Merit Medical Systems, Inc. (Q3 2024 Earnings)
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Corporate Speakers

- Fred Lampropoulos; Merit Medical Systems, Inc.; Chief Executive Officer
- Brian Lloyd; Merit Medical Systems, Inc.; Chief Legal Officer and Corporate Secretary
- Joseph Wright; Merit Medical Systems, Inc.; President
- Raul Parra; Merit Medical Systems, Inc.; Chief Financial Officer and Treasurer

Participants

- John Young; Canaccord; Analyst
- Jayson Bedford; Raymond James; Analyst
- Gursimran Kaur; Wells Fargo; Analyst
- Jason Bednar; Piper Sandler; Analyst
- David Rescott; R. W. Baird.; Analyst
- Michael Matson; Needham; Analyst
- Craig Bijou; Bank of America Securities; Analyst
- James Sidoti; Sidoti & Company; Analyst
- Michael Petusky; Barrington Research; Analyst
- Steven Lichtman; Oppenheimer; Analyst

PRESENTATION

Operator^ Good day. And thank you for standing by. Welcome to the Merit Medical Q3 2024 Earnings Conference Call. (Operator Instructions)

Please be advised that today's conference is being recorded.

I would now like to turn the conference over to your speaker for today, Fred Lampropoulos.

Please go ahead.

Fred Lampropoulos^ Thank you, Operator. And welcome, everyone.

I am joined on the call today by Raul Parra, our Chief Financial Officer and Treasurer; Joe Wright, our President; and Brian Lloyd, our Chief Legal Officer and Corporate Secretary.

Brian, would you mind taking us through the safe harbor statements, 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 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 the expectations and projections expressed or implied by our forward-looking statements.

In addition, any forward-looking statements represent our views only as of today, October 30, 2024, 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 sections entitled cautionary statement regarding forward-looking statements in today's press release and presentation for important information regarding such statements.

For a discussion of factors which could cause actual results to differ from these forward-looking statements, please also refer to our most recent filings with the SEC, which are available on our website.

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 sections of our press release and 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 cover during our prepared remarks.

I will start with an overview of our third quarter financial results and a discussion of the strategic acquisition we announced on September 17. After my opening remarks, Joe Wright will provide an update on the notable progress we have achieved in recent months on our U.S. WRAPSODY program as well as a summary of our revenue results for the third quarter. Then Raul will provide a more in-depth review of our quarterly financial results and our financial guidance for 2024, which we updated today in the press release.

Then we will open the call for your questions.

Now beginning with a review of our third quarter results.

We reported total revenue of $339.8 million, up 7.8% year-over-year on a GAAP basis and up 7.9% year-over-year on a constant currency basis. The constant currency revenue growth we delivered in the third quarter modestly exceeded the high end of the range of growth expectations that we outlined on our quarter two call.

Specifically, we expected constant currency revenue growth for the third quarter in the range of 6.4% to 7.8% year-over-year.

Importantly, the 7.9% constant currency revenue growth in the third quarter was driven by strong organic growth and contributions from acquired products, both of which came in at the high end of our growth expectations. With respect to our profitability performance in the third quarter, we delivered financial results that exceeded our expectations.

We leveraged the solid revenue results to deliver non-GAAP operating profit growth of 19% and a non-GAAP operating margin of -- excuse me, 19.2% of sales, up approximately 175 basis points year-over-year.

We also delivered 21% growth in our non-GAAP EPS, which exceeded the high end of our expectations as well. Perhaps most notably, we generated $38 million of free cash flow in the quarter and have generated more than $120 million of free cash flow over the first nine months of 2024, representing an increase of 116% year-over-year.

We believe our third quarter results reflect continued strong momentum in the business, and we remain confident in our team's ability to deliver the updated financial guidance for 2024 that Raul will review later on the call.

We are focused on delivering continued strong execution, solid constant currency growth, improving profitability and strong free cash flow in 2024 as well as continued progress in our continued growth initiatives program and related financial targets for the 3-year period ending December 31, 2026.

Now before turning the time over to Joe, I would like to take a few minutes to discuss the important acquisition we announced on September 17.

We announced the signing of a definitive asset agreement to purchase Cook Medical's lead management portfolio for a total cash consideration of approximately $210 million and the assumption of certain liabilities.

We believe this acquisition represents multiple strategic and financial positives.

And importantly, this acquisition is consistent with and will not distract us from our continued growth initiatives. This proposed transaction represents another example of Merit's selectivity investing to expand our product portfolio in key strategic markets that leverage our existing commercial footprint.

Strategically, we believe the proposed acquisition will position Merit to offer clinicians an increasingly comprehensive set of solutions to support cardiac intervention patients from diagnosis to therapy and intervention to post-procedure care. Cook Medical's lead management business has many years of operating history and provides a comprehensive end-to-end product portfolio of medical devices and accessories used in the lead management procedures for patients who need a pacemaker or an implantable cardioverter defibrillator, an ICD, lead removed or replaced. The assets we propose to acquire from Cook include a full portfolio of tools for complete case support including hand-triggered rotating extraction devices, sheets and snares for manual extraction and lead control tools for grasping and removing leads.

We believe these assets generated approximately $37 million of revenue over the 12-month period ended December 31, 2023, with sales to customers in the U.S., EMEA, APAC and Rest of World representing approximately 41%, 42%, 11% and 6% respectively.

We believe this transaction will strengthen our fast-growing high-margin electrophysiology and cardiac rhythm management or CRM business with the addition of differentiated products and an established commercial infrastructure.

We believe the transaction will enhance our position in the cardiac intervention market, particularly in Europe, which is strategically attractive and has our commercial team very excited.

We estimate this transaction represents an annual addressable opportunity of more than $900 million in the U.S., EMEA and APAC regions.

Specifically, we anticipate that beginning in fiscal year 2025, the addition of Cook's lead management business will position Merit to represent more than $100 million in combined annualized electrophysiology and CRM revenue serving the global cardiac intervention market.

In addition to the strong strategic rationale, we believe the financial profile of the proposed acquisition is extremely compelling. Rahul will share some additional color on the favorable financial profile of the acquisition later on in the call.

In the interim, I'll share that we expect sales contributions from the acquisition post-closing in the range of $4 million to $6 million over the balance of 2024, and we expect this acquisition to add approximately $40 million of revenue on an annualized basis beginning in fiscal year 2025.

Now with that said, let me turn the time over to Joe for an update on our U.S. WRAPSODY program and a review of our third quarter revenue performance.

Joe?

Joseph Wright^ Thank you, Fred.

I share Fred's sentiments as it relates to the notable progress we have made on our U.S. WRAPSODY program in recent months.

First, with respect to our progress in the areas of clinical validation and raising awareness of the compelling safety and efficacy profile of WRAPSODY among clinicians.

On September 16, we announced positive six-month findings from the randomized arteriovenous or AV fistula arm of our WRAPSODY WAVE pivotal trial.

The data were shown at the Cardiovascular and Interventional Radiological Society of Europe, or CIRSI, annual congress in Lisbon, Portugal. Dr. Mahmood Razavi, the co-principal investigator of the WAVE trial, presented the extremely compelling results.

Specifically, the primary efficacy endpoint was target lesion primary patency, which represents the percentage of patients that did not need a clinical revascularization or have thrombosis. And patients treated with WRAPSODY was 89.8%.

This was 27 percentage points higher than patients treated with the control percutaneous transluminal angioplasty, or PTA, which is the current standard of care. With respect to the primary safety endpoint in the pivotal study, there were fewer adverse events for patients treated with WRAPSODY.

However, the difference in the proportion of patients who experienced an adverse event was not statistically significant between the two cohorts. Dr. Razavi was quoted saying the superiority of the six-month efficacy data is compelling and provides clinicians the chance to evaluate how WRAPSODY can help us prolong the vascular access of our patients.

WRAPSODY should be the new standard of care for these patients.

We were also pleased with the positive response and feedback from participants of the 2024 Controversies in Dialysis Access, or CiDA meeting in Washington, D.C. on October five including positive commentary related to our WAVE trial for many participants at the meeting.

We expect further increases in awareness of WRAPSODY's safety and efficacy among clinicians including more clinical data results, and look forward to WRAPSODY being featured in scientific sessions at the VEITH meeting on November 23 in New York City.

Second, we have made considerable progress in our U.S. regulatory and reimbursement strategies, and in developing our post-approval commercial strategy for WRAPSODY.

As discussed on our last earnings call we completed the clinical study report and filed the final module with the FDA for premarket approval, or PMA, by the end of the second quarter of 2024 as expected.

We are ready and willing to engage with FDA during their review as they review our PMA application for this innovative technology. The WRAPSODY Cell-Impermeable Endoprosthesis is built to combat the challenges dialysis patients can often experience due to stenosis and occlusions in the dialysis outflow circuit.

We believe this technology can extend long-term vessel patency rates and reduce the complications associated with existing treatment options on the market today including the need for repeated interventions, frequent trips to the hospital and inadequate dialysis treatments.

Our Renal Therapies group has been working through intensive WRAPSODY training covering a range of important areas including technical story, anatomy and physiology, and deployment technique. Clinical data training and live hands-on training are scheduled to increase in the coming months.

We are focused on ensuring we are ready to enter the U.S. market following PMA approval. The team has completed a thorough evaluation of the U.S. market opportunity and is developing a comprehensive U.S. commercial strategy.

Importantly, our plans for U.S. commercialization post PMA approval are part of a broader commercial strategy for our Renal Therapies group.

We have an experienced, dedicated sales and customer support team offering a strong portfolio of dialysis products that address the entire end-stage renal disease continuum of care including our HeRO Graft, our Surfacer Inside-Out Access Catheter System and our portfolio of acute, chronic and peritoneal dialysis catheters.

We are excited to add WRAPSODY to this offering following PMA approval. The team is also focused on developing and executing our reimbursement strategy for WRAPSODY. Earlier this month, we submitted our application requesting a new technology APC assignment for Medicare's acute inpatient prospective payment system. The new technology add-on payment or NTAP designation enables new medical service or technology meeting certain eligibility criteria to receive additional reimbursement payment for a period up to three years.

We believe that WRAPSODY meets the eligibility criteria, particularly as it relates to the requirement that the technology represents an advance that substantially improves relative to technologies previously available the treatment of Medicare beneficiaries.

The application is currently under review, and we look forward to participating in the New Technology Town Hall meeting on December 11, 2024, which is the annual meeting held to provide a mechanism for public input on the eligibility criteria for NTAP applications before final decisions are made.

We are targeting submission of an application for transitional pass-through payment under the Medicare Hospital Outpatient Prospective Payment System or OPPS. The Transitional Pass-Through payment or TPT program is intended to facilitate access for Medicare beneficiaries to the advantages of new and innovative devices by allowing for adequate payment for these new devices while the requisite cost data is collected.

We believe WRAPSODY meets the substantial clinical improvement threshold for new category eligibility for a pass-through payment. Post PMA approval, if awarded pass-through status, WRAPSODY would be eligible for this additional payment as early as Q3 2025 and will continue for at least two years thereafter.

It is fair to say that we have made significant progress in our WRAPSODY program this year, and I applaud our team's efforts to ensure we are prepared and well positioned to introduce WRAPSODY to the U.S. market following PMA approval.

For avoidance of doubt, we intend to continue providing updates as we achieve material milestones in our WRAPSODY program going forward.

We also intend to host a WRAPSODY specific virtual investor event in advance of our U.S. commercial introductions.

Details for this event will be shared once we secure PMA approval.

I will now provide a detailed review of our revenue results in the third quarter, beginning with the sales performance in each of our primary reportable product categories. Note, unless otherwise stated, all growth rates are approximated and presents on both a year-over-year and constant currency basis. Third quarter total revenue growth was driven by 6% growth in our Cardiovascular segment and 86% growth in our Endoscopy segment, both of which modestly exceeded the high end of the expectations we outlined on our second quarter call.

Our total revenue results included approximately $6.8 million of revenue from our acquisition of EndoGastric Solutions, Inc.

Excluding sales of acquired products, our total revenue growth in the third quarter was 5.7%, and our Endoscopy segment revenue growth was 11.5% on an organic constant currency basis.

Sales of our peripheral intervention, or PI, products increased 7.7%, representing nearly 60% of total Cardiovascular segment growth in the period. Growth in the PI product category was driven by sales of our radar localization products, which increased 17% and sales of our drainage products, which increased 10%. Together, they represented more than half of total PI sales growth in Q3.

Sales of our custom procedural solutions, or CPS, products increased 4%, which was slightly better than the low single-digit increase we expected in Q3.

Growth was driven by strong sales of critical care products, offset partially by more modest sales of kits and trays as expected due to the ongoing SKU rationalization efforts discussed on prior calls. Cardiac intervention product sales increased 2%, slightly above the high end of our growth expectations, driven primarily by strong sales of EP/CRM products and to a lesser extent, growth in sales of fluid management products.

Sales of our OEM products increased 8.5% in Q3 and were the only area of our Cardiovascular segment that came in softer than our growth expectations heading into the quarter. Notably, demand trends from customers in the U.S. improved from Q2 as expected.

Product sales to OEM customers outside the U.S., however, were significantly lower than expected in Q3.

We had a discrete logistics-related issue that impacted our Q3 OEM results, but the softer-than-expected product sales to OEM customers outside the U.S. is primarily related to navigating a more challenging raw material and supply chain environment.

Our updated revenue guidance for 2024 reflects the softer-than-expected OEM sales in Q3 and modestly lower OEM sales expectations in Q4 as compared to what our prior guidance range assumed. Demand remains strong, but as a result of supply chain

challenges, we now expect OEM sales growth of approximately 7% in 2024 compared to 10% previously expected.

Turning to a brief summary of our sales performance on a geographic basis.

Our third quarter sales in the U.S. increased 10% on a constant currency basis and 7% on an organic constant currency basis.

We were pleased to see improving trends in our U.S. business as we outlined on our second quarter call.

We continue to expect to deliver approximately 6% organic growth in the U.S. at the midpoint of our 2024 guidance range. Note, this growth assumption contemplates our updated expectations for OEM growth in the second half of 2024, offset by stronger organic growth in the non-OEM portions of our business, which, by way of reminder, are expected to represent approximately 87% of our total organic constant currency revenue in 2024.

International sales increased 4.5% year-over-year and increased 4.4% on an organic constant currency basis, exceeding the low end of our growth expectations.

Sales results in Rest of World and APAC exceeded the high end of our expectations, while sales in the EMEA region were softer than expected, largely related to the aforementioned OEM challenges in the quarter.

With respect to China specifically, sales decreased 5.1%, modestly better than what our guidance had assumed.

We continue to see quarter-to-quarter variability in growth trends related to volume-based purchasing tenders as expected.

By way of reminder, while we are not providing country-specific growth assumptions in our guidance messaging, the midpoint of our 2024 constant currency growth guidance range now assumes our total international sales will increase 4.8% year-over-year, driven by 2% growth in APAC, 6% growth in EMEA and 15% growth in the Rest of World region compared to 0%, 7% and 11% respectively assumed in our prior guidance range. The improving growth trends in APAC assumed in our updated guidance is driven by better-than-expected results in China over the first nine months of 2024, driven primarily by better-than-expected sales of units, which are now expected to modestly offset continued pricing headwinds related to volume-based purchasing. With that, let me turn the call over to Raul, who will take you through a detailed review of our third quarter financial results, balance sheet and financial condition at September 30.

Raul Parra^ Thank you, Joe. Beginning with a review of our P&L performance, 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 2024, and all growth rates are approximated and presented on a year-over-year 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. Gross profit increased approximately 10% in the third quarter.

Our gross margin was 50.9%, up 108 basis points.

The increase in gross margin year-over-year was driven by pricing uplift, favorable product and geographic revenue mix, and improvement in freight and distribution costs, offset partially by manufacturing variances compared to the prior year period.

Operating expenses increased 6% from the third quarter of 2023. The increase in operating expenses was driven by a 5% increase in SG&A expense and an 8% increase in R&D expense compared to the prior year period. Total operating income in the third quarter increased $10.2 million or 19% from the third quarter of 2023 to $65.1 million.

Our operating margin was 19.2% compared to 17.4% in the prior year period.

The 175 basis point increase in operating margin was driven by a 108 basis point increase in our non-GAAP gross margin and by a 67 basis point decrease in our non-GAAP OpEx margin compared to the prior year period. Third quarter other expense net was a benefit of $0.9 million compared to expense of $4.5 million last year. The change in other expense net was driven by an increase in interest income associated with our higher cash balances, partially offset by an increase in net interest expense associated with increased borrowings. Third quarter net income was $51.2 million or $0.86 per share compared to $41.4 million or $0.71 per share in the prior year period.

We are pleased with our profitability performance in the third quarter where we leveraged stronger-than-expected revenue results to drive significant expansion in operating margins and a strong growth in non-GAAP diluted earnings per share, both of which exceeded the high end of our expectations.

Note, our third quarter non-GAAP EPS results included incremental dilution related to our convertible debt that represented approximately $0.01 to Q3 EPS versus what our guidance had assumed. Turning to a review of our balance sheet and financial condition.

As of September 30, 2024, we had cash and cash equivalents of $523.1 million, total debt obligations of $770.5 million and available borrowing capacity of approximately $697 million compared to cash and cash equivalents of $587 million, total debt obligations of $846.6 million and available borrowing capacity of approximately $626 million as of December 31, 2023.

Our net leverage ratio as of September 30 was 2.08x on an adjusted basis.

We generated $38 million of free cash flow in the third quarter and have generated more than $120 million of free cash flow over the first nine months of 2024, up 116%.

The improvement in free cash flow generation is a result of growth in net income and significant improvement in cash used in working capital compared to the first nine months of 2023.

We now expect to generate approximately $150 million of free cash flow in 2024 compared to our prior guidance of $130 million. And importantly, we continue to believe our CGI program will generate more than $400 million of free cash flow in the 3-year period ending December 31, 2026.

For reference, we have included a table in our earnings press release, which details each of our updated formal financial guidance items and how those ranges compare to the prior ranges as of September 17, 2024, when we updated our guidance to reflect the projected impact of our proposed acquisition of lead management assets from Cook Medical.

By way of a reminder, our updated financial guidance assumes that Cook Medical transaction closes on November 1, 2024.

Our updated guidance ranges now assume the following: GAAP net revenue growth of 6.9% to 7.6%, net revenue growth of approximately 5% to 6% in our Cardiovascular segment, and net revenue growth of approximately 49% to 52% in our Endoscopy segment, and a headwind from changes in foreign currency exchange rates of approximately $7 million or approximately 60 basis points in growth year-over-year. Excluding the impact of changes in foreign currency exchange rates, we expect total net revenue growth on a constant currency basis in the range of 7.4% to 8.1% in 2024. Note, the increase in constant currency growth expectations at the low end of the guidance range reflects the flow-through of the better-than-expected revenue results in Q3, $2 million lower FX headwind to GAAP revenue, and the contributions from our acquisition of assets from Cook Medical from the expected closing date of November one to December 31, offset partially by our revised expectations for our OEM business in the fourth quarter. All other assumptions supporting our Q4 growth expectations remain unchanged versus what our prior guidance had assumed.

Finally, our total net revenue guidance for the fiscal year 2024 now assumes inorganic revenue contributions from the acquisitions announced on June 8, 2023, July 1, 2024, and September 17, 2024, in the range of $29.5 million to $32.5 million in the aggregate.

For avoidance of doubt, this aggregate range consists of approximately $11.6 million of inorganic revenue related to our acquisition of assets from AngioDynamics, Inc. in Q1 and Q2, plus the contributions from our acquisition of assets from EndoGastric Solutions in Q3 and Q4 in the range of approximately $40 million to $50 million, plus the contributions from our acquisition of assets from Cook Medical post-closing in the range of approximately $4 million to $6 million. Excluding inorganic revenue, our updated

guidance reflects total net revenue growth on a constant currency organic basis in the range of approximately 5.1% to 5.5%. With respect to our updated profitability guidance for 2024, we now expect non-GAAP diluted earnings per share in the range of $3.33 to $3.38, representing an increase of 17% to 19%. Note, this updated range reflects the better-than-expected EPS results in Q3 and includes the expected dilution related to our acquisition of assets from Cook Medical, which, as disclosed on September 17, is expected to be in the range of $0.01 to $0.02.

As Fred discussed earlier, we believe the Cook Medical acquisition offers a very attractive financial profile.

While we believe the proposed acquisition will be modestly dilutive to our full year 2024 non-GAAP profitability given the partial year contribution and the impact of approximately $1.8 million of lower interest income on cash balances used for the total purchase consideration, we expect the acquisition to be accretive to our non-GAAP gross and operating margins in the first full year post closing.

We expect the acquisition to be accretive to our non-GAAP net income and non-GAAP EPS in the second full year post closing.

For modeling purposes, our updated fiscal year 2024 financial guidance now assumes non-GAAP operating margins in the range of approximately 18.5% to 18.8%, up 130 to 160 basis points, non-GAAP interest and other expense net of approximately $0.9 million of income, non-GAAP tax rate of approximately 21.3%, diluted shares outstanding of approximately 59.1 million compared to 58.8 million previously. And we now expect CapEx of approximately $50 million and free cash flow of at least $150 million.

We would also like to provide additional transparency related to our growth and profitability expectations for the fourth quarter of 2024.

Specifically, we expect our total revenue to increase in the range of approximately 5.5% to 8.2% on a GAAP basis and up approximately 6.1% to 8.8% on a constant currency basis. The midpoint of our fourth quarter constant currency sales growth expectation assumes approximately 12% growth in the U.S. and 2% growth in international markets. Note, our fourth quarter constant currency sales growth expectations include inorganic revenue in the range of $11 million to $14 million.

Excluding inorganic contributions, our fourth quarter total revenue is expected to increase in the range of approximately 3% to 4% on an organic constant currency basis. With respect to our profitability expectations for the fourth quarter of 2024, we expect non-GAAP operating margins in the range of approximately 17.8% to 18.8%, and we expect non-GAAP EPS in the range of $0.80 to $0.86. That wraps up our prepared remarks.

Operator, we would now like to open up the line for questions.

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) And the first question that we have for the day is coming from John Young of Canaccord.

John Young^ First, with the Cook acquisition, I just wanted to ask a bit of a 2025 question. I'm not sure if you can totally answer it, but just are you expecting a halo effect essentially with the other products in the CI segment?

Joseph Wright^ Yes. This is Joe. I think that's exactly the rationale behind the acquisition. We have a number of very good EP/CRM-focused products but not really an anchor portfolio.

So I think with this acquisition, it gives us the revenue, the gross margin profile, and allows us to actually build out an EP-focused sales force that can drive not just the Cook acquired product revenue, but also some of the products we have already, whether it be transseptal crossing products or some that we have in our product roadmap.

So yes.

Fred Lampropoulos^ And Joe, can I add that just like RTG, we've seen success inaligning and having the focus to get deeper into those specific products, John.

Raul Parra^ It will add about $40 million in annualized revenue starting in fiscal year 2025, John.

John Young^ That's all very helpful. And then just a point of clarification on WRAPSODY for the add-on payment. Do you also expect NTAP to go live Q3 '25 if you got that? Or is that just TPT? And also, when it comes to pricing the product, will you price the product with NTAP in mind?

Joseph Wright^ The answer is we have submitted for NTAP. And yes, we will price as if we are going to get that NTAP. But of course, we won't know for several months.

As far as the add-on payment, that will be submitted or that application will be submitted after we receive FDA approval.

Operator^ And our next question will be coming from Jayson Bedford of Raymond James.

Jayson Bedford^ Congrats on the progress. Maybe just two to keep it moving here. With the WAVE results on WRAPSODY, has the data impacted traction in Europe at all?

Joseph Wright^ Yes. I think it's a little bit too early to say, Jayson.

Of course, we released the six-month data at the Lisbon conference -- or the Lisbon --

Fred Lampropoulos^ CIRSI.

Joseph Wright^ -- CIRSI. Thank you, Fred. And that was very well received.

Of course, there are a lot of European physicians there. But I think it will take some time for that to really take hold.

We have made great progress though in pushing awareness of the product and particularly that excellent data we released.

Jayson Bedford^ Okay. And then maybe for Raul or others. The 3% to 4% organic growth guide for 4Q, I realize it's a tougher comp, but what's the expected weight on growth to get to that level?

Raul Parra^ Yes. I mean I think generally, I'll start, Jayson, by just highlighting kind of the overall performance that we're going to -- that we've guided to.

I think for the year, it's going to be a solid execution on the revenue front, operating margin expansion and really strong earnings growth.

We called 17% to 19% growth on the EPS side.

But look, I think when we look at our guidance for the fourth quarter, it's really not materially different than what we've been guiding to since Q3 or even before that.

It's right in line with kind of our expectations. Really, the delta that we're kind of adjusting for is just the OEM expectations.

We had a little bit of a supply chain challenge that could impact the fourth quarter, which we've accounted for.

Obviously everybody knows about the Baxter IV impacting procedures. And I think we've tried to account for any disruption that may happen there.

But generally speaking, we feel really strong about the year that we're putting together. And then obviously the fourth quarter is going to be strong too, just from a growth perspective overall and just an earnings perspective.

Operator^ And our next question will be coming from Larry Biegelsen of Wells Fargo.

Gursimran Kaur^ This is Simran on for Larry. Maybe just to start off on WRAPSODY. Congrats on the results there. The data looked really strong. And I appreciate all the color on the reimbursement pathway.

I guess just to ask the question in a more pointed way, is it reasonable to assume WRAPSODY will be priced at a significant premium to the competitive sense in order to meet that cost criteria for the add-on payment?

Joseph Wright^ Yes. Typically, that's how it would work.

So we'll see as we get closer to launch and we'll give more detail at an Investor Day post approval. But yes, that's a fair assumption.

Gursimran Kaur^ Okay. Great. And then just any additional color on the commercial strategy? How are you positioning the sales force to add WRAPSODY to the bag? And are you going to be able to launch the product right away after FDA approval?

Fred Lampropoulos^ So this is Fred.

Look, we are preparing on the clinical side, regulatory, reimbursement and the commercial side, and we will follow all this up shortly after our approval.

We'll have a virtual meeting and go through all these details at that time when all these things play out and come together, and we will share that publicly in a virtual meeting.

Operator^ And our next question will be coming from Jason Bednar of Piper Sandler.

Jason Bednar^ Fred, I'll preface this by saying please don't shoot me for asking this, but I'll -- because I'm going to ask it anyways. The -- you've got the NTAP, the TPT, you're pursuing on WRAPSODY. You sound confident in securing each. Both maybe could take effect next year, TBD, I guess, on NTAP.

But you're launching next year presumably after approval.

I'll take a stab here. How should -- how do you want the analyst community thinking about the volume and/or revenue opportunity for WRAPSODY in '25? You like taking a prudent approach with setting guidance, setting expectations, but I think all of us are trying to feel out how much this could actually add in '25 or the first full year of launch. You've got a lot of different variables to consider.

So how do you want us thinking about that?

Fred Lampropoulos^ Well first of all, these are all good comments that we're receiving today, and we're very excited about the product as we have been.

We'll provide more at the appropriate time. We're going to hold steady to the course, as we've said, and we'll be as conservative as always.

But again, you're going to have to wait, Jason.

I wish we could do it faster, but that's not what we're going to do. We've given you -- we've given you everything we have what we want you to have now. We'll look forward to talking to that to you in the virtual meeting.

Jason Bednar^ Okay. All right. Fair enough.

Fred Lampropoulos^ Nice try. Nice try.

Jason Bednar^ It's all been very helpful today. So we do appreciate it.

Fred Lampropoulos^ I hope so. We hope so. We're working hard and we're progressing. We're doing things that have to be done.

Raul Parra^ And Jason, as we've talked, our intent is to provide material updates every quarter as they happen. So we provided a pretty good amount of color today and more to come.

Jason Bednar^ No. you did and more than I think a lot of us were expecting.

So that's -- it's all been helpful. Maybe I'll shift over to the margin side. This has been extremely successful and impressive here in the last few years.

Can you talk about whether you have additional SKU rationalization plans for the businesses over the next few quarters or next year? Or maybe just bigger picture as we start thinking about our models for next years, any other considerations that we should think about in sustaining this margin improvement, not looking for specific guidance, of course, big picture items that we should have in mind?

Raul Parra^ Yes. Look, I mean I'll take -- the question is pretty broad, Jason.

So I'm going to take just a minute to highlight the 108 basis point improvement year-over-year. We hit 50.9%. Obviously the sales team is working really hard on pricing uplift. They've been working really hard on the favorable kind of product and geography revenue mix. And our operations group has been doing a great job on the freight and distribution side.

So that's all driving the gross margin improvement. And as we talked about in CGI when we laid out those goals for 2026, a significant portion of the improvement comes from gross margin, right, on the low end. And as we get to the higher end, obviously there's an incremental gross margin improvement there too with additional leverage to the operating expense line.

So generally speaking, I think this gives us a big vote of confidence for us that we're heading in the right direction.

We're making the right improvements. But it's progressing, I guess, as we planned, and it's part of the CGI program to increase the gross margin and let it flow through to operating margin. And maybe just one more thing, Jason.

I didn't hit on the SKU rationalization piece. So let me answer that here real quick.

But generally speaking, our commitment there hasn't changed. There's two aspects to the SKU rationalization.

One is just replacing our legacy products with newer products that are the same, but just improvements and also obviously lower cost to manufacture. And then the second piece, the more material one that I think people generally ask about is whether we're going to exit businesses or exit products.

And generally, we'll give color and we'll give people a heads up when those material kind of items come up.

We don't anticipate anything for 2025. It will be more of the internal stuff that you guys won't really notice or we hope you don't notice other than through the incremental margin improvement.

Operator^ And our next question will be coming from David Rescott of R. W. Baird.

David Rescott^ Congrats on the quarter and I appreciate all the color on WRAPSODY. Just a couple on WRAPSODY from us and maybe attacking some of the market opportunity questions a little bit of a different way. You look at the, we'll call it percent covered graft market out there where some of the physician feedback is obviously very positive around the potential to transition toward a WRAPSODY product. The trial itself obviously looked at use of the therapy versus PTA. And so I'm curious when you think about the opportunities to enter these markets, is the stent covered graft kind of the lowest hanging fruit out there and going after kind of what you looked at in the control arm is more upside? Or do you think that both of those markets are kind of up for grabs with WRAPSODY once you get out there?

Fred Lampropoulos^ Yes. David, first of all, a very thoughtful question, and we appreciate why you're asking. And we look forward -- we're going to share all of the thoughts on all of these issues in the future.

As everything plays out, we're focused on preparing for the commercial launch as we speak, and then we will talk about all of this stuff at our virtual meeting.

I'm sorry to have to repeat that, and I appreciate you guys trying.

But listen, we are focused on CGI. We're focused on launching this product. We're focused on operating margins, free cash flow, all the things we've talked about.

So the WRAPSODY is important to us, but we have a big business we have to run, and we'll talk to you as soon as we get to that closing time and get ready -- in the meantime, we're getting ready to go to the market.

David Rescott^ All right. And then just maybe as a follow-up on that and some of the prior comments you made, you talked about, again, the out-year margin expansion story. Just -- I'm not sure you're going to provide much on it, but just curious on the assumptions around not the impact WRAPSODY would have, but assuming that the WRAPSODY contribution on a margin perspective should be aligned with the expansion story over the CGI?

Joseph Wright^ Yes. Again, thanks for the question, but we're obviously focused on the PMA approval, getting through that process. And we're excited about the product just as everybody is.

But clearly, we're focused on delivering at least 20% operating margins per CGI. That's the goal. That's what everybody is focused on.

We're also focused on making sure that we get the WRAPSODY product line across the finish line from a PMA approval. There's a lot of work that's being done internally.

We're just as excited as everybody, but we're just going to hold off on kind of the financial modeling questions until we actually -- that post-approval meeting that we have.

So again, I appreciate the question.

Operator^ And our next question is coming from Mike Matson of Needham.

Michael Matson^ So just kind of a higher-level question. Merit has been sort of making this move from more kind of basic accessory type products into these more physician preference item, therapeutic products like WRAPSODY, the Cook lead management devices and then the EndoGastric Solutions products.

So do you believe that your sales force has sort of the right skill set to sell these types of products that are more kind of dictated by physician preference and physician relationships as opposed to maybe kind of more of the purchasing or C-suite side of the hospital?

Joseph Wright^ Yes. I think those are fair questions. I'm very confident in our sales team. We have been selling a lot of more accessory type devices, that's for sure. But that's really built the company to where it is today and has enabled us to make these select bets on therapeutic products.

There's clearly a change in selling, I'll be clear about that. But we're confident that we can get our -- attract and retain top sales talent that know how to sell therapeutics.

We're -- already this year, we've been training up our renal therapies group in preparation for WRAPSODY. They're already selling physician preference products in that portfolio, and we're confident they can take on WRAPSODY. And listen, we'll do the same with the Cardiac Therapies group really anchored by Cook's lead management business.

Brian Lloyd^ And our EGS, our endoscopy group, too. Yes.

Michael Matson^ Okay. Got it. And then just one more -- I got to try one more on WRAPSODY. I know you may not answer this, but one more stab at the market opportunity here. I mean can you just tell us like what the kind of TAM is for the indications you're expecting to get here?

So in other words, covered stents used specifically for AVGs or AVFs. I mean I've ballparked it kind of in the $300 million to $600 million range, but it's not very scientific. So I don't -- is that reasonable? And sorry, that's a U.S. number specifically.

Fred Lampropoulos^ Yes. Mike, we are not going to confirm or deny anything.

What we are going to say is, yes, we can provide it at the virtual meeting right after we get approved.

Operator^ And our next question will be coming from Craig Bijou of Bank of America Securities.

Craig Bijou^ I wanted to start with the OEM business. And maybe just -- I guess the question is any of these logistical challenges, can that bleed into '25? And I guess that's the first part. And then -- just how to think about that business going forward in terms of a growth rate? Obviously over the last couple of years, it's been a pretty strong grower for you. Maybe it slowed down a little bit this year. But would love any thoughts you had on that business and any potential disruption kind of bleeding into early '25.?

Raul Parra^ Yes. No, great question.

First of all, I think just to highlight, right, I mean I think Q3 revenue came in above the high end of our guidance.

So generally speaking, even though we did have a little bit -- we weren't as high on the revenue growth in OEM as we expected.

We were still able to beat the high end of our guidance.

And also, I just -- I want to make sure that it's clear, like we're not concerned here internally about OEM. I mean if you look at Q1, they were down 5%. They were up 5% in Q2, and they were up 8.5% in Q3.

So the demand is there. The logistics issue was kind of is really isolated to Q3, is a customer that couldn't arrange pickup for Q3.

Then you ran into kind of the Chinese New Year that led to some delays. So it was really kind of a discrete item.

Fred Lampropoulos^ It's Golden Week, just for clarification.

Raul Parra^ Yes, Golden Week. Thank you. And so we can put that one kind of behind us. I think what we've tried to accommodate for is really the supply chain. That's something that kind of -- that we don't really have control over.

As we've talked before in multiple quarters, there are still some areas of -- that haven't recovered from a supply chain standpoint. And this just happens to be one of the areas that's limiting us to be able to deliver on the demand that we're seeing from customers. So the demand is there.

We have visibility to that. We continue to be excited about OEM. And again, we're still talking about 7% growth in 2024 for OEM, which is at the high end of our CGI guidance. So again, we have good visibility into the business.

We're confident in the expectations. We're not going to provide anything for 2025.

But I want to make sure that everybody understands that the kind of the impacts that we were seeing in Q1 and coming out of into Q2 are really different from what we're seeing heading into Q4.

They're discrete. So again, super confident in the overall business.

I think if you look at the U.S. growth on a constant currency basis, organic, we are approaching almost 7%, really solid number for the U.S. The rest of our U.S. business is almost 86%, 87%.

So we're really talking about a small portion of our business, but continue to be excited about the demand we're seeing in OEM.

Craig Bijou^ Got it. And maybe for Fred or Joe, obviously we're all excited about WRAPSODY.

I'm going to spare you a question on WRAPSODY specifically. And I don't mean to look past it, but you guys have talked about the Cook deal, the product roadmap.

Fred, I think in past quarters, you've even teased that there's -- you have other pipeline products beyond WRAPSODY.

So maybe just help us understand when we may hear about some of these new products or what the pipeline looks like or when you would disclose that to us? Or just how we should think about the pipeline other than WRAPSODY over the next couple of years?

Fred Lampropoulos^ Yes. Well listen, it's -- again, these have all been really good questions, which we appreciate.

Look, we're not revealing the details. I will say that we're focused on this CGI as we've been talking about on the call.

I think in terms of new product development, it continues to be a priority at Merit.

We have certain technologies here that we developed over the last several years. And when appropriate, we'll bring it forward. So we just want to keep focused on the things that are in front of us. But in the meantime, there's ongoing product development.

Operator^ Our next question will be coming from James Sidoti of Sidoti & Company.

James Sidoti^ Can you talk a little bit more about the integration of the Cook Medical products? Are you bringing on any of their sales folks? And will you move the manufacturing to your facilities?

Joseph Wright^ Yes. We are planning on taking on some sales professionals in the transaction. And yes, we will be transferring the manufacturing of that product to a Merit facility. In the meantime, however, we will have a TSA to bridge the time between close and transfer to a Merit site.

James Sidoti^ So once that transfer is complete, what will the impact be on gross margins?

Fred Lampropoulos^ Well we'll talk about that, Jim, when it's complete.

Raul Parra^ Yes. I mean again, I think if you look at our original guidance that we gave out when the acquisition came out, we said it was going to be accretive to non-GAAP gross margins, accretive to non-GAAP operating margins in the first full year post close.

James Sidoti^ Okay. And if you look at the business now compared to where you were 7, eight years ago, I mean the cash flow has just improved dramatically.

What's the plan long term with the cash? Do you anticipate continuing to use cash for acquisitions? Or would you ever consider -- are there other options out there for it?

Fred Lampropoulos^ Well Jim, as you can see, we've made acquisitions because we have not only a line, that line comes from our ability to generate cash.

I think we've done a great job. You can see the numbers that we're talking about for this year. And as someone told me that lives in New York City, cash is king. And you might know that guy quite well.

Raul Parra^ Yes. Thank you for the question, first of all.

We're working really hard to make those improvements. I think it's obviously shown in the performance that we've generated.

Obviously we're off to a really good start under our CGI program, Jim. We're at $120 million of free cash flow for the year. We're going to do a minimum of $400 million under the CGI program. So we're off to a good start.

We've got plenty of capacity, our balance sheet is strong, and we continue to work on our working capital. So all solid points that are generating that free cash flow.

James Sidoti^ All right. And then with WRAPSODY, I know you don't want to answer a lot of questions. But when it does get approved, is this something that you think you can get in the market with relatively quickly? Or do you think there'll be a significant amount of training involved to launch the product?

Joseph Wright^ Yes, great question. The training has started this year.

So we've had ongoing training sessions with our sales groups, and we'll be ready to go from that perspective.

As far as adoption out of the gate, keep in mind, this is a -- this, like most new medical devices, will require a VAC committee in most cases. So that takes time.

But I don't think it's any greater than any other product. And of course, with the data we have, we expect that process to be certainly not easy, but easier than it would be without such great data.

Operator^ The next question will be coming from Michael Petusky of Barrington Research.

Michael Petusky^ I've challenged myself to try to ask WRAPSODY question you guys can't answer. So let's see if it's -- how it works. I'm just curious, in terms of your communication with the FDA, have there been -- have there -- I guess, the clock started at the end -- maybe the end of June or the 1st of July. Have there been any stoppages during your -- any communication with the FDA since then?

Fred Lampropoulos^ Yes. So as you know Mike, we promised or we indicated that we would file by the end of the second quarter, which we did. There's 180 FDA days and we have had no stoppages. So we'll leave it at that.

Michael Petusky^ All right. I'm going to try my luck with a second one.

In terms of just website traffic or inquiries, have you guys noticed any pickup just in people clicking around and trying to learn about WRAPSODY since the day in Portugal?

Fred Lampropoulos^ Yes. I haven't. I haven't candidly looked at it. But guys, do you want to speak to that, Joe?

Joseph Wright^ Yes. I mean look, I think it continues to track well in multiple markets where it's available commercially.

Obviously there's a lot of positive feedback from clinicians, and there continues to be a lot of data release in the coming months, Mike.

So I mean I think that's all generating a buzz, generally speaking, as you saw just today alone, just with the questions we're getting. So that's probably the best way to answer it.

Michael Petusky^ Absolutely. All right. Last one real quickly.

In terms of M&A, you guys for a few years there were pretty quiet. You've picked up a little bit, not doing anything huge, but doing some deals that seem meaningful, both strategically and even financially.

Just curious, in terms of comfort with leverage, I mean is there a number -- and forgive me if you put this out either tonight or recently, but I'm just not sure I heard it. Is there sort of a leverage ratio you guys are comfortable with going up to?

Raul Parra^ Yes, Mike, I think had you asked me this year -- this question three years ago when the interest rates were low, we'd probably say a higher number, right? We'd probably go up to 4x.

I think, generally speaking, in this interest rate environment, we're probably somewhere around three unless we can delever really quick, right? But look, I think we're -- our discipline on the transactions that we're showing right now I think they're real, right? I mean I think you're looking at the transactions.

You can pick up on the theme pretty easily. We're looking at areas that we can go deeper into the bag that we can make investments in sales forces to make sure that they can get deeper into the bags that we already have including the new products that we're bringing on with these acquisitions. And we're sitting right now at 2.08x levered.

We've got plenty of cash on the balance sheet. We have a strong balance sheet and we've got plenty of firepower, but we're going to continue to remain disciplined.

We've got our crosshairs on the CGI program. And that's our goal is to execute to the CGI program that we've promised. And everything that falls under that scope, I guess, we're making sure that any transaction that we do generally meets or exceeds those targets.

Operator^ And our next question will be coming from Steven Lichtman of Oppenheimer.

Steven Lichtman^ I guess, first on Cook, where do you see the biggest sales synergy opportunities with your legacy CRM franchise, whether is it cross-sell in the U.S., store opening in other countries? Any thoughts on that would be helpful.

Joseph Wright^ Yes. One of the nice things about these assets are they truly are global unlike a lot of the acquisition candidates we evaluate. They have about as much revenue in the U.S. as they do in Europe.

I guess I should have said that the other way around.

But also some exciting opportunities in APAC, we think. So globally, it really helps our global franchises.

As far as products we have, we have the Worley, we have the SNAP Splittable Sheath. We have the Ventrax, which will be coming out soon. We have transseptal crossing catheters, both steerable and fixed curve. We have the PTA balloon.

So we have a number of products that really haven't had the attention they deserve. And we're confident in the products we already have that if we put the folks behind them, we will get more adoption. And with more dedicated feet on the street, we're confident that will happen.

Steven Lichtman^ And then just a follow-up on China. Good to see growth continuing to hold up for you guys there.

Can you talk about the environment overall there? How much VBP are you absorbing, your confidence on procedure volume growth? Thoughts there would be great as well.

Raul Parra^ Yes. Look, I think -- Steve, look, I think it's -- for us, first of all, volume-based purchasing has kind of come in as expected.

I think the nice thing that we've seen is we've seen a strong demand and an increase in units, which is why you're seeing the better-than-expected results in China.

So I think for us, the business continues to be strong or stronger than we anticipated. And we're dealing with volume-based purchasing, which is, as you know continues to be from quarter-to-quarter, pretty volatile, I would say.

But generally speaking, we're outpacing it with the unit growth. And so I think we continue to be excited about the performance of our Chinese team. And generally speaking, just the APAC region.

Operator^ And this does conclude the Q&A session for today.

I would now like to turn the call back over to Fred for closing remarks. Please go ahead.

Fred Lampropoulos^ Well listen, it's been a long call.

We appreciate all the questions. Rahul and I and Joe will be around for the next couple of hours. Best wishes.

It's cold out in Salt Lake City. Warm us up with your questions. Thanks again for taking the time.

We appreciate it. And good evening from Salt Lake City. Good night.

Operator^ Thank you for participating in today's conference call. You may all disconnect.