Merit Medical Systems (Q2 2025 Earnings)
July 30, 2025

Corporate Speakers:

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

Participants:

- Jason Bednar; Piper Sandler; Analyst
- Jayson Bedford; Raymond James; Analyst
- Robert Marcus; JPMorgan; Analyst
- Steven Lichtman; Oppenheimer; Analyst
- James Sidoti; Sidoti & Company; Analyst
- Unidentified Participant; Unknown; Unknown
- Michael Matson; Needham & Company; Analyst
- David Rescott; Baird; Analyst
- Michael Petusky; Barrington Research; Analyst

PRESENTATION

Operator^ Welcome to the Merit Medical Systems Second Quarter 2025 Earnings Conference Call. (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.

Fred Lampropoulos^ Thank you. Welcome, everyone. I am joined on the call today by Raul Parra, our Chief Financial Officer and Treasurer, and Brian Lloyd, our Chief Legal Officer and Corporate Secretary.

Brian, would you mind taking us through the safe harbor statements, please?

Brian Lloyd^ Thank you, Fred. 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 July 30, 2025, and should not be relied upon as representing our views as of any other date. We specifically disclaim any obligation to update such statements except as required by applicable law. Please refer to the section entitled cautionary statement regarding forward-looking statements in today's press release and presentation for important information regarding such statements. For a discussion of factors that 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. Let me start with a brief agenda of what we will cover during our prepared remarks. I will start with a summary of our second quarter 2025 financial results. I will then discuss two important strategic announcements we made during the second quarter and will provide an update on our reimbursement strategy for the WRAPSODY CIE. Then Raul will provide a more in-depth review of our quarterly financial results and our financial guidance for 2025, which we updated in today's press release.

Then we will open the call for your questions. Beginning with the review of our second quarter results, we reported total revenue of $382.5 million, up 13% year-over-year on a GAAP basis, and up 12.5% year-over-year on a constant currency basis. The constant currency revenue growth we delivered in the second quarter exceeded the high end of the range of growth expectations that we outlined on our quarter one 2025 earnings call. The better-than-expected constant currency revenue results were driven by a 6.7% constant currency organic growth which exceeded the 6% high end of the range we outlined in our second quarter guidance.

With respect to our profitability performance in the second quarter, we delivered financial results that significantly exceeded our expectations. We delivered another quarter of notable year-over-year improvement in our non-GAAP operating margin, which increased nearly 109 basis points year-over-year to a 21.2%, representing the highest non-GAAP operating margin performance in any quarter in the company's history as a public company. We also delivered 10% growth in our non-GAAP EPS which exceeded the high end of our expectations, and we generated $70 million of free cash flow, an increase of 20% year-over-year, This performance was a direct result of the team's continued hard work and commitment to our strategic objectives.

We're very proud of the strong execution our team delivered in the second quarter of 2025. We believe our second quarter results reflect continued strong momentum in the business, and we are confident in our team's ability to deliver the total revenue guidance for 2025 we updated in today's press release. Despite the continued challenges related to the dynamic and uncertain global macro environment, our team is executing well. We remain focused on delivering continued strong execution, solid constant currency growth and strong free cash flow generation in 2025 as well as continued progress and our continued growth initiative program and related financial targets for the 3-year period ending December 31, 2026.

Turning to a discussion on two key announcements we made since our last earnings call. On May 20, 2025, we announced the acquisition of Biolife Delaware, L.L.C. for aggregate transaction consideration paid in cash and an assumption of liabilities of $120 million. This strategic acquisition positions Merit to provide clinicians with more products designed to standardize, simplify and minimize post-procedure care and maintenance. Biolife is headquartered in Sarasota, Florida, manufactures unique patented hemostatic devices under the brand name StatSeal and WoundSeal.

These products are effective, differentiated hemostatic solutions for percutaneous devices with a broad range of clinical applications including vascular closure and indwelling catheter bleeding complications. Sales of Biolife products generated approximately $15 million of revenue over the 12-month period ended December 31, 2024, and we believe these products will have a significant potential growth opportunity as they penetrate an estimated $350 million global addressable market.

Many Merit products operate through small openings in skin that require efficient solutions to stop bleeding, promote patient recovery and minimize costly complications. In such cases, StatSeal specifically works with the patient's blood to rapidly form a protective seal over the procedure site. Adding StatSeal to Merit's hemostatic portfolio is intended to provide healthcare partners with an additional effective solution that complements a wide range of percutaneous procedures including interventional radiology and cardiology, dialysis, electrophysiology, biopsy and drainage.

On July 7, we announced the appointment of Martha Aronson as Merit's new President and Chief Executive Officer effective October 3, 2025. I'm very excited to welcome Martha to Merit and believe that she is uniquely qualified to lead the company into the

future. As discussed on prior calls, the Board executed a thorough search and a selection process as part of our CEO succession strategy. Martha brings extensive expertise and understanding of the industry and more importantly, she was identified as an exceptional fit for the organization, consistent with the Merit way which we believe makes her the ideal leader for Merit's next stage of growth. I will continue to serve as President and CEO and Chairman of the Board through October 3, 2025. Upon Martha's appointment, I will continue to serve as Chairman of the Board.

I would like now to provide an update on our commercial strategy for the WRAPSODY CIE in the United States. As outlined on our investor call in January, our Renal Therapies Group launched the U.S. commercial strategy for WRAPSODY CIE following our PMA approval last December. This strategy is comprehensive and multifaceted including a comprehensive marketing plan focused on raising awareness and expanding upon the existing strong physician relationships and clinical partnerships supporting the current RTG portfolio offering. Engaging with new and existing customers to work through the back approval processes as well as working with the largest GPOs and some of the largest IDNs across the country and hosting physician training events at centers of excellence with physician partners who are passionate about the product and educating their peers on the benefits of the WRAPSODY CIE.

The RTG team has executed the U.S. commercial strategy for WRAPSODY CIE well during 2025. And more importantly, they have exceeded our expectations with respect to leveraging the new access to customers from the early commercialization of WRAPSODY CIE to identify opportunities to drive adoption and utilization of the rest of our dialysis product portfolio.

By way of reminder, our pricing strategy is an important input to our U.S. commercial strategy for WRAPSODY CIE. Specifically, our go-to-market strategy is based on selling the WRAPSODY CIE at a premium price relative to the competitive coverage offered in the U.S. today. We believe the WRAPSODY CIE is a completely new treatment options for patients, as evidenced by our Breakthrough Designation from the FDA.

The WRAPSODY CIE is a novel, differentiated product that improved dialysis maintenance procedure outcomes as demonstrated in the compelling body of clinical evidence evaluating safety and efficacy to date, and we offer unique size offerings with our 14 and 16-millimeter diameter devices that represent potential treatment options for clinicians previously not available in the marketplace. The data suggests that the WRAPSODY CIE requires fewer reinterventions to maintain patency at the lesion site and more importantly, that the access circuit remains functional, which is key for any dialysis patient.

We believe the WRAPSODY CIE offers a compelling opportunity to not only improve patient outcomes but also to reduce the cost of treating this patient population. These factors, together with demonstrated clinical outcomes and the fact that the WRAPSODY CIE is the only device that has been designed specifically for dialysis access maintenance supports our belief that the WRAPSODY CIE is a premium product in the market.

Our U.S. commercial and pricing strategy was designed to maximize the compelling long-term opportunity for the WRAPSODY CIE in the U.S. market. Importantly, these strategies were aligned with our efforts to secure reimbursement coverage and payment as well. As discussed on prior calls, our reimbursement strategy is focused on securing add-on payment for procedures completed in both inpatient and outpatient sites of care. For the inpatient setting, our efforts to secure add-on payment remain on track.

On April 11, CMS released proposed fiscal year '26 payment rates for the hospital inpatient prospective payment system, which included CMS proposal to approve the WRAPSODY CIE for new technology add-on payment, or NTAP, for the fiscal year 2026. CMS proposed that the maximum new technology add-on payment for a case involved in the use of the Merit WRAPSODY CIE would be $3,770 for fiscal year 2026 and which, if finalized as proposed, which support our anticipated cost to the hospital, inclusive of all components and accessories of $5,800. We understand that the effective date for this NTAP add-on payment is anticipated to be October 1, 2025, for CMS 2026 inpatient fiscal year.

With respect to our progress towards securing add-on payment for procedures in the outpatient setting, candidly, a fulsome update requires additional discussion and clarification. First, and for the avoidance of doubt, our strategy for securing reimbursement for WRAPSODY CIE procedures outside the hospital inpatient setting has not changed. However we would like to clarify the terminology we have used in the past to describe our strategy for this portion of the market. Our strategy has been focused on the hospital outpatient or HOPD setting instead of the office-based lab or OBL setting as we have previously referenced.

The outpatient setting represents a significant portion of the initial addressable market opportunity in the U.S. for the WRAPSODY CIE. According to Clarivate's dialysis access treatment devices, Market Insights U.S. report published in September 2024, there were 95,000 stent units implanted for dialysis access maintenance in 2023, approximately 79% were implanted in nonhospital sites of care, the majority of which were in the outpatient setting.

We would also like to clarify a point concerning our application for reimbursement for WRAPSODY CIE in the U.S. HOPD setting. In late February, we submitted an application for new technology, ambulatory payment classification, or APC assignment under the hospital outpatient prospective payment system, or OPPS. This was the first time Merit pursued reimbursement for a PMA product, and we engaged external advisers to assist in that process. Our external advisers filed an application to secure an APC assignment and confirmed filing prior to the deadline.

Unfortunately, our team believe that the application filed was for the transitional pass-through or TPT add-on payment. Our internal discussion and references to this portion of our U.S. strategy as well as our public commentary reflected this misunderstanding. WRAPSODY CIE was not awarded a new technology APC assignment as part of the

calendar year 2026 OPPS and Ambulatory Surgical Center proposed rule published on July 15, 2025.

We are executing on a strategy to respond to CMS' determination on the WRAPSODY CIE APC assignment. We have engaged with CMS in recent weeks to understand why we were not awarded a new APC assignment for 2026. While the review of our application has been completed by CMS, we are utilizing the 60-day comment period to provide further supporting evidence which CMS will review. The deadline for submission of additional information is September 15.

We believe we will hear CMS' final decision on this application as part of the calendar year 2026 OPPS and Ambulatory Surgical Center Final Rule, which is expected to be published in November. We appreciate the discussions with CMS in recent weeks, and we believe we have a solid plan for utilizing the comment period to enhance our case that WRAPSODY CIE meets the requirements for an APC assignment.

Separately, we are preparing our application for TPT add-on payment under Medicare's OPPS system. We are targeting submission of our allocation by September 1, 2025 deadline and anticipate receiving a decision with respect to the award of TPT add-on payment for procedures in the outpatient setting in December 2025.

With all of that said, I want to reiterate that our reimbursement strategy for the outpatient setting has not changed. However Raul and I are disappointed. Our intention with respect to all of our U.S. WRAPSODY messaging was to be transparent with the investment community regarding the key milestones related to our reimbursement strategy following PMA approval. We did not communicate the strategy effectively. We are correcting our mistake this afternoon, and we are focused on executing the strategy for the significant portion of the U.S. market. Clearly, we all have a better understanding of the process and terminology from this experience.

Importantly, we recognize that this represents a 2-quarter delay in expected timing for securing add-on reimbursement in the outpatient setting. We have not changed our expectations for the long-term addressable market in the U.S. for WRAPSODY CIE growth or the potential contributions to our long-term growth profile as we commercialize this technology in years to come.

With that said, let me turn the time over to Raul now for an in-depth review of our quarterly financial results and our updated financial guidance for 2025. Raul?

Raul Parra^ Thank you, Fred. I will start with a detailed review of our revenue results in the second 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 both a year-over-year and constant currency basis.

Second quarter total revenue growth was driven by 10% growth in our Cardiovascular segment and 81% growth in our Endoscopy segment. Cardiovascular segment sales

exceeded the high end of the expectations we outlined on our first quarter call and Endoscopy sales came in at the high end of our expectations.

Our total revenue results included approximately $19.6 million of revenue from our acquisitions of the lead management product portfolio from Cook Medical, the assets of EndoGastric solutions. and to a lesser extent, the acquisition of Biolife following the May 20 close. Excluding sales of acquired products, segment revenue growth on an organic constant currency basis was 6.8% for our Cardiovascular segment and 1% for our Endoscopy segment.

Turning to a review of our second quarter revenue results by product category. Cardiac intervention product sales increased 23% and represented the largest driver of Cardiovascular segment growth in the period. Excluding the contributions from the sale of acquired products, cardiac intervention product sales increased approximately 10% on an organic constant currency basis, well above the high end of organic growth expectations we assumed for Q2.

Rounding out the Q2 performance across the rest of our Cardio segment, sales of our peripheral intervention products and our Custom Procedure Solutions products increased 6%, which was in line and above the high end of our expectations, respectively. Sales of our OEM products increased 4% in Q2, modestly lower than our expectations. The softer-than-expected OEM performance in Q2 was entirely related to sales to OEM customers outside the U.S. which continues to see demand trends impacted by the macro environment. Sales to OEM U.S. customers increased in the high teens year-over-year in Q2.

Turning to a brief summary of our sales performance on a geographic basis. On the second -- our second quarter sales in the U.S. increased 17% on a constant currency basis and 10% on an organic constant currency basis, exceeding the high end of our organic growth expectations by 230 basis points. We were pleased to see continued strong demand from our U.S. customers in the second quarter. International sales increased 7% year-over-year and increased 2% on an organic constant currency basis. Sales results in APAC exceeded our expectations. EMEA was in line and sales result in the Rest of the World region were slightly below the expectations supported in our Q2 guidance range.

With respect to China specifically, sales decreased 6% compared to a low single-digit growth rate assumed in our guidance. We attribute the softness to the broader macro environment as the VBP impact was essentially in line with expectations in Q2.

Turning to 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 second quarter of 2025, 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 items in our press release and presentation available on our website. Gross profit increased approximately 17% in the second quarter. Our gross margin was 53.2%, up 167 basis points. Approximately half of the increase in gross

margin was driven by lower tariff impact versus what our guidance contemplated with the balance coming from favorable product, geographic revenue mix and improvements in pricing.

Operating expenses increased 15%. The increase in operating expenses was driven by a 13% increase in SG&A expense and a 24% increase in R&D expense compared to the prior year period. Total operating income in the second quarter increased $13.1 million or 19% to $80.9 million. Our operating margin was 21.2% compared to 20.1% in the prior year period, an increase of 109 basis points year-over-year.

Second quarter other expense net was $2.3 million compared to income of $1.4 million last year. The change in other expense net was driven by lower interest income associated with lower cash balances, offset partially by lower interest expense compared to the prior year period. Second quarter net income was $61 million or $1.01 per share compared to $53.8 million or $0.92 per share in the prior year period.

We are pleased with our profitability performance in the second quarter, where we leveraged stronger-than-expected revenue results to drive significant inspection in operating margin and strong growth in non-GAAP diluted earnings per share, both of which exceeded the high end of our expectations. Note, our second quarter non-GAAP EPS results included incremental dilution related to our convertible debt that represented approximately $0.01 to Q2 EPS.

Turning to a review of our balance sheet and financial condition. We generated $70 million of free cash flow in the second quarter of 2025, up 20% year-over-year. As of June 30, 2025, Merit had cash and cash equivalents of $341.8 million, total debt obligations of $747.5 million, an outstanding letter of credit guarantees of $2.9 million, with additional available borrowing capacity of approximately $697 million. compared to cash and cash equivalents of $376.7 million, total debt obligations of $747.5 million and outstanding letter of credit guarantees of $2.9 million. with additional available borrowing capacity of approximately $697 million as of December 31, 2024. Our net leverage ratio as of June 30 was 1.7x on an adjusted basis.

Turning to a review of our fiscal year 2025 financial guidance, which we updated in today's press release. For reference, we have included a table in our earnings press release, which details each of our formal financial guidance ranges and how those ranges compare to our updated guidance ranges issued as part of our press release on May 20, 2025. Our updated 2025 guidance assumes the following: GAAP net revenue growth of 10% to 11% year-over-year, which we expect to result from net revenue growth of approximately 9% to 10% in our Cardiovascular segment and net revenue growth of approximately 32% to 34% in our Endoscopy segment and a tailwind from changes in foreign currency exchange rates of approximately $6.2 million or approximately 46 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 a range of 9.7% to 10.6% in 2025.

Among other factors to consider when evaluating our projected constant currency revenue growth range for 2025 are the following items.

First, the midpoint of our total constant currency growth rate now assumes 12% growth in the U.S. and 8% growth outside the U.S. The 8% constant currency growth we expect outside the U.S. continues to assume low double-digit growth in EMEA, mid-teens growth in Rest of the World region and approximately 2% growth in the APAC region.

Second, our total net revenue guidance for fiscal year 2025 also assumes inorganic revenue contributions from the business and assets acquired from EndoGastric Solutions, Cook Medical and Biolife on July 1, 2024, November 1, 2024 and May 20, 2025, respectively, in the range of $56 million to $58 million in the aggregate. Excluding this inorganic revenue, our guidance reflects total net revenue growth on a constant currency organic basis in the range of approximately 5.6% to 6.4% year-over-year.

Third, for the full year 2025 period, we now forecast U.S. revenue from the sales of WRAPSODY CIE in the range of $2 million to $4 million. This updated range reflects the impact of our revised timing for securing add-on reimbursement in the outpatient setting.

Our prior guidance range assumed the third and fourth quarters of 2025 would see strong customer adoption and utilization trends as a result of incremental add-on reimbursement and improving procedure economics. For CMS guidelines, applications for TPT add-on reimbursement submitted by the next deadline of September 1, 2025, if awarded, will be eligible for use beginning January 1, 2026.

With respect to profitability guidance for 2025, we now expect non-GAAP diluted earnings per share in the range of $3.52 to $3.72 compared to our prior guidance range of $3.28 to $3.41. The change in our non-GAAP EPS expectations for 2025 reflects the flow-through of the better-than-expected financial performance over the first half of 2025 at both the low and high ends of the non-GAAP EPS range, specifically $0.35 and $0.21, respectively. The low and high ends of the updated non-GAAP EPS range also reflect the impact of higher interest expense and a higher non-GAAP tax rate assumption, representing the offsets the aforementioned first half '25 EPS flow-through of $0.04 and $0.07, respectively. The high end of non-GAAP EPS range also includes our updated projected impact of tariffs, trade policies and related actions recently implemented by the U.S. and other countries. Specifically, the high end of our updated guidance range assumes tariff-related manufacturing cost in our total cost of goods line of approximately $7 million compared to $26.3 million previously.

Importantly, the $7 million figure is based on available information as of July 30, 2025, and does not include any impact from new and/or additional tariffs or retaliatory actions or changes to currently announced tariffs which could change the anticipated impact to our non-GAAP EPS in 2025.

The ultimate impact from new and/or additional tariffs or retaliatory actions or changes to currently announced tariffs on our business will depend on the timing, amount, scope and nature of such tariffs, among other factors, most of which are currently unknown. The tariff situation and potential retaliatory measures by other countries remain highly uncertain and dynamic. As such, the low end of our EPS range continues to reflect a tariff-related impact on our 2025 cost of goods of $26.3 million.

Returning to a discussion of our updated 2025 financial guidance assumptions, for modeling purposes, our fiscal year 2025 financial guidance now assumes non-GAAP operating margins in the range of approximately 19% to 20% and compared to 17.6% to 18% previously. Note, the change in our 2025 non-GAAP operating margin expectations is primarily attributed to lower expected impact from tariffs and, to a lesser extent, the flow-through of stronger-than-expected financial performance in the first half of 2025.

Non-GAAP interest and other expense net of approximately $8 million compared to $4.8 million previously. Non-GAAP tax rate of approximately 22.5% compared to 21% previously and diluted shares outstanding of approximately 61 million. Note, our weighted average share count assumption continues to reflect incremental dilution of approximately 0.9 million shares related to our convertible debt facility. We continue to estimate incremental share dilution related to our convertible debt facility represents an impact of approximately $0.05 and to our non-GAAP EPS in 2025.

Finally, we continue to expect to generate free cash flow of at least $150 million in 2025, inclusive of the expectation that we invest approximately $90 million to $100 million in capital expenditures this year. We would also like to provide additional transparency related to our growth and profitability expectations for the third quarter of 2025. Specifically, we expect our total revenue increase in the range of approximately 8.6% to 10.5% on a GAAP basis and up approximately 8% to 9.8% on a constant currency basis. The midpoint of our third quarter constant currency sales growth expectations assumes approximately 7% growth in the U.S. and 11% growth in international markets.

Note our third quarter constant currency sales growth expectations include inorganic revenue in the range of $13.3 million to $14.3 million. Excluding inorganic contributions, our third quarter total revenue is expected to increase in the range of approximately 4% to 5.6% on an organic constant currency basis.

With respect to our profitability expectations, for the third quarter of 2025, we expect non-GAAP operating margin in the range of approximately 16.9% to 18.5% compared to 19.2% last year, and non-GAAP EPS in the range of $0.76 to $0.85 compared to $0.86 last year.

That wraps up our prepared remarks, Operator. We would now like to open up the line for questions.

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) The first question that I have for today will be coming from the line of Jason Bednar of Piper Sandler.

Jason Bednar^ Congrats on another nice quarter with the P&L here. I'll kick things off on WRAPSODY and I'll just preface this by saying it's sorry for any confusion. It's a busy afternoon here and bouncing between a few calls. But I'm not receiving TPT maybe just lay it out, was there -- I guess was there a problem with the actual filing or -- and sorry, just trying to read through the script and I was not necessarily clear to me. Did you receive feedback from CMS? Maybe talk about your engagement with CMS since? I think a lot of investors are trying to handicap the likelihood of receiving TPT under the new December timeline. So maybe you can clarify and just what gives you confidence in this new timeline?

Fred Lampropoulos^ Yes. Jason, this is Fred. Let me walk through the WRAPSODY fact-based story, so that you can hear this all in sequence. Again we provided an update on U.S. reimbursement in an outpatient setting. We applied for new technology APC assignment by the 3/1 deadline. CMS did not award a new APC assignment as part of the proposed rule on 715. Now that the application for the new APC assignment is completed, we intend to submit an application for transitional pass-through or TPT. The deadline for that submission is 9/1 and if awarded, it will become effective January one of 2026. Revised 2025 revenue expectations for U.S.

WRAPSODY due to the 6-month delay for potential contributions related to TPT add-on and we have not changed any of our expectations for the long-term addressable market in the U.S. to the WRAPSODY CIE or the potential contributions to our long-term growth profile of the company.

We corrected our prior commentary on the application for reimbursement in the outpatient setting. And for the avoidance of doubt, our prior commentary regarding our submission for TPT add-on by the March one deadline was not correct.

We are targeting submission for TPT add-on by September one and which is the deadline.

So I hope that, that brings it and that we -- I hope that answers your question. That's a lot of information.

Jason Bednar^ Yes. I know it's always -- I always find it complex dealing with reimbursement and some of the different rules and deadlines here. But maybe, Fred, can you -- to follow up, can you maybe give investors the confidence or maybe describe what gives you the confidence on hitting that new deadline or securing -- not necessarily hitting the deadline, but securing TPT under the new deadline that you have set or the expectations you've set here.

Then I'm sure you don't want to go there on unpacking all the different possible paths. But maybe you can talk about the commitment you have to securing TPT against maybe

a more aggressive commercial launch without TPT. If in the scenario that you don't receive in December. I guess I'm just curious how many times you want to go down this road in going after it. I would think a lot because it's economically attractive, but there's some puts and takes here. So maybe if you can have that discussion as well it would be helpful.

Fred Lampropoulos^ Go ahead, Raul.

Raul Parra^ Yes. Just to clarify, Jason, I think essentially, what we're saying is we were under the assumption that we had filed for TPT, right, but it had not. So it's not like we're refiling. We went for APC. It was clear that, that was filed timely, didn't get the outcome that we wanted, just to be clear. We're engaging with CMS and having those discussions and making sure that we're clear. But we are confident that we'll meet the deadline for TPT.

I would say that nothing has changed. We continue to like our expectations for meeting all the TPT guidelines. We think we meet them. Obviously clearly, we have to submit, and then it's the waiting game. And -- but I think we all around here are encouraged just by the fact that we have the best data. We've got a great product and we know we'll do what we thought we were going to do and submit the application by its deadline.

Fred Lampropoulos^ So Jason, this was the first time that Merit pursued reimbursement for a PMA product, and I think you said that it's complicated. We engaged external advisers to assist. Our external advisers filed an application on the APC assignment and confirmed filing. So unfortunately, our team believed that the application filed for TPT add-on payment was the APC. That's how we understood it, and we own it. Our internal discussion reference to our strategy as well as our public comments reflected this -- the misunderstanding.

We expected to receive a response on the application on the proposed rule for 2026 issued on the 15th of July. And as we pointed out, CMS did not award an APC assignment as part of the proposed rule. And now that, that application is complete, we intend to submit an application for the TPT, as I mentioned and Raul mentioned on 9/1 which is essentially 30 days from now.

Jason Bednar^ Yes. Okay. I'll let others hop in here. But just to maybe to put a bow on it, you've high confidence on securing TPT later this year.

Fred Lampropoulos^ We believe in our product, we believe, in the data. We believe that it is the product we think it is, and we believe all of those things, and we have high confidence in that product. Yes. This process even though we made a mistake. I think we've said that. We own it. Nobody else owns it. We own it. It's going to delay. But that's, I believe, the only thing it's going to delay.

Raul Parra^ I think just bottom line, nothing from a long-term perspective has changed from our standpoint strategically for this product. So the unfortunate part is, obviously we

thought we had filed the TPT. We got the wording wrong. Obviously we filed for APC. Now we know where we stand on that, and we move on to the net step, which is TPT, have a high level of confidence in the product, Jason.

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

Jayson Bedford^ Can you hear me, Fred?

Fred Lampropoulos^ We've got you, Jason.

Jayson Bedford^ Yes. I wasn't sure who got picked here. So geez, I really want to use a three-letter acronym here, but I'm not going to use it.

Fred Lampropoulos^ Please don't.

Jayson Bedford^ Yes. So I think I understand the difference between APC and TPT, I think a lot has to do with the newness of the technology. But I'd love for you to describe maybe why you're optimistic that you may be able to secure a TPT if you got rejected for an APC, right? So I guess my point is, why would they not apply the same logic.

Fred Lampropoulos^ Okay. I'm going to take it Raul take it up.

Raul Parra^ So this is all new to us, right, and we're now get to be expert in it. But APC is essentially around the procedure, Jason. Correct. right? And that's kind of the distinction where TPC is cost based around the product.

Fred Lampropoulos^ Does that help, Jason?

Jayson Bedford^ It does. I assume APC kind of lumpy in with everyone else, whereas TPT acknowledges the difference. Is that fair?

Fred Lampropoulos^ Again I think what Raul said, it's procedure-based, and that was -- they couldn't see the difference. We believe our procedure was different. The CMS believes that there are other situations like that, that are covered, which is why we didn't receive it. TPT acknowledges the differences in the performance of the device, but it's cost based. Does that help?

Raul Parra^ Yes. One of the things that we -- we do get a comment period, right, even though the APC assignment is complete, we do get to comment, and we can provide additional information as to why we think it's a different procedure. But at the same time we also know what that outcome is, which means that we can take the other road and file for TPTs.

Jayson Bedford^ Okay. Maybe just two other quickies. Down 6% in China, not necessarily related to VBP. Is there a specific category? Is it competition? Or would you chalk it up to just general demand?

Raul Parra^ No. I mean I think it's just the current environment, the macro environment, Jason. But I think other than that, there's not much else to see. We continue to expect low single-digit growth in APAC for 2025. I don't think that's changed for us. So I'd say it's kind of as expected, quite frankly. That takes and puts, but ultimately, we're kind of where we thought we'd be.

Fred Lampropoulos^ Puts and takes of the whole up and down thing.

Operator^ And the next question will be coming from the line of Robbie Marcus of JPMorgan.

Robert Marcus^ Great. Congrats on a good quarter. Maybe I could start on margins. Obviously a really strong margin upside, both on gross and operating margin. Some of it came from less negative tariff impact, but part of it was also underlying. Maybe you could tease out what's what in gross and operating margin and then walk us through the balance of the year on both?

Raul Parra^ Yes. Look, I mean I think obviously super proud of the team of how we're performing. I think there's two things that I'd like to highlight. One is, obviously our sales force continues to execute at a very high level with another strong quarter. That obviously helped from a leverage standpoint on operating expenses and all the gross margin. Gross margin, it's a lot of everything. I think ops lessons helped us. Pricing helped us. Our mix has helped us. Again our sales force delivering really good kind of mix and geography mix.

Fred Lampropoulos^ Yes. And Rob, I was just going to say I think it has to do with foundations for growth, and it has to do with continued growth initiatives. Those things have not left us. They're still what we use as alignment for compensation and how we measure ourselves and very candidly, how our Board measures us. So those are -- that's part of the too and that momentum. I also think the more attention made on pricing and positioning the product and so on and so forth.

Raul Parra^ Really, the only kind of sour spot I would call is the tariffs, which were kind of outside of our control that we had to deal with. So we ended up with about half of what we anticipated in the P&L, but we're able to overcome it with strong sales and obviously the discipline that we showed on pricing and mix.

Robert Marcus^ And how should we think about the cadence, particularly on gross margin in third quarter, fourth quarter, any upgrade there, what's less negative tariffs and what's underlying?

Raul Parra^ I was hoping you're going to forget about that question, Robbie, because we typically don't guide on gross -- actually, we don't guide on gross margin. But I think if you look at the expectations for our operating margin, clearly, we took that up. We're in the 19% to 20% range for the year. Clearly, we expect some margin to be -- gross margin be contributor.

So I'll just leave it at that, that we continue to feel really comfortable with our guidance for operating margin. I think we're -- as we look to finish up the second year, I think it sets us up really well for CGI and what we want to do for there. I mean I think if we hit the high end of our guidance, we're already looking at the bottom end of CGI, which I think is a really good spot to be in.

Robert Marcus^ You can't blame me for trying, given all the moving parts.

Raul Parra^ No. I appreciate it. Yes. Yes.

Operator^ And the next question will be coming from the line of Steve Lichtman of Oppenheimer.

Steven Lichtman^ I wanted to start first with the sales beat in the quarter, particularly around cardiac intervention, which saw a nice uplift even ex the acquired products. Can you talk a little bit more about what the drivers of that were? And what kind of sustainability of that growth we could see?

Fred Lampropoulos^ Yes. Let me pick that one up. We generally don't mention names of products, so I won't do that. But I think a lot of this comes out of Merit's products that we have developed internally. I think a lot of it has to do with presence in the lab. And I think the Cook acquisition and the presence in the cardiac area is important. To be candid, we expect that to continue with the other products and other things that Merit develops internally. So we think it's going to continue to be one of the strong areas in the company that we focused on and it's a lot of things that other people overlook, and we just don't, and we'll focus.

Raul Parra^ Add a little more color, right? I think Fred mentioned the Cook acquisition, which obviously isn't organic yet. But if you remember, one of the reasons we did that acquisition, the strategy behind that was to get deeper into our cardiac bag and specifically those products. You see the sales force focused on them. They're excited about that. And so you're seeing a little bit of uptick there too.

Fred Lampropoulos^ There's some pull-through too with the access products that Merit makes you've got to get in there. That's kind of our strong suit. So that's another part of it as well.

Steven Lichtman^ Great. Just shifting to margin. Obviously you're benefiting here by being -- from your conservatism on the first quarter call relative to tariffs. Raul, you talked at that time about some work you'd look to do to offset tariffs. How much of that

work can still flow through and maybe drive excess margin now even at the lower -- hopefully, lower tariff impact?

Raul Parra^ Well I mean I think we're trying to be nimble on some of those things that we're doing, right? I mean a lot of it was things that we could do easily, right? Redirect shipments, product line transfers that were already on the books. Can we pull those forward? Those are all things that are being worked on. I think the hard part, quite frankly, is that it's a fast-moving target that changes almost on a daily basis, right? I think we had two changes just this week. One was confirmed and one was just a rumor out there that--

Fred Lampropoulos^ And the President can change his mind, they're going to see what he thinks.

Raul Parra^ So look, I think the nice thing, quite frankly, is just being as transparent as possible on these tariffs. I think our guidance covers a lot, right? I mean I think when you look at the high end, we've got roughly $7 million of impact there. When you look at the low end, we essentially left that a real amount of $26 million that we originally called out in the guidance.

So I think we have a good number within the range of our guidance to cover all sorts of changes that may come our way but it is a moving target. So I would just say that we're comfortable where we're at. I think our operations group is doing everything they can to try and mitigate the expense but we're also making sure that they stay focused on what really matters, and that's their CGI targets which is things that they can control.

Fred Lampropoulos^ And getting products to our customers.

Raul Parra^ Products to our customers.

Fred Lampropoulos^ That's the key to all of this, no matter what.

Raul Parra^ Yes. Yes, yes.

Steven Lichtman^ Got it. Then just my one last question and on WRAPSODY is what's happening or going to be happening on the ground here as sort of reimbursement work is being done. Obviously you have an approved product, you have great data, what's going on in terms of education, training so that when you hopefully get that reimbursement sorted out, kind of hit the ground running?

Fred Lampropoulos^ Well listen, I think our updated range assumes that we maintain a premium price. We believe it's a premium product. That has not changed. We do not expect to see a ramp in adoption utilization in the outpatient setting in the second half, but we do expect to gain market share in the hospital setting where we have approval and where we have NTAP. So anyway we have plenty to do. It gives us more time to train, more time to get ready for other expanding markets from a regulatory point of view. So

this was a punch we took, but it didn't hurt very much. I mean it hurts. Don't get me wrong, but--

Raul Parra^ Or either watering, but we're--

Fred Lampropoulos^ But we're still in the fight. We're still swinging.

Operator^ And the next question is coming from the line of Jim Sidoti of Sidoti & Company.

James Sidoti^ Talk a little bit about Biolife and the distribution for StatSeal. Did they have international sales? And is that something you can put through your reps?

Fred Lampropoulos^ Yes. Part of the attractiveness of this whole deal was they had four distributors in the United States. I can tell you that we've converted all of those and negotiated through all of those and all of our sales are now coming in direct. So we get orders and we deliver those directly to customers.

On the international side, they're approved, but they didn't have any footprint. We do. So that's always been the attractiveness for us is the growth potential of the product with Merit. This goes back to the cardiac and you'll see that fall into line in that part that we were talking about earlier. So it's something, again I've been watching for 10 years. It's something that our physicians have encouraged us to look at because they use it, you need to have this. And finally, the right time came up and the way we go. We feel very good about the product but maybe more importantly than us sitting in the room is the sales force. They are the guys that are out there that are fired up about it. And that's what we always want. It's that enthusiasm that drives the revenue.

James Sidoti^ Right. With regards to cash flow, another good quarter for cash flow. Are you thinking -- you're at a point where you'll start to pay down some of the debt going forward? Or do you think you're going to keep the cash in the bank for additional deals?

Raul Parra^ Yes. No. I mean I'll take this question and use it to highlight our free cash flow again which was $90 million year-to-date, $70 million in the quarter, which is just fantastic. For now Jim, we'll continue to hoard the cash, I'll say. We do have some capital expenditures that are coming in the back half of the year as we get started on this building. I say started, but we've already got walls up, and it's going to be coming at us here pretty quickly. And so -- but for now--

Fred Lampropoulos^ They are all in our forecast, in our guidance, they're in everything. So --

Raul Parra^ So we're feeling pretty good about it and continue to deliver strong free cash flow. Again I'll highlight our operations group, I think is doing a pretty good job of balancing the inventory, which is the primary driver of our working capital, allowing us to have these strong free cash flow number.

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

Unidentified Participant^ It's calling in from Larry Biegelsen. My first is just around your guidance update. So you beat Q2 revenue by about $10 million at the midpoint of your guidance raise on a constant currency basis, the increase is less than $10 million. Is that all due to WRAPSODY being moved out six months? Or is there anything else that changes about your second half outlook? And I have another question after that.

Raul Parra^ Sure, sure. I mean there's takes and puts across the board. But I think generally, our practice is to kind of look at the first half beat and obviously flow some of that through. I think we ended up in a really good spot. Like you said, the midpoint of our updated guidance is about $10 million. I think we all felt pretty good about where we got. There's a lot of uncertainty out there. I think the business continues to execute at a really high level. But just with all the tariffs and all the noise, there's a lot of things out there that just kind of give you a little bit of pause as well as the business is doing.

So I'd say we feel pretty good about the guidance. And I think we have a high level of confidence in it. I'll just say that.

Unidentified Participant^ Okay. That's helpful. Then second question is around tariffs. I think in the past, you said you can offset up to 45% of annualized tariff for -- in 2026. Is that still true? Any commentary on how we should think about tariffs for next year?

Raul Parra^ Yes. I mean I would say that, that was true based on that initial assessment of what happened then, right? I think we'll -- we feel pretty confident that we can overcome some of them. I just have to see, quite frankly, where we end up at the end of the year, what's real, what's the news headline but I think we have a good game plan. I would say nothing has changed from that last update that we gave other than things have gotten a little bit better, and we've gotten some clarity, but it's still kind of a lot of moving parts. So I'll just say that I think our guidance kind of contemplates everything that's out there right now right, on the high end and the low end. So we feel pretty confident. And also, I'll just -- one additional item is we have not changed our CGI targets, right? We're still committed to those, which I think is really important

Operator^ And the next question will be coming from the line of Mike Matson of Needham & Company.

Michael Matson^ Yes. I guess I'll ask one more on WRAPSODY. Hopefully, this wasn't addressed earlier, but just you did say something about OBLs in the prepared remarks. And just curious, are you -- do you have any plan to pursue any additional reimbursement in the OBL setting? And how important is that? I mean how many of these procedures have you done in that setting?

Raul Parra^ The focus is on outpatient, right? It's the largest area of the market. So I think that's the biggest percentage and that's where the focus is right now Mike.

Michael Matson^ Okay. Got it. Then just one more on the Biolife acquisition. So given the nature of the products, are those going to be sold by -- in both the peripheral and the cardiac business? Because I can imagine it could be used in both types of procedures potentially.

Fred Lampropoulos^ Yes. The answer is yes. It's used on radio procedures. It's used for PIC lines, ports, any place where you're bleeding and where -- they're using those as we speak.

Raul Parra^ Yes. It's one of the exciting parts about that business when we acquired it is that it's one of the few products that we've acquired that really fit in just about every bag that we have.

Michael Matson^ Okay. Then just -- I think you referred to having some prior sort of -- some sort of prior hemostatic product that you guys were selling. So what were those? And how do those come out fit with Biolife, Biolife products?

Fred Lampropoulos^ Well yes, some of these are things that actually work together. So if you take a look at this patch and stop the bleeding, they'll oftentimes put use a sync and use this, in fact. Yes, radio compression device. So they'll use that and this to get faster hemostasis so that you can get to an ambulatory state and get them out of the hospital.

So [there] are often used. In fact, as I mentioned earlier, Mike, this was something that physicians encouraged us to look at because they used it and say it would be nice just to buy this from one company and some of that has a full suite of products. That was something that we said years ago, and we just kept falling along until they finally aligned.

Operator^ And the next question will be coming from the line of David Rescott of Baird.

David Rescott^ Can you guys hear me?

Fred Lampropoulos^ Yes. We got you, David.

David Rescott^ Great. I wanted to ask on the guide for the year, particularly on the lower end of this EPS guide since in general, it's probably a good gauge of apples-to-apples from earlier the year, since you have the $26.3 million in there from the tariff perspective. I guess one, why I guess keep that headwind at the low end if we're halfway through the year already, and we know that China tariffs are maybe less than they were a couple of months ago. So is there anything else in the other updated tariffs that are kind of getting you back to that $26.3 million.

Then second part to this, I think you beat by $0.15 or so. The lower end went up by $0.24, or so, I think. So there's about a $0.10 delta of the underlying business versus

Biolife I think the convert impact is the same. So can you just help us bridge the gap on what was better in the quarter versus second half?

Raul Parra^ Yes. I'll walk you through. So right. So Q1, we had about a $0.14 beat. So we flowed that through Q2, and this is obviously -- I'm just talking strictly low end, so I don't want to confuse anybody. On the low end, we flowed through the $0.21 for Q2. And as you pointed out, we didn't make any changes to our tariff amount. Then you had an offset there for interest expense, that increase. So that's going to be $0.04, and that's due to the -- obviously to the acquisition that we just did. Then as you know there was some tax changes that were just signed into law. So that will be a $0.07 impact also. So you end up with the $0.24 that you just talked about.

But this is -- I'm glad you said what you said, David, because this is exactly why we left the low end the way we did because you just implied right, that the China would be better. that's just a rumor, right? That's what -- that was a headline that came out a few days ago. There was two conflicting stories on it. We actually don't know if that's going to happen. I think the President said that it might.

So I think from our standpoint, still a lot of complexity to this and a lot of moving parts to it. I think we just felt like the low end just reflects a high level of confidence in our 2025 outlook, if there's significant changes to the tariffs, right? And so I think we felt comfortable just leaving it as is.

Fred Lampropoulos^ And this is a point of interest. In FT, there's a big article today about the issue of the Chinese Navy and that the increased tensions in South China Sea. Is that going to affect what's going on with tariffs and that dialogue and the answer is absolutely. So again who knows how that shakes out. So I think we're taking the right approach. I agree with you, Raul. I mean that's what we've talked about for a long time and several times in the last several days. Yes.

David Rescott^ Okay. Then I might have missed it in the earlier Q&A. I know you set out earlier this year with the 7% to 9% for the contribution from WRAPSODY. I believe at the time that didn't necessarily contemplate any reimbursement kind of uplift, whether it's TPT or NTAP. Have you reiterated that contribution for the full year? Then how are or how is kind of the sale force in your view responding maybe a little bit to this delay in the reimbursement uplift? Does anything change on the commercial front over the next couple of months until you are able to secure that if you are?

Raul Parra^ Well I mean no. So right. So we updated our range to $2 million to $4 million, David. I'm not sure if you caught that but -- and just for the sake of clarity, our guidance originally included all sorts of scenarios and assumptions around the adoption and utilization of these add-on reimbursement processes.

So clearly, for us now we've got clarity on one. We still think that we're obviously going to use the comment period to add additional color to CMS and then we're also going to follow up for the additional add-on on the TPT.

Fred Lampropoulos^ David, as you know we're just delayed six months and on that one product. But let's talk about -- you asked about the sales force, that RTG group is doing extraordinarily well. They have numerous products. We're seeing strength in all of those products across the board. So yes, I'm sure that you'd like to have everything in the bag, but they're doing very well and have plenty to sell and all of those are doing well. So I've talked to several of the sales force about their enthusiasm, about their targets and this that and the other. They're all aligned, and they're all -- I mean I'll use the word, they're on fire. These sales guys are fired up. because they have products that are distinct.

Raul Parra^ I mean we were going to hold our premium pricing.

Fred Lampropoulos^ Yes.

Raul Parra^ I know our competitors are not. I think they're listening, but --

Fred Lampropoulos^ There's a few of them on the call four to be exact. I was wondering when you were going to raise that. Okay. I hope that helps. Did that answer your question?

David Rescott^ Yes. That's great. I did miss the two to four update, so thanks for clarifying that.

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

Michael Petusky^ I wanted to ask, and maybe I missed a more fulsome explanation. But China, the language you're using around the China quarter is sort of similar to last quarter where you sort of say well soft macro environment, just came in below what we thought but not anything -- unless I missed it with real specificity. I'm just curious, like two soft quarters in China and not related to is not typical for you guys. I'm just curious if you're digging into that. Or did I miss a more full explanation of that.

Raul Parra^ Well I mean I think -- well I think the big explanation is that we continue to expect low single-digit growth in APAC for 2025, right? I mean I think we've been very clear about that all year long. And China is a big contributor to that. So I would say that, yes, it came in lower than expected, but also we just -- it's China, right? There's just a lot of -- it's a tough macro environment there. And I would say that we've had quarters where we've done better than anticipated.

But I don't think anybody around here is kind of hitting the panic button, Mike, to be honest with you. I mean I just think it's just the environment we're in right now. It's not isolated to any one customer or any one segment, it's just a general softness. That's all I have to say to it. Obviously volume-based purchasing continues to be a headwind, and as we've talked about over the last couple of years.

Michael Petusky^ Okay. I just want to ask a quick question, and it's hard to keep track of how long any of these tariffs were actually on in the second quarter. But is any of the $7 million, was it actually -- like did any of that actually hit in Q2? Was there an impact from tariffs?

Raul Parra^ Yes. We are about $2 million that flow through that's included in the gross margin.

Michael Petusky^ You said $2 million?

Raul Parra^ Yes, or $1.2 million, sorry, $0.02.

Michael Petusky^ Okay. Got you. Okay. Then just a last question for Fred. Just curious, the balance sheet leverage is despite you guys being fairly active the last couple of years is still pretty low in part due to the good cash flow. Just curious, are there assets out there that are interesting? What are you seeing? What are you seeing in terms of valuation? Anything you can add on that would be great.

Fred Lampropoulos^ I'll just be very broad. There are opportunities. We look at them if they're right for Merit, we'll do something about it. If not, we'll just continue to march. We may have to wait 10 years like we did for one of them. They're out there, but got to be patient and -- but they're there.

Operator^ Thank you. This concludes today's Q&A session. I would like to go ahead and turn the call back over to Fred for closing remarks. The floor is yours, sir.

Fred Lampropoulos^ Thank you very much. Ladies and gentlemen. thank you very much for your time on such a busy day. It's an interesting time for me. This will be the last publicly held quarterly report that I will speak to. I'll still be involved in the company. I will be the Executive Chairman after October 3, and I'll still be a member of the Board for a number of years. But I want to thank you for all that you've taught me. I want to thank you for all the scolding you've given me and helped us as a business and brought things to our attention that were necessary. So best wishes to all of you. And again, thank you. Signing off now from Salt Lake City, Utah, the home of the 2034 Winter Olympics. Good evening.

Operator^ This concludes today's presentation. You may all disconnect.