

MMSI's Q2 2021 Earnings Call

July 29, 2021

Corporate Speakers:

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

Participants:

- Jayson Tyler Bedford; Analyst; Raymond James & Associates, Inc.
- Shagun Singh Chadha; Analyst; Wells Fargo Securities, LLC
- Unidentified Participant; Analyst; Unknown
- James Philip Sidoti; Analyst; Sidoti & Company, LLC
- Michael Stephen Matson; Analyst; Needham & Company, LLC
- Steven Michael Lichtman; Analyst; Oppenheimer & Co. Inc.

PRESENTATION

Operator^ Good afternoon, ladies and gentlemen, and welcome to the Second Quarter 2021 Earnings Conference Call for Merit Medical Systems Inc. At this time, all participants have been placed in a listen-only mode. 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 Fred Lampropoulos, Merit Medical Systems' Founder, Chairman and Chief Executive Officer. Please go ahead, sir.

Fred P. Lampropoulos^ Thank you, Valerie, and welcome, everyone to Merit Medical Systems second quarter 2021 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 just take a moment please and take us through the Safe Harbor provision, please?

Brian G. Lloyd^ Thank you, Fred. I would like to remind everyone that this presentation contains forward-looking statements that receive Safe Harbor protection under federal securities laws. Although we believe these forward-looking statements are based upon reasonable assumptions, they are subject to unknown risks and uncertainties. The realization of any of these risks or uncertainties as well as extraordinary events or transactions impacting our Company could cause actual results to differ materially from those currently anticipated.

In addition, any forward-looking statements represent our views only as of today, July 29, 2021, and should not be relied upon as representing our views as of any other date. We specifically disclaim any obligation to update such statements, except as required by applicable law. Please refer to the section entitled Cautionary Statement regarding forward-looking statements in today's presentation for important information regarding such statements. Please also refer to our most recent filings with the SEC for a discussion of factors that could cause actual results to differ from these forward-looking statements.

Our financial statements are prepared in accordance with accounting principles which are generally accepted in the United States. However, we believe certain non-GAAP financial measures provide investors with useful information regarding the underlying business trends and performance of our ongoing operations and can be useful for period-over-period comparisons of such operations. This presentation also contains certain non-GAAP financial measures. 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 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, and 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 investor's page of our website.

I will now turn the call back to Fred.

Fred P. Lampropoulos^ Thank you, Brian. First of all, 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 performance in the second quarter, including the business trends we experienced during the quarter and the areas of our business that performed well, driving better than expected revenue and financial results during the second quarter.

After my opening remarks, Raul will provide you with a more in-depth review of our quarterly financial results and the formal financial guidance for 2021 that we updated in this afternoon's press release as well as a summary of our balance sheet and financial condition. And then of course, we will open the call for your questions.

Now beginning with a review of our second quarter revenue performance. We reported total GAAP revenue of \$280 million in the second quarter, up 28.4% year-over-year. Our total GAAP revenue growth was driven by 34.4% growth in U.S. sales and a 21.3% growth in international sales. Excluding the benefit to our GAAP revenue as a result of changes in exchange rates compared to the prior year period, our total revenue increased 25.5% year-over-year in the second quarter on a constant currency basis. Our total

constant currency growth was driven primarily by 36.1% increase in U.S. sales and a 13.1% increase in international sales.

Our second quarter revenue results were notably better than the expectations provided on our first quarter call, which called for Q2 constant currency revenue to increase in the range of approximately 11% to 13% year-over-year. Our second quarter revenue exceeded the midpoint of this guidance range by close to \$30 million or approximately 14 percentage points of growth year-over-year now. Needless to say, we're extremely proud of the strong constant currency growth performance we delivered in the second quarter.

We are pleased to see broad based growth across our primary reportable product categories in both the cardiovascular and endoscopy segments of our business, although the majority of our year-over-year increase in total revenue was a result of strong sales in our cardiovascular business, which increased a little more than \$60 million year-over-year in the second quarter.

Sales of our peripheral interventional products increased 45.4% year-over-year, representing more than half of the total cardiovascular segment year-over-year. Sales of our SCOUT radar localization products increased more than 90% year-over-year in quarter 2 and represented the largest contributor to total PI growth in the quarter.

Sales of our biopsy products nearly doubled in the second quarter and drainage and embo therapy products, which together represent roughly 1/3 of our total PI business increased nearly 40% year-over-year in quarter 2.

Sales of our cardiac intervention products increased 29.8% year-over-year, representing approximately 1/3 of our total cardiovascular segment growth year-over-year. More than half of the growth in our C&I product category in quarter 2 came from strong sales of our intervention products and sales of our fluid management products.

On the intervention side, our basics and map lines performed well. On the fluid management side, our Medallion products performed well as they continued to benefit from higher demand as a result of COVID vaccination programs.

Sales of our CPS products increased 7.3% year-over-year in quarter 2. However, the improving demand trends in this area of our cardiovascular business was masked by the \$4 million headwind from sales of the Cultura product line in the prior year period. Excluding Cultura, sales of our CPS product category increased approximately 18% year-over-year in quarter 2.

Sales of our OEM products increased 14.8% year-over-year in quarter 2, driven by improving demand from larger customers replenishing their inventory levels. We also had better-than-expected sales performance in our endoscopy segment in quarter 2, with sales increasing 29.7% year-over-year from strong demand of our EndoMAXX stents and Elation products.

Now turning to a brief summary of our sales performance on a geographic basis. As I mentioned, our second quarter sales in the U.S. increased 36.1% year-over-year and our international sales increased 13.1% year-over-year, both on a constant currency basis.

Sales to U.S. customers was the largest contributor to total Company growth in quarter 2, led by our U.S. direct business, which increased approximately 42% year-over-year. Sales in our 3 primary global regions, APAC, EMEA and Rest of World, increased 4.5%, 22.3% and 33.6% respectively on a constant currency basis in the second quarter.

Similar to the OUS trends we outlined on our first quarter earnings call, we experienced overall improvement in trends during the second quarter. However, we continue to see notable variation in the pace of recovery across regions of the world where we do business, including wide variation within certain geographic regions. APAC is a perfect example of this dynamic.

China represented the largest contributor to APAC revenue growth in the second quarter, but sales only increased approximately low to mid-single digits on a constant currency basis. Now while China continues a measured pace of recovery, business trends lag in Southeast Asia and Australia, and our sales declined in these markets compared to the year-ago period.

We would also like to highlight the reported sales growth in the APAC region includes the sales related to our ITL procedure pack business in Australia, which we closed in December of 2020. Excluding those sales from the divested business, our APAC constant currency revenue growth was approximately 8% in the second quarter.

The EMEA region was spotty as well in quarter 2, as the region continued to see material impacts from COVID-19 and is still in the early stages of recovering. Restrictions and lockdowns are changing constantly across regions, causing limitations to sales contact and lower demand for elective procedures.

We experienced improving trend demand in the United Kingdom and in certain countries in Continental Europe, including Germany and France, primarily due to improving access in these direct markets.

The weak demand trends in emerging markets we experienced in quarter 1, continued in quarter 2, with challenging conditions in the Middle East, Russia and Turkey as governments have diverted health care budgets to fight COVID-19 and the overall weaker demand for elective procedures continues to impact the timing of tenders in the region.

In summary, we're very pleased with the 25.5% constant currency growth in our total revenues that we delivered in the second quarter. Now to be clear, we believe our second quarter results are not just an example of above average growth rates earned on an easy comparison. Rather, we believe our second quarter results reflect the combination of strong execution and overall improvements in the operating environment, access to

patients and elective procedures during the quarter. For the avoidance of doubt, I would like to highlight our second quarter revenue results as compared to the second quarter of 2019 in interest of stripping out any benefit to our growth performance from an easy comparison.

Specifically, our reported quarter 2, 2021 revenue results represent growth of approximately 10% over the second quarter of 2019, driven by high-teens growth in the sales of our peripheral intervention products, high single-digit growth in the sales of our cardiac intervention products and low to mid-single-digit increases in our CPS and OEM products.

In the case of our CPS, if you exclude sales of the ITL business we divested in quarter 2 of '19, sales increased 7% in quarter 2 of 2021 versus quarter 2 of 2019. Our second quarter growth over quarter 2 '19 reflects a material improvement in growth trends in each of these product categories.

We continue to be encouraged by measured improvements in the operating environment in quarter 2, particularly in the U.S., where we saw more willingness and reception from hospital customers to evaluate new product offerings in recent months, which we believe is reflective of continued improvement in the underwriting operating environment in the U.S. during the period.

Now Raul and I'm very pleased and proud of the organization's strong execution. And we are pleased to see the improvement in business trends we experienced in the second quarter, both of which resulted in revenue results that were materially ahead of guidance expectations provided in our quarter 1 call at the end of April.

Our performance in the second quarter and first half of 2021 gives us further confidence in the outlook we introduced in our fourth quarter call last year, which called for a return to normalized year-over-year growth trends in the third quarter of 2021.

Raul will of course review the details of our full year guidance which we updated in our press release this afternoon in a few moments from now.

I'll just say that we remain confident in our plan for the year and look forward to continued strong execution from the team going forward.

Now before I turn the call over to Raul, I wanted to comment on a few other noteworthy items in the quarter. First, we delivered another quarter of impressive profitability improvement, margin expansion and free cash flow generation in quarter 2. Our non-GAAP gross profit, non-GAAP operating income and non-GAAP net income reflects strong operating leverage in the period, increasing 40%, 88% and 103% respectively compared to the prior year period. Our non-GAAP gross operating margins increased 400 basis points and 520 basis points respectively year-over-year, and we generated \$34.6 million of free cash flow in the quarter.

We believe our financial results over the first half of 2021 represents early evidence that we are making progress towards our goal of enhancing Merit's long-term growth and profitability profile. We have expanded our non-GAAP gross margin 230 basis points year-over-year, expanded our non-GAAP operating margin 400 basis points year-over-year and, most importantly, we have generated more than \$63 million of free cash flow over the first 6 months of 2021, a 34% increase over the prior year period.

Second, we are pleased with the progress during the second quarter of our clinical study, the WAVE study of the WRAPSODY Endovascular Stent Graft, an investigational device being studied for the treatment of stenosis or occlusion within dialysis outflow circuits. We have more than 40 clinical sites identified, more than half of which are actively enrolling patients. The study has been designed to evaluate the safety and efficacy of WRAPSODY's Endovascular Stent Graft for the treatment of venous outflow circuit stenosis or occlusion in dialysis patients and represents an important step of our goal of establishing the WRAPSODY as the standard-of-care for more than 2 million patients suffering from kidney disease around the world.

With respect to expanding clinical awareness of the clinical efficacy of WRAPSODY, we look forward to presenting the 12-month data from our first-in-man feasibility study called WRAPSODY First, which included 46 patients in Europe at multiple medical meetings in the second half of this year.

Finally, I wanted to provide a brief update on our Foundations for Growth program. Specifically, we have made very good progress over the first half of 2020, including skew rationalization, product line transfers and manufacturing initiatives are all on-track.

In human resources, new global bonus programs aligned with FfG, in addition to, of course, a new Vice President of Corporate Communications and other initiatives are on-track. Support functions in finance and IT initiatives are on-track. Commercial and marketing excellence initiatives are in the process of starting. Overall, we continue to execute on our Foundations for Growth initiatives and are excited about the progress and the results we're seeing across the business.

Well, that's a lot, but now the best is yet to come. I will turn the time over to Raul, who will take you through the detailed review of our second quarter financial results and 2021 financial guidance which we updated in this afternoon's press release. Mr. Parra, the time is yours.

Raul Parra^ Thank you, Fred. Given Fred's detailed review 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 second quarter and first 6 months of 2021. We have included full reconciliations from our GAAP reported results to the related GAAP items in our press release this afternoon.

Gross profit increased approximately 40% year-over-year in the second quarter. Our gross margin was 48.7% compared to 44.7% in the prior year period. The approximate 400 basis point increase in gross margin year-over-year was primarily due to changes in product mix, decreased obsolescence expense and improvements in manufacturing efficiencies on higher volumes, offset partially by inflationary headwinds we are seeing in raw materials, labor, et cetera.

Second quarter operating expenses increased 24% year-over-year. The year-over-year increase was driven by a 25% increase in SG&A expense, and a 21% increase in R&D expense compared to the prior year period. The increase in SG&A expense was primarily due to higher selling expense, including commissions and bonus expense and other increase in sales year-over-year and lower OpEx in Q2 2020 from cost cutting initiatives, lower headcount and lower discretionary spending as a result of the reduced travel, training and shows and conventions during the COVID 19 pandemic.

Our continued focus on managing expenses proved effective again in this quarter as we were able to limit the growth in G&A only expenses to just a 3% increase year-over-year. The increase in R&D expenses in Q2 was driven by the combination of the lower spend in the prior year period related to COVID and outside expenses for certain R&D projects, in particular related to WRAPSODY clinical study and an increased compensation expense related to our acquisition of KA Medical and 2 other new projects.

Note, as discussed on our first quarter call, we expected to see a modest increase in our operating expenses in the second quarter as a result of some modest timing related delays in discretionary selling and marketing spend in Q1, and the fact that our WRAPSODY clinical study would be enrolling patients for a full quarter versus a partial period in Q1. Despite these expected increases, we were pleased with the operating leverage we delivered on a sequential basis in Q2 with non-GAAP operating expenses increasing just 8% quarter-over-quarter compared to the 13% sequential increase in sales.

Total operating income increased \$21.4 million or 88% year-over-year to \$45.8 million. Our operating margin was 16.3% compared to 11.2% in the prior-year period, an increase of 120 basis points year-over-year.

Second quarter Other expenses net was \$1.9 million compared to \$3.2 million last year. The change in Other expenses net was driven by lower interest expense, as a result of lower effective interest rate and a lower average debt balance.

Second quarter net income was \$35.3 million or \$0.62 per share compared to \$17.4 million or \$0.31 per share in the prior year period. We are very pleased with our profitability performance in the second quarter, where we reported growth in net income and diluted earnings per share of 103% and 100% respectively year-over-year.

Turning to a brief review of our financial results over the first half of 2021. Total revenue for the 6 months ended June 30 was \$529.2 million, up \$67.3 million or 15% year-over-year. Total revenue for the first half of 2021 increased 12% year-over-year on a constant

currency basis. Gross profit increased 20% year-over-year to approximately \$259 million, representing 48.9% of sales in the first half of 2021 compared to 46.7% of sales in the prior-year period, a 230 basis point increase year-over-year.

Operating profit increased 53% year-over-year to \$84.6 million, representing a 16% of sales in the first half of 2021 compared to 12% of sales in the prior-year period, a 400 basis point increase year-over-year.

Net income increased 69% year-over-year to \$65.2 million or \$1.14 per share compared to \$38.5 million or \$0.69 per share in the prior year period.

Turning to a review of our balance sheet and financial condition as of June 30, 2021. Our strong profitability performance in the second quarter of 2021 combined with strong working capital efficiency resulted in strong free cash flow generation of \$34.6 million in the second quarter. We have generated a \$63.6 million of free cash flow over the 6 months of 2021, representing a 34% increase over the prior year period.

Our free cash flow generation over the first 6 months of 2021 is a result of great execution from the team, and importantly, continued evidence that we are clearly focused on enhancing the profitability and cash flow profile of our Company going forward.

We continue to expect to generate approximately \$100 million of free cash flow for the full year 2021 period, driven by continued improvement in our profitability and strong working capital efficiency, offset partially by investment in capital expenditures of approximately \$40 million this year.

We have used a portion of our strong free cash flow to reduce our outstanding debt obligations over the first half of 2021. Specifically, we paid down approximately \$58.9 million of debt on our line of credit facility, including \$28 million, which we paid down in the second quarter.

As of June 30, 2021, we had cash on hand of approximately \$69.7 million, long-term debt obligations of approximately \$293 million and \$444 million of available borrowing capacity compared to cash on hand of approximately \$56.9 million, long-term debt obligations of approximately \$352 million and available borrowing capacity of \$389 million as of December 31-2020.

Our net leverage ratio as of June 30 was 1.1 times on an adjusted basis.

Turning to a review of our fiscal year 2021 financial guidance, which we updated in the afternoon's earnings release. For the 12 months ended December 31, 2021, the Company now expects GAAP net revenue in the range of \$1.06 billion and \$1.07 billion, representing an increase of approximately 10% to 11% year-over-year. The prior guidance range assumes growth of approximately 3.1% to 5.2% year-over-year.

The GAAP net revenue range now assumes a benefit from a change in foreign currency exchange rates in the range of approximately \$10.5 million to \$11.5 million, representing a tailwind of approximately 110 to 120 basis points to our GAAP growth rate this year.

The prior guidance range assumed a benefit in the range of approximately \$8 million to \$8.5 million or 90 basis points to our GAAP growth rate in 2021.

The GAAP net revenue guidance range also assumes net revenue from cardiovascular segment of between \$1.028 billion and \$1.038 billion, representing an increase of approximately 10% to 11% year-over-year. The prior guidance range assume growth rate of approximately 3.1% to 5.2% year-over-year.

Net revenue from the endoscopy segment of between \$32.5 million and \$32.7 million, representing an increase of approximately \$9.6 million or 9.6% to 10.2% year-over-year. The prior guidance range assumes growth of approximately 4% to 7% year-over-year.

With respect to profitability guidance for 2021, our updated guidance calls for GAAP net income in the range of \$43.2 million to \$51.8 million or \$0.75 to \$0.91 per diluted share. The prior guidance range assumes GAAP net income in the range of \$47.3 million to \$55.9 million or \$0.83 to \$0.98 per diluted share. Non-GAAP net income in the range of \$118.8 million to \$127.1 million or \$2.07 to \$2.22 per diluted share. The prior guidance range assumed non-GAAP net income in the range of \$104.8 million to \$112.7 million or \$1.84 to \$1.98 per diluted share.

For modeling purposes, our updated fiscal year 2021 financial guidance now assumes non-GAAP gross margins in the range of approximately 48.8% to 49.1% compared to the prior range, which assumed 48.5% to 49.8%. Non-GAAP operating margins in the range of approximately 15% to 16% compared to 13.7% in fiscal year 2020.

Approximately \$7.5 million of other expenses compared to the prior guidance range which assumed approximately \$8 million, driven by lower interest expense as a result of the reduction in debt obligations outstanding as compared to the prior year. A non-GAAP tax rate in the range of approximately 22% to 23% compared to prior guidance, which assumed a non-GAAP tax rate for full year 2021 in the range of 24% to 25% and diluted shares outstanding in the range of \$57 million to \$57.5 million compared to prior guidance, which assumed approximately 56.8 million shares for full-year 2021.

Lastly, we expect our total revenue in the third quarter of 2021 in the range of \$259 million to \$263 million, representing growth of approximately 6% to 8% year-over-year on a GAAP basis and growth of approximately 5.3% to 7.6% year-over-year on a constant currency basis.

Note, our third quarter growth expectations assume the improvements in the operating environment we saw in Q2, continue, offset partially by the normal seasonality we experienced in the third quarter each year. We also expect flattish non-GAAP gross

margins quarter-over-quarter and we expect a low single-digit increase in our non-GAAP operating expenses compared to Q2 '21.

With that I will turn the call back to Fred.

Fred P. Lampropoulos^ Well, very good, sir, and thank you very much Raul. Now before we open the call to questions, I wanted to review the important considerations and key assumptions for the investment community to bear in mind as they evaluate our updated 2021 revenue guidance. We have 2 items to call out as contributors to our 2020 revenue results that represent material headwinds to growth rates, our guidance assumes for 2021. We also have 1 assumption impacting our 2021 revenue expectations over the second half.

Now let me provide some additional color on each of these items now. And I'll note that we have a detailed reconciliation of these items impacting our 2021 revenue growth in our earnings call presentation slides which are available on the Investor Relations page of our website.

Now regarding the 2 areas that represent headwinds to our 2021 revenue growth, first, as discussed on private calls and disclosed in filings during fiscal year 2020, we announced strategic decisions to exit 3 businesses in 2020. The suspension of Merit's distribution agreement with NinePoint Medical in quarter 1, 2020; the disposition of assets related to manufacturing of Merit's Hypotube product in August 2020; and the closure of the ITL Healthcare procedure pack operations in Australia in December 2020. Together, these businesses contributed revenue of approximately \$11.1 million during the fiscal year 2020 and will not contribute to our revenue results in 2021.

Second, our 2020 revenue results benefited from the sale of the Cultura nasopharyngeal swab and test kits used to collect and transport samples for COVID-19 testing, which we developed, manufactured and distributed beginning in the second quarter 2020 in response to the critical need as a result of the COVID-19 pandemic. We believe this represents a great example of not only Merit's strong R&D and manufacturing capabilities, but also our ability to adapt quickly to our markets and to respond to time-sensitive demand from our customers.

Importantly, Cultura is not a core product line for Merit going forward, and we expect to generate approximately \$2.5 million to \$3 million in sales from this product line in 2021 compared to more than \$19 million in 2020. Now this represents a material headwind to our year-over-year revenue profile in 2021. Roughly \$13 million of this headwind will impact our second half 2020 results, representing roughly 270 basis points to second half growth year-over-year.

Now the third item I wanted to highlight for investors to consider when evaluating our 2021 revenue growth profile is a key assumption that impacts our APAC revenue over the second half of 2021. Our revenue guidance includes approximately \$11 million to \$12

million of headwind related to lower pricing as a result of tenders in the second half of 2021.

Overall, we continue to expect our total revenue in China to increase in low single digits year-over-year in 2021 despite the expected pricing headwind as a result of strong unit growth we expect during the year.

While we are pleased to see strong demand driving unit growth, such that we were able to offset the expected pricing headwind related to the tenders this year, we note that the \$11 million to \$12 million of lower pricing represents approximately 120 basis points headwind to our total Company constant currency growth in 2021 and represents a 240 basis point headwind to our total Company constant currency growth rate in the second half of 2021.

Now we are confident in our updated 2021 guidance which calls for total revenue growth on a constant currency basis of 9% to 10% year-over-year. Importantly, excluding the impact of divestitures and product sales that uniquely benefited from pandemic-related demand trends in 2020, our constant currency revenue growth now reflects growth of 12% to 13% year-over-year in 2021.

Excluding the expected pricing headwinds from China tenders over the second half of 2021, our total revenue guidance for fiscal 2021 now reflects growth in the range of approximately 13% to 14% year-over-year on a constant currency basis.

Now we also expect to report improving non-GAAP gross margins, operating margins, strong free cash flow in 2021, driven by strong execution and contributions from our multi-year strategic initiatives related to the Foundations for Growth program.

Now this wraps up our prepared remarks. Operator, we would now like to open up the line for questions. Thank you very much.

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) Our first question comes from Jayson Bedford of Raymond James.

Jayson Tyler Bedford^ Congratulations for the nice quarter. Results were clearly ahead of expectations. Do you think -- this is a tough answer here, but do you think the quarter benefited at all from pent-up demand, given the flow through in 3Q? My guess is, no, but if you can comment on that, that would be great.

Fred P. Lampropoulos^ Yes, Jayson. I think that there is pent-up demand and I think we'll see it over the next 12 to 18 months. I don't think it's just all popped up in this quarter. But as we've kind of been saying all along, we never believed in kind of a V. We adopted

and patented -- I'm joking now -- the Raul swoosh. But we are seeing positive trade -- the environment, especially in the US as been very, very positive.

New products are getting looked at much more often, and they're selling. And, listen, I would be disingenuous if I didn't say that whenever you have sales like this, you've got to make it, you got to produce it. And so I think our execution from an operational point of view is also something I'd like to mention that our ability, again, going back to -- the ability we have to respond and react to be able to meet customer needs.

Raul, do you want to comment at all?

Raul Parra^ No, I would just say that you've got that Jason. And also, I mean, hats off to our sales force for being ready to take advantage of that.

Fred P. Lampropoulos^ Good point.

Raul Parra^ I think they did a great job.

Jayson Tyler Bedford^ Okay. Fred, you mentioned some softness in a handful of emerging markets. What percent of your business do you think is tied to those emerging markets that are still lagging?

Fred P. Lampropoulos^ To be honest, really, I don't have that right in front of me. Maybe Raul can comment on that, but we're really talking about places like Indonesia and some of those areas in Southeast Asia and also in the Middle East. It's kind of a geographic part of that. Raul, do you want to comment on percentages?

Raul Parra^ Yes. Percentages, I don't have here with me, Jayson. I don't know that we want to give that much detail. But Middle East, Russia, Turkey, and EMEA and then APAC is just a little spotty too. But overall, I think it's generally improving, I would say.

Fred P. Lampropoulos^ Yes. And of course, the biggest market of all is the United States and that's the one that's responding. And of course, the most important. I would consider emerging markets is probably the best, but description both in EMEA and APAC.

Jayson Tyler Bedford^ Okay. Just on the, the China tenders that still impacting the growth in terms of the guidance. When will we know? Meaning, is there a timeframe here that we should look to?

Fred P. Lampropoulos^ Well, we've always expected that we'd start to hear things kind of in the third quarter as tenders went out. It's -- we'll be there. We're there now in terms of the turnaround. So you can never rely or nor do we know when they respond. We haven't seen anything yet, but we don't want any surprises. So we're kind of maintaining that until we have for the evidence one way or the other.

Jayson Tyler Bedford^ Okay. Thank you. And I guess just last one for me. The sales force clearly has some momentum there. Can you just comment on new product flow? Maybe I realized WRAPSODY is up and running, but maybe some other new products that you expect to introduce in the second half of the year, and I'll drop. Thanks.

Fred P. Lampropoulos^ Yes. Well, listen, we have a lot of them from the last year. It really didn't get much attention because of the back committees and that sort of thing. And as the market is open back up, we have, I don't know -- no less than 10 products that really didn't get a fair shot and then we have, as you know, every year 10 to 12 to 15 new products coming out. So things like the splash wire, things like the focus, products like the, our gelfoam products and others.

So it's nice to see they're getting attention and reorders and that sort of thing, Jayson. So that's the best way without getting into too much detail, but there is plenty out there. I guess the bottom line is, there's plenty out there for our sales guys to sell and plenty of reasons for customers that want to see our folks, because the products we make help people to do better job, safer jobs and provide both physicians and for patients.

Operator^ Thank you. Our next question comes from Larry Biegelsen of Well Fargo.

Shagun Singh Chadha^ This is Shagun in for Larry. I was hoping you could talk to us a little bit about trends in the second half, perhaps across the different business segments or geographies. Especially relative to 2019, how we should think about the cadence at the back half? And then similar question on margins. It seems like just given your guidance, it seems like you're assuming flattish gross margins in the back half versus the first half, but lower operating margin. So any color there would be helpful.

Raul Parra^ Yes. So I guess to break down the question, I'll maybe attack the revenue piece first. You know clearly, we see, I guess, what I'll call modest improvement, we see some momentum in the business and we're doing better or we wouldn't have updated guidance. So again, I think when you look at the growth and -- maybe I'll just hit on our guidance, right.

So if you take the bottom of our guidance, the \$994 million that we had previously provided, you tack on \$66 million to our new updated guidance of \$1.06 billion. Really the first \$50 million was the strong beats in the first half of the year. And I guess we're feeling that we can do a modest improvement in the back half of the year and we're tacking on \$16 million there, which I think is a modest improvement and I think it shows kind of the upbeat nature of what we're expecting, but also knowing that we're not completely out of the woods yet.

And so I think it's important to call that out, because I think when you see the increase in the guidance it does look like a big number, but a big portion of that has already been -- it's already in hand, I guess, I'll say.

Fred P. Lampropoulos^ Well, then we can't forget about this resurgence of COVID, and so we are being cautiously optimistic, and also on the seasonality. We are coming into the summer quarter, but listen, I don't want to take away from our confidence in the business and the momentum in the business. But at the same time, we don't want to get over our skis. So Raul, do you want to.

Raul Parra^ Yes, so on the gross margin. Look, I think we've done a great job this year. We did tighten the range. We brought it up. And really the assumption is driven by product mix and in some of the inflationary headwinds we're seeing that everybody has seen. But I think the real focus should be on operating margin, which we're really excited about. And you can see the leverage that we're getting there. And so, I think we continue to be excited and we continue to be excited about using -- being able to use the full P&L to drive higher profitability.

Shagun Singh Chadha^ I got it. And then just a question on China. I believe it represents about 10% of total Company sales and it looks like value-based, purchasing tenders. They that could expand into other categories. So how are you thinking about growth in China over the next few years?

Fred P. Lampropoulos^ Yes, I think we still have a lot of confidence in China. There are a lot of wins and types and that sort of thing. But I think our idea is that we talked about on our last call about expanding into markets that cater for, I don't want to say been ignored. But there are a lot of, I think I mentioned last quarter there is like 30 cities with over 5 million people as you move kind of into the center of the country. I think our strategy is to move into those areas that will give us more opportunity. We haven't lost faith at all in China.

Operator^ Our next question is Matt O'Brien from Piper Stanley.

Unidentified Participant^ This is Gerome [ph] on for Matt, and congrats on the impressive quarter here. I wanted to start off on the free cash flow number. Obviously, very impressive. Well ahead of the Street and it seems like it puts you guys on schedule as far as getting to that \$100 million target for the year. So just wondering if you could speak to the stickiness of that level of performance, especially as the spend starts to ramp up a little bit and then what's a good jumping-off point as we start to think about that metric in 2022.

Raul Parra^ Yes, well, look, I won't give you the 2022 number, but I will tell you that as part of our Foundations for Growth program, we have a minimum of \$300 million target out there. So I guess the stickiness, It's a goal that we have set and we're pretty dedicated to it. Obviously, as we look at the \$100 million target for this year, we do have capital that, I would say we've underspent for the first half of the year. We do plan to spend a budget for the back half, and we have met with our operations group just to look at initiatives where -- for efficiencies. And so, we do plan to just to use additional capital in those areas.

So I would say I feel it's pretty sticky. We do have working capital programs in place to try and make sure that we hit our targets. In addition to, we just have a more robust capital allocation process for fixed assets and then whatnot.

Fred P. Lampropoulos^ I think we instituted some other programs. I mean, we met yesterday. We go for week -- each month we monitor and approve or ask for more information. I think we're very disciplined. And listen, if you go back a couple of years ago and I won't finish quickly. If you go back a couple of years ago was one of the big criticisms. We listened to what shareholders told us and we performed.

So I think we're doing a great job. And then like Raul said. in some cases, we really want to spend our money on automation and things will help to offset labor in these other issues that are going to be an issue for everybody going forward. So I think it's -- and one last thing, we are also compensated. I mean part of our compensation is to make sure that we hit the goals that we set out in our Foundations for Growth. So the interest are aligned to make sure that we do that, but still grow the Company.

So we're not going to stop spending. We need to expand and invest, but we have goals and we'll hit those goals. So that's a long platitude, but that's -- it's sticky, very sticky.

Unidentified Participant^ Good to hear and very helpful. And then just second question from me, I apologize for being a little bit nitpicky here. I mean, I know you just alluded to it a little bit. But on the gross margin side, just a little step down versus Q1, is that primarily a mix dynamic? And then, as we're thinking about the full year, is there anything from a mix perspective or otherwise that we need to be aware, just as we're modeling that gross margin?

Raul Parra^ Yes. No, look, I think we brought the bottom up. So we went from 48.5% to 48.8%. And again, I think we're, as we look forward, there is a lot of inflationary pressures that we're -- I think we're trying to account for, and just be cautious with We're seeing freight expense go up. That cost us roughly 20 basis points in the quarter. Even though we have -- we actually negotiated better rates last year and as a percentage it was down. We actually ended up paying more because of air freight, more product to our customers, and so -- and our distribution centers.

So I think our Foundations for Growth program is just getting started at 6 months in. We've got a lot of initiatives for our operations group for the cost of goods line. And I think we feel pretty good about where we're at right now.

Fred P. Lampropoulos^ And I also think Raul that as we go down the road here, we believe that these freight issues, let me give you an example. We're sending a lot more by air. And part of that because things getting blocked up in ports, the surface approach -- shipping, there is not enough ships out there. But we believe that that market will balance out in time like they do. So there is an under-supply. It will swing the other way. And so that's something that we don't think is permanent. But it is here for now until we get back into equilibrium.

Raul Parra^ And just, maybe just call it out, because I think our guidance, it basically implies 170 to 200 basis point expect expansion. So again, I want to call that out, because I think it's critical.

Operator^ Our next question comes from Jim Sidoti of Sidoti & Company.

James Philip Sidoti^ Just a follow-up on that. You, obviously, you are seeing growth across all your business lines and several of the companies that reported already have indicated that. Some of them are concerned about having enough supply to meet demand in the back half of the year. Are you guys prepared? If business keeps ramping up, is your supply chain able to handle it?

Fred P. Lampropoulos^ Listen, as I think you know and I want to make sure everybody else as well as that Merit is a very much a vertically integrated Company, and whether it be sensors for critical care or for other product lines, inflation devices and so on, or better extrusion or catheters or injection molding, all of those things we do. And we feel criticized sometimes. I'm saying we have don't do that. But I'm really glad that we've done that over the years.

But at the same time, we didn't see much in the previous 12 months, maybe even 15 months. But as those suppliers has got used up, I mean you can hear them, whether it be chips, whether it'd be resins, whether it'd be this or that, almost everybody, and we're not immune. But I think with the really important part is if you look at our revenue numbers, those are orders that were built and shipped.

And do we have more than we did last year? And the answer is yes. However, our ability to respond and to be able to work through these things because we're involved in it every day. Raul, you had a comment.

Raul Parra^ No. I just want to make it clear, right, Jim, because I think it's a valid point. And again, I'll point to the modest increase in the back half of our guidance, right. So again, we're excited about the business, a lot of good momentum. But we are also being cautious, just given the headwinds.

So we've essentially got \$60 million uptick in our guidance for the back half. So I just want to make sure that that's called out and people understand that, because it is a big uptick in our guidance and we've already got \$50 million in the bag.

James Philip Sidoti^ All right. And then just another kind of a big picture question. I think, Fred, you and I are old enough to remember inflation, but I'm not sure how many other folks on the call are. But it definitely seems like we're in an inflationary environment. Are you -- do you have pricing power or do you have hedges in place on the materials and are you able to handle some inflation in the near term?

Fred P. Lampropoulos^ Yes, listen, we all know and we hear about it every day. We all know the wages and the ability to bring people back to work. Wages are never going to go down in my belief. I've never seen in my lifetime. So you do have those and the ability to attract people.

So I think that's going to continue. However, to offset those, there's things like automation, moving products to other facilities that are more competitive and that sort of thing in terms of cost. So I mean we have those things in place. Raul?

Raul Parra^ And lastly, I mean, I -- look, we've been able to absorb certain things, because of FfG program. So I don't want to take away from the operational group, because they've done a lot of work on the purchasing side. That's helped offset some of these headwinds and some of the automation and things that they've already done.

Fred P. Lampropoulos^ Well -- and another point Raul is, as part of our Foundations for Growth., you've heard us talk about this, I mean, several times today. But part of that was SKU rationalization. SKU rationalization, which is a big initiative, helps us to be more efficient in our manufacturing by not making 10 of something, but better to make 10,000 of something. And we think we can do that without really affecting the revenue stream.

So that's another thing is that we can become more efficient and then that's all going to flow through. So Jim, I think -- we're not immune. We have some issues, but not anything that I can currently see that would create a problem for us to meet our goals. So I'm going to make sure that that's understood as well.

James Philip Sidoti^ Fred, when you founded this business back in the '80s selling inflation devices. When did you think you'd get to \$1 billion in sales? And is there going to be some kind of event at Merit when you do cross that threshold?

Fred P. Lampropoulos^ Well, listen, it's -- there'll be about a 30 second, some punch. And maybe I'll have those cakes that you've put on a big tray that's about best I think of. I think we'll do that. And then, of course, the target is now making sure that -- and by the way, Jim, I think there is a lot of opportunity in the marketplace. When you talk about our stuff, we're seeing a lot of problems from competitors. And that plays into Merit's hand and our ability to respond to customers.

The number for us now is making sure we have a plan in place and that we're working towards both infrastructure, efficiency, strategy, therapeutics, the \$2 billion. So I mean, \$1 billion without sound cavalier is almost in the rear-view mirror.

Operator^ Our next question comes from Mike Matson of Needham & Company.

Michael Stephen Matson^ So I took a look at the growth that your category saw over the second quarter of 2019. And it looks like peripheral was the strongest, up about 19% from '19. But then Custom Procedural was kind of the weakest, up just 30%. So I was wondering if you could just comment on those 2 businesses, what's really driving the

growth there, the difference, I guess in the growth rates? And I would assume the Custom Procedural areas, maybe an area where you've had some of the SKU rationalization.

Fred P. Lampropoulos^ Yes, I'm glad you brought that up because the growth actually if you compare it is around 7% once we strip out the ITL business, which is you'll recall we got rid of last year, right? So that's the pack business that was sitting there. So when you strip that out, the growth in CPS is 7%.

Michael Stephen Matson^ Okay. No, that's fine. But just from a higher level, I mean -- I guess, what's sort of appropriate volume [ph]? Why is that performing so well right now? I mean, there is new products and just procedures rebounding more quickly, give any feel for that or

Fred P. Lampropoulos^ Yes. I mean, I think it's the same reasons that we had such a strong growth in Q2 2021 compared to 2020 last year. I mean, you look at the SCOUT radar localization. That was up almost 90% in Q2, biopsy products nearly doubled. Drainage and embo therapy products up, I think 40%.

Michael Stephen Matson^ Cardiovascular.

Fred P. Lampropoulos^ Yes, I mean, I think there's just a lot of -- we've got a pretty robust portfolio, I would say, and it's just unreal well, along with our sales force going out there and deliver that.

Raul Parra^ And as I mentioned earlier, Mike, I think there are a lot of products that weren't getting much attention because we didn't have the access. That's improving. So those products are starting to show, I think -- and it's still very early. I think there is a long runway here for these new products. But I think that's part of it. And that means the sales guys are getting out there.

I had a sales rep call me and say, we have a little product, I won't mention the name of the product, but the sales guy called me today and said, "Fred, I got a call from a doctor, they're starting to call me because one of his buddies was using the product and he asked me to come over because he wants to use it." So I mean, we haven't had that kind of discussion for a long time, for at least the last 15 months, where people are calling you up and saying please come on over to see me.

So we're starting to see -- and again, that's -- and even with the Delta variant, yes, if there is a lot of new this and lot of new that, but it's not going to be the best. I'm not a physician or an epidemiologist, but it's not going to be like that initial part. There'll be people get sick, there'll be this and that, and so on and so forth. But I just think we're going to see that improving environment continue overtime, because hospitals have learned to deal, even though, I mean if you look the press everything's full and everything is at the end of the world. But our evidence is maybe a little different than that. Yes, they might be full, but hospitals have learned how to do both and manage both, because they need to run their businesses.

Michael Stephen Matson^ And then you've obviously come a long way since the challenges from -- that you experienced in 2019 and Foundations for Growth is going really well. I know it's just in the early stages of being implemented. But your balance sheet's also in better shape. I mean, your leverage ratio is down, I think you said 1.1%. So I guess where does M&A fit in Foundations for Growth? I mean, is it still really off the table or would you consider doing some deals here now that things have stabilized and kind of on the upswing in terms of the growth in market and everything.

Fred P. Lampropoulos^ We did take a vacation. We had to put things in place. We had to get Foundations for Growth. We had to clean up our house. But no, it's not off the table, but it's still has to meet the needs of our Foundations for Growth and not frustrate the goals that we've set forward and that we promised we would deliver to our shareholders.

Now, I mean, clearly if you did something and you had the free cash flow, we still have to do all of that, Mike. So there are deals out there, but as you all know and everybody on this call knows, they are pretty pricey. And we just need to have that discipline to look at the right things. But we don't feel like we have to do anything.

The one great thing about having internal R&D, as you know, we've got those 10 to 15 new products this year and the ones from last year, we have plenty to sell. But on the other hand, there will be opportunities and I think the word people have used is opportunistic. And if it's the right business at the right price and it fits our goals, we'll be there looking.

Michael Stephen Matson^ Congrats on the quarter.

Operator^ Thank you. Our next question comes from Steve Lichtman of Oppenheimer.

Steven Michael Lichtman^ Congrats, guys. I guess it's 2 from me. Fred, on the WRAPSODY First data, obviously assuming it's positive, how do you think it can help in your education and marketing effort in Europe? Do you see that as a catalyst for sales in Europe?

Fred P. Lampropoulos^ Yes, I don't think there's any doubt about that at all. We're enrolling in the U.S. study. That hasn't been easy, because even though you have access to the physicians, well, a lot of hospitals cut back and their investigators and things like that. But we have, I think close 40 -- 30 to 40 --

Raul Parra^ 47.

Fred P. Lampropoulos^ 47 accounts that have been up and that have been trained and better authorized for these procedures. But in Europe, I think we mentioned in our press release, our comment about the 1-year data, and we did not identify and it's not appropriate to do so for us today, but we did say that in an upcoming medical convention,

medical show, in the proper discipline that Merit will be hopefully publish and release that 1-year data.

And again, in a product like this, it's all about data. And then of course we have the U.S. going, and then we're looking at other studies or other types of things, small little things that we would do that help to support what we believe is really an extraordinary -- not just another stent graft. I want to go on saying, this is not just another stent graft. But I hope that you'll pay attention when this -- well, you won't have to. We'll let you know about it. When this is published, we will make a press release. And you can study that and come to your own conclusion.

Steven Michael Lichtman^ And then Raul, obviously, you guys are driving strong operating leverage. What's your latest thoughts on potential tax rate leverage? Do you see opportunities in the near term or you still in more of a wait and see approach given the landscape change there?

Fred P. Lampropoulos^ I wish I could say that we've got an initiative out there to go out and look at, see if we can drive it lower. I think the reality is, you've got a new administration. We're still trying to -- they are still trying to define some of the last tax law changes. And so I just think there's a lot of noise there and to go out and invest dollars in that area right now, and then have a change, we're just -- it's just not an area that we currently want to invest in. But it is a discussion that we are having internally. We're just trying to figure out what the right timing is.

And I think we're up to our last call now. So let's say go ahead and get our last one up and we then will follow-up with other phone calls. So I think Bill from Canaccord. You're up.

Unidentified Participant^ On for Bill tonight. First, just on SCOUT sales. I know you said over 90% year-over-year and large contributor to PI in the quarter. Is there anything specific driving that, is it just uptake or is there specific changes to the product that you've made or from a sales standpoint driving this?

Fred P. Lampropoulos^ Yes. Well, remember now we're approved in other locations, so like, for instance, Europe. We had to get the CE Mark, we have the CE Mark, so that's part of what's driving it. I think it's utilization and I don't have any difficulty saying that I was with the physician just last week, and the comment was, actually physician in Long Island saying, "There is no question. We've looked at all the other products, but you guys have the best technology and the best product." So I think it's uptake. I think it's geographic.

Raul Parra^ Little bit of pent-up demand there.

Fred P. Lampropoulos^ And some pent-up demand coming from the fact that it was considered to be elective. If you can imagine some that has breast cancer being elective, but anyway. So I think that's part of it, and I think you'll see continued momentum there.

Unidentified Participant^ And then just for a follow-up to, we noticed some changes to the WAVE study on clinicaltrials.gov. I see this 2 new arms added about 120 more patients. How you see this impacting timeline? I believe last call you targeted the 6-month follow to be complete by year-end '22. Does this extend that a little bit or any changes there?

Fred P. Lampropoulos^ So the 6-month data is already out. The 1-year data will be coming, we think, in the next couple of months, and we haven't changed anything on the back end at this point at all.

Raul Parra^ Yes. Enrollment, we expect enrollment still end at December 2022, which is what it says out there.

Operator^ Thank you. I'm showing no further questions at this time. I'd like to turn the call back over to Fred Lampropoulos for any closing remarks.

Fred P. Lampropoulos^ Thank you very much. Ladies and gentlemen, thank you for joining us. I know it's a busy night. So we're not going to spend a lot of time -- take any more of your time. You've got a lot of work to do.

Listen, we're enthused about the business, as you can see. I think we are working hard to meet our goals and we're committed. I mean, we've always been committed. We put plans together. We've executed the plans. Kudos to the sales force, to our R&D group, our operations group, they are the ones that really are carrying the water. And I want to just call that out.

So thank you all for your time. We'll be available for follow-up calls which are scheduled. And again, we look forward to reporting again in the very near future. Thank you very much and good night.

Operator^ Thank you. Ladies and gentlemen, this does conclude today's conference. Thank you for participating. You may all disconnect. Have a great day.