Merit Medical Systems, Inc(Q3 2022 Earnings)

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Corporate Speakers:

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

Participants:

- Jayson Bedford; Raymond James & Associates, Inc.; Research Division, MD & Senior Medical Supplies and Devices Analyst
- Lawrence Biegelsen; Wells Fargo Securities, LLC; Research Division, Senior Medical Device Equity Research Analyst
- Michael Matson; Needham & Company, LLC; Research Division, Senior Analyst
- William Plovanic; Canaccord Genuity Corp.; Research Division, Analyst
- Joseph Downing; Piper Sandler & Co.; Research Division, Research Analyst
- James Sidoti; Sidoti & Company, LLC; Research Analyst
- Michael Petusky; Barrington Research Associates, Inc.; Research Division, MD & Senior Investment Analyst

PRESENTATION

Operator^ Welcome to the Medical Systems Third Quarter 2022 Earnings Conference Call. (Operator Instructions) Please be advised that today's conference is being recorded. I would now like to hand the conference over to your speaker today, Fred Lampropoulos. Please go ahead.

Fred Lampropoulos^ Thank you, and welcome, everyone, to Merit Medical Systems Third Quarter of Fiscal Year 2022 Earnings Conference Call. I am joined on the call today by 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 provisions, please?

Brian Lloyd^ Thank you, Fred. 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 upon 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 anticipated.

In addition, any forward-looking statements represent our views only as of today, October 26, 2022, 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 those 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.

A 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 Lampropoulos^ Thank you, Brian. And let me start with a brief agenda of what we will be covering during our prepared remarks. I will start with an overview of our better-than-expected revenue 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 2022 that we updated in today's press release as well as a summary of our balance sheet and financial condition. We will then open the call for your questions.

Beginning with a review of our third quarter revenue performance. We reported total GAAP revenue of $287 million in the third quarter, up 7.5% year-over-year. Our total GAAP revenue growth was driven by 8.6% growth in U.S. sales and a 6.1% growth in international sales. Our total revenue increased 10.5% year-over-year in the third quarter on an organic constant currency basis, excluding the headwind to our GAAP revenue growth related to changes in exchange rates compared to the prior year period.

We delivered constant currency revenue results that exceeded the growth expectations that we discussed in our second quarter earnings calls. Specifically, we shared our expectation for constant currency revenue growth in the range of 4% to 6% year-over-year in quarter three.

The better-than-expected constant currency revenue results were driven by solid execution from our team, stronger-than-anticipated demand in the U.S. and more favorable than anticipated international sales trends, particularly in EMEA and the APAC regions.

Now, let me provide you with a more detailed review of our revenue results in the third quarter, beginning with a sales performance in each of our primary reportable product categories. Note, unless otherwise stated, all growth rates are approximated and are on a year-over-year and constant currency basis.

We have included reconciliations from our GAAP reported results to the related non-GAAP item in our press release and presentation available on our website. Third quarter total revenue growth was driven by 10% growth in our Cardiovascular segment and 14% growth in our Endoscopy segment. Sales of our peripheral intervention products increased 12%, representing the largest driver of total cardiovascular segment growth again in this quarter.

Within the PI category, sales of our embolics and access products increased 18% and 24%, respectively, and together represented nearly half of total PI growth. And sales of our Scout radar localization and geography and biopsy products each increased in the low double digits year-over-year and together represented roughly 1/3 of our total PI growth.

Within our cardiac intervention business, sales increased 12% in quarter 3, representing the second largest contributor to total cardiovascular segment growth year-over-year. Cardiac intervention growth was primarily driven by 26% growth in sales of intervention products and 25% growth in the sales of our EPE CRM products.

Intervention products are the largest portion of our CI product category, which makes the 26% growth in quarter three even more impressive. Intervention products growth was driven by a notable increase in the sales of our MAP angioplasty packs and mid-teens growth in sales of our basic inflation devices. We also saw strong demand for our PhD hemostatic valve products in quarter three. The 25% growth in sales of our EP CRM products was driven by strong demand for our Snap sheets and our hard ban cheese and transseptal needles.

Sales of our OEM products increased 23% and outperformed our expectations more than anywhere else in the business in quarter three. Some of this is a function of the challenge in predicting this type of business with quarterly precision, but we believe the third quarter revenue performance reflects continued improving demand from larger customers in multiple categories, including kits, cardiac access, coatings and fluid management.

While OEM growth was certainly a positive surprise, sales of our CPS products declined 3%, modestly unperforming relative to the flattish growth assumed in our guidance.

Finally, sales in our Endoscopy segment increased 14% in quarter 3 at the high end of the growth range we provided on our quarter two call. Recall that our quarter 3 guidance had assumed a notably wider range of sales in our Endoscopy segment, given the potential business disruption issues with a third-party contract manufacturer.

As indicated on our quarter two call, we viewed this disruption as transitory and indeed it was. We managed through the transition and delivered sales results at the high end of the growth range. Of note, endoscopy growth was driven by strong demand for both our elation and esophageal balloon products and our EndoMAXX fully covered esophageal stents.

Now, turning to a brief summary of our sales performance on a geographic basis. Our third quarter sales in the U.S. increased 7% year-over-year. Sales to U.S. customers came in above the high end of our growth expectations and represented 36% of our total company constant currency growth this quarter.

OEM standout performance represents the largest contributor to the better-than-expected U.S. growth this quarter. PI, CI and Endoscopy revenue all came in at the high end of our expectations, reflecting continued strong execution and overall improving trends in the U.S.

Our third quarter international sales increased 16% year-over-year, which is a strong performance in light of the challenging global macro environment in quarter 3. All 3 of our major regions posted growth in the mid- to high teens in the third quarter, specifically, sales in APAC, EMEA and the rest of the world regions increased 14%, 17% and 19%, respectively, year-over-year.

While all three regions exceeded the high end of our guidance expectations, EMEA and APAC drove more than 80% of the upside. EMEA growth was driven by demand from customers in Eastern Europe, the Middle East and Western Europe, specifically in the U.K., France, Germany and Italy. APAC growth was driven primarily by mid-teens growth in China where we are seeing strong demand for our PI and CI product, which is more than offsetting the continued headwinds related to volume-based purchasing.

And lastly, in our Rest of World region, we delivered 19% growth year-over-year, which was also ahead of expectations, driven by strong demand from customers in Canada and Brazil. In summary, we are encouraged by the improving growth trends and proud of our team's strong execution despite another quarter marked by challenging operating environments, particularly in the international markets.

Now, before I turn 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, non-GAAP operating income and non-GAAP net income increased 6%, 17% and 23% year-over-year, respectively, in quarter 3. Our non-GAAP operating margin increased 130 basis points year-over-year to 16.1%, and we generated $20 million of free cash flow in the quarter.

We believe our financial results over the first 9 months of 2022 represent clear evidence that we are executing towards our goal of enhancing Merit's long-term growth and profitability profile.

We remain committed to the financial targets that we outlined in the Foundations for Growth program for the 3-year period ending December 31, 2023, which by way of reminder, call for constant currency organic revenue to increase at a CAGR of at least 5%; non-GAAP operating margins of at least 18% and cumulative free cash flow generated of more than $300 million.

Second, I wanted to highlight another area where our team has been executing well towards one of our key strategic initiatives, specifically the development clearance and commercialization of new products. In addition to the four new product updates discussed on our quarter two call, we highlighted our continued progress in these areas with 4 notable press releases in the third quarter.

In July, we announced the launch of a new version of our Elation pulmonary balloon dilator, one that happens to be the smallest and shortest configuration offered in our range of multistage pulmonary balloon configurations. The unique balloon size fits a critical need in the pulmonary care space. Historically, physicians have relied on single-stage cardiovascular balloons that were often too large and too long for use in smaller airways.

This new configuration allows physicians to accurately match balloon diameter and length to specific small airways in the lungs, bringing treatment options to more patients. In August, we announced the launch of our Safeguard Focus Cool compression device.

This new compression device builds upon the original Safeguard Focus, a revolutionary idea that provides compression over closed surgical sites, which can assist hemostasis in patients with pacemaker and implantable cardio defibrillator pocket. The Safeguard Focus Cool offers the same high performance but with an easy-to-prepare cooling solution that does not require refrigeration, making it ideal for the lab environment.

In September, we announced the launch of our Prelude Roadster Guide Sheath. The Prelude Roadster is the newest addition to Merit's vascular peripheral access portfolio, which includes introducers and other products, including access kits, vessel dilators and accessories. The Roadster is designed for deliverability, visibility and resilience in torturous peripheral vascular anatomies.

Indicated for use in a variety of procedures, we believe this device will also help deliver devices used to diagnose and treat the estimated 6.5 million people aged 40 and older in the U.S. suffering from peripheral artery disease, or PAD. PAD is a serious condition where there is a narrowing or blockage of the vessels, mainly in the legs and lower extremities that prevents blood flow to these areas. PAD is associated with a twofold increased prevalence of heart failure as well as the risk of limb amputation.

To diagnose and treat PAD procedures are performed to detect an open block vessel, Merit's Prelude Roadster can help make these procedures available to more patients. And finally, in late September, we announced the launch of our TEMNO Elite Soft Tissue Biopsy System. The TEMNO Elite is the latest addition to Merit's comprehensive portfolio of biopsy devices and is a single-use device indicated for use in various soft tissue locations such as liver, lung, lymph nodes, kidney and other soft tissue suspect lesions.

We believe that TEMNO Elite represents another example of Merit's ongoing commitment to the advancement of biopsy procedures with its broad portfolio of products aimed at improving diagnostic accuracy in pathology labs across the nation.

I'm proud of the team's continued commitment to strong execution in the areas of development, clearance and commercialization of new products. Now with that said, let me turn the call over to Raul, who will take you through a detailed review of our third quarter financial results and our 2022 financial guidance, which we updated in today's press release. Mr. Parra.

Raul Parra^ Thank you, Fred. Given Fred's detailed discussion 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 of fiscal year 2022. We have included reconciliations from our GAAP reporting results to the related non-GAAP items in our press release and presentation available on our website.

Gross profit increased approximately 6% year-over-year in the third quarter. Our gross margin for the third quarter was 48.4% compared to 49.1% in the prior year period. The 66 basis point decrease in gross margins year-over-year was primarily due to unfavorable manufacturing variances, specifically purchase price variances.

As expected, we experienced higher freight costs compared to the prior year period. We continue to prioritize meeting customer demand and managing back orders, which has led to a higher mix of air shipments and delayed the transition back to a more cost-effective ocean alternative.

As expected, our third quarter results reflect the inflationary headwinds we are seeing in freight, logistics, labor and increasingly in raw materials. Similar to what we experienced in Q2, while our guidance assumes higher raw material costs and freight logistics expense year-over-year, our third quarter results included incremental headwinds from higher-than-expected raw materials and freight and logistics expenses, each of which represented headwinds to our non-GAAP gross margins of roughly 30 basis points on a year-over-year basis.

Third quarter operating expenses increased 1% compared to the third quarter of 2021. The year-over-year increase in operating expenses was driven by a 2% increase in SG&A expense and a 3% decrease in R&D expense compared to the prior year period. Our operating expense performance in Q3 was better than expected and reflects continued prudent expense management.

Total operating income in the third quarter increased $6.7 million or 17% year-over-year to $46.2 million. Our operating margin for Q3 was 16.1% compared to 14.8% in the prior year period. The year-over-year change in operating margin was driven by a 128 basis point reduction in our non-GAAP operating expense margin compared to the prior year period, offset partially by the 66 basis point decrease in our non-GAAP gross margin.

Third quarter other expense net was $800,000 compared to $1.6 million last year. The change in other expense net was primarily related to decreased expense from realized and unrealized foreign currency losses compared to the prior year period, partially offset by increased interest expense due to a higher effective interest rates year-over-year.

Third quarter net income was $37 million or $0.64 per share compared to $30.2 million or $0.52 per share in the prior year period. We are very pleased with our profitability performance in the third quarter, where we delivered year-over-year growth in both non-GAAP net income and diluted earnings per share of 23%, exceeding the high end of our guidance range, which calls for low single-digit net income and EPS.

Turning to a brief review of our financial results over the first 9 months of 2022. Total revenue for the 9 months ended September 30 was $856.6 million, up $61.3 million year-over-year or 10% growth on a constant currency basis. Gross profit increased 7% year-over-year to approximately $46 million, representing 48.5% of sales compared to 49% of sales in the prior year period, a 50 basis point decrease year-over-year.

Now, compared to the first estimate that we have experienced incremental headwinds to our gross margin of more than 250 basis points related to inflationary pressures in raw materials, freight and logistics. The early benefits we were seeing as a result of the team's hard work and dedication to our Foundations for Growth program are the primary reason we have been managed to offset the majority of these inflationary headwinds to our gross margins this year.

Operating profit increased 15% year-over-year to $142.8 million, representing 16.7% of sales compared to 15.6% of sales in the prior year period, a 110 basis point increase year-over-year. We are driving strong operational leverage through prudent expense management, which is resulting in operating profit growing faster than revenue growth over the first 9 months of 2022. Net income increased 15% year-over-year to $109.7 million or $1.91 per share compared to $95.4 million or $1.67 in the prior year period.

Turning to a review of our balance sheet and financial condition. As of September 30, 2022, we had cash and cash equivalents of $51.5 million, long-term debt obligations of approximately $217 million and available borrowing capacity of approximately $509 million. This compares to cash on hand of $67.8 million, long-term debt obligations of approximately $243 million and available borrowing capacity of approximately $490 million as of December 31, 2021.

Our net leverage ratio as of September 30 was 0.7x on an adjusted basis. With respect to our cash flow generation in the third quarter, our strong profitability performance in the third quarter of 2022, combined with strategic working capital investments resulting in a strong free cash flow generation of $20 million in the third quarter.

As expected, our use of free cash for working capital increased compared to the prior year period. In recent quarters, we have discussed our strategy to proactively invest in our inventory balances to build the requisite safety stock and ensure high customer service levels. We generated $54 million of free cash flow during the 9 months ended September 30, 2022. We continue to expect strong free cash flow generation this year and remain on track to deliver our goal of generating at least $75 million of free cash flow in 2022.

Of note, this free cash flow target assumes planned investments related to the Foundations for Growth program that are expected to drive our CapEx investments in the range of $55 million to $60 million in 2022.

Turning to a review of our fiscal year 2022 financial guidance, which we updated in today's press release. For the 12 months ended December 31, 2022, we now expect GAAP net revenue growth of approximately 6.5% to 7.1% year-over-year. This GAAP net revenue range now assumes a headwind from the changes in foreign currency exchange rates in the range of approximately $23.7 million, representing a headwind of approximately 220 basis points to our forecasted GAAP growth rate this year.

This FX impact reflects an incremental headwind of $5 million as compared to our prior 2022 guidance. Note, roughly $2 million of this incremental FX headwind was realized in Q3 with the balance of the increase expected to impact our GAAP revenue results in Q4.

The GAAP net revenue guidance range now assumes net revenue growth of approximately 6.6% to 7.1% in our Cardiovascular segment compared to 5% to 6% in our prior guidance range and net revenue growth of approximately 3.8% to 5.4% in our Endoscopy segment compared to our prior guidance, which assumed a range of a 5% decline to an increase of 8% year-over-year.

With respect to profitability guidance for 2022, we now expect GAAP net income in the range of approximately $64.8 million to $68.3 million or $1.13 to $1.19 per diluted share. This compares to our prior guidance range, which assumes GAAP net income in the range of $62.4 million to $68.3 million or $1.08 to $1.18 per diluted share.

Non-GAAP net income in the range of approximately $146.9 million to $150.4 million or $2.55 to $2.61 per diluted share. This compares to our prior guidance range, which assumes non-GAAP net income in the range of approximately $139.6 million to $145.5 million or $2.42 to $2.52 per diluted share.

For modeling purposes, our fiscal year 2022 financial guidance now assumes non-GAAP gross margins in the range of approximately 48.5% to 48.8% compared to a range of 49% to 49.15% previously. While we are pleased with our continued progress, we are seeing as a result of our FFG initiatives in the area of pricing, we continue to see significant increases in the areas of raw materials and freight logistics.

The 40 to 50 basis point revision to our non-GAAP gross margin expectations reflects the impacts of rising raw material costs and freight and logistics expenses over the second half of 2022, which are incremental to the increases contemplated in our prior guidance assumptions. Note, roughly 20 basis points of the change in our gross margin expectations was related to Q3, with the balance expected to impact our Q4 financial results.

Finally, while the impact of higher raw material cost is largely outside of our control, the impact on our gross margins in the second half of 2022 comes from a higher mix of air freight versus shipping freight, which is a direct result of our strategic decision to respond to the stronger-than-expected demand for our products around the world.

Returning to a review of other key modeling assumptions supporting our updated financial guidance for 2022. We now expect non-GAAP operating margins in the range of approximately 16.8% to 17.1% compared to a range of 16.6% to 17.1% previously. GAAP and non-GAAP other expenses of approximately $6.1 million and $4.2 million, respectively, compared to $6.5 million and $4.8 million previously, a full year 2022 tax rate of approximately 22% versus 24% previously and diluted shares outstanding of approximately 57.6 million.

Lastly, given the continued uncertainty in the global macro environment, we would like to provide additional transparency related to our growth and profitability expectations for the fourth quarter of 2022. Specifically, we expect our total revenue to increase in the range of approximately 3% to 5% increase year-over-year on a GAAP basis and up approximately 6% to 8% year-over-year on a constant currency basis.

Note, the midpoint of our fourth quarter constant currency sales growth expectations assumes approximately 5% growth year-over-year in the U.S. and approximately 10% growth year-over-year in OUS markets. With respect to our profitability expectations for the fourth quarter, we expect to see non-GAAP gross margins in the range of flat to up 100 basis points on a sequential basis.

We also expect to see non-GAAP operating margins increase in the range of 120 basis points to 240 basis points on a sequential basis. These margin expectations, combined with a notable increase in our non-GAAP tax rate compared to last year, specifically 23% versus 13% in Q4 of '21 are expected to drive a change in non-GAAP net income and EPS in the range of down high single digits year-over-year on a low end to flat year-over-year on the high end of the range. With that, I'll turn the call back to Fred.

Fred Lampropoulos^ Well, thank you, Raul. A lot of numbers and a lot of work done there. So I appreciate it very much. In closing, our third quarter growth and profitability performance exceeded our expectations, which we believe is a direct result of our team's continued strong execution and relentless focus on our strategic initiatives.

We now know how hard they are working and how they are delivering these strong results despite the continued challenging operating environment around the world. We'd like to thank all of our team members around the world that made our performance over the first 9 months of 2022 possible.

Importantly, we are not resting on our prior success, we remain committed to continued progress. We're confident in our 2022 guidance, which now calls for the total revenue growth on a constant currency basis of 9% year-over-year. We also continue to expect to report improving non-GAAP operating margins and strong free cash flow in 2022.

Now that wraps up our prepared remarks, and we'll turn the time back over now to our administrator for your questions. And then following that, Raul and I will be available for the next couple of hours to visit and get into more detail if necessary. We'll now turn it over to the administrator. Thank you very much.

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question will come from the line of Jayson Bedford from Raymond James.

Jayson Bedford^ So I guess just a few for me. First, fourth quarter guidance, specifically on the implied organic growth there. I guess the question is, and I can appreciate it's a dynamic market out there. But was there anything onetime-ish in the third quarter result that kind of propped up the organic growth in the quarter?

Fred Lampropoulos^ Jason, the answer is no.

Jayson Bedford^ Okay. Maybe for Raul or Fred, some of the gross margin dynamics. You stressed kind of the ocean versus air in terms of freight. When does that dynamic flip? I'm guessing sometime in '23, but any kind of framing on that would be great.

Raul Parra^ We won't get ahead of ourselves to talk about 2023, Jayson. But I think what we're looking for is reliability. I think things are definitely opening up and there's more capacity. It's just not reliable enough for our customers' needs, quite frankly. And so to the extent we continue to see the demand that we're seeing, we'll continue to kind of use the current air versus ocean mix that we have. So I guess it's dependent a little bit on that reliability of the carriers and the demand from our customers.

Fred Lampropoulos^ Yes. And I would just say that's correct. And I think you saw that international result, and that was a result of making decisions to meet customer needs. It's as simple as that.

Jayson Bedford^ And maybe just a last one for me, product related. Can you comment on Rhapsody in Europe? And then just a reminder as to where we stand in terms of U.S. timing for that product?

Fred Lampropoulos^ Sure. Rhapsody is in terms of timing, we're about halfway through -- pretty close to halfway through the trial. Again, there was a number of -- we had the whole COVID thing and then -- but it has been accelerating in terms of that enrollment. So I'm going to still say it's 2 to 2.5 years out. for that approval. We still continue to be very pleased, and we've also seen a lot of interest to continue to build the business over in Europe as well as Brazil.

Operator^ Our next question comes from the line of Larry Biegelsen from Wells Fargo.

Lawrence Biegelsen^ Fred, I just wanted to start maybe on 2022. I mean year-to-date, OpEx is relatively flat. R&D spending is actually down a little bit. So how are you holding OpEx flat in an inflationary environment?

Fred Lampropoulos^ Yes, it's a good question, Larry. I'm going to -- Raul and I were talking about this, and I think he has a better explanation than I would have. I'll let him pick this spend then I'll come back and comment if I need to add anything further. Raul?

Raul Parra^ Yes. I mean I think we've -- a lot of the right investments this year, Larry, in certain things like trade shows and travel, some of that expense is up, and you'll see it in the SG&A line. I think on the R&D line, quite frankly, there's cost initiatives and things that are ongoing from that standpoint, including R&D and clinical. I think on the clinical side, things have been a little bit slower than we anticipated on the enrollment. So that helps. And also just as we shift and move on priorities within R&D, that tends to push expenses out one way or the other.

So again, I think it's just prudent expense management on our side, making sure that we understand that we're still in a choppy environment. On the way to kind of normalize recovery. So just being patient with our expenditures. And then some of it is just kind of outside of our scope.

Fred Lampropoulos^ And let me just add to that. And you've heard me say this many, many times. Our vertical integration allows us to control our production and to adapt to the conditions. And that continues to be a very big deal for us. Merit just does it really well. I mean we made those investments a long time and over the years, but it's made a difference. Raul?

Raul Parra^ I think lastly, too, I just want to make sure that I point out our executive team and our employees, we're all really committed to achieving the 18% non-GAAP operating margin as we head into 2023. So I think there's a broad commitment from the executive team and the employees on making sure that we're frugal in our expenses.

Lawrence Biegelsen^ If I think about 2023, you guys could have flat sales essentially and still meet your foundations for growth, 5% CAGR because you've done so well since you gave those goals in 2020. Fred, how do you want people to think about the momentum you have here? I mean the (inaudible) implies about 9% organic growth in 2022, the momentum? And how do you want people to just think about the growth algorithm for Merit going forward?

Fred Lampropoulos^ Larry, we want them to think about February of 2023 when we will go through our entire program. That's what we want people -- we want to finish the year. We want to stick to the goals that we've set. And in 2023, around February-ish, we will go through and we will lay out our plan from there.

Operator^ Our next question will come from the line of Mike Matson from Needham.

Michael Matson^ Yes. I want to ask one on currency. I understand you're pretty clear of the impact on your top line. But I was just wondering if you can maybe talk about the impact on the expense side or the P&L. Has it had a material impact on your earnings? How well hedged are you? And as we head into 2023, is there a risk of any surprises there in terms of hedges rolling off or anything like that?

Raul Parra^ So we obviously have a hedging program in place that buffers some of the impact that we're seeing. We also have natural hedges in place. As you know, we have operations in Europe and then also some level of expenses in the APAC region that help also with our hedging.

So I'd say, generally, we don't disclose the impact to the rest of the P&L. I would say that we might have some geography mixes within gross margin and OpEx because of the FX. But our hedging program is really designed to minimize the impact on EPS. And so I think that's why you're seeing kind of a minimal impact on the earnings side.

Michael Matson^ Okay. And just as we head into 2023, I mean there's no reason to expect that to change at all that you should be able to continue to offset most of the impact.

Raul Parra^ I think we're going to be like most people, right, from an FX standpoint, I think most people, as things lapse, you're probably looking at the first half of the year next year that people are going to be challenged with FX. But again, for us, I think it's kind of business as usual.

Fred Lampropoulos^ Well, and I think, Raul, to your point, we have what we think is a successful program, and we'll stick with that program. That's right.

Michael Matson^ Okay. Got it. And then just one on China. So I think you said you saw mid-teens growth there, but you did call out some impact from the VBP program. So I don't know if you're willing to quantify what -- like how much better your growth would have been without VBP? And then just what's the longer-term outlook there in terms of

VBP? Do you expect continued headwinds from that over the next few years as they expand into more product categories?

Fred Lampropoulos^ Yes. Mike, listen, volume-based purchasing tenders are happening, but they are conflating in our guidance. So we've taken that. We don't talk specifically about this, that or the other, but we have contemplated those and those are part of our guidance that we've provided and will be part of our discussion in February.

Operator^ Our next question comes from the line of William Plovanic from Canaccord.

William Plovanic^ A question on guidance for this year. If I'm doing my math right, and please correct me if I'm not. You're basically saying revenue is going to be flat sequentially in Q4 and EPS will be about flat sequentially when we get to the low end of guidance. What are you contemplating in that low end of guidance? The fourth quarter is typically a much bigger quarter for everything. So I'm just trying to understand what gets us to the low end versus the high end.

Raul Parra^ Sure, for sure. Look, I think, first of all, we had a great Q3. I think our Q4 growth really reflects kind of the continued improvement in the operating environment, as we've talked about over the last 1.5 years. So again, a kind of a recovery -- a choppy recovery to normal is kind of how we see things.

So we expect Q4 total revenue growth of approximately 6% to 8% year-over-year on a constant currency basis. The midpoint of our fourth quarter constant currency sales growth expectations assumes roughly approximately 5% constant currency growth year-over-year in the U.S. markets. and approximately 10% constant currency growth year-over-year in our OUS markets. So I think those are pretty solid growth numbers when you look at it on a year-over-year basis.

William Plovanic^ And then how does FX the hedging impact your gross margins? Obviously, you're taking a hit to revenue. Do you -- how does -- help us understand because the question really lies is, okay, so you haven't -- your gross margins has actually come down a little. It doesn't seem like you get to benefit from it depending on where you put your FX into the P&L.

And I'm just trying to understand, okay, as rates kind of the dollar peaks strengthening and starts weakening again, how does that flow through into next year in terms of gross margin as we're looking at it.

Raul Parra^ We're not going to get into the details of that. As you know, Bill, I mean, these things are pretty complex, especially as companies -- from company to company. I would just generally say that we have operations in Ireland. So as the euro drops, obviously, that helps us, but also as revenue drops, that hurts us. So there's a lot of offsets and hedging that goes in place along with intercompany balances that also kind of feed into that from a hedging standpoint.

So I'd say it's pretty complicated stuff, but -- which is why we don't get into all the details of what it does to the rest of the P&L. I'll just end with saying that our hedging program is made to really minimize the impact on EPS, right? So that's the ultimate test for us is how is our EPS moving one way or the other. And so far, I think it's done a pretty good job of keeping us within our original guidance.

William Plovanic^ Last question, if I may, just on China. I mean, you guys have significant exposure to China. I think it's 13% of your sales or something like that. It's a pretty big piece of your business. Help us understand, obviously, in this day and age, there's just a lot more protectionism coming in. And how are you protected from a top line and bottom line perspective in terms of that business?

Raul Parra^ Well, I mean, look, I think if you look at our growth for one, I mean, we had outstanding growth in almost every region. So I would say that we're not overly dependent on China. I mean our APAC growth was pretty stellar. So I would say that generally, China is a big part of our business, but -- and we continue to invest there. We continue to register products -- but I think there's other areas that we're investing also that can help minimize the impact from that standpoint.

Operator^ Our next question will come from the line of Jason Bednar from Piper Sandler.

Joseph Downing^ You got Joe Downing here on for Jason. So a bigger picture question on pricing dynamics. It sounds like some of the initiatives from the company are having some real positive effects and a few intertwined questions here. But could you give us a sense as to where you're having the most success taking price in this environment on a product level or a country-level basis? And then how sticky do you think this price increase trend can be as we look forward to '23?

Fred Lampropoulos^ Yes. Let me just say that the pricing is part of one of the pillars of our foundations for growth. And I think that is generally the area -- I'm not going to address specifically, but it is one of those issues that we identified a long time ago, and it's helping a lot. So I'll just leave it at that. And it helps to offset, of course, the inflationary pressures. And it's part of the reason we delivered the financial results in the third quarter. So it's an important part of our overall program. And again, we'll talk about maybe these factors sometime in February.

Joseph Downing^ And one more for us. So I have in my notes that you were (inaudible) to get some product line transfers from our Texas facility down to Mexico. And we were wondering if you could update us here on the progress you've made with that initiative? Is it complete? And what's the right way to think about the cost savings from the (inaudible)?

Fred Lampropoulos^ I'm going to let Raul pick that one up.

Raul Parra^ Yes. It's obviously one of our foundations for growth targets. We don't give detailed kind of status of where things stand. I would say it's in progress. It is a multiyear effort. As you can imagine, moving that many product lines that are registered all over the world just takes time, which is why we don't call out the specific details. But I would say the work is ongoing and there's still wood to chop there.

Fred Lampropoulos^ And it's part of another pillar in our foundation for growth. These are the things that we identified, and we talked about when we came out with our program in terms of footprint and consolidation. So it's an important part of our overall program of improving the operations of the company.

Operator^ Our next question will come from the line of Jim Sidoti from Sidoti.

James Sidoti^ So you increased your revenue guidance despite an increase in the currency headwinds. So are you doing that because you're seeing share gains? Are you getting better traction with the new products? Or are the price increases starting to take effect?

Fred Lampropoulos^ Yes, yes and yes. I don't want to be a wise guy, but I think the performance is always, as you know, Jim, a function of a lot of factors. Yes.

Raul Parra^ I mean I'll take a minute to maybe thank our sales force for the efforts and the execution on their part, not just one region. I mean, it's across multiple regions and then also our operations group for being able to deliver the product. I think it's a challenging environment right now, procuring raw materials and getting people to show up to work, and they're doing a magnificent job, not only on execution on the sales side, but then being able to also deliver the product. So we're pretty excited about the efforts on their part and want to just thank them, I think, publicly.

James Sidoti^ It sounds like the supply chain issues with the endovascular business are behind you at this point. Do you see any of the other supply chain issues starting to improve? Or do you think there's still going to be a factor going into next year?

Raul Parra^ Jim, that's a great question. We continue to see kind of modest disruption, right? I think it's hard to predict. That's what I would say. I think things are generally getting better, but we have a hard time predicting whether things are going to be stable or not. And it's just one-offs. That's the problem that we see, right? It's a little plastic part that you wouldn't have thought of. And it's just -- it's random things and it's still difficult.

But again, I think we're doing a pretty good job. Obviously, you can see the sales numbers. We're executing at a very high level, and that's not possible without our operations delivering the product.

So I think it's going to -- I don't know how long it will stick around, but what we want to be able to see before we're comfortable with it is just getting a little -- forecasting those raw material purchases a little bit better and not getting surprises is what we're looking for. They're out there. I'd say generally, it's better, but we're still getting surprised. So there you go.

James Sidoti^ And you highlighted a few of the new products that benefited during the quarter. And then you mentioned that you're about 50% enrolled on Rhapsody. When Rhapsody gets approved, do you think that will be a contributor on the same order of magnitude as the new products you have now? Or do you think that will be something that will be a much larger contributor?

Fred Lampropoulos^ Well, I'm not going to go into that number, Jim, in terms of matching it up on something that we have a belief in this that we'll wait to see how this develops. And again, it will be maybe part of our discussion down the road. But I think what is really important is that Merit's ability to work through the supply chain, meet the demands of customers and continue are the same thing that Merit's been known for, for so long, and that's coming out with the new products.

Whether it be breakthrough designations or the new Scout BX delivery system, the mini-reflector, the RESOLVE pneumothorax tray. All of those things all add up and I think are part of Merit's heritage.

James Sidoti^ And then the last one for me. If we do hit a -- if there is a recessionary environment next year, are there any product lines that you're concerned about in particular? Or do you think you'll be able to file through that?

Fred Lampropoulos^ It's a good question, Jim, and it's one that I'm happy to answer. And that is, generally speaking, over the years, our business does not suffer from -- as you might have other consumer types and other product lines and businesses, people still get sick, people still need to be treated. And so recessions are not a big factor at Merit. It's just as simple as that. I think history would -- if you go back and look at it, you'll find that Merit has done quite well during these economic pullbacks.

Operator^ Our next question will comes from the line of Michael Petusky from Barrington Research.

Michael Petusky^ So I guess, Fred, first of all, impressive Q3. When you sort of think about all the macro issues that are out there, whether it's labor retention, inflation, shipping challenges, currency headwinds as the previous question, a possible recession, flu, COVID possibly coming back heavy in the winter.

I mean what are -- what's the two or three things, if you could narrow them down to two or 3 things that you really are sort of like this concerns me or this is going to be a challenge? Or we're really going to have to be bringing our A game to this particular area or this particular headwind. I mean how do you sort of -- I can't remember a time when there's been more to think about on a macro level than right now.

Fred Lampropoulos^ I think when you were talking about, Raul said war. I mean that's another factor, what's that going to do and what goes in on these places. I think maybe the better way to answer or the best way to answer that question is if we looked over the 35-years of Merit's history, whether it be financial meltdowns, whether it be threats here and there, whether it be wars, whether it be terrorism.

I mean, when you really kind of look at all of this, COVID, we can't forget all those other things that happened. What it did, the slow down, 9/11, war in Iraq and war in Afghanistan.

I mean all of these things, we've been hit by all of these things over the years. So Mike, I guess, to answer -- the best way to answer your question is the ones we've already been hit with, we know how to deal with those generally.

It's always the one that you don't see coming. But even with that, as COVID came through Merit adapted, our workforce adapted, our sales force adapted to meet customer needs. We found products that we could build like the swabs that were temporary, but it helps the business to keep 200 people employed. We helped people. We helped the nation.

So I think a success of a business, and I'm going to speak military for 30 seconds, you adapt to the conditions. That's the key to it, and it's one of Merit's strong suits. It always has been. So take it on, whatever it is.

Raul Parra^ A lot of it, too, we talk a lot about all the issues that are out there, Mike. I think you could lose focus very quick if you just focus on those issues, right? But the reality is a lot of that is outside of our control. And so really being focused on what we can control and execute on is what we've been doing really the last few years. And I think it's helped us tremendously obviously.

Fred Lampropoulos^ And I think that's a terrific answer. We'll work on the things that we can and we'll adapt to the things that we can't.

Michael Petusky^ So then sort of a pivot off that question. I suspect that some other companies maybe haven't managed through all of this quite as cleanly as you guys have, and I'm not minimizing. I know it's been a herculean effort on your part, but there are probably some other companies out there that maybe are looking to divest product lines or that sort of thing.

And really, what I'm getting round to is you're generating a lot of cash, balance sheets delivered, in great shape. I mean, I would assume valuations for assets are coming down as far as the type of assets you guys look at? I mean what are you seeing? And what are your thoughts?

Fred Lampropoulos^ Well, I think you're right. I think those things are out there, but I want to make sure that I emphasize again that Merit's goal is to finish that third year of

Foundations for Growth while keeping our eyes open. We understand that we do and are in a position to look at things. So -- but they have to fit, and we're very patient and the business, I think, is doing fine. It's just the discipline and the focus. And I think that's what's helped us to be able to deliver these kinds of results.

So we know they're out there. We've talked about them. There's opportunities. But again, they have to be consistent with the long-term goals that we've set out in our Foundations for Growth, Mike. So I mean, that may sound like a canned answer. It kind of is because we have a canned program. We are focused, laser-focused on what we want to accomplish and what we promised.

Michael Petusky^ I suspect a lot of investors are giving you a standing O for that answer. Last quick question on the -- on just this idea that flu could be heavy this winter and maybe COVID comes back. Are you hearing anything from your contacts in hospital systems about concerns about staffing of hospitals or anything that would sort of really curtail surgical volumes?

Fred Lampropoulos^ Not specifically into surgical, but staffing. We have a member of our Board that runs a hospital system. And staffing is a problem for everybody. Until we get the participation rate higher and things like this, it's a challenge for everybody, Mike. It's not going away. So we're not hearing the things that we were hearing before like elective procedures and that sort of stuff. I'm not hearing that language. Just staffing in general is a problem, but not in terms of procedural rates at this point.

Operator^ That will conclude Q&A. I'll turn it over to Fred for any closing remarks.

Fred Lampropoulos^ Well, ladies and gentlemen, thank you very much for your time. It's a busy day. And just one closing note. It's snowing like crazy out here. Come out and see us. We'd love to host you here in Salt Lake City. Thank you again for the time, and we look forward to talking to you again soon. Best wishes and good night from Salt Lake.

Operator^ This concludes today's conference call. Thank you for participating. You may now disconnect. Everyone have a good day.