Merit Medical Systems, Inc (Q3 2023 Earnings)

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Corporate Speakers:

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

Participants:

- Michael Petusky; Barrington Research; Managing Director & Senior Investment Analyst
- Steven Lichtman; Oppenheimer & Co; Analyst
- Jayson Bedford; Raymond James; Senior Analyst
- Zachary Day; Canaccord Genuity; Equity Research Associate
- Jim Sidoti; Sidoti & Co; Analyst
- Michael Matson; Needham and Company; Analyst

PRESENTATION

Operator^ Welcome to the third quarter of fiscal year 2023 earnings conference call for Merit Medical Systems, Inc. (Operator Instructions) Please note that this conference call is being recorded and that the recording will be available on the company's website for replay shortly. I would now like to turn the call over to Mr. Fred Lampropoulos, Merit Medical Systems' Founder, Chairman and Chief Executive Officer. Please go ahead, sir.

Fred Lampropoulos^ Thank you, and welcome, everyone, to Merit Medical Systems' Third Quarter of Fiscal Year 2023 Earnings Conference Call. I'm joined on the call today by Raul Parra, our Chief Financial Officer and Treasurer; and Brian Lloyd, our Chief Legal Officer and Corporate Secretary. Brian, would you mind taking us through the safe harbor 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 unknown risks and (technical difficulty) 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 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 thank you for joining us on a very busy reporting day. Let me start with a brief agenda of what we will cover during our prepared remarks. I will start with an overview of our revenue results for the third quarter, followed by an update on a few noteworthy operating highlights in recent months.

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 updated in today's press release as well as a summary of our balance sheet and financial condition as of September 30, 2023. We will then open the call for your questions.

Now beginning with a review of our third quarter revenue performance, we reported total GAAP revenue of $315.2 million in the third quarter, up 10% year-over-year.

Our total GAAP revenue growth was driven by a 14% growth in U.S. sales and 4% growth in international sales. Our total revenue increased 10% year-over-year in the third quarter on a constant currency basis, excluding the 10-basis point headwind to our GAAP revenue growth related to changes in exchange rates compared to the prior year period.

The constant currency revenue growth we delivered in the third quarter was significantly stronger than the high end of the range of growth expectations that we outlined on our Q2 earnings call. Specifically, we expected constant currency revenue growth in the third quarter in the range of 5% to 7% year-over-year. Importantly, the better-than-expected total constant currency revenue results in the third quarter was driven almost entirely by strong organic growth, reflecting a broad-based strength across each of our primary product categories, particularly in the U.S.

Third quarter total revenue results also included $7.3 million of sales from the portfolio of interventional solutions we acquired from AngioDynamics on June 8, 2023, which notably also came in above the high end of the range we provided on our second quarter earnings call.

Let me now provide you with a more 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 presented on a year-over-year and constant currency basis. We've included reconciliations from our GAAP reported results to the related non-GAAP item in our earnings release and presentation available on our website.

Third quarter total revenue growth was driven by 10% growth in our Cardiovascular segment and 11% growth in our Endoscopy segment. In our Cardiovascular segment, constant currency growth exceeded the high end of our expectations for the third quarter, while Endoscopy segment sales came in at the high end of expectations.

Sales of our peripheral intervention or PI products, increased 16%, representing the largest driver of total cardiovascular segment growth again this quarter. Excluding sales of acquired products, PI sales increased 9% on an organic constant currency basis.

Organic growth in the PI product category was driven by the sales of our radar localization and drainage products, which increased 19% and 15%, respectively, and together represented a little more than half of total PI sales growth.

And by sales of our delivery systems and angiography products, which increased 19% and together represented roughly 1/3 of our total PI growth in Q3. Sales of our OEM and cardiac intervention products were key contributors to our total cardiovascular segment growth this quarter, increasing 11% and 3%, respectively.

Sales of our OEM products exceeded the high end of our growth expectations, which we attribute principally to continued solid demand from larger customers in multiple categories, including angiography, coatings, EP, CRM, intervention and kit products, which together increased 25% in Q3.

Cardiac intervention products sales also exceeded the high end of our growth expectations, driven primarily by strong growth in sales of both our access products, which increased 20% and our angiography and hemostasis products, which together increased 20%.

Sales of our custom procedure solutions or CPS products, increased 6%, which was notably better than the low single-digit decline we expected in Q3. Sales results benefited from higher demand from our customers outside the U.S. for certain kit product lines that we have been identified for SKU rationalization as part of our foundations for growth initiatives.

We expect CPS sales to decline in the fourth quarter on a year-over-year basis as demand trends for these kit products lines normalize. But our guidance continues to assume that

CPS product category delivers roughly flattish growth over the second half of 2023 compared to the prior year period.

Lastly, sales in our Endoscopy segment increased 11%, which was at the high end of the growth range we assumed in our third quarter guidance. As expected, we continue to see improving sales trends in the third quarter, and we continue to expect mid-teens growth in our Endoscopy business in the second half of 2023.

Now turning to a brief summary of our sales performance on a geographic basis. Our third quarter sales in the U.S. increased 14% on a constant currency basis and 10% on an organic constant currency basis, exceeding the high end of our growth expectations by more than 400 basis points in the period.

Our U.S. growth performance reflects continued strong execution and overall improving trends in the U.S. market during the third quarter, particularly in our direct business, which continues to see impressive volume growth in sales of our vascular products.

International sales increased 3.5% on a constant currency basis and increased 2.9% on an organic constant currency basis, modestly exceeding the high end of our expectations in the quarter. Organic constant currency growth to customers outside the U.S. was driven by low single-digit growth in APAC and high teens growth in the Rest of the World region, while growth in the EMEA region was flat year-over-year.

Growth in the APAC region was at the lower end of our expectations in Q3. EMEA was in line with expectations, and the Rest of the World region was modestly ahead of our growth expectations.

With respect to China specifically, sales were flat year-over-year and were impacted by the headwinds related to volume-based purchasing tenders discussed on our Q2 call as expected.

With respect to our profitability performance in the third quarter, we leveraged the strong revenue results in the third quarter to deliver non-GAAP gross profit and operating profit growth of 13% and 25%, respectively, and we delivered non-GAAP net income and EPS growth of 18% and 16%, respectively, as well.

We believe our third quarter financial results demonstrate that the team's continued hard work and commitment to our Foundations for Growth program are paying off. We remain focused and confident in our team's ability to deliver our financial guidance for the fiscal year 2023, driving continued progress in year three of our Foundations for Growth program and the related financial targets for the three-year period ended and ending December 31, 2023.

Now before turning over the call to Raul, I would like to share a brief update on several areas of operational progress in recent months. On August 3, we announced the completion of enrollment in the WRAPSODY, arteriovenous access efficiency or WAVE pivotal study.

The WAVE study is a prospective, randomized, controlled multicenter study comparing the Merit WRAPSODY cell-impermeable endoprosthesis to percutaneous transluminal angioplasty for treatment of stenosis occlusion in the venous outflow circuit in patients undergoing hemodialysis.

The WAVE study enrolled 244 patients with arteriovenous fistulas in 113 patients with arteriovenous grafts across sites in Brazil, Canada, the United Kingdom and the United States.

We are collecting safety and efficacy outcomes throughout the study follow-up period and expect to have primary endpoint data for the last enrolled patient in February of 2024.

We currently expect that the monitoring, data cleaning and analysis phase will be completed early in the second quarter of 2024. We plan to complete the clinical study report and be in a position to file primary outcomes with the FDA for premarket approval or PMA by the end of the second quarter of 2024. With respect to the two acquisitions we announced in early June, we have made significant progress in integrating their operations.

During the third quarter, we completed sales training and customer KOL engagement efforts. We are transitioning product SKUs to Merit branded packaging along with launching all related marketing materials and sales tools under the Merit brand. We look forward to continued engagement with existing customers and deleveraging the opportunity to raise awareness among potential new customers at industry events, including the controversies in dialysis access or CiDA and the VEITH symposium.

These are exciting times for Merit Renal Therapies business. We have a clear strategy to leverage our established position in the dialysis and biopsy markets built on a differentiated commercialized products like HeRO graft and the Surfacer Inside-Out Access Catheter system, and of course, our WRAPSODY Cell-Impermeable Endoprosthesis, amongst others.

Together with the recently acquired dialysis catheter portfolio, including the innovative BioFlo DuraMax dialysis catheter with Endexo Technology, the Surfacer Inside-Out Access system, and the BioSentry Biopsy Tract Sealant System, we have an extremely compelling foundation of growing interventional solutions. That will allow us to leverage our physician relationships and the commercial infrastructure to serve more patients in the multibillion dollar dialysis and biopsy markets.

Finally, I wanted to share a few thoughts on two items that we know are key focus areas for investors evaluating the intermediate to longer-term investment opportunity in Merit Medical. Specifically, executive leadership and financial targets beyond fiscal year 2023.

With respect to executive leadership, succession planning is something our Board takes very seriously, and the formal process was initiated in recent months.

Importantly, this is a process that I am not directly involved in. Our Lead Independent Director in Compensation and Talent Development Committee of the Board are leading this initiative with the active involvement of all of our independent directors. The Board continues to target having a formal announcement to share with the investment community by the end of 2023. I continue to be fully engaged in the business, and I serve at the pleasure of the Board on behalf of our shareholders.

With respect to longer-term financial targets, -- as we approach the end of the final year of our transformational company-wide program to evaluate all aspects of our business to better position the company for long-term sustainable growth and enhanced profitability. I would like to reflect on what the team has accomplished in this important Foundations for Growth program.

From the outset, we wanted to use the Foundations for Growth program as be able to think holistically and comprehensively across the business to challenge the status quo and to deliver an ambitious improvement in profitability while preserving our historically market-leading growth profile, our legacy of customer-driven innovation and the strength of the Merit culture that has served us so well for so many years. By the way of reminder, the Foundation for Growth program was established with three clear objectives in mind.

First, to main growth above market, designed to preserve our proven ability to innovate together with our customers and deliver unique solutions to the market that fuel our top line growth; second, to significantly improve our non-GAAP operating margins with operations designed to exploit scale where it exists while preserving autonomy and flexibility where it matters. And to build a foundation for sustained success, we will continue to invest in our people, and we will build new capabilities to meet the evolving needs of our changing health care markets.

As discussed on each of our earnings calls since the program was formally announced in November of 2020, we expect that our team's strong execution of this program would result in significant financial results as outlined by our formal financial targets, including at least a 5% organic constant currency revenue CAGR and more than 400 basis points of non-GAAP operating margin expansion, ending in 2023 with more than $1.1 billion of revenues and non-GAAP operating margins of at least 18%.

We also expected our efforts to drive significant improvements in our balance sheet and the financial condition as we targeted cumulative free cash flow generation of more than $300 million during the three-year fiscal years ending December 31, 2023. We -- we believe the team has executed exceptionally well in the face of many headwinds that were not contemplated when the program was announced in November of 2020, and we are extremely proud that we continue to expect to deliver or exceed the formal growth and profitability targets in our Foundations for Growth program.

With respect to cumulative free cash flow target, we have generated $244 million since the end of 2020, not including the $119 million that we generated in fiscal year 2020, and we continue to target generating more than $300 million of cumulative free cash flow by year-end, as we discussed on our quarter two call, certain working capital items may push the achievement of this target in additional quarter.

Importantly, -- as we have said throughout the Foundations for Growth program, our efforts to continue to enhance Merit's foundation for long-term, sustainable growth and improving profitability will not end on December 31, 2023.

We continue to believe there are opportunities for further improvement in years to come. Accordingly, on our fourth quarter earnings call in February, we plan to introduce new formal financial targets for the three-year period ending December 31, 2026.

In the interim, we remain exclusively focused on delivering the current targets for our Foundation for Growth program and look forward to discussing future goals, opportunities and financial targets on our call next year.

With that said, let me turn the call over to Raul, who will take you through a detailed review of our third quarter financial results and our 2023 financial guidance, which we updated in today's press release. Mr. Parra?

Raul Parra^ Thank you, Fred. Given Fred's detailed discussion of our revenue results, I will begin with a review of our financial performance across the rest of the P&L. For the avoidance of doubt, unless otherwise noted, my commentary will focus on the company's non-GAAP results during the third quarter of fiscal year 2023. 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 13% year-over-year in the third quarter. Our gross margin for the third quarter was 49.8%, up 140 basis points year-over-year. The increase in gross margin year-over-year was lower than expected due primarily to revenue mix by product and by geography.

Operating expenses increased 7% year-over-year in the third quarter. The year-over-year increase in operating expenses was driven by a 6% increase in SG&A expense and a 12% increase in R&D expense compared to the prior year period. Our operating expense performance in Q3 was better than expected and reflects strong operational leverage, principally due to our continued focus on expense management and prioritization of investments to support our future growth initiatives.

Total operating income in the third quarter increased $11.5 million or 25% year-over-year to $57.7 million. Our operating margin for Q3 was 18.3% compared to 16.1% in the prior year period. The 220 basis point increase in operating margin was driven by 140 basis point increase in our non-GAAP gross margin and by an 80 basis point decrease in our non-GAAP OpEx margin compared to the prior year period. Third quarter other expense net was $4.5 million compared to $0.8 million last year.

The change in other expense net was primarily related to an increase in interest expense associated with increased borrowings and rising interest rates as well as expense associated with realized and unrealized foreign currency losses compared to income in the prior year period.

Third quarter net income was $43.5 million or $0.75 per share compared to $37 million or $0.64 per share in the prior year period. We are pleased with our profitability performance in the third quarter, where we delivered 18% growth in non-GAAP net income and 16% growth in non-GAAP diluted earnings per share, exceeding the high end of our expectations.

Turning to a review of our balance sheet and financial condition. As of September 30, 2023, we had cash and cash equivalents of $58.7 million, total debt obligations of $287.1 million and available borrowing capacity of approximately $558 million compared to cash and cash equivalents of $58.4 million, total debt obligations of $198.2 million and available borrowing capacity of approximately $523 million as of December 31, 2022. Our net leverage ratio as of September 30 was 1x on an adjusted basis.

We generated $42.5 million of free cash flow in the third quarter, up 115% year-over-year and up nearly fourfold on a quarter-over-quarter basis. The sequential improvement in free cash flow generation in the third quarter was primarily a result of significant improvements in cash used in working capital, specifically in the areas of inventory and accrued expenses, offset partially by an uptick in payable days. We continue to expect to generate strong free cash flow generation in 2023.

Turning to a review of our fiscal year 2023 financial guidance, which we updated in today's press release. We have included a table in our earnings press release, which details the updated ratings for each of our formal financial guidance items and how those ranges compared to the prior year period. We now expect GAAP net revenue growth of approximately 8% to 9% year-over-year.

The GAAP net revenue guidance range now assumes net revenue growth of approximately 8% to 9% in our Cardiovascular segment. net revenue growth of approximately 13% in our Endoscopy segment and a headwind from the change in foreign currency exchange rates of approximately $5.4 million or approximately 50 basis points to 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 8.4% to 9.1% in 2023.

Note the midpoint of this range now assumes approximately 11% growth year-over-year in the U.S. and approximately 6% growth year-over-year in international markets compared to 9% and 6%, respectively, assumed in the guidance provided on our second quarter earnings call.

The higher U.S. constant currency growth expectation versus prior guidance reflects the stronger-than-expected third quarter results and the anticipated contributions from our acquisition, which we now estimate in the range of approximately $14.4 million to $15.4 million of revenue in fiscal 2023 compared to a range of $13 million to $15 million assumed in our prior guidance.

Excluding revenue from these acquisitions, our guidance reflects total net revenue growth on a constant currency organic basis in the range of approximately 7% to 8% compared to the 6% to 7% range assumed in our prior guidance.

With respect to profitability guidance for 2023, we have updated our GAAP net income and diluted earnings per share ranges driven primarily by the better-than-expected financial results in the third quarter to $89 million to $92 million and $1.52 to $1.58 compared to $76 million to $81 million and $1.30 to $1.39 per diluted share previously.

We have updated our non-GAAP net income and diluted earnings per share ranges driven primarily by the better-than-expected financial results in the third quarter to $171 million to $174 million and $293 million to $299 million compared to $1.64 compared to $164 million to $170 million and $2.81 to $2.92 per diluted share previously.

For modeling purposes, our fiscal year 2023 financial guidance now assumes non-GAAP gross margins in the range of approximately 5% to 50.7%, up 170 to 190 basis points year-over-year. Non-GAAP operating margins in the range of approximately 18.1% to 18.3%, up 120 to 140 basis points year-over-year.

GAAP other expenses of approximately $14 million compared to $13 million previously; and non-GAAP other expense of approximately $12.7 million compared to a range of $11 million to $12 million previously. The increase in both ranges is primarily related to higher interest expense on outstanding borrowings. Non-GAAP tax rate of approximately 19.4% compared to a range of 21% to 22% previously and diluted shares outstanding of approximately $58.4 million.

Lastly, we would like to provide additional transparency related to our growth and profitability expectations for the fourth quarter of 2023. Specifically, we expect our total revenue to increase in the range of approximately 5.5% to 8.3% year-over-year on a GAAP basis and up approximately 5% to 8% year-over-year on a constant currency basis.

The midpoint of our fourth quarter constant currency sales growth expectations assumes approximately 9% growth year-over-year in the U.S., including approximately $6.6 million of acquired revenue and approximately 2% growth year-over-year in international markets.

Note, the revenue growth ranges for the fourth quarter of 2023 implied by our updated full year 2023 guidance are essentially unchanged versus what our prior guidance for 2023 assumed.

With respect to our profitability expectations for the fourth quarter, we expect non-GAAP gross margins in the range of approximately 50.5% to 51.3%, up 100 to 180 basis points year-over-year and non-GAAP operating margins in the range of approximately 18.1% to 18.8%, up 25 to 100 basis points year-over-year.

These updated margin expectations are expected to drive a non-GAAP EPS in the range of $0.73 to $0.78 roughly $0.01 lower than what we -- what our prior guidance range assumed. That wraps up our prepared remarks. Operator, we would now like to open up the line for questions.

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question comes from Jason Bednar with Piper Sandler. Our first question comes from the line of Michael Petusky with Barrington Research.

Michael Petusky^ A really impressive quarter and a lot of -- across a lot of different aspects. Congratulations. I guess just real quick on China. Was that performance -- VBP has been talked about to death, but I'm just curious, was that performance about what you guys had anticipated for Q3. Is that sort of shaping up in the second half the way you anticipated? A little better, a little worse? Can you just comment on that?

Fred Lampropoulos^ Yes. I think it was about what we expected, was baked into our numbers. It's baked into our year-end numbers. Again, as we've talked about many times, Mike, you've talked with Raul about this, and that is -- that's today's -- I don't -- it changes. But right now, it's in our numbers based on our best estimates what we think what China will do.

Michael Petusky^ Okay. I feel like this is almost an obligatory question in Q3. But Fred, do you have any thoughts on sort of the weight loss drugs, the GLP-1s and possible longer-term impact on Merit Medical and the space you guys serve?

Fred Lampropoulos^ Yes. And I appreciate the question. Listen, we take all of these issues very seriously, and we don't just think they're passing. If you go back and we talked about things like China, we talked about MDR, we like to stay out in front of these things. In fact, Raul and I yesterday, we're talking to several adviser physicians who are in our market areas.

In fact, one of them was actually taking the drug. So there was a number of issues that came up in terms of the effect that they thought it would have long term. I think they all somewhat indicated that it will be 10 years before you see that, that pricing is going to be one of the things that -- but in terms of elderly or hypertensive patients, for at least and these are people who are doing interventional nephrology types of procedures. And in fact, one of the comments I made was that 20% of the people that work in the lab were on the drug.

There were a bunch of different things that they talked about in terms of if you take the drug and some of the effects. But the bottom line is that they didn't see an immediate effect.

It's there. They're using it. There are some complication issues. But I think all in all, it was something we didn't feel that was immediate, but something that we will continue to do panels. We will go out and meet with our customers, and we think that's the best source of information. So that's a long response to the question. Raul, do you want to add anything to that?

Raul Parra^ No. I mean, I guess, two things that I would add, right? Obviously, type 1 diabetes is not going to be impacted. These are individuals that are born with the disease. And so you won't get to the kind of the real -- you won't have a renal stage impact, I guess, we'll say that which would impact our business.

So you're really talking about the type 2 diabetes patients that would be impacted. And that's really out in kind of 10 years is kind of what several doctors kind of threw out as kind of an example of when they would think they would see an impact if they did see an impact. But to Fred's point, we always try and stay ahead of these things. We're very aware of risk, and we're very good at pivoting and adjusting as needed. So we'll keep an eye on it.

But for now, our business is not being impacted by it. These drugs -- some of these drugs have been in the market since '17. So they're not new. I think they are getting a lot more news now, but we'll keep an eye on it and we'll adjust as necessary.

Fred Lampropoulos^ And I think if I could just might just say, having that ability to talk to physicians who are doing the procedures who are seeing various patients looking at pricing and reimbursement, all those things, I think, gives us a relatively unique look at all the factors that go into -- that affect our business. These are our customers and our advisers. So we'll stay on top of it.

Michael Petusky^ Right. And let me just confirm to me, it sounds like the commentary around the acquired businesses, particularly Angio. It sounds like it's -- you've integrated well, and it sounds like you're running maybe a little bit ahead of plan in terms of revenue generation. Is that a fair sort of summary of what you guys tried to communicate there?

Fred Lampropoulos^ I think so. And I think a reminder that, remember, a portion of that is biopsy. And I think sometimes everybody thinks it is just being those dialysis catheters. And I think we're doing a very good job of integration. We've actually moved the BioSentry move this week or late last week is actually moving to our Mexico facility.

And by the end of this year, maybe early first quarter, we'll have moved the other product and it will be fully integrated.So I think it's doing just fine for now. I think there's still upside potential in that business quite a bit actually. And I think we're performing better on the financial side of it than we expected. Raul, do you want to add anything to that?

Raul Parra^ I mean I think if you look at our guidance, we brought up the bottom by about $1 million. So I think we're well within the range that we have given the Street. And again, we narrowed at the range and we brought it up. So I think things are on track. And like Fred, integration is going great. Our Mexico team and the Salt Lake City team are doing a great job of integrating that stuff.

Fred Lampropoulos^ Well -- and just finally on that, Joe Wright, who is our Chief Commercial Officer, who is sitting in the room with us, I think that's been another really important part is the contact with customers. These are existing customers that buy many of the products in our renal therapy group. So I think it wasn't a reach for us in terms of who the customers were. I think it was 98% of the customers already existed for Merit. So that was another really important factor that we looked at and considered in terms of the commercial outreach.

Operator^ Our next question comes from Steve Lichtman with Oppenheimer & Co.

Steven Lichtman^ Congrats on the quarter, guys. Fred, I wanted to ask about WRAPSODY. Obviously, we still have a little bit of time here, but with the completion of the trial, getting closer and closer into view, can you sort of update us on your thoughts on the market opportunity there, particularly as we get closer to filing here?

Fred Lampropoulos^ Yes. Listen. We started this project, as you know, a number of years ago. It's a product that's vertically integrated. I think that we are going to -- we've closed the enrollment, as you know, -- the last patient will roll out on the -- in February of some time.

And we expect that we will then monitor to the data cleaning and the analysis phase early in the second quarter of 2024, and we plan to complete the clinical study report and we'll be in a position to file with the FDA PMA by the end of the second quarter in 2024. Once we get to that point, then it's up to the FDA to go through their process.

I think we can say that we've always been very excited about the product. But I think, again, without trying to avoid the question, I'd rather wait until we have our update in February to laid out as we get closer to the data to be able to lay out what we're going to do and what our thoughts are as we present our plan for next year.

Raul Parra^ We're really focused on just making sure that the filing goes according to plan. I think from a revenue and market opportunity standpoint, we'll talk about that, I think, post-PMA approval, but super excited about that and super excited about the quarter just in general.

Fred Lampropoulos^ Yes, yes.

Steven Lichtman^ Great. And then just secondly, you talked your bullishness on continued free cash flow and your net leverage ratios remain low here. Just thinking about M&A looking forward, obviously you were quite acquisitive already year-to-date, but given valuations or should we expect a little more additional activity, looking ahead at a Merit?

Fred Lampropoulos^ Well, listen, I think we all understand that the world has changed. The cost of capital is higher. We see that I mean, I don't know what the fed's going to do, but we saw what the economic activity was which was positive today. Values have come down. I think a lot of the other institutions that would be helpful to startups and companies like that I have quite a bit different view than they maybe did a year ago or even two years ago.

Values are starting to come into place, as you'll recall, I think we're very disciplined and in some ways I don't want to say criticized, but we were very cautious.

We didn't want to overpay now. All that being said, we're probably seeing as much activity and opportunities. We've just returned from TCT. There are a lot of opportunities out there. But the really important thing is, we have a plan.

We have requirements that we want to hit. We have a commercial team and things have to fit for us. We don't need to do anything. We can just do our organic. We have WRAPSODY coming. If they're the right products, in the right channels of our product and meet the criteria and there are some that we think they can do that.

So there's a lot of stuff out there and we expect not that necessarily that we're going to be very active and do anything, but that if it meets that and it meets the discipline that we require, we'll look at those opportunities and they will be there. I have no doubt about that.

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

Jayson Bedford^ Congrats on the quarter. Nice result. I apologize if I missed some of this. I got on a little late. Was Russia a headwind to growth in 3Q?

Fred Lampropoulos^ Listen, we were able to get our licenses approved in late August, and we started making some shipments in September. So we had a small benefit, very small. But really, those things are going to roll into this fourth quarter. But the point is, we have our licenses. I think somewhere around 90% or 95% of our Russian licenses have been approved by the United States government.

And so we will see that those will come back online to some extent now with all the things that are going on, Jayson, in Russia, in the Middle East, we built all of these things into our numbers, but there will be some Russia as we go forward.

Raul Parra^ Yes, I think just generally speaking, EMEA was in line with expectations, Jayson. And I think even with Russia coming back, we did have some SKU rationalization products that sold through in the third quarter, which also helped. We won't have those in the fourth quarter, so mix should be a little bit better. But, yes, I think generally we came in kind of in line with expectations.

Jayson Bedford^ Okay, helpful. Just on gross margin did the move from the acquired products moving from upstate New York down to Mexico, did that have an impact on gross margin?

Raul Parra^ No, those won't have an impact until next year, Jayson. As you can imagine, we build bridge inventory just to make sure that things go accordingly. And as Fred mentioned, we are just in the process of moving things. We had the Biopsy device just left last week on a truck, and the rest of the products will continue to move over the next three months over to our Mexican facility. So really it's a 2024 impact that you'll see.

Jayson Bedford^ Okay. And I think you mentioned geography as a bit of a pressure on gross margin. Is that not much, but is that a dynamic of mix? Or is that more a comment on the inflationary dynamics in Mexico?

Raul Parra^ No, it's really mix, product mix. Right. So we had some products, some SKU rationalization related to FFG, specifically our pack business. So you'll see that our CPS products were up. Normally they're flat. That really related to that business that we're exiting just because the gross margins aren't what we want them to be.

Jayson Bedford^ Okay. And we haven't talked about the move from air to water in a while, just kind of, where are you in that? And is that a bit of a tailwind to margin as we look to 2024?

Fred Lampropoulos^ Yes. Listen, Jayson, our team has executed to plan. We still have more to go, but I think it'll be a benefit to us moving forward. And our team has executed well on that.

Raul Parra^ Yes. I mean, I'd say they're on pace for what we forecasted. It's included in our numbers.

Operator^ Our next question comes from Jon Young with Canaccord Genuity.

Zachary Day^ It's Zachary on for Jon today. Thank you for taking my question. Congrats on the quarter. I know you guys talked about the WRAPSODY commercial efforts, and you're waiting on that a bit. But do you have any insight on what reimbursement could look like or the timing of that with the launch? Just the reimbursement stuff in particular. If there's any color. Thank you.

Fred LampropoulosYes, I think the only color is first of all, we'll talk about that whole program as we get closer and we file. It is a breakthrough product. I'll just leave it at that.

But we'll discuss all of this as we get closer to and we actually file the product and then have an expectation of a window because all relying on the FDA. So we'll do a full review of the product and all the things we've seen globally as we get into next year's plan.

Right now, the goal is, let's finish this year. Let's finish this foundations for growth. As you all know, we have been just laser focused on this, and I'm proud about the team, but we're not at the finish line, and we still have a couple of months to go, and so that's where we're focused. We will, though, I think, discuss in depth WRAPSODY at the appropriate time.

Operator^ Our next question comes from Jim Sidoti with Sidoti & Co

Jim Sidoti^ Overall, really strong quarter. The two things that jumped out to me, one was the SG&A expense. It's down year-over-year. It's down quarter-over-quarter. I know you had an insurance payment there, a refund. Was that one of the offsets of SG&A? But even with that, it seemed like it was down pretty significantly. What's driving that? And is it sustainable?

Raul Parra^ Yes, just to clarify on that reimbursement, because we had added that back as a non-GAAP item, we actually added it back. So we actually didn't get credit for that reduction. Jim, just on a non-GAAP basis. On a GAAP basis. You're absolutely correct.

But just to clarify. Look, I think we've been pretty open about making sure that we leverage our operating expenses. We also said that we wouldn't spend ahead of the gross margin not coming in. I think the third quarter for us is always a little tricky because we do see a seasonal decline in the business sequentially from Q2. And so we're always a little bit more cautious in the spend and then just making sure that we understand kind of what the gross margin is going to do.

Just giving because we are deleveraging from a revenue standpoint. So, I think we were a little cautious, and we just continue to exercise that expense management that we've built up over the last few years.

Jim Sidoti^ Okay. And then the other thing that stood out was the cash flow generation and the fact that you put a lot of that towards debt pay down. Can you -- which debt did you pay down and what's the blended rate now for the debt?

Raul Parra^ Yes, look, we continue to pay down our debt from any free cash flow that we generate. That's been the goal. We did talk about having a pretty strong free cash flow for the, back half of the year. Just given what our goal is for foundations for growth at the minimum of $300 million, I can tell you that coming out of the second quarter, given the amount of free cash flow we had generated, my confidence was a little low. And now heading into the third quarter with this huge free cash flow number of [42.5], my confidence is a little bit higher.

But we've still got some work to do here for the next little bit of time, and we'll go ahead and continue to pay down our debt. Our blended rates somewhere around [5.5] on the debt.

Jim Sidoti^ All right. And then last thing for me, the Endoscopy business has been a bit of a headwind the past few quarters. It sounds like this quarter, it was a good quarter. Are you past the supply chain issues for that business, should we...

Fred Lampropoulos^ Yes, Jim, we're on the final part. There's still a small part of it. So we still have a back order. Remember, the issue was we had a vendor that just stopped doing the work that we needed on the coatings. We shifted, which I think was the right thing to do, clearly, to a U.S.

Company, and they're in the final qualification of the final product. So we're coming down the back stretch on that one. And then I think there's a lot of other products in that portfolio, like our balloons and other things that have helped that. So we expect to see that business continue to grow very nicely going forward.

Operator^ (Operator Instructions) Our next question comes from Mike Matson with Needham and Company.

Michael Matson^ Yes, thanks for taking my questions. I did join the call a little late. Apologize if you've already addressed this, but I did want to ask one about China. Just given you saw slower growth in the third quarter, what are you assuming for the fourth quarter?

And then I know you're not giving guidance overall for 2024 yet, but just your general thoughts on the outlook there. Can you get back to decent growth next year in that market, or is there going to continue to be headwinds, do you think?

Raul Parra^ Yes, so I'll start with the last part of the question, but 2024. You're right, Mike. We're not going to talk about that. We'll give you our thoughts when we give our guidance sometime in February. And so I'll kind of take that one off the table.

But as far as China, that came in within the expectations of what we thought. Obviously, we'll still have some sort of impact in the fourth quarter we talked about. So, I'd say generally, China came in at expectations.

Michael Matson^ Okay, got it. And then just with the updates or the extension, I guess, of the foundation for growth targets. I know you're not going to say what that is right now, but just in terms of the framework, in terms of giving guidance around sort of revenue growth, margin targets and cash flow targets, I mean it's that kind of it should look similar to what you gave before, just with sort of newer numbers, essentially.

Fred Lampropoulos^ Well, look. Hi, Mike. I appreciate the question. Here's where we're at. I'm just going to use a football analogy here. We are at a full sprint right now. We've got 15 yards to score a touchdown, and we are just not going to drop the ball. Right? We do not want to drop the ball. And so we're going to punt on that response to the next quarter when we give you our updated guidance for 2024.

But, look, we'll talk about the framework and what we're thinking there. Right now, we're just really focused on finishing FFG. Look, we're just super excited about how the business is done. I think you look at this quarter; we had almost 10% organic constant currency growth. We had strong gross margin expansion.

We leveraged operating expenses. It was just, honestly, a really perfect P&L and with really strong free cash flow. So we're just going to continue to stay focused on the fourth quarter and finish off FFG, and then we're excited to talk about what comes next.

Operator^ Thank you. That concludes the question-and-answer session. At this time, I would like to turn the call back to Mr. Fred Lampropoulos for closing remarks.

Fred Lampropoulos^ Well, listen, it's a busy day. Everybody's very busy. A lot of stuff going on with trade shows and a lot of people reporting. We appreciate you taking the time. Raul and I will be available for the next several hours to talk to you and clarify issues that you have interest in. We appreciate it. Thank you very much. And best wishes from snow in the mountains and colder temperatures in Salt Lake City, Utah. Good evening.

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