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PRESENTATION

Operator

Welcome to the Fourth Quarter of Fiscal Year 2022 Earnings Conference Call for Merit Medical Systems, Inc. (Operator Instruction]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 ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Thank you, and welcome, everyone, to Merit Medical Systems' Fourth 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 our safe harbor provision.

Brian G. Lloyd ***Merit Medical Systems, Inc. - Chief Legal Officer & Corporate Secretary***

Thanks, 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 from anticipated.

In addition, any forward-looking statements represent our views only as of today, February 22, 2023 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. 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 P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Well, 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 strong revenue results for the fourth quarter. And 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 2023 that we introduced in today's press release as well as a summary of our balance sheet and financial condition as of December 31, 2022. Following that, we will open the call for your questions.

Now beginning with a review of our fourth quarter revenue performance, we reported total GAAP revenue of $293 million in the fourth quarter, up 5% year-over-year. Our total GAAP revenue growth was driven by 7% growth in the U.S. and 3% growth in international sales. Our total revenue increased 8% year-over-year in the fourth 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 at the high end of our growth expectations that we discussed in our quarter 3 earnings call. Specifically, we shared our expectations for constant currency revenue growth in the range of 6% to 8% year-over-year in the fourth quarter.

Quarter 4 constant currency revenue results were a result of solid execution from our team and were primarily driven by a more favorable than anticipated international sales trend, particularly in the EMEA region. And demand in the United States that was in line with the growth expectations we outlined in our third quarter call. Now let me provide you with a more detailed review of our revenue results in the fourth quarter, beginning with the sales performance in each of our primary reportable product categories. Note unless otherwise stated, all growth rates are approximated on our 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.

Now fourth quarter total revenue growth was driven by 9% growth in our Cardiovascular segment, offset partially by a 6% decline in our Endoscopy segment. Cardiovascular growth exceeded the high end of our expectations in Q4 and Endoscopy growth came in within the range of our expectations in quarter 4. Sales of our peripheral intervention products increased 9%, representing the largest driver of total cardiovascular segment growth again this quarter. Within the PI product category, Sales of our embolics and access products increased 14% and 15%, respectively, and together represented roughly 44% of our total PI growth and sales of our radar localization and geography and biopsy products each increased in the low double digits year-over-year and together represented roughly 41% of our total PI growth in quarter 4.

Cardiac invention product sales increased 10% in Q4, representing the second largest contributor to total cardiovascular segment growth year-over-year. Within our cardiac intervention business, the 3 largest contributors in the fourth quarter were 16% growth in sales of angiography products 6% growth in sales of interventional products and 19% growth in the sales of EP CRM products. Angiography products growth was driven by impressive growth results in our inquired diagnostic guidewires. Intervention products growth was driven by another strong quarter of demand for our PhD hemostatic valve products and EP/CRM product growth was driven by strong demand for our Snapsheet and our heart span sheets. Sales of our OEM products increased 16%, exceeding the high end of our expectations in Q4, which we attribute to continued improving demand from larger customers in multiple categories, including merit coatings, kits and angiography products.

Finally, sales of our CPS products increased 2%, and sales in our Endoscopy segment decreased 6%, both of which were largely in line with the range of growth assumptions supporting our Q4 revenue expectations. Now turning to a brief summary of our sales performance on a geographic basis. Our fourth quarter sales in the U.S. increased 5% year-over-year. Sales to U.S. customers came in at the midpoint of our growth expectations and represented 34% of our total company constant currency growth this quarter. International sales increased 12% year-over-year, which is strong performance in light of the challenging global macro environment in certain international markets in Q4. We -- all 3 of our major regions posted growth at the high end or above the high end of our expectations in the fourth quarter specifically. Sales in EMEA, APAC and the rest of the world regions increased 15%, 11% and 9%, respectively, year-over-year. While all 3 regions were strong in Q4, we saw the most upside versus expectations in the EMEA region, driven primarily by demand from Germany, France, the United Kingdom and Eastern Europe. APAC growth was driven primarily by high single-digit growth in China, where we are seeing strong demand for PI and CI product, which is more than offsetting the continued headwinds related to volume-based purchasing. Low double-digit growth in Japan also contributed to strong growth in the APAC region in Q4. We -- and lastly, in our rest of the world region, we delivered 9% growth year-over-year, which was also ahead of expectations, driven by 20% growth in Canada and mid-teens growth in Latin America and Mexico, partially offset by high single-digit declines in Brazil compared to the prior year period.

In summary, we're encouraged by the solid growth trends and part of our team's strong execution despite another quarter marked by a challenging operating environment, particularly in international markets. Now before turning the call over to Raul, I want to comment on a few other noteworthy items in the quarter. First, we delivered another quarter of profitability improvement, margin expansion and free cash flow generation in Q4. We -- our non-GAAP gross profit, non-GAAP operating profit and non-GAAP net income increased 4%, 8% and 13% year-over-year, respectively, in Q4. Our non-GAAP operating margin increased 47 basis points year-over-year to 17.8%, and we generated $15.5 million of free cash flow in the quarter. We believe our financial results in the fourth quarter represent a continuation of the strong performance that we've delivered throughout fiscal year 2022.

Importantly, we believe our financial results this year represent clear evidence that we are executing towards our goal of enhancing Merit's long-term growth and profitability profile. Specifically, in fiscal year 2022, we delivered more than 9% constant currency revenue growth, improvements in our profitability profile with a 17% non-GAAP operating margin, a 91 basis point improvement year-over-year, and we generated strong free cash flow of nearly $70 million. 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 the way, a reminder called 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. Throughout fiscal year 2022, we highlighted via press releases, our progress, including 8 new product launches, a FDA 510 clearance and a breakthrough designation from the FDA. I'm proud of the team's continued commitment to the strong execution in the areas of development, clearance and commercialization of new products in 2022. Finally, we also made progress in recent months towards our strategic initiative to expand the body of clinical evidence for our product.

Specifically, our clinical study, the WAVE study of the Rhapsody endovascular stent lap, an investigational device being studied for the treatment of stenosis or occlusion within dialysis outflow circuits continues to progress. We have 42 clinical sites actively enrolling patients, and we are targeting full enrollment of the first cohort by the end of quarter 3 of 2023. We were pleased to begin enrollment in

Brazil in the fourth quarter as well. The RAP study is underway with 27 sites selected in 10 countries around the world. Roughly half of these sites have already been enrolling patients in a study design to evaluate the clinical benefits association associated -- excuse me, with the use of Rhapsody, cell impermeable Endoprosthesis in patients receiving hemodialysis that experience a narrowing or stenosis or blockage of blood vessels required for dialysis.

The STREAMLOCK study is progressing towards a start-up phase in the coming months, and we are working through site selection for this Canadian registry study intended to demonstrate the utility of the Scout surgical guidance system to improve workflow and efficiency in Canadian centers diagnosing and treating breast cancer.

Finally, we have 4 sites enrolling patients in our prospective observational study of EmboCube embolization gelatin used to control bleeding or hemorrhage. The study is designed to enroll 100 patients across multiple centers in Australia and France and represents a key step towards expanding our clinical portfolio of embolic agents that provide critical relate to diverse patient populations worldwide. With that, let me turn the call over now to Raul, who will take you through a detailed review of our fourth quarter financial results and our 2023 financial guidance, which we introduced in today's press release. Rahul?

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

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 fourth quarter of fiscal year 2022. We have included reconciliations from our GAAP reported results to the related non-GAAP items in our press release and presentation available on our website. Gross profit increased approximately 4% year-over-year in the fourth quarter. Our gross margin for the fourth quarter was 49.5% compared to 50% in the prior year period. The 57 basis point decrease in gross margins year-over-year was primarily due to unfavorable manufacturing bases, specifically purchase price variances.

As expected, our fourth quarter gross margins were impacted by the inflationary headwinds we are seeing in freight, logistics, labor and increase in raw materials. Despite the continued challenging operating environment, we were pleased to deliver gross margin results at the high end of the expectations we outlined on our Q3 call, which called for gross margins to be flat to up 100 basis points on a quarter-over-quarter basis. Fourth quarter operating expenses increased 2% compared to the fourth quarter of 2021. The year-over-year increase in operating expenses was driven by a 7% increase in SG&A expense, offset partially by a 16% decrease in R&D expense compared to the prior year period. Our operating expense performance in Q4 was largely in line with expectations and reflects continued prudent expense management, offset partially by continued investments to support our future growth initiatives. Total operating income in the fourth quarter increased $4 million or 8% year-over-year to $52.3 million. Our operating margin for Q4 was 17.8% compared to 17.4% in the prior year period.

The 47 basis point increase in the operating margin was driven by 104 basis point reduction in our non-GAAP operating expense margin compared to the prior year period. offset partially by the 57 basis point decrease in our non-GAAP gross margin. Fourth quarter other expense net was $0.1 million 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 higher effective interest rates year-over-year. Fourth quarter net income was $46 million or $0.79 per share compared to $40.8 million or $0.71 per share in the prior year period. We are pleased with our profitability performance in the fourth quarter, where we delivered low double-digit growth year-over-year in both non-GAAP net income and diluted earnings per share, exceeding the high end of our expectations.

Turning to a brief review of our financial results for fiscal year 2022. I Total revenue for the 12 months ended December 31 was $1.15 billion, up $76.2 million year-over-year or 9.3% growth on a constant currency basis. Gross profit increased 6% year-over-year to approximately $561 million, representing 48.8% of sales compared to 49.3% of sales in the prior year period, a 50 basis point decrease year-over-year. Note, compared to fiscal year 2021, we estimate that we have experienced incremental headwinds to our gross margin of approximately 240 basis points related to inflationary pressures in raw materials, freight and logistics. The early benefits we are seeing as a result of the team's hard work and dedication to our Foundations for Growth program are the primary reasons we have managed to offset the majority of these inflationary headwinds to our gross margins in fiscal year 2022.

Operating profit increased 13% year-over-year to $195.1 million, representing 17% of sales compared to 16% of sales in the prior year period, a 91 basis point increase year-over-year. We are driving strong operating leverage through prudent expense management in our FFG program, which resulted in operating profit growing notably faster than revenue growth in fiscal year 2022. Net income increased 14% year-over-year to $155.8 million or $2.70 per share compared to $136.2 million or $2.37 per share in the prior year period. Turning to a review of our balance sheet and financial condition. As of December 31, 2022, we had cash and cash equivalents of $58.4 million, total debt obligations of approximately $198 million and available borrowing capacity of approximately $523 million. This compares to cash on hand of $67.8 million, total 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 December 31 was 0.6x on an adjusted basis.

With respect to our cash flow generation in the fourth quarter, -- our solid profitability performance in the fourth quarter of 2022, combined with strategic working capital investments resulted in strong free cash flow generation of $15.5 million in the quarter. As expected, our use of cash for working capital increase 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 $69 million of free cash flow during the 12 months ended December 31, 2022. This was modestly below our target of $75 million due to higher cash taxes year-over-year and continued proactive investment in our inventory balances as part of our strategy to build the requisite safety stock to ensure we can meet customer demand amidst the ongoing challenges and disruptions in the global supply chain environment.

Turning to a review of our fiscal year 2023 financial guidance, which we introduced in today's press release. For the 12 months ended December 31, 2023, we expect GAAP net revenue growth of approximately 4% to 5% year-over-year. This GAAP net revenue range assumes a headwind from the changes in foreign currency exchange rates of approximately $10 million to $11 million, representing a headwind of approximately 90 to 100 basis points to our forecasted GAAP growth rate this year. The GAAP net revenue guidance range now assumes net revenue growth of approximately 3% to 5% in our Cardiovascular segment and net revenue growth of approximately 14% to 16% in our Endoscopy segment. Note the midpoint of our 2023 constant currency sales growth expectation assumes approximately 5% growth year-over-year in the U.S. and approximately 6% growth year-over-year in OUS markets.

With respect to profitability guidance for 2023, we expect GAAP net income in the range of approximately $100 million to $105 million or $1.72 to $1.80 per diluted share and non-GAAP net income in the range of approximately $163 million to $168 million or $2.80 to $2.89 per diluted share. For modeling purposes, our fiscal year 2023 financial guidance assumes non-GAAP gross margins in the range of approximately 50.4% to 51%; non-GAAP operating margins in the range of approximately 18% to 18.2%, GAAP and non-GAAP other expense of approximately $7.6 million and $7 million, respectively, non-GAAP tax rate of approximately 21% and diluted shares outstanding of approximately 58 million. We expect CapEx in the range of $55 million to $60 million and free cash flow of approximately $115 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 first quarter of 2023. Specifically, we expect our total revenue to increase in the range of approximately 1% to 3% year-over-year on a GAAP basis and up approximately 3% to 5% year-over-year on a constant currency basis. Note, the midpoint of our first quarter constant currency sales growth expectations assumes approximately 7% growth year-over-year in the U.S. and approximately 1% growth year-over-year in our U.S. markets. With respect to our profitability expectations for the first quarter, -- we expect to see non-GAAP gross margins increase in the range of 90 to 190 basis points year-over-year. We also expect to see non-GAAP operating margin in the range of down 10 basis points to up 80 basis points year-over-year. These margin expectations, combined with higher interest expense assumptions are expected to drive a year-over-year change in both our non-GAAP net income and non-GAAP EPS in the range of down 1% year-over-year on the low end to up high single digits year-over-year on the high end of the range. With that, I'll turn the call back to Fred.

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Thanks, Raul. In closing, our fourth quarter growth and profitability performance came in at the high end of our expectations and importantly, capped off a great year of results in 2022. We -- we believe this is a direct result of our team's continued strong execution and relentless focus on our strategic initiatives. We would like to thank all of the team members around the world that made our performance in fiscal year 2022 possible. Our 2023 financial guidance reflects our confidence in our team's ability to deliver continued strong execution despite the operating environment around the world. We intend to build upon the significant progress we have made during the first 2 years of our Foundation for Growth program, and we remain committed to the financial targets that we outlined for the 3-year period ending December 31, 2023. That wraps up our prepared remarks. We would like to now turn -- open up the line for questions.

QUESTIONS AND ANSWERS

Operator

Thank you, sir. (Operator Instruction] and our first question â€" will come from Steve Lichtman with Oppenheimer.

Steven Michael Lichtman ***Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst***

I guess I'll ask my one and follow-up around the area of cash. So, it looks like you're implying a nice step-up in free cash flow conversion in 2023. I guess, Raul, can you talk a little bit about beyond margin expansion, some of the dynamics there and your confidence in that growth? It looks like you're also stepping up CapEx. I'm wondering some of the moving parts there. And then just as a follow-up to that, just given the cash position, balance sheet position, Fred, I was just wondering if you could sort of update us on your views on M&A. Could we see you getting a little bit more aggressive on that front in 2023? And just talk about that environment overall.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

All right. Yes. Thanks, Steve. Yes, look, I think the step up is really around the working capital piece. If you remember, at the beginning of the year, we made a commitment to make a bigger investment in inventory as we brought inventory back to normal levels. And then as we progress throughout the year, we also saw an investment in inventory to meet the demand that we were seeing, specifically as you saw kind of the logistics issues happening and also the supply chain. So, we wanted to make sure that we made that investment. We're not expecting to have as big as an investment this year, which feeds into that. And obviously, we're going to be more profitable, which will also help. So those are the 2 things kind of driving the increase in the free cash flow.

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

And Steve, let me go to the M&A. I mean you can see where we are in terms of our balance sheet, it's very strong. And I think it's really a matter of patience. -- and finding the right businesses that meet the need of our sales point, gross margins that are complementary to our foundations for growth. And you heard me kind of really emphasize that commitment to foundations for growth, but it has to be the right thing. And we've been spending time, we've been looking. And when we find it, we'll move, but we're not in any hurry. I don't think, by the way, personally, values are still a little high. There's no rush, but at the same time, I mean, we're in the best position we've ever been in. So, we're looking, we're spending time. I think we're better organized in terms of internal with great 3D and with John Alkire, working on all that and Chris Durham. So, we're organized -- we have our views, Raul and I look at them, we meet, we'll discuss, but patients and doing the right thing is more important than doing anything...

Steven Michael Lichtman ***Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst***

There's a lot of deals out there.

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

And there are a lot of deals -- many of them are early, and that creates a somewhat problematic because it conflicts. So , I'm going on and on, but I think you can get the theme of what I'm trying to say in that is that there will be deals and opportunities. There'll be divestitures from larger companies. There'll be opportunities, but we just have to make sure it's the right deal.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

So that's my best way to answer your question... Thank you.

Steven Michael Lichtman ***Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst***

Thank you. That's helpful color.

Operator

Thanks guys... Our next question comes from Jayson Bedford with Raymond James.

Jayson Tyler Bedford ***Raymond James & Associates, Inc., Research Division - MD & Senior Medical Supplies and Devices Analyst***

Congrats on the success this year. Thanks, I'll just kind of keep it to the 2. You talked about high single-digit growth in China of what I remember was a pretty strong comp. But you also mentioned that the growth was offset by VBP measures. So, I just wanted to confirm that I heard that correctly and that you're facing and fighting through ongoing VBP measures in your business?

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

Yes, Jayson, we continue to see volume-based purchasing that will impact us. The way we're kind of looking at it, just to give a little bit of color is really, hopefully, we can kind of get through the bulk of it here through early 2024 and then kind of that becomes the low end or volume-based purchasing, and we can kind of get past it. But -- as of now, we do have it -- it's in our guidance. We don't call it out specifically. We will say that China is a big material driver of the 6% to 7% in constant currency growth that we're expecting in the APAC region. And so, we continue to be high in China. But we've been able to offset some of that growth just by the delivery and execution by our sales force there and leadership.

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

And if I can just add that we continue to register products that we think give us an advantage that may not exist or produce locally and that takes time, but we continue to do that, and we think that will pay as part of our strategy going forward.

Jayson Tyler Bedford ***Raymond James & Associates, Inc., Research Division - MD & Senior Medical Supplies and Devices Analyst***

Okay. And I hate to waste my other question on other expense, but I feel like it kind of notable. The $7 million in other expense, it seems like a pretty big step-up from what you did in '22. So, can you just walk us through why the step up?

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

Yes. A portion of that is interest expense, obviously, with the higher interest rates. There's also -- we did pick up some exchange rate, foreign exchange gains that flow through there. We're not expecting that big of a benefit this year as rates kind of reset to normalized levels. So those are really the 2 primary things that hit that line item.

Jayson Tyler Bedford ***Raymond James & Associates, Inc., Research Division - MD & Senior Medical Supplies and Devices Analyst***

Okay. I'll keep it to 2 and go back in the queue.

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Jason, thank you.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

Thank you, Jason.

Operator

Our next question comes from Mike Matson with Needham & Company.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

Yes. I guess I'll start with the -- just on Rhapsody. So you have the 2 trials going on Wave and Wrap. So what -- I think the WAVE trial is the pivotal for U.S. FDA approval? And can you maybe just talk about when you think we could potentially see data from that? And what's the latest expectation around the timing of the FDA approval?

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Yes. So, the -- the WAVE study, I'm sorry, the wave study continues to progress. As you recall, Mike, there's 3 cohorts. Any one of those will trigger the opportunity to prepare and file a PMA -- we have one segment, I'm not going to get specific into which cohort, but we have one that's kind of leading the way there. And I think that we're using a -- if I recall, is at the end of the -- it's in the third quarter, end of the third quarter 2023 of this year that we'll have, we think, at least one cohort, possibly 2, that will be completed. So, it has accelerated from just coming out of Covid and contrast issues. But I think we're making a lot of progress. I mean we're getting there, and we've had all the sites are enrolled. So, I think it's going to be just fine. And then you just filed a PMA. And I think it's a 1-year follow-up, if I recall, on the data, Rahul. I think that's correct.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

So we're getting there, Mike. And in the meantime, as you -- you'll recall that's kind of where we're going to stick for right now, but we are pleased that we began enrollment in Brazil in the fourth quarter. And of course, as you will all recall, we also continue to sell the product in Europe and Brazil and other locations. But as we all know, the U.S. is the big plum. And we're just working diligently to get down the road. So that's the update that we're going to provide today.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

No, that's fine. So, I just want to make sure I'm understanding that. So, you're saying that the enrollment would be completed in the third quarter of this year. And then you have like a 1 year -- you have the follow-up period. And then after that, you'd be able to submit to the FDA the PMA...

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

That's my understanding. Interestingly, in that third quarter, we'll have at least one cohort, not the entire study, the centrals. There's -- I'm not going to go through all of them because for competitive and other reasons, but we'll have at least one of those that will be finished in the third quarter...

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

But when you say finished, you just mean the enrollment, not the follow...

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

That's correct. That's correct Okay.

Michael Stephen Matson ***Needham & Company, LLC, Research Division - Senior Analyst***

All right. And then I guess my other question would just be around -- I apologize if you went through this, but the gross margin kind of guidance for '23, what have you assumed in terms of currency inflation impact there?

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Raul, I'm going to let you read pick that one up.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

Yes. So, on the gross margin, obviously, it's a little more robust than it was this last year. We're looking at the low end of the guidance is about 170 basis points up to 220 basis points. Obviously, we don't expect as many headwinds as we had in 2022 related to the pricing of raw materials, freight and logistics. And so as we move forward, we think we can make some headway there. We're really focused on our FFG initiatives there on pricing and also leveraging our fixed costs. So a lot of initiatives around operations and really leveraging that gross margin line, so we can make some investments in OpEx. We will have some tailwinds related to FX. And then we're also expecting some tailwinds related to the freight and logistics as we get back to ocean shipping versus air.

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Great. Thanks, Mike...

Operator

Thank you. Our next question comes from James Sidoti with Sidoti & Company.

James Philip Sidoti ***Sidoti & Company, LLC - Research Analyst***

Good afternoon, thank you for questionâ€¦

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Thanks, Jimmy.

James Philip Sidoti ***Sidoti & Company, LLC - Research Analyst***

So, if you look at least on a GAAP basis, the R&D expense over the last couple of years have gone up fairly substantially. Is that primarily European regulatory costs, clinical trials? And how much -- how soon do you think that some of those investments start to turn into sales?

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

Well, that's the funny thing about MDR, right? I mean you're registering products that are currently being sold. But you're absolutely right, Jim. That's a lot of the expenses, the increase there. It's reregistering of those products and getting them up to the new standard. Obviously, we expect that expense to trickle down to normalized levels here over the next couple of years, I would say. There is just additional upkeep that comes with MDR that we'll have to absorb. But those products are being sold right now, and it's really just to maintain those sales going forward. It's one of the unfortunate parts.

James Philip Sidoti ***Sidoti & Company, LLC - Research Analyst***

And then as far as the inflationary costs, are you starting to see those come down now? Or do you think that it will be another 6 or 8 months before you start to see things like shipping and freight costs to come down?

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

I think it will get gradually better through the year.

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Yes. Thanks, Jimmy.

Operator

Our next question comes from Lawrence Biegelsen with Wells Fargo.

Lawrence H. Biegelsen ***Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst***

Fred, could you talk a little bit about price in 2022 and what your expectations are for '23, please?

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Yes. Well, listen, I will answer that by saying that price is one of our strategic initiatives as part of FFG. It's -- as you recall from our previous conversations, we hired an experienced person to do that. Some of this will be layered in as we have national accounts come due. So, we picked up some, but some of them will be expiring. And I think we've been extremely vigilant in terms of changing dramatically the way that we look at the business and how we price, whether they be for new products coming out in the U.S. or what we're doing in terms of taking advantage of the opportunities. And by the way, as you guys all know, I mean we were not immune to inflationary costs ourselves. So, we've been doing pass-ons that and that program continues. So, it's not just a 1-year program. It was something that started from the beginning. It took a little time to get started. I think we had a very positive year. Do you want to add some of that, Raul?

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

Yes. I was just going to say, really, our pricing initiative or foundations for growth is really about just maturing the company to a different level than we were at before. So, we have better tools. We have better visibility, better transparency around what we're doing. As Fred mentioned, this is kind of a multiyear approach as we get through contracts, both here in the U.S. and globally. So, there's a lot of work. I think we were pretty happy with what we were able to accomplish in the first year of its initiative last year, and there's more work to be done to get to where we want to be. A lot of opportunities still here.

Lawrence H. Biegelsen ***Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst***

I mean... Is pricing net positive for you guys? Are you willing to say how much?

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

We're not going to quantify it, Larry.

But we... Is positive real... It's positive, yes.

Lawrence H. Biegelsen ***Wells Fargo Securities, LLC, Research Division - Senior Medical Device Equity Research Analyst***

Okay. And on 2 of the businesses, Fred, OEM was extremely strong in '22. Could you talk about the sustainability there? And endoscopy, what drives the acceleration in the guidance in '23?

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

So, listen, on the OEM, we, of course, exceeded the high end, which we attribute to the improving demand from larger customers. going away from, I'll call it, the just in time. People are starting to make sure they have enough product. We all know that everybody was cutting it to. It includes merit coatings, Kitch and geography. It's a dynamic business. We are -- this next year I think we called it out, didn't we?

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

Yes. It's high single digits for '23, Larry. I think what we're seeing is a lot of opportunity in the OEM business, especially as people struggle with their logistics and supply chain, I think we're becoming -- we've been very fortunate and be able to deliver to our customers because of our vertical integration. And so, I think there's a lot of customers that continue to come to us and explore new opportunities for us to be their supplier. But we are, I would say, temporary that growth. I mean we were again, high single digits is what we're expecting for 22...

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

So I think that's Personally, I think to go to your question, the sustainability of that at that high single digit is historically where we've been at and we think that it has that sustainability. Let me go on to the endoscopy. That's really quite simple. I mean it was -- you know we had a problem with the vendor. We qualified 3 out of 4. There's still some supply chain issues, but it is improving and will continue to improve. And I think if you look at the -- what we call out this year for the full year, it's dramatically up from last year.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

15% to 16%...

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Yes. I mean, that's significant in the script that talks about that the 14% to 16% versus down. So, it's just working off on the back end of that challenge. We've got a lot of work to solve that and bring it onshore. Larry, and I think it's going to be a big contributor going forward. It's a great business.

Operator

Our next question comes from Michael Peske with Barrington Research.

Michael John Petusky ***Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst***

So I don't think you've touched on this. The free cash flow, sort of the cadence in '22 was sort of all over the board. I'm just curious if you have any commentary whether it's by first half, second half or anything else? I assume Q1 will probably be relatively low, but will it sort of jump around? Or do you think it's going to be a little bit more consistent...

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Yes, it will definitely be paced by the FFG initiatives, but thank you for calling that out, Mike, because I don't think I did a very good job last year of given the cadence. Just as a reminder, Q1 will be kind of just -- it's probably the low end. We do have bonus payments that go out, tax payments, and we also have additional expense. So that flows through specifically this year as we ramp up on the sales meetings that we haven't had in 2 years. So, there will be a cadence to it. I think it will typically line up with our cadence for earnings, but Q1 will be the low point.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

Well, if I could add, the $115 million that we're calling out is a full year target, and that's impressive. I mean it's a big deal. And again, the focus, Mike, is to finish what we committed to. And that's what we'll do. And I just have to tell you, it's got everybody's attention, and it's also tied to compensation. So, there's a lot of incentives to make sure that people are paying attention and the discipline of saying no and trying to prioritize. So, I think we've done a good job. But at the end of the day, there's one more year.

Michael John Petusky ***Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst***

Yes. And just as a reminder, just for everybody listening, we said FFG would deliver a minimum of $300 million in free cash flow. And so that's what we're focused...

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Over the 3-year period. I have to say I did like that 0.06 let... That 0.6, whatever it is. But I mean... It just continues to improve. And these are things that people were calling out 2 or 3 years ago, and we listened to what you said. So, Mike, we listened to you because you were one of the guys that we're speaking to it. So, thank you with a lot of voice for having to...

Michael John Petusky ***Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst***

I don't about that. But thank you. I'll take credit work. no creditors do whatsoever. So, I did want to ask also, Fred, you guys, during the last few years have sort of tried to streamline your R&D projects and really focus on what you thought was the highest potential ROIs, et cetera. And I guess just in sort of looking at it right now. I mean do you feel like -- you feel like that's worked in terms of, hey, yes, I feel like we picked the right projects? Or have there been some sort of misses and some things that maybe were eliminated initially and you've gone back to. I'm just curious how that sort of played out in practice.

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Well, let me just say that in terms of the availability of ideas, there's plenty of them out there. I think what has happened going back to the previous question is sitting down with the team and prioritizing those and make sure that they're budgeted for so that we can afford to pay them and afford them, I think has been very important. And you'll recall, Mike, a couple of years ago, we talked about, we may have had -- in fact, we did have too many things going. It was spread out a lot and that made up a lot of capital, and it slowed things down. So, I think I'd like to always would like to have more money for R&D. That money has to be earned. I think it's budgeted for. And I think we have the priorities because it's not just me, I've got Joe Wright, who's our Chief Commercial Officer, JoAnne, Alkire, I've got Jim Matola and our sales force. We sit and meet and talk about the things that you need, the things that we fit into our franchise, the things that will give us the competitive advantage. To go to your question, I think it's much more disciplined and much more focused. And there has to be a buy-in. Again, I don't have to have everybody nodding their head. But it's nice that we're all on the same page.

Michael John Petusky ***Barrington Research Associates, Inc., Research Division - MD & Senior Investment Analyst***

Okay. Very good. Well, congratulations on a great 22...

Operator

Thank you. Our next question comes from Jason Bednar with Piper Sandler.

Jason M. Bednar ***Piper Sandler & Co., Research Division - VP & Senior Research Analyst***

Other congratulate on the results. First, apologies in advance any of these have been covered that have happened between calls. But maybe as a follow-up to some prior questions. I'd be curious if you could talk about whether maybe in response to Larry's question, you're expecting greater price contributions in '23 versus '22? It sounds that way. But maybe if you could confirm that. And then kind of on a related point, does China grow faster in '23 than what we saw last year, now that we're on the other side of the zero Covid policy and procedure volumes presumably accelerate here this year?

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Okay. I'm going to -- I'll let you pick the China one, and I'll come back to the other question. Go ahead. Yes. I mean I think from a China perspective, it is a contributor to our APAC growth. It's one of the largest contributors. But we're not going to call out the specific country growth. Just know that we're excited about what is contributing, and it is a material driver to that 6% to 7% organic constant currency growth in the APAC region.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

And now that I listen to him, Jason, you got to restate the question pricing. -- pricing. We don't spell it out. It is a key initiative, and it is part of our compensation. I think that answers the question. It's FFG, and it's got our attention, and it's got a lot of our attention. So, I'll answer it that way.

Jason M. Bednar ***Piper Sandler & Co., Research Division - VP & Senior Research Analyst***

Yes. Maybe to clarify, I mean, any reason to think it's not as good as it was in...

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Jason, Jason, Jason, I think I answered the question, but thank you very much for asking again. -- good... He's really good at this.

Jason M. Bednar ***Piper Sandler & Co., Research Division - VP & Senior Research Analyst***

I'll follow up maybe then a couple on -- on the margin side. Maybe can you discuss with where you're at with your transition efforts down to Mexico. And then as you do transition back to more of a normal structure of air and ocean freight, can you throw a dart at where you'd anticipate normalized logistics structure this year? I mean getting back to 80% ocean, 20% error, does that happen 2Q, 3Q, 4Q? Just trying to figure out if it's reasonable to think we should see some margin benefits from that initiative this year.

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

So, it is an initiative, Jason. I just -- we are not going to share the specifics on the cadence of how we're going to get there. I just think it just confuses things too much. But it is an initiative as part of our foundations for growth and its initiative for expansion of our gross margin this year, and it's got our focus on it. As far as Mexico, we continue -- it's not a 1-year initiative, right? I mean we've spent the last 5 years moving stuff to Mexico. I would say that there's been things that have moved ahead of plan at plan and behind plan. I mean that's just the way it works. We continue to move stuff down there, continue to analyze our business for things that make sense and we'll continue to do so over the years.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

But just in conclusion to that thought in those comments, it's been a great success overall and continue to have our focus going forward. And -- but again, as Rob pointed out, it's not perfect. There's this that transfer, particularly on the early parts when you're going through Cohort were very difficult. I think that has smoothed out in most cases. But at the same time, little things pop up from time to time. But we actually had a board meeting down there about 3 months ago. And it was impressive to be there and particularly to have the board there as well. So, I think whenever the board goes some place, that's peach volumes.

Jason M. Bednar ***Piper Sandler & Co., Research Division - VP & Senior Research Analyst***

Yes. Okay. Definitely. And maybe I'll try one more time with a clarifying follow-up here. But on the Ocean Air, I mean, normalizing that structure, is it right to think that we should have that complete by the end of this year?

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Well, it is an initiative for our gross margin. As we called out, we're looking to get 170 to 220 basis points for the year, and it will definitely be a tailwind to our gross margin as we increase percentage towards Ocean. Okay. Thanks, Jason. He's good.

Operator

[Operator Instruction] Our next question comes from William Plovanic with Canaccord...

William John Plovanic ***Canaccord Genuity Corp., Research Division - Analyst***

So, you've done a tremendous job growing the top line. And this kind of folds into the original M&A question earlier. But as we think of '23 and beyond in that 5% growth that you've targeted and you've definitely been growing beyond that. Is that something that you can maintain organically? Or do you need to meet or exceed 5% on a longer-term basis M&A to help augment what you have?

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Yes. Listen, we understand what -- the Street is focusing on what is next for our growth and profitability. Again, we're 100% focused on the FFG in those targets as we -- and listen, the race isn't over to you across the line. And we may be seeing a little bit stubborn, but what we have been doing and what we said we would do and the commitments we've made, we've kept up with that. In terms of the numbers that you have updated that we've given, of course, that's all organic when we talk about this year. And if you look at the history, and I'll let you do that work, Bill, but if you look at the history, you'll see that it's well within what we've done for many, many, many years. So, you have a better finely tuned company that has been growing for a long time. And I think if you just quickly look at that back and look back at that growth rate. But I want to say something. You said we've been doing great at growing the top line. I think we've done fine. But take a look at that bottom line and what we've improved there over the last 2 to 3 years, and that is extraordinary as well. So, I just can't have one part of it without talking about the other.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

Yes. I mean I think if you look at the operating margin and the expansion that we've done over the last couple of years, the last few years, to be honest, has just been anything but impressive. I mean I think there's a lot of hard work that goes into it from our employees. And I hate to not have you call that an...

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Yes, I had to. I mean -- and again, that's -- if you take a look at the objectives. The growth 5 to 7. If you take a look at the operating margin and the free cash flow, they speak to top and bottom.

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

Yes. I think lastly, too, Bill, I know there's a lot of -- people want to focus on beyond 2023. But we still have a lot of work to do in 2023. It's the final year of FFG. And we just want to make sure that we can deliver what we promised. And we don't want to lose sight of that, but we've got more work to do, but we've got a solid game plan. We do have a case...

William John Plovanic ***Canaccord Genuity Corp., Research Division - Analyst***

You took the second half of my question, which is where does the incremental operating margin really leverage come from outside of gross margin. So, if we talk about OpEx, you've spent a couple of years really optimizing the organization. Where do you see the real incremental improvements in terms of leverage on the OpEx standpoint driving from? Is it just scale in R&D? Or is it really more of a leverage of the G&A line? I mean, how do we think about it...

Raul Parra ***Merit Medical Systems, Inc. - CFO & Treasurer***

I think it's a great question. And I can't wait to discuss it when we get to 2024 and we finished 2023. We're just focused on delivering FFG. And it's a great question, and I understand the question -- the reasoning behind it, but we're just not going to get ahead of ourselves. But I do want to go back and say this, if I could. And that is we said that we were going to leverage every aspect of that income statement. That's always been the goal. And I just want to bring that back to your attention.

Operator

Thank you -- that concludes our Q&A session. I'd now like to turn the call back over to Mr. Fred Lampropoulos for any closing remarks.

Fred P. Lampropoulos ***Merit Medical Systems, Inc. - Founder, Chairman, CEO & President***

Yes. Well, again, thank you very much. Incidentally just for a point of interest. We're inviting you all out to Utah. We've had a major blizzard, and we've got 2 feet of snow outside. And I think they're doing that up in Minneapolis today, I heard as well. All that being said, thank you for your interest. I think you can hear our commitment. It's been solid. It hasn't changed. We have work to do. We'll complete this program. And then next year about this time, we'll tell you about where we're going from there. We have a lot of work to do and a lot of exciting opportunities in this company. We appreciate your interest. We thank you for your time today, and we'll sign off from a snowy blizzard in Salt Lake City, Utah. Have a good evening. Good night.

Operator

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