Merit Medical Systems, Inc.(Q2 2022 Earnings)
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Corporate Speakers:

- Fred Lampropoulos; Merit Medical Systems; Founder, Chairman, CEO & President
- Brian Lloyd; Merit Medical Systems; CLO & Corporate Secretary
- Raul Parra; Meri Medical Systems; CFO & Treasurer

Participants:

- Jayson Bedford; CIMB Research; Analyst
- Larry Biegelsen; Wells Fargo; Analyst
- Steve Lichtman; Oppenheimer & Co.; Analyst
- Jim Sidoti; Sidoti & Co.; Analyst
- Mike Matson; Needham & Co.; Analyst
- William Plovanic; Canaccord; Analyst
- Joseph Downing; Piper Sandler; Analyst
- Mike Petusky; Barrington Research; Analyst

PRESENTATION

Operator^ Please standby. Welcome to the Second Quarter of Fiscal Year 2022 Earnings Conference Call for Merit Medical Systems, Inc. (Operator Instructions) Please note that this conference call is being recorded and that the recording will be available on the company's website for replay shortly.

I would now like to turn the call over to Fred Lampropoulos, Merit Medical Systems' Founder, Chairman and Chief Executive Officer. Please go ahead, sir.

Fred Lampropoulos^ Thank you, and welcome, everyone, to Merit Medical's second quarter of fiscal year 2022 earnings conference call. I'm joined today with Raul Parra, our Chief Financial Officer and Treasurer; and Brian Lloyd, our Chief Legal Officer and Corporate Secretary. Brian, would you mind taking us through the safe harbor statements, please?

Brian Lloyd^ Thank you, Fred.

I would like to remind everyone that this presentation contains forward-looking statements that receive safe harbor protection under federal securities laws. Although we believe these forward-looking statements are based upon reasonable assumptions, they are subject to unknown risks and 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 27, 2022, and should not be relied upon as representing our views as of any other date. We specifically disclaim any obligation to update such statements, except as required by applicable law. Please refer to the section entitled Cautionary Statement Regarding Forward-Looking Statements in today's presentation for important information regarding such statements. Please also refer to our most recent filings with the SEC for a discussion of factors that could cause actual results to differ from these forward-looking statements.

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

This presentation also contains certain non-GAAP financial measures. A reconciliation of non-GAAP financial measures to the most directly comparable U.S. GAAP measures is included in today's press release and presentation furnished to the SEC under Form 8-K. Please refer to the section of our presentation entitled Non-GAAP Financial Measures for important information regarding non-GAAP financial measures discussed on this call.

Readers should consider non-GAAP financial measures in addition to, not as a substitute for, financial reporting measures prepared in accordance with GAAP. Please note that these calculations may not be comparable with similarly titled measures of other companies. Both today's press release and our presentation are available on the Investors page of our website.

I will now turn the call back to Fred.

Fred Lampropoulos^ Thank you, Brian. And let me start with a brief agenda of what we will cover during our prepared remarks. I will start with an overview of better-than-expected revenue results for 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 2022 that we updated in today's press release, as well as a summary of our balance sheet and financial condition. We will then open the call for your questions.

Now, beginning with a review of our second quarter revenue performance. We reported total GAAP revenues of $295 million in the second quarter, up 5.2% year-over-year. Our total GAAP revenue growth was driven by a 3.7% growth in U.S. sales and 7.2% growth in international sales.

Our total revenue increased 7.4% year-over-year in the second quarter on an organic constant currency basis, excluding the headwind to our GAAP revenue growth related to changes in exchange rates compared to the prior year period. We delivered constant currency revenue results that exceeded the growth expectations that we discussed in our quarter 1 earnings call. Specifically, we shared our expectation for constant currency revenue growth in the range of a flat to up 2% year-over-year in Q2. The strong constant currency revenue results were driven by solid execution from our team, stronger than anticipated demand in the U.S., and more favorable than anticipated international sales trends, particularly in the EMEA and rest of world regions.

Now let me provide you with a more 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 are on a year-over-year and constant currency basis.

Second quarter total revenue was driven by 7.5% growth in sales of cardiovascular products and a 4.4% growth in sales of endoscopy products. Sales of our peripheral interventional products increased 7%, representing the largest driver of total Cardiovascular segment growth in quarter 2.

Within the PI product category, sales of our angiography products increased 18% and were the largest driver of our total PI growth year-over-year. Sales of our embolics, access and drainage products increased nearly 8% year-over-year in quarter 2 and together contributed roughly 1/2 of our total PI growth year-over-year. Notably, sales of our SCOUT Radar Localization products increased 9% year-over-year, driven by continued positive demand for this highly differentiated wireless radar-guided localization system used to assess breast surgeons in identifying tumors for removal during breast conserving surgery.

Within our cardiac intervention business, sales increased 7% in quarter 2, representing the second largest contributor to total Cardiovascular segment growth year-over-year. We had standout contributions in total CI growth in quarter 2 from sales of our intervention products, which increased 12% year-over-year, driven by sales of our Basix inflation device, continuing to deliver strong contributions to growth, increasing 14% in quarter 2 and a notable pickup in demand for our PhD hemostatic valve products.

Sales of our OEM products were all stronger than expected in quarter 2, increasing 15% year-over-year, driven by improving demand from larger customers in multiple categories, including cardiac intervention and access, fluid management, coatings and kits. We were pleased to see that sales of our CPS products posted a 5% growth in quarter 2, fueled by low double-digit growth in sales of trays.

Finally, sales in our Endoscopy segment increased 4% in quarter 2, ahead of expectations, as we saw strong demand for our Elation esophageal balloon products, which offset the expected business disruption related to issues with a third-party contract manufacturer discussed in our last earnings call.

Now turning to a brief summary of sales performance on a geographic basis. Our second quarter sales in the U.S. increased 2.6% year-over-year on a constant currency basis. Importantly, our second quarter sales results reflect improving U.S. growth trends on both a 2- and 3-year basis. Our second quarter international sales increased 13.6% year-over-year on a constant currency basis. And encouragingly, despite the challenging global macro environment in quarter 2, our international sales results reflect improving growth trends on a 2-year basis and largely consistent growth trends on a 3-year basis.

We saw contributions to our total international growth in each of our 3 primary regions around the world with EMEA sales growth representing the largest driver of total international growth in quarter 2. EMEA growth was driven by demand from customers in Western Europe, the Nordic regions and Africa and sales to customers in Russia, which was not contemplated in our quarter 2 outlook, given the ongoing conflict in that region of the world.

APAC posted mid-single digit growth in quarter 2, which was modestly softer than expected, with strong sales in Japan, Southeast Asia and Korea more than offsetting the 1% sales decline in China. Our rest of the world region posted 57% growth year-over-year in quarter 2, which was well ahead of expectations as we saw particularly strong demand from customers in Latin America and Brazil.

In summary, we're encouraged by the improving growth trends and proud of our team's strong execution, despite another quarter marked by a challenging operating environment.

Before we 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 increased 7%, 23% and 20% year-over-year, respectively, in quarter 2. Our non-GAAP gross margins increased 69 basis points year-over-year, despite continued inflationary headwinds. And our non-GAAP operating margin increased 280 basis points year-over-year to a record 19.1%. We also generated $31.5 million of free cash flow in the quarter.

We believe our financial results in the second quarter and the first half of 2022 represent further evidence that we are making progress towards our goal of enhancing Merit's long-term growth and profitability profile. We remain committed to the financial targets that we outlined in the Foundations for Growth program for the 3-year period ending December 31, 2023, which call for our constant currency organic revenue to increase at a CAGR of at least 5%, non-GAAP operating margins of at least 18% and cumulative free cash flow generated of more than $300 million.

Second, we are pleased with the progress in recent months towards our strategic initiative to expand the body of clinical evidence for our products. Specifically, 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, continues to progress. We have 40 clinical sites actively enrolling patients.

We also announced first patient enrollment in two new studies in recent months, the WRAP study and the STREAMLoc study. The WRAP study will evaluate the clinical benefits associated with the use of the WRAPSODY Cell-Impermeable Endoprosthesis in patients receiving hemodialysis that experience a narrowing, or stenosis, or blockage occlusion of blood vessels required for dialysis vascular access.

This is a prospective, multicenter, observational study of up to 500 subjects with outflow circuit stenosis, or occlusion, who are receiving hemodialysis at medical facilities throughout Europe, South America, Australia and New Zealand. Clinical outcomes of patients after the initial placement of the WRAPSODY Cell-Impermeable Endoprosthesis will be evaluated over a 2-year period in accordance with instructions associated with its CE mark.

The STREAMLoc study is a Canadian registry intended to demonstrate the utility of the SCOUT Surgical Guidance System to improve workflow and efficiency in Canadian centers diagnosing and treating breast cancer. The secondary objective of the study is to further evaluate the safety and performance of the SCOUT Surgical Guidance System when used according to the IFU in 500 consented patients with BI-RADS scores of 4c or 5. By assessing the utility of the reflector insertion at the time of biopsy, this study is designed to measure the impact on patient visits to the breast center for invasive procedures between biopsy and surgery and quantify this value to the Canadian public health care system.

Now with respect to our efforts to expand clinician awareness of the clinical efficacy of our products, we continue to work with KOLs to identify opportunities to feature our products in leading publications and look forward to Dr. Katerina Malagari's abstract on the European mCRC registry study, which was completed in December 2021. The European mCRC study evaluated the use and value of transarterial chemoembolization of metastatic colorectal cancer to the liver with Merit's HepaSphere Microspheres loaded with irinotecan . Dr. Malagari's abstract was accepted for the CIRSE meeting that will be in Barcelona in September.

Our marketing and medical affairs team were excited to host the inaugural [Wassat] Summit meeting here in South Jordan this week. And I will just say, it is a wonderful meeting to meet with these KOLs. This is a multiday meeting offered a valuable opportunity to engage with them from around the world on a variety of topics, including an overview of our endovascular intervention and embolic platforms, new technologies, our WAVE and WRAP studies and GAE planning.

Finally, I wanted to highlight another area where our team has been executing well towards one of our key strategic initiatives, specifically the development, clearance and commercialization of new products. During the first half of 2022, we have highlighted our progress in these areas with four notable press releases. We received breakthrough device designation for Embosphere Microspheres in the use in genicular artery embolization for symptomatic knee osteoarthritis.

We received clearance for the SCOUT Bx Delivery System, a notable addition to the Merit oncology, breast and soft tissue localization portfolio. This system addresses roughly 40% of breast biopsies performed under stereotactic or MRI guidance and the related need for an additional visit for reflector replacement prior to surgery. The SCOUT Bx is compatible with most commonly used stereotactic and MRI-guided breast biopsy devices on the market, allowing the patient to avoid an additional office visit and procedure.

We also announced the launch of our new SCOUT Mini Reflector. The SCOUT Mini Reflector is designed for use in soft tissue such as breast and lymph nodes and measures 8 millimeters in length, 33% shorter than the standard SCOUT Reflector, offering more utility in difficult-to-localize areas. The SCOUT Mini Reflector offers enhanced directionality to achieve more precise pinpointing affected tissues within plus or minus 1 millimeter of accuracy, consistent with Merit's standard SCOUT reflectors.

The SCOUT Mini Reflector supports multiple treatment needs, including placement in breast tissue and lymph nodes, and can be used pre or post neo-adjunctive chemotherapy at the time of biopsy and for bracketing. The SCOUT indication for use also supports placement in other soft tissue malignancies, broadening the use of SCOUT technology outside the traditional use for breast cancer treatment.

And finally -- I keep saying finally -- we announced the launch of the ReSolve pneumothorax tray. The ReSolve pneumothorax tray is the latest addition of Merit's vascular peripheral drainage offering of a portfolio of interventional catheters, stent systems, drainage systems, bottles, procedure trays, sets and complementary procedures. The new ReSolve pneumothorax tray contains all products needed to perform a thoracostomy, a minimally invasive technique that allows patients to avoid an open surgical procedure to drain fluids or air from the chest. Each tray component is placed in order of use, supporting procedural efficiency and ease of use.

Now I'm proud of the team's continued commitment to strong execution in the areas of development, clearance and commercialization of new products. Now with that said, and this will be my last, finally, let me turn the call over to Raul who will take you through the detailed review of our second quarter financial results and our 2022 financial guidance, which we updated in today's press release. Raul?

Raul Parra^ Thank you, Fred. Given Fred's detailed discussion of our revenue results, I will begin with a review of our financial performance across the rest of the P&L. For the avoidance of doubt, unless otherwise noted, my commentary will focus on the company's non-GAAP results during the second quarter of fiscal year 2022. We have included reconciliations from our GAAP reported results to the related non-GAAP items in our press release and presentation available on our website.

Gross profit increased approximately 7% year-over-year in the second quarter. Our gross margin for the second quarter was 49.3% compared to 48.7% in the prior year period. The 69 basis point increase in gross margins year-over-year was primarily due to changes in product mix and lower obsolescence expense, offset partially by unfavorable manufacturing variances primarily related to purchase price variances and higher freight costs compared to the prior year period.

As expected, our second quarter results reflect the inflationary headwinds we are seeing in logistics, labor and increasingly in raw materials. Specifically, while our prior guidance assumed higher raw material costs compared to the second quarter of 2021, our second quarter results included an incremental headwind to our non-GAAP gross margins of approximately 50 basis points from higher than expected raw material expenses.

Second quarter operating expenses decreased 2% compared to the second quarter of 2021. The year-over-year decrease in operating expenses was driven by a 1% decrease in SG&A expense and a 5% decrease in R&D expense compared to the prior year period. Our operating expense performance in Q2 was better than expected and reflects continued prudent expense management as well as modest delays in hiring expenditures, given the ongoing challenges in the labor market.

Total operating income in the second quarter increased $10.7 million, or 23% year-over-year, to $56.4 million. Our operating margin for Q2 was 19.1% compared to 16.3% in the prior year period. The year-over-year change in operating margin was primarily driven by the 69 basis point increase in our non-GAAP gross margin and a 210 basis point reduction in our non-GAAP operating expense margin compared to the prior year period.

Second quarter other expense net was $1.1 million compared to $1.9 million last year. The change in other expense net that was primarily related to decreased interest expense as a result of lower average debt balance, despite a higher effective interest rate.

Second quarter net income was $42.3 million, or $0.73 per share, compared to $35.3 million, or $0.62 per share in the prior year period. We are very pleased with our profitability performance in the second quarter where we reported year-over-year growth in non-GAAP net income and diluted earnings per share of 20% and 19%, respectively, despite the incremental pressure on our gross margin and a higher than expected tax rate in the period.

Turning to a brief review of our financial results over the first half of 2022. Total revenue for the 6 months ended June 30 was $570.4 million, up $41.2 million year-over-year or 9% growth on a constant currency basis.

Gross profit increased 7% year-over-year to approximately $277 million, representing 48.6% of sales in the first half of 2022 compared to 48.9% of sales in the prior year period, a 36 basis point decrease year-over-year.

Operating profit increased 14% year-over-year to $96.6 million, representing 16.9% of sales in the first half of 2022 compared to 16% of sales in the prior year period, a 95 basis point increase year-over-year.

Net income increased 12% year-over-year to $72.7 million, or $1.26 per share, compared to $65.2 million, or $1.14 per share, in the prior year period.

Turning to a review of our balance sheet and financial condition. As of June 30, 2022, we had cash, cash equivalents and restricted cash of $65.2 million, long-term debt obligations of approximately $246 million and available borrowing capacity of approximately $481 million. This compares to cash on hand of $67.8 million, long-term debt obligations of approximately $243 million and available borrowing capacity of approximately $490 million as of December 31, 2021.

Our net leverage ratio as of June 30 was 0.8x on an adjusted basis.

With respect to our cash flow generation in the second quarter, our strong profitability performance in the second quarter of 2022, combined with strategic working capital investments, resulted in strong free cash flow generation of $31.5 million in the second quarter. As expected, our use of cash for working capital increased compared to the prior year period. In recent quarters, we have discussed our strategy to proactively invest in our inventory balances to build the requisite safety stock and ensure high customer service levels.

This strategy represented roughly 1/2 of our total working capital use of cash in the second quarter. We generated $34 million of free cash flow during the 6 months ended June 30, 2022. We continue to expect strong free cash flow generation this year and remain on track to deliver our goal of generating at least $75 million of free cash flow in 2022. Of note, this free cash flow target assumes planned investments related to the Foundations for Growth program that are expected to drive our CapEx investments in the range of $55 million to $60 million in 2022.

Turning to a review of our fiscal year 2022 financial guidance, which we updated in today's press release. For the 12 months ended December 31, 2022, we now expect GAAP net revenue growth of approximately 5% to 6% year-over-year.

This GAAP net revenue range now assumes a headwind from the changes in foreign currency exchange rates in the range of approximately $18.6 million, representing a headwind of approximately 170 basis points to our forecasted GAAP growth rate this year. This FX impact reflects an incremental headwind of $15 million to $15.6 million as compared to our prior 2022 guidance had assumed. Note, roughly 1/3 of this incremental FX headwind was realized in Q2, with the balance of the increase expected to impact our GAAP revenue results in the second half of 2022.

The GAAP net revenue guidance range now assumes net revenue from growth of approximately 5% to 6% in the Cardiovascular segment and net revenue in our Endoscopy segment in the range of a 5% decline to an 8% increase year-over-year.

With respect to profitability guidance for 2022, we now expect GAAP net income in the range of approximately $62.4 million to $68.3 million, or $1.08 to $1.18 per diluted share. Non-GAAP net income in the range of approximately $139.6 million to $145.5 million, or $2.42 to $2.52 per diluted share.

For modeling purposes, our fiscal year 2022 financial guidance now assumes non-GAAP gross margins in the range of approximately 49% to 49.15% compared to a range of 50.1% to 50.6% previously. The revised gross margin expectations reflect inflationary pressures in the areas of raw materials and in freight and logistics. While we are pleased with the continued progress we are seeing as a result of our FfG initiatives and in the area of pricing, we have seen a material increase in raw material costs in recent months, and these cost increases were not contemplated in our prior guidance assumptions.

With respect to freight and logistics costs, recall that our prior guidance did include the assumptions that we would see freight and logistics headwinds dissipate in the second half of 2022, given easier comparisons based on the uptick in these expenses over the second half of 2021. Our updated guidance now assumes that we do not realize the benefits of these easing comparisons as we now assume a higher mix of air freight versus shipping freight over the second half of 2022. Importantly, this is a direct result of our strategic decision to respond to the stronger than expected demand for our products around the world.

Returning to a review of other key modeling assumptions supporting our updated financial guidance for 2022. We expect non-GAAP operating margins in the range of approximately 16.6% to 17.1% compared to a range of 16.6% to 17.3% previously. GAAP and non-GAAP other expense of approximately $6.5 million and $4.8 million, respectively. Diluted shares outstanding of approximately 57.7 million compared to approximately 58 million previously. And a full year 2022 tax rate of approximately 24% versus a range of 22% to 23% previously.

Lastly, given the continued uncertainty in the global macro environment, we would like to provide additional transparency related to our growth and profitability expectations for the third quarter of 2022. Specifically, we expect our total revenue to increase in the range of approximately 1% to 4% increase year-over-year on a GAAP basis and up approximately 4% to 6% year-over-year on a constant currency basis.

Our growth expectations for the third quarter of 2022 reflects 2 items of note. First, the midpoint of our third quarter growth expectations assume constant currency sales growth of approximately 3% year-over-year in the U.S. and approximately 7% year-over-year in OUS markets. Second, our third quarter guidance range assumes a notably wide range of sales of endoscopy devices, specifically a decline of 37% on the low end to an increase of approximately 12% on the high end as we continue to manage to business disruption related to issues with a third-party contract manufacturer. We view this disruption as transitory and expect to return to more normalized growth trends in the fourth quarter.

With respect to our profitability expectations for the third quarter, we expect to see flattish non-GAAP gross margin trends compared to last year and modest declines on a quarter-over-quarter basis, driven by previously mentioned inflationary pressures we are seeing in raw materials and incremental freight and logistics costs compared to the prior year. We also expect to see non-GAAP operating margin trends remain flattish to modest improvements compared to last year. These margin expectations, combined with a notable increase in our non-GAAP tax rate compared to last year, are expected to drive a change in non-GAAP net income and EPS in the range of down 4% to 5% year-over-year on the low end to up 3% to 5% year-over-year on the high end.

With that, I'll turn the call back to Fred.

Fred Lampropoulos^ Raul, thank you. And in closing, despite the challenging operating environment in quarter 2, I'm very, very proud that we were able to deliver revenue and profitability results that exceeded expectations. We're confident in our 2022 guidance, which now calls for total revenue growth on a constant currency basis of 5% to 6% year-over-year. We continue to expect to see progressive improvement in our operating environment, specifically access to patients and elective procedures as we move through 2022. We also continue to expect to report improving non-GAAP gross and operating margins and strong free cash flow in 2022, driven by strong execution contributions from our multiyear strategic initiatives related to the Foundations of Growth program.

Our team continues to execute well and remains focused on our strategic initiatives, while standing ready to adapt quickly to changes in the markets. We would like to thank all of our team members. You really can't do any of this without the entire team that made -- globally, by the way -- that made our performance over the first half of 2022 possible.

And with that said, I will turn the time back to our operator, and we'll now open up the line for questions.

QUESTIONS AND ANSWERS

Operator^ (Operator Instructions) And our first question comes from the line of Jayson Bedford of Raymond James.

Jayson Bedford^ So I guess first, 2Q was quite strong. I guess on the revenue side, were there any one-timers or notable orders that elevated the revenue level in 2Q?

Fred Lampropoulos^ No.

Raul Parra^ No.

Fred Lampropoulos^ No, I think we're business as usual, but it was strong, but nothing unusual.

Raul Parra^ Yes. Strong execution from the team. I think we saw stronger than anticipated demand in the U.S., and then just more favorable trends in EMEA and rest of the world.

Jayson Bedford^ Okay. And then -- so as I look at the implied third quarter guidance, it looks like sales will be down 7%, 8% sequentially, which seems a little heavier than historical. And so I guess what I'm asking is, what do you see here in the third quarter that may be a bit different than what you saw in 2Q?

Raul Parra^ Yes. I think the biggest thing that we're seeing there is really related to our endoscopy devices. So as we mentioned on the opening script, we're down on the low end, 37%, up to 12% on the high end. Just -- it really has to do with the disruption that we've seen from a third-party contract manufacturer.

We're on track to achieve what we think. But just in case something goes south, it is a dynamic environment. And I think for our perspective, we're just making sure we have a little bit of room there in case we don't meet our objectives. But we're confident in our updated 2022 guidance, which implies total revenue growth of 3% to 6% in the second half of 2022, which is really unchanged versus the prior guidance assumptions.

Jayson Bedford^ Okay. And then maybe -- I know I'm squeezing more than one question in here, but they're all kind of related. Just similar question on margin in the third quarter. I realize there's lower revenue sequentially, but it's also a big step down in operating margin. Is there a timing of spend that occurred that didn't occur in 2Q that will occur in 3Q? Just kind of curious as to the higher level of OpEx implied in the guide.

Raul Parra^ Yes. Most of it, quite frankly, is related to the modest decline in, I guess -- or flattish non-GAAP gross margin. With the inflationary pressures we're seeing in raw materials plus the incremental freight and logistics costs compared to the prior year, that's having an impact on the operating margin. We do expect operating expenses to incrementally go up from where they're at right now just because of the way the spend happens. But that's really what's driving that, Jayson.

Jayson Bedford^ Okay. I'll get back in queue.

Operator^ Our next question comes from the line of Larry Biegelsen of Wells Fargo.

Larry Biegelsen^ And Fred and Raul, congratulations on a nice quarter. Fred, there were 2 headwinds that don't seem to have impacted you much in the second quarter: the contrast shortage in the -- primarily in the U.S. and the lockdowns in China. How much better do you think you would have done if not for those two issues?

Fred Lampropoulos^ Right. Larry, I don't know. I think you're fair to say that we didn't see a lot of impact from the contrast. I thought we might, but we just didn't. It wasn't there. But it's hard to tell. China was always very hard to read. So it's a really difficult question, and I'd have to spend a lot of research on it to get to it. So I'm just going to leave it with a general comment, I don't know.

Larry Biegelsen^ Fair enough. And I guess given, Fred, the inflationary headwinds, what gives you the confidence in the Foundations for Growth targets for 2023? You'll come in this year -- or Raul, you'll come in this year, the midpoint of your guidance is for operating margin, 16.8% or so. What gives you the confidence that you could improve margins by more than 100 basis points next year?

Raul Parra^ Yes. I think I'll start off by saying, look, we just delivered a 19.1% operating margin. So the confidence is there. And I guess I'll just reaffirm what we called out for Foundations for Growth on our November 20 call. The constant currency organic revenue CAGR of 5% at least, feeling confident there. The non-GAAP operating margin by at least 18%, again, we just delivered 19.1%.

And then cumulative free cash flow generated of at least $300 million. Free cash flow, we continue to be very strong in. Delivered $31 million of free cash flow in the quarter, $34 million for the year, and we remain on pace to deliver the $75 million. So we see the initiatives working, the Foundations for Growth initiatives, and are really excited about continuing to deliver on those.

Fred Lampropoulos^ And Larry, look, I think, as we all know, there's the big mo, momentum. It's the focus of the staff. We talk about it. It's worked. We're committed to it. Our Board is committed to it. So I think it's really the focus of the goals that we've set. And this is in spite of all the other challenges that are out there. So it's just the focus of the team. And when you get that momentum, you get that spirit amongst people, it's -- I'm pleased with this team. It really is a team effort.

But I know that everybody says that. But everybody has a team; not all of them win. I just think that the way we're approaching it as a management team, the Board, but more importantly, the staff. They're the guys that have to execute, and they've done a good job. So I'm just thrilled with our people and (technical difficulty) they put forward.

And the rewards of late, very candidly, for all of them and the shareholders and everybody else, as this effort progresses. I'm pleased with it. I'm just glad we did it. And as you know from the history, we kind of started our -- the Merit Foundation (technical difficulty) progresses. I'm pleased -- I'm just glad we did it.

And as you know from the history, we kind of started our -- the Merit Foundations for Growth program prior to that, and we had a head start, but it works. We're well into the full second year when we take that extra 6 months of the initiatives. We worked before that, and then we got more data. So again, I don't want to linger on, but I'm convinced in this team and in their ability and our focus. You get all that together, and that'll take us where we need to go.

Operator^ Our next question comes from the line of Steve Lichtman of Oppenheimer & Company.

Steve Lichtman^ Fred, just given some of the underlying momentum you just talked about, it seems like you guys are you leaning in on some of the growth initiatives. You talked a lot about some of the R&D programs tonight. Where does the M&A fit in on that in your current thinking? You've given with the momentum and also the free cash flow you also talked about, is that potentially going to see some increased activity here for you guys over the next 12 to 18 months?

Fred Lampropoulos^ Yes. Listen, in terms of that area, I think we were very disciplined when we needed to be. Things were frothy and we stayed on the sidelines. You can look at our balance sheet and see the strength that we have there. So we're working, we're looking, but it has to fit the parameters that we've set aside so as not to frustrate the efforts. We don't want to disrupt that. So as values come into place and we're seeing more opportunities, and as pricing become more realistic, then there'll be more opportunities for Merit. But we're not -- we're on the field playing. Let me just put it that way. We're not just sitting up in the stands.

Raul Parra^ Yes. I think I'll add, Steve, that given our -- and Fred mentioned it -- the strength of our balance sheet, our leverage ratio is 0.8x on an adjusted basis. We did do 2 small investments that you'll see when the 10-Q goes out. One of them was for $1.4 million, Fluidx Medical. It's a company we had invested in previously, and we ended up buying additional stock in that company. We also did a second investment. It was a $3 million initial cash outlay to acquire Restore Endosystems. So we've done a couple small things, but we're definitely looking at what other possibilities are out there.

Steve Lichtman^ Great. And then just secondly on the macro, I guess two quick things. One, are you seeing success -- you alluded to pricing. I was wondering if you could maybe put some more color around perhaps getting some price to offset inflationary headwinds. And then secondly, are you seeing a backlog build at all? Are you missing some opportunities because of supply chain? Obviously, we know the impact on the expense side, but is it -- are you seeing any impact relative to supply constraints and maybe your ability to sell it all?

Fred Lampropoulos^ Listen, one of the great blessings that Merit has and fortunate things is that we're vertically integrated. We've talked about it a lot. And so although as we've said many times in the past, we're not immune to these pressures in the marketplace, we're in a good position because of our extrusions, our molding, braiding and so on and so forth, sensors, of the things that we make ourselves. So that's part of I think the thing that helps us in terms of the supply chain. Raul, you wanted to comment?

Raul Parra^ Yes. Look, I think one of the inflationary items that maybe give you a little bit more detail on is the freight and logistics. We had anticipated moving more to ocean shipments versus air. We haven't been able to do that, quite frankly, because of the demand of our products.

And we think it's important to meet our customer needs. And so we haven't been able to shift things as fast as we had anticipated. So from kind of a macro standpoint, that is something that we can control. I think we'll get to where we need to be over time, but when you're living quarter-to-quarter, you can't -- it just doesn't sometimes work out because your --

Fred Lampropoulos^ The ship doesn't turn that fast.

Raul Parra^ Yes. Yes. So I think we're trying to meet customer demands and so haven't been able to shift as much to ocean as we wanted to. And lastly, I'll just say, look, we're really excited about our FfG initiatives and the progress we've made. Fred mentioned it earlier about the team and everybody kind of doing their part, and one of those items is pricing. And so I think we're excited about what we're doing there, but there's definitely more wood to chop. And it'll be -- it doesn't come all in one quarter, right? It takes time to get to where you need to be.

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

Jim Sidoti^ So the 20,000-foot story here, it sounds like you're able to raise your top line guidance despite the stronger dollar. So obviously, you must be seeing stronger demand or stronger growth in procedures. Is that primarily in the U.S., or is that worldwide?

Fred Lampropoulos^ Well, I think I can speak to EMEA and I can speak to the U.S. I think we're seeing more demand for the procedures. I think those are progressing. And as I've listened to other players, I think that's a fact. What's going on? Raul, you wanted to comment. You have your hand up there.

Raul Parra^ No, I was just going to say that's true, specifically on a constant currency where we're up $60 million at the midpoint. So that was a good pickup, Jim, that I think we're excited about the momentum in the business. The U.S. constant currency growth is -- went from 3% to 5% versus the 1% to 4% in the prior guide that we had. So again, I think we're seeing the momentum in the business and tried to reflect that in the updated guidance.

Fred Lampropoulos^ And that was the biggest portion of our revenues.

Raul Parra^ Yes.

Fred Lampropoulos^ Gives us a big advantage there.

Raul Parra^ Yes.

Jim Sidoti^ And Raul, I think you mentioned in your part of the script that R&D expenses were down year-over-year. Is that just the timing of some of these trials?

Raul Parra^ Well, it's a little bit of the trials. It's also some of the hiring. The current market, it just takes longer to hire people, quite frankly, finding the right candidates. So that's been part of the slower spend that was anticipated, on top of people kind of managing their expenses better just given the environment.

Operator^ Our next question come from the line of Mike Matson of Needham & Company.

Mike Matson^ I guess, let me see -- we've got currency. Didn't hear a lot of comments, and maybe I missed it, but about the currency on your margins or bottom line. Is it effectively neutral due to hedges that you have, either national or otherwise?

Raul Parra^ Yes. We're not going to quantify the impact to our operating expenses or our gross margin. So we do talk about revenue, and I think we'll leave it at that. It just gets pretty complicated, as you can imagine.

Mike Matson^ Okay. But I mean, you're not really lowering your guidance or anything like that because it's a big enough headwind to your earnings, right, so --?

Raul Parra^ That's correct. Yes. The only -- really, the only impact, Mike, to our guidance was the gross margin, which we took down 110 to 150 basis points. But that, again, the one item that -- or the two items that really hit us there were the raw materials and the freight and logistics. Raw materials is a 50 basis point incremental to what we were expecting, and it's something that's kind of out of our control. I think on the freight side of things, that's 60 to 80 basis points.

We feel pretty good about that one because we tend to be able to control that. But given the demand that we're seeing for our product, we think it's an advantage to be able to deliver product in this environment right now. And so we've opted to deliver product as opposed to changing the ratio from air to ocean.

Mike Matson^ Okay. Got it. And then I wanted to ask a product question or a pipeline question, I guess, about this genicular artery embolization for knee arthritis. Can you maybe talk about the market opportunity there and the timing of when you could launch that indication, I guess, for your Embosphere product?

Fred Lampropoulos^ So as we mentioned in our press release, we have had a KOL meeting here all week, and we're talking about this opportunity. It's early, Mike. I'm just going to be very honest with you. There's studies and experience that has to be done. But it's with an existing product. That's the key to it. So we're working with our KOLs and other groups in terms of structures of things that they want to do in their facilities, whether it be in Canada or whatever as they go through this. So it's too early to comment on exactly the opportunity and the filing.

We already have the product. I think the evidence and the support has to come into place. And then I think we can -- but that's going to be a while. It would be premature. There are other people, as you know, working on this and talking about it. I don't know if they're throwing numbers around. We're going to -- we're not going to do that at this point, other than to say that we're actively working with people, physicians, rheumatologists and others to really take and understand the opportunity here.

There's -- and we will in the future take a look at that marketplace and how many people have osteoarthritis, we'll do some of those things, but that's not for today. So it's too early, but we're working on it, because like UFP or PAE, this is kind of that next horizon for our Embosphere, our microcatheters and our access products. So that's the best way I can answer it for now.

Mike Matson^ I understand. Got it.

Operator^ Our next question comes from the line of William Plovanic of Canaccord Genuity.

William Plovanic^ I just have one is, obviously interest rates are moving up, and doing a little back the napkin math, you're probably looking at an extra $0.5 million to $1 million a quarter. Does that help color your decision on M&A and kind of -- or do you just accelerate the paydown of the debt? Kind of how are you thinking about that and offsetting that kind of increased cost?

Fred Lampropoulos^ Yes, listen, interest cost and all those issues and cost of capital all have to be calculated in the formula when you look at stuff. So I mean that -- those are the realities and trying to handicap where those rates are going to go. So that's part of it. But in terms, I think, on your numbers, Raul, do you want to comment on that?

Raul Parra^ No, I was just going to say the same thing. Look, if you find the right asset, and the cost of capital is going to be obviously factored into that, so it should be kind of taken care of from that perspective. But we did factor in some rate increases in our debt calculation. We're obviously paying things down. And so we'll continue to do so to the extent we generate free cash flow. So I think things are on pace for what we anticipated. No changes there.

Operator^ Our next question comes from the line of Joseph Downing of Piper Sandler.

Joseph Downing^ Congrats on the solid quarter. I'm on air for Jason Bednar tonight. Just digging a little deeper into the China point. As you mentioned, it's a tough market to get a read on, but can you just describe in a little more detail what you're seeing on the ground in that market? How are procedure volumes recovering if lockdowns are lifted? And what are you seeing thus far on the tendering side, whether it be good or bad?

Fred Lampropoulos^ Yes. You know, it's interesting you asked the question. Just this morning, I read where they were talking about -- they were locking down Wuhan again and another 11 million people. Stay tuned. We'll see what happens tonight and tomorrow. It changes every day. I think all in all, I'll just say that everything as it pertains to China is contemplated in our guidance to the best of our ability to do so. So I'll answer the question that way because it is just there are a lot of factors and it changes daily. But to the best of our ability from on the ground, what's going on here, it's in our guidance and baked in.

Joseph Downing^ Okay. And then anything else...

Fred Lampropoulos^ Well, you mean on China or -- are you still on there?

Raul Parra^ I think he dropped.

Fred Lampropoulos^ Did he drop?

Raul Parra^ Yes.

Fred Lampropoulos^ Okay. I think we lost him. He might come back here.

Raul Parra^ We'll take Mike.

Fred Lampropoulos^ Yes, let's go ahead and take Mike.

Operator^ Our next question comes from Michael Petusky.

Michael Petusky^ I may have missed this, Raul. I'm trying to understand this endoscopy guidance. And I understand you guys were sort of looking for some impact in Q2. It didn't come. And now it appears like you're thinking that maybe it can come in Q3, but maybe it won't. And I guess my question is, is it absolutely sort of a downdraft inevitable, it's just timing? Or is it possible you avoid this issue all together?

Raul Parra^ So it did happen, Mike. I think what masked it was that we had increased demand on the balloons, on the Elation balloons at endoscopy. So we're neck deep in it. We're dealing with it. Like I said, we're on track to do better than that low end. But it is a very sensitive matter. We've got to go through qualifications, and there's a lot of -- the macro environment just right now doesn't -- we're trying to cover for the macro environment, quite frankly.

Fred Lampropoulos^ But Mike, it's not a mystery. It's not a, we don't have an idea. It's actively being worked and followed, and it'll come into play in the end of this quarter. The question is, what happens in this next quarter, the third? Does that roll into the early fourth or whatever? But in the meantime, as Raul pointed out, the Elation balloons were sold at record levels.

Michael Petusky^ Did you take the full hit that you expected to take in terms of that issue in the quarter, in Q2?

Raul Parra^ Not the full -- not the full hit that we anticipated. But for the most part, I think we probably ended up at 75%, 70% of the hit. I'd have to pull the numbers, Mike.

Fred Lampropoulos^ I will say the vendor, which is a U.S. company and someone we've worked with in the past, is one of the best vendors. These guys are solid --

Raul Parra^ Optimistic. Hopefully you're an optimist. But nevertheless, I think we've tried to cover for -- we didn't want to give anybody a surprise, even though things are on track.

Michael Petusky^ Sure. Okay. And I guess this one's mostly for Fred. Fred, you work the phones all the time talking to docs, talking to your sales guys, talking to hospitals. Any concerns as you sort of look out at sort of this new variant that seems to be contagious but doesn't seem to be nearly as deadly, do you have any concerns around either hospital staffing, procedure volumes? Anything you've picked up in terms of your conversations?

Fred Lampropoulos^ Yes. I think everybody is sick and tired of all of it. I think the variants out there, it's not going away. But listen, there's a different attitude at the hospital level. As soon as I get done with this, and I know we have some calls, I'm heading over to the hospital to do exactly what you just said. But I can meet with -- recently, I met with four doctors in a day in Southern California and up in Northern.

So the ability for us to meet, their attitudes, they're busy. They're glad to be back at full steam. It's quite a -- it's almost like it didn't happen, but it's still there. It's kind of interesting. It's like you had a broken arm, but it's fixed. Mike, so I think the general attitude out there, we've had enough of this, we've done the things we needed to do, and let's get on with it.

Raul Parra^ And the U.S. business continues to do --

Fred Lampropoulos^ Yes. It's doing better. So we're not having a problem getting into hospitals, and it's not 25% like it was at one time. We can get in any place we want to.

Michael Petusky^ Okay. Let me sneak one last one in. There's been a lot of talk about pricing power. Not as much about manufacturing efficiencies. Obviously, you guys did some heavy lifting in that area in the last couple of years and heading into COVID and just early into COVID. As you look out over this business the next few years, are there opportunities sort of on the manufacturing side where you guys can just get a little bit better and be a little bit more streamlined? Or do you think you've sort of captured most of what you can possibly capture there?

Fred Lampropoulos^ Listen, Foundations for Growth was a plan that was 3 years. Some of the benefits are in place and there's more to come, but it's a 3-year program. We're halfway through it. So I'll answer it by saying there's the other half to come, and that's the best way to do it. But again, if there were one message I could get across to everybody on this call today is we're committed to it.

It's not something that's just passing and we forgot about it. It's what we live. It's what we're compensated on. And it's what every employee in this company is incented by in their bonus program. So it's a big deal, and it's the commitment and the enthusiasm around it because they got paid for their effort. We all did. And that's a nice feeling. So Foundations for Growth, it's a key for us. Raul?

Raul Parra^ Yes. Mike, I think just to repeat what Fred said, Foundations for Growth contemplates not only product line consolidations but site consolidations and all sorts of efficiencies from a manufacturing standpoint, on top of pricing. So it's multiple levers that we're attacking to try and streamline and make COGS better, quite frankly.

Michael Petusky^ Guys, thank you so much. Nice job.

Operator^ And as there are no further questions in queue, are there any remarks from management?

Fred Lampropoulos^ Well, let's just close by thanking everybody. It's a busy day. We've taken the full hour. Again, please understand our commitment. We're pleased with the quarter. We hope you are. We'll look forward -- if you have any comments, we'll look forward. We're going to do some clarifications in our one-on-ones now. So thank you again for attending, and we'll look forward to reporting again to you in the very near future. Best wishes from Salt Lake City and good night.

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