MMSI's 3Q 2021 Earnings Call

October 28, 2021

Corporate Speakers:

- Fred P. Lampropoulos; Merit Medical Systems, Inc.; Founder, Chairman, CEO & President
- Brian G. Lloyd; Merit Medical Systems, Inc.; Chief Legal Officer & Corporate Secretary
- Raul Parra; Merit Medical Systems, Inc.; CFO & Treasurer

Participants:

- Michael Stephen Matson; Needham & Company, LLC; Analyst
- Jayson Tyler Bedford; Raymond James & Associates, Inc.; Analyst
- William John Plovanic; Canaccord Genuity Corp.; Analyst
- Unidentified Participant; Unknown; Unknown
- James Philip Sidoti; Sidoti & Company, LLC; Analyst
- Jason Bednar; Piper Sandler; Analyst

PRESENTATION

Operator^ Good afternoon, ladies and gentlemen, and welcome to the Third Quarter 2021 Earnings Conference Call for Merit Medical Systems, Inc. (Operator Instructions) Please note that this conference call is being recorded and that the recording will be available on the Company's website for replay shortly.

I would now like to turn the call over to Mr. Fred Lampropoulos, Merit Medical Systems' Founder, Chairman and Chief Executive Officer. Please go ahead, sir.

Fred P. Lampropoulos^ Thank you, and welcome, everyone, to Merit Medical Systems Third Quarter 2021 Earnings Conference Call. I am joined on the call today with Raul Parra, our Chief Financial Officer and Treasurer; and Brian Lloyd, our Chief Legal Officer and Corporate Secretary.

Brian, would you mind taking us through the Safe Harbor statements, please?

Brian G. Lloyd^ Thank you, Fred. Before we get started, I would like to remind everyone that this presentation contains forward-looking statements that receive safe harbor protection under Federal Securities laws. Although we believe these forward-looking statements are based on reasonable assumptions, they are subject to unknown risks and uncertainties. The realization of any of these risks or uncertainties as well as extraordinary events or transactions impacting our Company could cause actual results to differ materially from those currently expected.

In addition, any forward-looking statements represent our views only as of today, October 28, 2021 and should not be relied upon as representing our views as of any other date. We specifically disclaim any obligation to update such statements, except as required by applicable law. Please refer to the section entitled Cautionary Statement regarding forward-looking statements in today's presentation for important information regarding such statements. Please also refer to our most recent filings with the SEC for a discussion of factors that could cause actual results to differ from these forward-looking statements.

Our financial statements are prepared in accordance with accounting principles, which are generally accepted in the United States. However, we believe certain non-GAAP financial measures provide investors with useful information regarding the underlying business trends and performance of our ongoing operations and can be useful for period-over-period comparisons of such operations.

This presentation also contains certain non-GAAP financial measures. Reconciliation of non-GAAP financial measures to the most directly comparable U.S. GAAP measures is included in today's press release and presentation furnished to the SEC under Form 8-K. Please refer to the section of our presentation entitled Non-GAAP Financial Measures for important information regarding non-GAAP financial measures discussed on this call. Readers should consider non-GAAP financial measures in addition to, not as a substitute for financial reporting measures prepared in accordance with GAAP. Please note that these calculations may not be comparable with similarly titled measures of other companies. Both today's press release and our presentation are available on the Investors page of our website.

I will now turn the call back to Fred.

Fred P. Lampropoulos^ Thank you, Brian, and let me start with a brief agenda of what we will cover during our prepared remarks. I will start with an overview of our better-than-expected revenue and financial results for the third quarter. After my opening remarks, Raul will provide you with a more in-depth review of our quarterly financial results and the formal financial guidance for 2021 that we reaffirmed in this afternoon's press release as well as a summary of our balance sheet and financial condition. We will then discuss some recent corporate developments before opening the call for your questions.

Now beginning with a review of our third quarter revenue performance. We reported GAAP revenue of $267 million in the third quarter, up 9.4% year-over-year. Our total GAAP revenue was driven by a 5.9% growth in U.S. sales and a 14.5% growth in international sales. Excluding the benefit to our GAAP revenues as a result of changes in exchange rates compared to the prior year period, our total revenue increased 8.8% year-over-year in the third quarter on an organic constant currency basis. Our total constant currency growth was driven primarily by a 7% increase in U.S. sales and an 11.4% increase in international sales.

Our third quarter revenue results exceeded the guidance we provided on our quarter two call, which called for quarter three constant currency revenues to increase in the range of approximately 5.3% to 7.6% year-over-year. The strong revenue results in quarter three were driven by strong execution from our team and more favorable sales trends in China versus what our guidance range had assumed. Excluding the benefit to our revenue results this quarter from the lack of tender-related pricing headwinds, our total revenue increased approximately 8% year-over-year on a reported basis and a little more than 7% year-over-year on a constant currency basis. Importantly, these growth rates would have been at the high-end of our guidance range, which reflects the strong execution of our team during the third quarter.

Now turning to a review of our quarter results in quarter three, unless otherwise stated, all growth rates are on a year-over-year and constant currency basis. In terms of our sales performance by our primary reportable product categories, third quarter total revenue growth was driven primarily by a 9% growth in sales of Cardiovascular products, offset partially by a 3% decline in sales of Endoscopy products compared to the prior year period. Sales of our Peripheral Intervention products increased 16% year-over-year, representing almost 2/3 of the total Cardiovascular segment year-over-year. Sales of our SCOUT Radar Localization products increased 27%, 27% year-over-year in quarter three and represent the largest contributor to total PI growth in the quarter. Sales of our Biopsy products increased 19% year-over-year, and our drainage and embo therapy products, which together represent roughly 1/3 of our total PI business increased 18% year-over-year in quarter three.

Sales of our Cardiac Intervention products increased 15% year-over-year, representing the second largest contributor to local Cardiovascular segment growth year-over-year. We saw a balanced contribution to total CI product categories in quarter three from strong sales of our intervention products, angiography products and sales of our fluid management products, which increased 9%, 23% and 34%, respectively, year-over-year. On the Intervention side, our Basix and MAP lines posted mid-teens growth. On the fluid management side, our Medallion products more than doubled as they continue to benefit from higher demand as a result of COVID vaccination programs.

On the angiography side, we had strong demand for our diagnostic guidewires, cardiology diagnostic catheters and control syringe products. Sales of our OEM products increased 22% year-over-year in quarter three, driven by improving demand from larger customers replenishing inventory levels. Our total Cardiovascular sales was partially offset by a 13% decrease year-over-year in our CPS products.

However, the stable demand trends in this area of our Cardiovascular business masked by a nearly $9 million net headwind from sales of Cultura year-over-year. Excluding Cultura, sales of our CPS product category increased 3% year-over-year in quarter three. Finally, sales in our Endoscopy segment decreased 3%, driven primarily by a decline in sales of our EndoMAXX line due to a supply chain interruption, offsetting solid growth in other stent products and sales in our Elation and AEROmini product lines.

Now turning to a brief summary of our sales performance on a geographic basis. As I mentioned, our third quarter sales in the U.S. increased 7% year-over-year, and our international sales increased 11% year-over-year, both on a constant currency basis. Sales to U.S. customers represented nearly half of our total Company growth in quarter three, led by our U.S. direct business, which increased approximately 5% year-over-year. Sales in our three primary global regions, APAC, EMEA and Rest of the World increased approximately 9%, 12% and 27%, respectively, on a constant currency basis in the third quarter.

Similar to OUS trends we outlined on our quarter two earnings call, we experienced overall improvement in trends during the third quarter. However, we continue to see notable variation in the pace of recovery across regions of the world where we do business, including wide variation within certain geographic regions. The EMEA region was choppy in the quarter three as the region continued to see material impacts from COVID-19 and is still in the early stages of recovery. Restrictions and lockdowns are changing constantly across regions causing limitation to sales contact and lower demand for electric procedures. That said, overall sales growth trends improved in the third quarter as compared to what we experienced in the second quarter and EMEA sales were the largest contributor to total international growth in the third quarter.

We experienced improving demand trends in the U.K. and Italy and continued softer demand trends in emerging markets. APAC sales increased 9% in quarter three, although this growth was impacted by two important items of note that masked true normalized performance in the region. The first item is that sales in Australia were down 34% year-over-year in quarter three on a reported basis. But excluding the impact of the divestiture of our ITL business, sales to Australian customers increased more than 57% on a constant currency basis in quarter three.

The second item is that sales in China increased 16% year-over-year in quarter three, representing more than 1/3 of our total international growth in the period. As mentioned earlier, these results were far better than what was contemplated in our third quarter guidance as a result of a lack of tender-related pricing pressure in the period. The timing of tenders has been delayed in China, which means that our sales were roughly $4 million higher than expected in quarter three. Excluding the benefit from not having the tender-related pricing pressure this quarter, sales in China increased in the low single digits year-over-year in quarter three.

Again, we are very pleased with our third quarter results. The operating environment has been challenging in recent months. Everyone is trying to navigate the seemingly ever-changing dynamics surrounded COVID and the impacts are certainly being felt in all areas of our business, our customers, hospitals, clinicians, patients and as Raul will detail to you later in the call, in our supply chain and logistics as well. You'll recall that one of the statements I made during the prepared remarks last quarter was that based on our performance in the second quarter and first half of 2021, we were confident in our expectations for a return to normalized year-over-year growth trends in the third quarter of 2021.

Despite the tougher-than-anticipated operating environment in the quarter, we are proud that we were able to deliver results at the high-end of our guidance range, excluding the

China tender benefit. Raul will review the details of our full year guidance, which we reaffirmed in our press release this afternoon in a few moments. For now, I'll just say that we remain confident in our plan for the year and look forward to continued strong execution from the team going forward.

Now before turning the call over to Raul, I wanted to comment on a few other noteworthy items in the quarter. First, we delivered another quarter of impressive profitability improvement, margin expansion and free cash flow generation in quarter three. Our non-GAAP gross profit and our non-GAAP net income reflects strong leverage in the period, increasing 14% and 26% respectively, compared to the year ago period. Our non-GAAP gross margin increased 210 basis points year-over-year. As expected, we managed our operating expenses prudently, resulting in only a 1% increase in non-GAAP operating expenses compared to the second quarter. And importantly, we generated $18 million of free cash flow in the quarter.

We believe our financial results over the first nine months of 2021 represent early evidence that we're making progress towards our goal of enhancing Merit's long-term growth and profitability profile. We have expanded our non-GAAP gross margins 220 basis points year-over-year despite considerable headwinds in our cost of goods line compared to last year. We have increased our non-GAAP operating margins 250 basis points year-over-year, and most importantly, we have generated nearly $82 million of free cash flow over the first nine months of 2021.

Second, we are pleased with the progress during quarter three of our clinical study, the WAVE Study of the WRAPSODY Endovascular Stent Graft, an investigational the device being studied for the treatment of stenosis or poison within dialysis outflow circuits. We have more than 40 clinical sites identified, 28 of which are actively enrolling patients. The study has been designed to evaluate the safety and efficacy of the WRAPSODY Endovascular Stent Graft for the treatment of venous outflow circuit stenosis or occlusion in hemodialysis patients and represents an important step of our goal of establishing WRAPSODY as the standard of care for more than 2 million patients suffering from kidney disease around the world.

With respect to expanding clinician awareness of the clinical efficacy of WRAPSODY, we were pleased to announce in September that the results from a prospective observational first-in-human study to evaluate the safety and effectiveness of the Merit WRAPSODY Endoprosthesis were published in Cardiovascular and Interventional Radiology. The study reported anatomical, clinical and procedural success in all cases.

According to the primary investigator, Mr. James A. Gilbert, transplant and vascular access surgeon, Vascular Access lead at Oxford University Hospitals, “Early first in human studies show that the Merit WRAPSODY Endoprosthesis can be safely used to treat stenosis at key sites within a dialysis access circuit. Even more encouraging are the very promising primary 1-year target lesion patency rate of 84.6% and access circuit patency rate of 65.9%. To my knowledge, these are higher than any other published data and suggest that the novel features of the WRAPSODY Endoprosthesis may have a key role in preserving the longevity of precious dialysis access for our patients."

Now we are very encouraged by the WRAPSODY first-study positive results, and we look forward to assessing future study results regarding the Merit WRAPSODY Endoprosthesis and making a positive impact in the life of patients suffering from kidney disease.

Finally, I wanted to provide a brief update on our Foundations for Growth programs. Specifically, we've made very nice progress over the first nine months of 2021, including in the areas of SKU rationalization, product line transfers and manufacturing initiatives. The Foundations for Growth program continues to focus on scrap reduction across manufacturing sites, and we're seeing the early benefits of improving our manufacturing efficiency, which is helping to offset the inflationary cost pressures we're seeing in certain raw materials and in shipping and freight expenses. Overall, we continue to execute on our FfG initiatives, and we're excited about the progress and the results we are seeing across our business.

Well, that's a lot. But with that said, let me turn the time now over to Raul, who will take you through a detailed review of our third quarter financial results and our 2021 financial guidance, which we reaffirmed in this afternoon's press release. Raul, you're on deck, and now you're up to the play. Here you go.

Raul Parra^ Thank you, Fred. Given Fred's detailed review of our revenue results, I will begin with a review of our financial performance across the rest of the P&L. For the avoidance of doubt, unless otherwise noted, my commentary will focus on the Company's non-GAAP results during the third quarter and first nine months of 2021. We have included reconciliations from our GAAP reported results to the related non-GAAP items in our press release this afternoon.

Gross profit increased approximately 14% year-over-year in the third quarter. Our gross margin was 49.1% compared to 47% in the prior year period. The approximate 210-basis-point increase in gross margin year-over-year was primarily due to change in product mix, improvements in manufacturing efficiencies on higher volume, offset partially by inflationary headwinds we are seeing in raw materials, logistics and labor.

Third quarter operating expenses increased 18% year-over-year. The year-over-year increase was driven by a 16% increase in SG&A expense and a 24% increase in R&D expense compared to the prior year period. The increase in SG&A expense was primarily due to higher selling expense, including commissions and bonus expense on the increase in sales year-over-year and lower OpEx in Q3 of 2020 from cost-cutting initiatives, lower headcount and lower discretionary spending as a result of reduced travel, training and shows and conventions during the COVID-19 pandemic.

Our continued focus on managing expenses proved effective again this quarter as we were able to limit the growth in G&A-only expenses to just 6% increase year-over-year.

The increase in R&D expenses in Q3 was driven by the combination of lower spend in the prior year period related to COVID and outside expenses for certain R&D projects, in particular, related to the WRAPSODY clinical study and increased compensation expense related to our acquisition of KA Medical and to other new projects.

Total operating income increased $2.8 million or 8% year-over-year to $39.5 million. Our operating margin was 14.8% compared to 15% in the prior year period. Third quarter other expense net was $1.6 million compared to $2.7 million last year. The change in other expense net was driven by lower interest expense as a result of a lower effective interest rate and a lower average debt balance. Third quarter net income was $30.2 million or $0.52 per share compared to $24 million or $0.42 per share in the prior year period. We are very pleased with our profitability performance in the third quarter, where we reported growth in net income and diluted earnings per share of 26% and 24% respectively year-over-year.

Turning to a brief review of our financial results over the first nine months of 2021. Total revenue for the nine months ended September 30 was $796.3 million, up $90.4 million or 13% year-over-year. Total revenue for the first nine months of 2021 increased 11% year-over-year on a constant currency basis. Gross profit increased 18% year-over-year to approximately $390 million representing 49% of sales compared to 46.8% of sales in the prior year period, a 220-basis-point increase year-over-year. Operating profit increased 35% year-over-year to $124 million, representing 15.6% of sales compared to 13% of sales in the prior year period, a 250-basis-point increase year-over-year. Net income increased 53% year-over-year to $95.4 million or $1.67 per share compared to $62.5 million or $1.11 per share in the prior year period.

Turning to a review of our balance sheet and financial condition as of September 30, 2021. Our strong profitability performance in the third quarter of 2021, combined with a strong working capital efficiency resulted in strong free cash flow generation of $18 million in the third quarter. We have generated $81.8 million of free cash flow for the first nine months of 2021. Our free cash flow generation over the first nine months of 2021 is a result of great execution from the team, and importantly, continued evidence that we are clearly focused on enhancing the profitability and cash flow profile of our Company going forward.

We continue to expect to generate approximately $100 million of free cash flow for the full year 2021 period, driven by continued improvements in our profitability and strong working capital efficiency, offset partially by investments in capital expenditures of approximately $35 million this year.

We have used a portion of our strong free cash flow to reduce our outstanding debt obligations over the first nine months of 2021. Specifically, we paid down approximately $72.6 million of debt on our line of credit facility, including $13.7 million, which we paid down in the third quarter.

As of September 30, 2021, we had cash on hand of approximately $68.9 million, long-term debt obligations of approximately 279 and $456 million of available borrowing capacity compared to cash on hand of approximately $56.9 million, long-term debt obligations of approximately $352 million and available borrowing capacity of $389 million as of December 31, 2020. Our net leverage ratio as of September 30 was 1x on an adjusted basis.

Turning to a review of our fiscal year 2021 financial guidance, which we reaffirmed in this afternoon's earnings release. For the 12 months ended December 31, 2021, the Company continues to expect GAAP net revenue in the range of 1.06 and $1.07 billion, representing an increase of approximately 10% to 11% year-over-year. The GAAP net revenue range now assumes a benefit from changes in foreign currency exchange rates in the range of approximately $10.5 million to $11.5 million, representing a tailwind of approximately 110 to 120 basis points to our GAAP growth rate this year.

The GAAP net revenue guidance range also assumes net revenue from the Cardiovascular segment approaching 1.028 and $1.038 billion, representing an increase of approximately 10% to 11% year-over-year. Net revenue from the Endoscopy segment of between 32.5 and $32.7 million, representing an increase of approximately 9.6% to 10.2% year-over-year.

With respect to profitability guidance for 2021, we continue to expect GAAP net income in the range of $38.1 million to $46.4 million or $0.66 to $0.81 per diluted share. Non-GAAP net income in the range of $118.8 million to $127.1 million or $2.07 to $2.22 per diluted share. For modeling purposes, our fiscal year 2021 financial guidance assumes non-GAAP gross margins in the range of approximately 48.8% to 49.1%, non-GAAP operating margins in the range of approximately 15% to 16% compared to 13.7% in fiscal year 2020, other expense in the range of approximately $7 million to $7.5 million; a non-GAAP tax rate in the range of approximately 21% compared to prior guidance, which assumed a non-GAAP tax rate for full year 2021 in the range of 22% to 23% and diluted shares outstanding in the range of 57.5 million to 58 million compared to prior guidance, which assumed approximately 57 million to 57.5 million shares for full year 2021.

With that, I'll turn the call back to Fred.

Fred P. Lampropoulos^ A lot of numbers, Raul. Thank you very much. I appreciate your efforts. Well, first, I wanted to discuss the development subsequent to quarter end. Specifically, the Company made an announcement via Form 8-K filed on October 22, that pursuant to an action taken by the independent members of our Board of Directors, Justin Lampropoulos, is employment as our President of EMEA was terminated effective October 19. No change at this level of leadership is a sensitive issue for any company to manage. And in this particular case, as you can well imagine, given that Justin is my son. Of course, many of you would appreciate that has been especially a difficult situation for me.

For the avoidance of doubt, the decision to terminate Justin's employment was made by our independent directors in a meeting, which I did not participate in accordance with our governance policy. The action was taken in connection with an ongoing inquiry being conducted by an independent party. Because that inquiry is ongoing, it would not be appropriate for me to discuss that work at this point. I would also like to note that other than our public disclosure obligations which were satisfied with the filing of the Form 8-K last week, we do not publicly discuss personnel matters regarding current or former employees.

Now I began immediately the process of engaging with our team in the EMEA region to execute a plan to minimize potential risk disruption as a result of the termination. Importantly, I have appointed as Interim President of EMEA, Dr. Richard Svec. Richard is a vascular surgeon who transitioned from practicing medicine to a number of sales and marketing roles at Covidien and Stryker over a span of more than 20 years before joining Merit in 2015.

He has taken on roles of increasing responsibility in our sales and marketing team in EMEA over the last six years, most recently serving in a leadership role as the Vice President of Strategy Initiatives in EMEA. Dr. Svec and our team and EMA have been focused on engaging with customers and clinicians in the region, and we believe we are well-positioned to continue to deliver the growth objectives we established in the region coming into the year.

Last point on this subject. We appreciate the fact that initial messaging for the Street was less than optimal. And frustratingly, we believe that we missed an opportunity to be more transparent despite the sensitivity of the issue at hand. While we are not able to share additional color on the circumstances that led to the Board's decision, the Street may have found the announcement easier to digest if we had included the additional detail on the transition plan we are already executing. The strong interim leadership we have named an overall confidence in our ability to avoid material disruption in the region. Lesson learned.

In closing, despite the tougher than anticipated operating environment in quarter three, we are proud that we were able to deliver revenue results that exceeded our guidance. Quarter three also represents another quarter of impressive profitability improvement, margin expansion and free cash flow generation. We are confident in our 2021 guidance, which calls for total revenue growth on a constant currency basis of 9% to 10% year-over-year.

And importantly, excluding the impact of divestitures and product sales that uniquely benefit from pandemic-related demand trends in 2020, our constant currency revenue guidance reflects growth of 12% to 13% year-over-year in 2021. We also expect to report improving non-GAAP gross operating margins and strong free cash flow in 2021, driven by strong execution and contributions from our multiyear strategic initiatives related to our Foundations for Growth program.

Now this wraps up our prepared remarks. And operator, we would like to now turn the time back to you and to open up the line for questions.

QUESTIONS AND ANSWERS

Operator^ Thank you, sir. (Operator Instructions) And our first question will come from Mike Matson with Needham & Company.

Michael Stephen Matson^ I guess, I'll start with the Peripheral and Cardiac businesses, Cardiac Intervention businesses. They had really strong kind of mid-teens growth. That seems to be better than what we've seen from some other companies in that space. Just wondering if you could maybe talk about what some of the growth drivers were there and whether or not you think you're taking share maybe in some categories?

Raul Parra^ Yes. So a good pickup there. Our SCOUT Radar Localization products increased 27% on a constant currency basis. That was the largest contributor to our total PI growth. In addition, Biopsy products increased approximately 19% and then drainage and embolotherapy products increased 18%. So together, those represent about 1/3 of our total PI business. So those three products, they've been performing really well this year and continue that progress into Q3.

Michael Stephen Matson^ Okay. And then I wanted to ask one on China. So it sounds like the tenders haven't happened like you thought, but I just wondered what the outlook there was for potential tenders. Do you still expect them at some point? Do you think that they're off the table for now? Or have they just been delayed? And do you still expect it to be in the same kind of categories that you were expecting before, which I think was the balloon inflators primarily?

Fred P. Lampropoulos^ Yes. Listen, Mike, we believe that the long-term growth opportunity in China, despite all of these situations that may or may not be developing remain. So we are continuing to invest with new customers. And as I think I mentioned in previous calls that we were moving into the Midlands. We will discuss what we learned. We don't expect any impact on this year, but we will discuss all of this as we gather more information during this quarter, and then we'll be prepared to discuss this as we forecast in 2022. Raul?

Raul Parra^ Yes. No, I think maybe stepping back a little bit. China, we were expecting low single digits at the beginning of the year. We now expect kind of a 10% constant currency growth for the full 2021. While the pricing headwinds aren't going to impact us, we think this year, as we had originally thought, we are going to -- we are, I guess, experiencing some buying patterns, some small changes in buying patterns from some customers as they anticipate those price reductions.

So as of now, we now expect the tenders and the pricing-related headwinds to really impact us in the first half of 2022. But I guess the best way to say it is in light of the delayed postponed tenders, we really kind of expect China for the fourth quarter to be kind of be flattish.

Operator^ Our next question comes from Jayson Bedford with Raymond James.

Jayson Tyler Bedford^ I guess, just maybe to follow on the last line of commentary, are you still see new products into China. And I'm just wondering, is that still an opportunity for growth is just expanding the bag in China?

Fred P. Lampropoulos^ Yes. We believe that there's a lot of opportunity in China. I mean, we're not backing away. We've received approvals this year, the ASAP. We have embolics. We have a lot of new products have been approved, including the NINJA. We recently were approved for the SNAP. So we're continuing to invest in China. Our ground strategy has changed. And again, I won't go into a lot, I mean, I think we addressed that we're moving inland. We're moving into, I think I mentioned the last time we called we have 30 cities with over 5 million people.

So there's plenty of market there. And I think our strategy is to move towards our peripheral products where there's not much, let's say, attention, is the best way for me to answer it, Jayson.

Raul Parra^ Yes. I think we remain pretty confident in the long-term growth expectations for China overall, to be honest.

Jayson Tyler Bedford^ Okay. And then you mentioned a supply chain dynamic with EndoMAXX, I believe, that weighed on endoscopy growth. Where are you with cleaning up that supply chain dynamic? And is that going to be a drag here in the fourth quarter or into '22?

Fred P. Lampropoulos^ So the answer is that we have -- I'm not going to say solved it because solve means a conclusion, but we expect that by the end of the year that we will have that resolved and back on track. So we're managing it. I think we're doing a very good job. It wasn't us. But as you know, Jayson, a lot of people, a lot of companies that you've talked to today and during the week that have supply chain, this is one of them. I would just say overall, though, that we've been affected. We've seen more of it in the last six months than we did in the previous 18 months. But the good thing about being vertically integrating and being agile and nimble as many of those things we've been able to solve internally, or then tapping our second store.

So I think this one will be fine. But it was also offset by solid growth in the other stent products. And of course, as we continue our Elation dilation balloon and our AEROmini, which is really the pulmonary product line. So I think we'll have it solved. And our guys have done -- I mean, I've got my COO sitting here, and they've done a nice job. But it did affect us in that quarter, and it will be taken care of and we'll be back on track by the end of the year. And again, it will improve monthly as we go along.

Jayson Tyler Bedford^ Okay. I'll keep it at those.

Fred P. Lampropoulos^ Okay. All right. Thanks, Jayson. Good to hear your voice.

Operator^ Our next question comes from William Plovanic with Canaccord.

William John Plovanic^ Great. Thanks. Good evening and thanks for taking my questions. Your revenue was down 4% sequentially, 4.7% from Q3 from Q2, and that's more in line with historical trends. I'm just trying to understand what are you seeing in the field relative to hospital staffing and procedure trends? And more importantly, kind of what is contemplated in your guidance for the fourth quarter of this year? And then how do you see that playing out in 2021?

Fred P. Lampropoulos^ Yes. It's a good question. It's the question that everybody has been asking. I mean, we have followed all of the other companies and the different challenges that the industry is seeing. In our product lines generally, we have not -- better yet, let me restate that. We continue to see better access and more interest. And maybe more importantly than that, and I'm almost reluctant to say this, but a lot of our ability to be able to deliver products that our competitors can't. So one of the things that I think that we'll continue to see is gaining of market share. So anyway.

Now if you're referring to fatigue and staff and those sorts of things, we can read the headlines that's going on every day and everybody is concerned about it, Intermountain Healthcare here in Salt Lake. Everybody -- I think everybody is tired. I mean all of that's going on, but the beat goes on and patients have to be treated. So it is a problem, it is a challenge. But generally, I would say that our business has been well, I don't want to say we're doing better than others because that would be disingenuous. But I think we've been doing just fine. And I think our product mix is very, very broad, and that helps. Raul, you wanted to comment?

Raul Parra^ Yes. No, I think if you look at the updated guidance that we gave after the second quarter, we had the benefit -- we waited to update our guidance, unlike other companies where they came out of Q1. And so we have better visibility, I think to what we saw. And quite frankly, when we looked at the back half of the year, we -- it was in line with our expectations of a choppy recovery, COVID flare ups in certain areas and geographies. I think that's still in play. But now you've also got kind of the logistics issues you've got to worry about. You've got the employee shortfalls as somebody mentioned in the previous question.

So we're seeing all those dynamics. I think when you look at the low end of our guidance for the year, we're $1.60 billion, which is a 10% increase year-over-year. And as you do the math for the fourth quarter, we're really -- we essentially kind of feel like we've covered all the kind of the -- we've got, I guess, I'll say, a wide gap for the fourth quarter, right? So our guidance for the fourth quarter is pretty wide. And it's really trying to cover everything that we're seeing. The choppiness in the recovery, and really, what I want you guys to kind of focus on is the drivers in our Q4 expectations.

First of all, I think the U.S. is probably the most stable in our growth. I think as we model, the Q4 is very consistent with Q3. Our OUS assumptions now reflect some essentially prolonged COVID recovery, softer trends related to spikes in the Delta related cases in recent months. Also the China tenders, although we're not expecting the tender impact, we are seeing some delayed purchases by some distributors as they anticipate some of those price reductions.

So I think overall, if you look at -- kind of you plug in the numbers of what's left for the fourth quarter, I think our Q4 represents constant currency growth of 3% to 5%, excluding the divestitures, 5% to 9%, excluding divestitures and Cultura. So again, I think it's in line with what Fred and I have been saying most of the year, which is kind of getting back to normal growth rates on the back half.

Fred P. Lampropoulos^ And Raul, I think we've called this pretty well. I mean we haven't been overly aggressive. We've kind of called them as we see them. And I think it has served us well the way we've structured and the way we look at the business. So some people criticizes, others say, keep doing what you're doing. We're just looking at the numbers and just want to make sure that we can fairly represent what we see. And if we have upside, that would be wonderful. But I think what we have tried to do has worked for us and worked for our shareholders. So we're just going to continue what we've been doing.

Raul Parra^ Yes.

William John Plovanic^ Okay. And if I could ask a second question. Congratulations on a really good year. It's, you're generating a lot of free cash flow. I think you're well ahead of plan at this point, if I go back and look. And just curious how you're thinking about the cap structure today more in terms of, is continued pay down of debt the best use of cash? Is it acquisitions? Is it stock buybacks? How do you think about that today versus, it was a little while ago, you laid out Foundations for Growth, there's been a lot of changes in especially since you're generating cash faster.

Fred P. Lampropoulos^ So first of all, I think the team has done a very good job. I mean, and this really came from input from shareholders. So you guys were concerned about this, you ought to look at it, and it was one of the things that was very important in Foundations for Growth. One of the things that we've talked about the logistical issues and freight and all those sorts of things, supply chain, but labor is going to continue to be a problem. And even though supply issues in the marketplace may take care of those disruptions and eventually equivocate some, we don't see that in labor.

So one of the things that we'll be looking at is automation projects and spending our money on those projects that help to reduce the reliance and just become more efficient that way. So that's a big focus now to select those that will give us the best returns and be able to support the growth that we see going forward. Raul, do you want to add to that?

Raul Parra^ No. I mean, I think for now we continue to pay down debt. Obviously, acquisitions, you never know when those are going to come along. I don't know that we're avoiding those. I think we're just the hurdle rate, I think, internally is just much higher. We can't frustrate our Foundations for Growth program, which we're really focused on. So again, it's not that we haven't been looking. But as Fred mentioned, things are expensive. And again, we're really focused on Foundations for Growth, and we don't want to frustrate that program.

Fred P. Lampropoulos^ So we are looking. And anyway, I think, again, just to make a point that we are not avoiding things. We've looked at several things, but they are expensive and they have to fit into our plan. And if they don't, then we just have to move on or just be patient. In the meantime, run our business and spend our capital where it will give us the best returns, Raul?

Raul Parra^ And just as a reminder, just as a point of clarification, we're still targeting $100 million in free cash flow for the year, and CapEx, approximately $35 million. It's a big ramp from where we're at right now. But again, we want to make sure that we have the flexibility to make some of the investments for Foundations for Growth and product line transfers for our operations group, along with automation if they need it. So that's why we've left the budget as is.

Fred P. Lampropoulos^ And I wish you could see the green on our COO's face right now. So anyway.

Operator^ Our next question comes from Steven Lichtman with Oppenheimer & Company.

Unidentified Participant^ This is [Amir] in for Steve. And I guess you guys did sort of touch upon it earlier, but I guess, is there any other thoughts you guys would have in terms or comments, I guess, on just the overall inflationary pressure within your business and any other plans that you guys may have in terms of mitigating that pressure going forward?

Fred P. Lampropoulos^ Yes. Listen, it's a big part of our daily conversations. We're seeing price increases coming from vendors. Fortunately, for us, we had a head start on all of us, whether it be COVID or these inflationary things, Merit started our procurement, our freight, our negotiations. corrugate, I mean, you name it, and we've been involved in these negotiations not for six months or three or whatever for this year. We've been involved in for a year or two as part of our program going clearly back to the summer of 2019. I think we are looking and continue to pass on increases with a number of products in a number of areas in a number of divisions.

So I won't go into the specifics because someone might take that and said, “Oh, that was on the call, and they said this or guess what”? But I will just tell you that it has our attention and we are exercising it as we speak in a lot of areas. So Raul?

Raul Parra^ No, I would say we are facing the same thing everybody else is facing, right? I mean labor, freight, raw materials, despite those headwinds and inflationary pressures, our full year low-end guidance still represents a 48.8% gross margin, so up about 180 basis points.

So we're able to absorb, as Fred mentioned, just a second ago, some of those expenses because we had our Foundations for Growth program in place. And again, as we look forward into our 2023 plan, we continue to feel that the confidence that our FfG initiatives will drive us to our continued operating margin expansion that we set in that goal and a big portion of it is gross margin.

Fred P. Lampropoulos^ Yes. And I think that's really important, Raul, because, again, this is what we're focused on. This is what we've been working on. This is what's giving us the results. And yes, we're being hit as Raul said, like everybody else is. But there are a couple of other internal things that we've been able to do, and that's part of what I think is one of the things that Merit does well and that is the vertical integration.

I'll give you an example of one, silicon, we have our own foundry. But we're able to raise prices to our customers and offset those costs. and we have control of the supply chain. So I just have to think with our molding, extrusion, our braiding, our wafer fab. The things that we do and have been doing for a long time have been things that are helping us because we can control those expenses a lot better than just taking and getting the full brunt of what someone might pass on to you.

So there's a lot of things that we're doing. I'll give one last thing, and I'm going on before I should when I shouldn't. But we had a couple of shortages from people, and we looked at our own capabilities, and we were able to deliver the products that we needed to meet product demands in-house while saving $0.25 million. That $0.25 million in the big picture doesn't seem like a lot, but it seems like a lot to me. I'm just saying, we are as well prepared as anybody in my view to meet the challenges that we see in the marketplace, period.

Operator^ Our next question comes from Jim Sidoti with Sidoti & Company.

James Philip Sidoti^ So just to keep on the cost side. Fred, do you think because of the steps you've taken to vertically integrate, you'll be able to continue to grow margins even as cost increase over the next few quarters?

Fred P. Lampropoulos^ Jim, I'm not going to move beyond what we've talked about. I think one of the things that you have hopefully I think you understand this, we've really stick to the knitting and say we're going to talk about the periods and then we'll prognosticate and forecast when it's time to do so. Vertical integration is not something new. It's been something we've done from the beginning. So I'll leave it with that statement. It will continue to be a benefit to Merit. But we'll leave the other stuff until we get into February, and then we'll talk more about where we're going from there.

Raul Parra^ Yes. I mean, I think the -- we're still confident in our FfG goals.

Fred P. Lampropoulos^ And I think that's the important thing. I think if you listen to the -- what we put out on FfG, on cash flow, on operating margins and on earnings per share, if you look at all that stuff, those are the things that we're committed to. And that's what you should pay attention to in our view.

James Philip Sidoti^ And do you have any pricing power if it gets to the point where you're not going to be able to absorb these cost increases?

Fred P. Lampropoulos^ Yes, I think we do have some pricing power. And again, we're very conscientious about how we do things. We don't gouge. We don't take advantage. We look at cost, we look at markets, we look at those sorts of things. So I do think we have some pricing power, maybe that we haven't had in the past to be very honest with you. So yes, I think there is some. Raul?

Raul Parra^ Okay. All right.

Fred P. Lampropoulos^ Good to hear your voice, Jimmy.

Operator^ Our next question comes from Jason Bednar with Piper Sandler.

Jason Bednar^ Just a couple from our side. First, not to hammer here on the cost questions, but just one more follow-up. Just related to the inflationary pressures you called out, would you be able to quantify what those headwinds were that you were able to offset in the quarter?

Fred P. Lampropoulos^ Well, I'll tell you, there are things that we all -- that everybody has, what we go through this labor, there's freight, there's --

Raul Parra^ Every line item on costs --

Fred P. Lampropoulos^ Yes, every line item, I mean, raw materials, yes, I mean everything everybody else is doing.

Raul Parra^ Yes. I think if you do the math and you get to the kind of -- as you start to kind of calculate the fourth quarter range, right? I mean there's -- we have a pretty broad range for the fourth quarter. It's about 110 basis points from low end to high end. Obviously, one of the largest drivers is we also have a wide range on the revenue side. And again, I think what we're trying to do is we don't want to be in a situation where we, one, get ahead on our skis, and two, we're having to revise guidance.

So we're trying to account for everything. And if you look at the kind of the fourth quarter gross margin, part of that is the revenue, kind of the wider range on the revenue and that how it flows through. obviously, whether it's U.S. or OUS mix or which product category, so you have a mix component there.

The one of -- the fourth quarter gross margin also does reflect a 70-basis-point decline quarter-over-quarter driven by incremental inflationary pressures compared to Q3, as Fred mentioned, labor, freight and raw materials. But again, however, despite those pressures, I want to point you to our full year low-end guidance, which is 48.8% on the gross margin, a 180-basis-point improvement. And then again, I want to kind of reaffirm our Foundations for Growth targets and our confidence in that 2023 target.

Fred P. Lampropoulos^ And again, there maybe one message that came out today is our focus on our initiatives. It's a three-year plan. We're 10 months into a 36-month plan. And despite all of the other things, we have a plan to execute, and that's what we are focused on across the board. So there's a lot of factors that go into that. We've talked about automation. We've talked about this, that and the other. But we're focused on delivering what we said we would deliver. That's the message of the day.

Raul Parra^ Yes. I mean I think, to be clear, and I've said this over and over again, but I'll repeat it just to make it clear. We have a wide range of revenue and EPS in the fourth quarter and to hit our fiscal year '21 guidance. But it reflects that we are confident in our ability to deliver the low end of our guidance range, but also remain cautiously optimistic given the level of COVID-related uncertainties and all the other noise that you're hearing out there with a wide range of outcomes in Q4. So I think we've tried to anticipate everything that could hit us, I guess, is the best way to say it.

Jason Bednar^ Yes, absolutely. And you've all have been executing very well against that plan. So you deserve congrats on that. Raul, just maybe to follow up on one other earlier question. I think it was Mike's question on China. Is your point on China that customers are running more lean on inventory, I think you mentioned maybe distributors buying less.

I guess for maybe any additional color you can add on just that altered alter buying pattern that you alluded to, I guess just really trying to figure out if we end up having maybe a combination of price declines, but then maybe also some inventory normalization within your customer base in '22?

Raul Parra^ Yes. I mean I don't want to get into 2022 guidance or any color around there. Obviously, we did mention that we now expect that pricing component to hit us in the first half of 2022. But again, I think what we're seeing, at least for the fourth quarter, what we've kind of planned on is just a lower ordering from our customers. Just, I guess, in light of the delayed or postponed tenders, right? So they're anticipating a little bit of that. But again, we've tried to include it in our guidance. And once we get to 2022, I think we'll give you more color there, and I'd say dial-in February 2022.

Fred P. Lampropoulos^ But again, despite all of those issues, I hope you didn't miss that we're expanding into other areas with products that we have that are not in focus on very pricing issues. We have a strategy, is what I'm trying to say. It's not that we're just having it come at us. We're blanking, so to speak, and delivering our products and new opportunities there as well. And our long-term forecast continues to be positive in China. So that's -- I don't want you to forget that. It's not -- I mean, what I heard was just one side, if you got to hear the other side and why we remain confident.

Operator^ Our next question comes from [Ron Kempen].

Unidentified Participant^ Fred and Raul, a great quarter. That's really great.

Fred P. Lampropoulos^ We should have put you up first. I mean, I don't know why we waited, so thank you for your patience with us.

Unidentified Participant^ That's all right. It was a great quarter. The only question I have is I was thinking about this tax increase that Biden is proposing which, of course, is off the wall, but in any event, have you done any modeling to see what effect that might have on 2022?

Fred P. Lampropoulos^ First of all, yes. So as you've heard us in this entire call, we're not commenting on that. I would say this. If we were doing that, we would all have to take medications and other things because it changes every day. I mean, who knows, It's exercise in futility.

So I think we'll wait and see what happens, and then we'll report that under our forecasting. So I mean, we're as frustrated as you are in terms of just trying to understand where anything is going, who knows. But as we gather that information, we'll put it into our models, we'll deliver it in our forecast and our views for next year.

Unidentified Participant^ Very good, continued success, guys. I appreciate it.

Fred P. Lampropoulos^ Thank you, sir. I appreciate the call. I hope you call next time. We'll put you right up on top.

Operator^ There are no further questions at this time. Please proceed with any closing remarks.

Fred P. Lampropoulos^ Thank you, Michelle. And listen, we appreciate all of you at a very, very busy earnings season, we took a full hour here. I hope we were able to answer your questions. Raul and I will be around for the next 2.5, 3 hours. And we will speak further. Not anything that we haven't talked about, but just trying to get maybe detail on certain things should you ask. We don't know what your questions are, but we're here. Thank you very much.

Listen, there were no questions regarding the 8-K and that's fine. We look forward to taking your questions in our private meetings that are coming out in the next hour. Thanks, everybody, and best wishes for now and for holiday season, we have the holidays upon us, enjoy the fall. God bless you all and thank you. Good night.

Operator^ That does conclude our conference call for today. Thank you for your participation.