of we went into the year with an expectation of somewhere in the vicinity of \$40 million to \$45 million. And I think now we're expecting full year to be probably somewhere closer to \$30 million on a consolidated basis. There is some revenue that's going through the international franchise as well.

Craig William Bijou - Cantor Fitzgerald & Co., Research Division - Research Analyst

Okay. No, that's helpful. Just another follow-up on guidance. You have the range that you have, so \$5 million range for Q4. So it's a relatively large range. But I guess I just wanted to understand the assumptions or what can get you -- what can put you at either end of that range? And how to think about that?

Jonathon M. Singer - RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary

Yes. So there's a number of factors that play into it. Look, we were -- our forecast accuracy in the third quarter was obviously horrible. And so there's a level of conservatism that goes into the range. In a typical quarter, I go in with, I don't know, 98%, 99% forecast accuracy. And given where we were, not a good word, but surprised by the performance of certain aspects of the portfolio. There's just a level of conservatism that goes into the range, Craig. And then the organization has also stepped back in how they're forecasting. And so there's conservatism from Jon, the CFO, and what I'm presenting to you, and there's conservatism from the team that's giving me the roll-up, which is now rolling into the range. I think the key things that will impact where we are, are very much the same things we've been talking about all year, but progression of Coflex, progression of Slimmetry, there is a -- we are beginning, as Camille indicated, in certain areas to see solid performance as we've implemented the commercial operating model. We're continuing to roll that out in other areas. We're continuing to hire and train sales folks. So as they get up to speed and begin to contribute, I would say stabilization and impact of new launches in Established Therapies is built into the guidance range. We do and have had some products on back order. And so if we stabilize the supply side from a donor and donor quality perspective, that will impact the range and then there's always a certain element of delivery window with the OEM customers that have come into play at the end of the quarter. So those are the factors that go into it. I don't know if that's helpful or not.



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Craig William Bijou - *Cantor Fitzgerald & Co., Research Division - Research Analyst*

Thank you for walking through that. Just last one for me. Would you guys be willing to quantify the impact of the customer loss?

Jonathon M. Singer - *RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary*

It's probably somewhere in the vicinity of \$0.5 million in the quarter.

Operator

I am showing no further questions at this time. I would now like to turn the conference back to you, Camille.

Camille I. Farhat - *RTI Surgical Holdings, Inc. - CEO, President & Director*

Thank you. And thank you for your ongoing interest in RTI Surgical Holdings. Our OEM franchise continues to demonstrate predictability and strength. In our Global Spine business, we are committed to accelerating growth as we continue to invest in differentiation and scale. We see early evidence of progress on the implementation of our commercial operating model to drive adoption of our Novel Therapies, and we are dedicating resources and focus to rapidly develop and introduce new products for Established Therapies. We are confident our efforts will result in a return to growth in this business in 2020. We are focused on the execution of our plans and look forward to updating you on our ongoing progress. Thank you very much, and have a great day.

Operator

Ladies and gentlemen, this concludes today's conference. Thank you for your participation. Have a wonderful day. You may all disconnect.

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