CORPORATE PARTICIPANTS

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

CONFERENCE CALL PARTICIPANTS

James Philip Sidoti  Sidoti & Company, LLC - Research Analyst
Jayson Tyler Bedford  Raymond James & Associates, Inc., Research Division - Senior Medical Supplies and Devices Analyst
Matthew Oliver O'Brien  Piper Sandler & Co., Research Division - MD & Senior Research Analyst
Michael Stephen Matson  Needham & Company, LLC, Research Division - Senior Analyst
Shagun Singh Chadha  Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst
Steven Michael Lichtman  Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst

PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and welcome to the First Quarter 2021 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 P. Lampropoulos  Merit Medical Systems, Inc. - Chairman, CEO & President

Thank you, and welcome, everyone, to Merit Medical Systems First 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 mind taking us through the safe harbor provision, please?

Brian G. Lloyd  Merit Medical Systems, Inc. - Chief Legal Officer & Corporate Secretary

Thank you, Fred. Before we get started, 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, including the unpredictable effects of the ongoing COVID-19 pandemic 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 April 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 the presentation furnished to the SEC under Form 8-K. Please refer to the sections of our presentation entitled non-GAAP financial measures and notes to 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 page of our website.
I will now turn the call back to Fred.

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Thank you, Brian. Let me start with a brief agenda of what we will cover during our prepared remarks today. I will start with an overview of our revenue performance in the first quarter, including the business trends we experienced during the in the areas of our business that performed well despite the challenging operating environment. I will then provide an update on our operating progress and highlights during the first 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 we will open the call up for questions.

Now beginning with a review of our first quarter revenue performance. We reported total GAAP revenue of $249 million in quarter 1 up 2.2% year-over-year. Our total GAAP revenue growth was driven primarily by a 4.9% growth in international sales and a 0.2% growth in U.S. sales. Our U.S. sales growth was driven by low single-digit increases in sales of both our peripheral intervention and cardiac invention products, which offset low single-digit declines in sales of our CPS and OEM products.

Our International sales increased 4.9% year-over-year in the first quarter, all of which was driven by the benefit of changes in exchange rates compared to the prior year. Sales to international customers declined 0.5% year-over-year on a constant currency basis. Excluding FX benefits, our international sales results were driven by high single-digit growth in sales of our peripheral intervention products and mid-single-digit growth on sales of our OEM products, which offset declines in sales of our CPS and cardiac intervention products compared to the year ago period.

Total first quarter revenue increased 0.6% year-over-year on a constant currency basis, reflecting the benefit of our GAAP revenue results as a result of changes in exchange rates compared to the prior year period. Our constant currency growth results were notably better than the expectations we provided on our quarter 4 call, which called for Q1 constant currency revenue to decline 6% year-over-year. Our constant currency growth performance was driven by a 0.7% growth in sales of our cardiovascular products, which partially offset a 1.2% decrease in sales of our endoscopy products compared to the prior year. Importantly, while our constant currency sales increase was only modest, we are pleased to return to year-over-year growth for the first time since the first quarter of 2020.

Now while we were pleased to deliver positive constant currency growth in the quarter, we believe the intra-quarter trends we experienced in quarter 1 reflect 2 important dynamics at play thus far in 2021. First of all, after a slow start to the quarter, we saw modest improvement growth trends in each month but our total sales were still down mid-single digits over the first 2 months of the quarter. We then experienced a significant acceleration in growth trends during the month of March, which ultimately represented the largest March into the company’s history. Now despite the overall improvement in trends during the quarter, 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.

In terms of our first quarter constant currency sales performance by major geographic region, recall that more than 90% of our international sales come from APAC and EMEA regions, which represented 47% and 46% of international sales in the fourth -- first quarter, respectively. Sales growth in APAC increased in the mid-teens on a constant currency basis, fueled by strong demand from customers in China, aided in part by an easier growth comparison in the prior year period, which was impacted by the early onset of COVID in the region. We would also like to highlight that reported sales growth in the APAC region include the sales related to our ITI procedure pack business in Australia, which we closed in December of 2020. Excluding those sales from this divested business, our APAC constant currency sales was approximately 20% in quarter 1, which is quite encouraging as we monitor the pace of recovery and returning to normalized growth in the region.

With respect to our EMEA business in the first quarter, sales declined in the low double digits on a constant currency basis as the region continues to see material impacts from COVID-19 and is still in the early stages of recovery. Restrictions and lockdowns are changing constantly across the region, causing limitations to sales contact and lower demand for elective procedures. The weak demand trends in emerging markets during quarter 4 continued during the first quarter with challenging our conditions in Saudi Arabia, Iraq, Iran, Egypt, 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.

Now despite the continued challenges in the EMEA region in the first quarter, I would like to really call out 2 bright spots. The first is that the demand for critical care products remained strong throughout Europe in the first quarter. And the second is that we did see a notable improvement in sales trends on a GAAP basis in each month of the quarter from down high teens in January to flat in February and posted low single-digit growth year-over-year in March.

Turning to the U.S. Simply stated, the recovery from the pandemic in the U.S. continues to be choppy. Sales increased 0.2% year-over-year driven by low single-digit growth in sales of our PI and CI products, which offset declines in sales of our CPS and OEM products. We reported a low single-digit decline in U.S. sales of CPS products in quarter 1, but these results were aided by roughly $900,000 for our Cultura swabs, which, by way of reminder, are not expected to contribute materially to our CPS sales results over the balance of 2021. Excluding sales of Cultura, our U.S. CPS business declined in the mid-single digits year-over-year in quarter 1.

Our OEM business continues to be slower to recover as a result of inventory management as our customers adjust to products demand in response to COVID-19. In quarter 1, sales to U.S. OEM customers decreased in the low single digits year-over-year.

Finally, Our U.S. direct business posted 3% growth in quarter 1, fueled by strong demand for our radar localization products and for sales of our Medallion products, which benefited from higher demand as a result of COVID vaccination programs. We also saw more willingness and receptivity from hospital customers to evaluate new product offerings during the first quarter, which we believe is reflective of continued improvement in the underlying operating environment in the U.S. during the period.

So we delivered financial results that far exceeded our expectations in quarter 1. But I’m sure you guys are thinking, what does this mean for the full year. Well, if you're hearing a measure of cautious optimism in our tone, You're not just imagining it. Raul and I are very proud of the organization’s strong execution in the first quarter, which resulted in revenue results that were materially ahead of the guidance expectations provided on our fourth quarter call at the end of February. Raul will review the details of our full guidance, which we reaffirmed our constant currency growth guidance in our press release this afternoon in a few minutes.

But I will remind you of what we outlined during our guidance discussion on the fourth quarter call, where we indicated that, "While we expect to see measured improvement in our operating environment as we move through 2021, fueled by the wider availability of vaccines and an increasing percentage of vaccinated Americans, our guidance assumes no material improvement in the operating environment, access to patients and elective procedures over the first half of 2021."

The guidance we outlined on our fourth quarter call assumed progressive improvement in these headwinds and a return to normalized year-over-year growth in the third quarter of 2021. These remain our expectations and key assumptions supporting our guidance for 2021, which we reaffirmed in our press release this afternoon. 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 time over to Raul, I wanted to comment on a few other noteworthy items in the quarter. First, we leveraged low-digit revenue growth to drive impressive growth in our non-GAAP operating income and non-GAAP income, which increased 26% and 41%, respectively, compared to the prior year period. We also continue to make progress to our goals -- towards our goals of enhancing Merit’s long-term growth and profitability profile. And there’s no better evidence of that than our early success in this area with the $29 million, I’ll say, again, $29 million of free cash flow we generated in the first quarter.

Second, on March 11, we announced that Dr. Jeffrey Hager at the RAC Surgery Center, LLC in Raleigh, North Carolina successfully enrolled the first 2 patients in 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. Now the study has been designed to evaluate the safety and efficacy that the WRAPSODY Endovascular Stent Graft for the treatment of venous outflow circuit stenosis or occlusion in hemodialysis patients represents an important step towards our goal of establishing the WRAPSODY as the standard for care for more than 2 million patients suffering from kidney disease around the world. The WAVE study follows successful completion of the WRAPSODY first -- a first-in-man study feasibility study, which included 46 patients in Europe.
We’re pleased to announce that the 6-month data from this study was the subject of a podium presentation at the recent Charing Cross meeting. We also look forward to having the 12-month data from this study presented at the Cardiovascular and Interventional Radiological Society of Europe, known as SIRSE at their Annual Meeting in October of 2021.

And finally, I wanted to highlight 2 important additions to our executive teams in the recent months. In late December, Michael Voigt, joined as Chief Human Resources Officer. Michael brings more than 20 years of experience in HR at various positions, most recently as the Chief Human Resources Officer at [Mavenir] from 2017 to 2020 and prior to that, he worked at Galderma Skin Health, Lexicon Pharmaceuticals and Verizon.

In March, Rob Fredericks joined as Chief Strategy and Innovation Officer. Rob is a seasoned industry executive most recently serving as the Vice President and General Manager of the Vascular Access Devices business at Becton, Dickinson and at the CR Bard operation dating back to 2015. He also worked at Medtronic from 2003 to 2015 in various positions, including Vice President of Global Marketing, R&D and Strategy, Vice President of Finance and Senior Marketing Director. Now we’re very excited to add these sharp and talented individuals to our executive team as part of our effort to continue to enhance the company’s foundation, which we expect to support many years of strong growth, profitability and cash flow generation going forward.

Now with that said, I will go ahead and turn the time over to Raul who will take you through a detailed review of our first quarter financial results and our 2021 financial guidance, which we reaffirmed this afternoon in our press release. Raul?

Raul Parra  
Merit Medical Systems, Inc. - CFO & Treasurer

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 first quarter of 2021. We have included full reconciliations from our GAAP reported results to the related non-GAAP item in our press release this afternoon.

Gross profit increased approximately 4% year-over-year in the first quarter. Our gross margin was 49.2% compared to 48.5% in the prior year period. The approximate 80 basis point increase in gross margin year-over-year was primarily due to changes in product mix as well as decreased obsolescence expense and improvement in manufacturing efficiencies on higher volume. The first quarter operating expenses decreased 4% year-over-year. The year-over-year decline in operating expense was driven by a 6% decrease in SG&A expense offset partially by a 9% increase in R&D expense compared to the prior year period. The reduction in SG&A expenses were a result of lower compensation expenses as a result of reduced head count from cost-cutting initiatives in 2020 and lower discretionary spending as a result of reduced travel, training and shows and conventions during the COVID-19 pandemic. The increase in R&D expenses was largely due to increased outside expenses for certain R&D projects and particularly related to WRAPSODY, and increased compensation expense related to acquisitions of KA Medical and other new projects.

Note, while we were pleased with our operating expense performance in the first quarter, our expenses did benefit from some modest timing-related delay in selling and marketing spend and our investment in our WRAPSODY clinical study for a partial period in Q1. Both of these dynamics will result in a sequential uptick in operating expenses in the second quarter.

Total operating income increased $7.9 million or 26% year-over-year to $38.9 million. Our operating margin was 15.6% compared to 12.7% in the prior year period, an increase of 290 basis points year-over-year. First quarter other expense net was $1.5 million compared to $3.4 million last year. The change in other expense net driven by decreased -- was driven by decreased interest expense as a result of lower effective interest rate and lower average debt balance.

First quarter net income was $29.9 million or $0.52 per share compared to $21.1 million or $0.38 per share in the prior year period. We are very pleased with our profitability performance in the first quarter, where we reported growth in net income and diluted earnings per share of 41% and 39% year-over-year, respectively, in a quarter where our sales were up less than 1% on a constant currency basis compared to the prior year period.
Turning to a review of our balance sheet and financial condition as of March 31, 2021. Our strong profitability performance in the first quarter, combined with strong working capital efficiency, resulted in strong operating cash flow generation in the first quarter of $35.2 million, an increase of 22% year-over-year. Our efforts to control our capital expenditures resulted in a year-over-year decrease in CapEx of roughly 56%, which fueled very strong free cash flow generation of more than $29 million in the first quarter. Our Q1 free cash flow generation is the 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.

As of March 31, 2021, we had cash on hand of approximately $58.5 million, long-term debt obligations of approximately $321 million and $418 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 March 31 was 1.4x on an adjusted basis.

Turning to a review of our fiscal year 2021 financial guidance, which we updated in this afternoon's earnings release. For the 12 months ended December 31, 2021, the company expects GAAP net revenue in the range of $994 million and $1.014 billion, representing an increase of approximately 3.1% to 5.2% year-over-year as compared to net revenue of $963.9 million for the 12 months ended December 31, 2020. The net revenue range now assumes a benefit from the changes in foreign currency exchange rates in the range of approximately $8 million to $8.5 million, representing a tailwind of approximately 90 basis points to our GAAP growth rate this year compared to the prior guidance range, which assumes a benefit in the range of approximately $4 million to $4.5 million or 40 basis points to our GAAP growth rate in 2021.

The fiscal year 2021 GAAP revenue guidance range assumes net revenue from the cardiovascular segment of between $963 million and $982 million, representing an increase of approximately 3.1% to 5.2% year-over-year as compared to net revenue of $934.2 million for the 12 months ended December 31, 2020. The prior guidance range assumed growth of approximately 2.7% to 4.8% year-over-year. Net revenue from the Endoscopy segment of between $30.8 million and $31.9 million representing an increase of approximately 4% to 7% year-over-year as compared to net revenue of $29.7 million for the 12 months ended December 31, 2020. This net revenue range is unchanged from prior guidance expectations. GAAP net income in the range of $47.3 million to $55.9 million or $0.83 to $0.98 per share compared to GAAP net loss of $9.8 million or $0.18 per share. For the 12 months ended December 31, 2020, the GAAP net income range is unchanged from prior guidance expectations. Non-GAAP net income in the range of $104.8 million to $112.7 million or $1.84 to $1.98 per share for the 12 months ended December 31, 2020. The non-GAAP net income range is unchanged from prior guidance expectations.

For modeling purposes, our fiscal year 2021 financial guidance assumes non-GAAP gross margins in the range of approximately 48.5% to 49.8% and modest increases on a year-over-year basis in our non-GAAP operating expenses largely driven by higher selling and marketing expenses related to the increase in sales as well as phasing out of temporary salary reductions partially offset by prudent G&A expense management and approximately $8 million of other expenses largely 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 24% to 5% and approximately 56.8 million diluted shares outstanding.

Lastly, while it is not our standard guidance practice, given the significant impact of the COVID pandemic in the second quarter of 2020 and the related benefit to our Q2 ’21 year-over-year growth rate, for the avoidance of debt, we expect our total revenue in the second quarter of 2021 to increase approximately 14% to 16% year-over-year on a GAAP basis and increase approximately 11% to 13% year-over-year on a constant currency basis.

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

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

It's a lot of information, Raul, and I think very well presented. Thank you very much. And before we open the call for questions, I wanted to review the important considerations and key assumptions for the investment community to bear in mind as they evaluate our 2021 revenue guidance. We have 2 items to call out as contributors to our 2020 revenue results that represent material headwinds to the growth rate of our guidance, which is assumed for 2021. We also have a key assumption impacting our 2021 revenue expectations over
the second half of 2021.

Let me provide some additional color. Regarding the 2 areas that represent headwinds to our 2021 revenue growth expectations, first, as discussed on prior 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 of 2020; the disposition of assets related to the manufacturing of Merit’s Hypo 2 product in August 2020; and, most importantly, the closure of the IPL health care procedure pack operations in Australia in December of 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 sales of the Cultura nasopharyngeal swab and test kits used to test and collect transport samples of COVID-19 testing we developed, manufactured and distributed beginning in the second quarter of ‘20 in response to the critical need as a result of the COVID response by our organization to help the state of Utah and other states and prepare for the swab shortage in April of last year, and we quickly directed resources to the development of this kit with our engineers, technicians, marketers and production staff, working tirelessly to bring this product line from start to finish in 30 days. Now 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 changes in our markets and to respond to time-sensitive demand from our customers. Importantly, Cultura is not a core product line for Merit. And so going forward, we expect to generate approximately $1 million to $2 million in sales from this product in 2021 compared to more than $19 million in 2020. This represents a material headwind to our year-over-year revenue growth profile.

The third item I wanted to point out for investors is 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 a headwind related to lower pricing as a result of tenders in the second half of 2021. Overall, we expect our total revenue in China to increase in the 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.

Now while we’re pleased with the strong demand driving unit growth, such that we are able to offset this expected pricing headwind related to the tenders, we note that $11 million to $12 million of lower pricing represents approximately 120 basis points of headwind to our total company constant currency growth rate in 2021. Excluding the revenue contributions in 2020 from exited businesses and sales of Cultura as well as the pricing headwinds from China tenders over the second half of 2021, our total revenue guidance for fiscal year 2021 reflects growth in the range of approximately 6.6 to 8.7 year-over-year on a constant currency basis. With respect to our expectations for year-over-year constant currency revenue growth for the second quarter in the range of 11% to 13% include approximately basis points of growth headwind related to the revenue contributions in 2020 from the exited businesses and the sales of Cultura.

Now we remain confident in our 2021 guidance for total revenue growth on a constant currency basis in the to mid-single digits year-over-year. And importantly, excluding the impact of divestitures and product sales that uniquely benefited from pandemic-related demand trends in 2020, our constant currency revenue guidance continues to reflect growth in the mid- to high single digits year-over-year in 2021. We also expect to report improving non-GAAP growth in operating margins and strong free cash flow in 2021, driven by strong execution and contributions for our multiyear strategic initiatives program related to the Foundations for Growth.

Now that is a lot of information. And -- but that does wrap up our prepared remarks. And I think right now, to our administrator, we would now like to open up the line for questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question coming from the line of Jayson Bedford with Raymond James.
Jayson Tyler Bedford Raymond James & Associates, Inc., Research Division - Senior Medical Supplies and Devices Analyst

So I got on the call a little late, so I apologize if these have been covered. Just on the guidance, very strong 1Q that exceeded your guidance. You've integrated the full year. So I'm just wondering is there anything out there that you can point to as a reason for not raising guidance? Or is this more reflective of the overall caution given the dynamic world we're living in these days?

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Yes. Well, I'll comment brief and then Raul will weigh in if he wants to. But we still have this pricing issue that's unresolved in China. We don't know how that's going to shake out, and so that's part of it. There's still some hotspots out there. And so I think, Jayson, it's just -- we're confident in our full year, confident in that. And I think we were just -- that confidence remains. Business is improving, as we discussed. But it just seems to be a little bit early with those potential headwinds out there and without that knowledge to move it up. And it's only the first quarter. I think we'll reevaluate it in the second quarter as we're able to look at how the business progresses. Raul?

Raul Parra Merit Medical Systems, Inc. - CFO & Treasurer

Yes, Jayson, I think I'll just start off with saying we're really excited how Q1 panned out. We're excited about our -- feel really confident in our guidance for the year. I think really kind of came down to is we got off to a slow start for the beginning of the quarter. First couple of months, we're kind of in line with our original guidance that we had given. And then we just saw a really, really good March. And so I think what we want to do is just let's see how the rest of the quarter plays out. At the end of the second quarter, we can kind of evaluate where we're at and update guidance if we need to. But for now, there's just -- still some choppiness and we want to see some more consistency before we move on from that.

Jayson Tyler Bedford Raymond James & Associates, Inc., Research Division - Senior Medical Supplies and Devices Analyst

Have trends in April differed from the trends you saw in March?

Raul Parra Merit Medical Systems, Inc. - CFO & Treasurer

So we gave some Q2 color. I think that's kind of where we're going to leave it at. Obviously, if you look at kind of what -- that guidance, I think you'll see that it does show no improvement but more.

Jayson Tyler Bedford Raymond James & Associates, Inc., Research Division - Senior Medical Supplies and Devices Analyst

Okay. And last one, and then I'm sure there's others that want to get in. When do you expect to hear about the, let's call it, the at-risk China tender, the one that's impacting 11, 12 months of your guidance, what's the time line on that?

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Yes. So those tenders open up in the third quarter, early third quarter. So I mean we'll start to get a feel for it. There's We haven't had any indications of anything at this point. But again, as we discussed in the fourth quarter and on this call, there's that risk out there, and we thought it much better to point that risk out. And again, as we all know, if it happens, we think we have a number that might be a reasonable number, if not, then it's to the benefit of the business. So we -- again, we still stand by the fact that it needs to be there until we see otherwise.

And again, as you know and will recall, it was really based on some trends and some other issues that you're seeing out there and with some other companies and things we were following. Maybe we avoid it, maybe we don't. But nothing -- I don't have anything that would indicate today one way or the other. I think that's really the point I want to make, Jayson.

Operator

Our next question coming from the line of Steven Lichtman with Oppenheimer.

Steven Michael Lichtman Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst

First, if you could talk a little bit about WRAPSDODY in Europe. I know you mentioned some early data. But I'm wondering if you could just talk about the progress of WRAPSDODY rollout in Europe overall.
Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Yes. Well, listen, as you all know, and everybody follows this every day, Europe is very choppy. Now there was some announcement, this was on the news today, that there are certain places that are going to open up. And this -- and other places are still hot. So we are selling the product. I think maybe a bigger indicator is just this evening, we were part of a symposium sponsored by the British Society of Interventional Radiology, And we had approximately 130 physicians on this call. I was told that this involvement, this participation was higher than anything that they had recently. So I think it shows the interest in the product. It's being sold. We're getting new orders almost every day. But again, it's going to take a little bit more time to get this opened back up so we have more access.

And I will say this also, Steve, is that there's more access in the U.S. than there is in Europe. It's still -- and I think I've discussed this on other calls, but I haven't -- if I haven't, we're seeing right now, I'm going to use this kind of as a general number of about 50% of our sales reps can get access to hospitals. They can show products, they can do this now, 50%. And that's up, by the way, dramatically. It's almost doubled from the previous quarter. In Europe, it's at best 25%. So it's about half of that access. And that comes from kind of almost 0. So again, these are our numbers that are anecdotal, but they're coming from reports that come from our sales force. So it's improving but -- the access in Europe.

But to go to the base of your question, we're selling the product. Maybe what's even more exciting is when you see people that have ordered in the past reordering. And as you know, reorder is almost as important, if not more important, than making that initial sale.

So I'm fine with where we are. I'm fine with the technology. I think it's still going to be everything we hope for. is just playing itself out. And then, of course, as we announced in the prepared comments, we've now opened up, of course, the U.S. trial. And as that starts to online and we get more hospitals in there, we're going to see that trial move along. At the end of the day, when we get that done, it's going to be 2 or 3 years. again, our enthusiasm for the WRAPSODY has not changed at all. And if anything, I would say, it has improved.

Steven Michael Lichtman Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst

Great. Great. And then just free cash flow, obviously continues to impress. I guess given that and where your leverage ratios are. Are you thinking about increasing M&A, tuck-in M&A at all? Or just wondering what you're thinking about in terms of use of cash and to what the landscape is out there.

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Yes. As we previously said, when we generate that cash, we're paying down our debt. I think you -- I think you said this, Steve, that the -- we have a very strong balance sheet, and we're very capable. We're out looking. There are things that come to us. I think you have to be very disciplined in this market. You have to buy right, you have to look right. So we're there and we're actively looking around and things are coming our way and considering things but nothing, of course, to talk about. But again, I want to remind everybody of the discipline [in this elective]. And the important thing and maybe the whole question is, we don't have to do anything. We're not forced to do it so we can grow. We have a full pipeline of R&D projects. As these markets open back up, things will get back to normalization. And -- but if the right thing comes along, we'll be prepared to move.

Steven Michael Lichtman Oppenheimer & Co. Inc., Research Division - MD & Senior Analyst

Great. And then just lastly, I apologize if you mentioned this. I know you're keeping the sort of conservatism on the potential China tenders. When do you think you'll get visibility as to whether those are in place or not? Obviously, I know you've already built it into guidance, but just wondering on that.

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Yes. It's the question of the day. We know that they'll go out in Q3. Remember, it's done province by province. So it's like dealing with each state almost. You get -- these guys will do it, you get this in. So we'll start to have some visibility as we go into the third quarter because we know the tenders go up from lots of things. It's not just our products or a lot of products but it will play itself out in the third quarter.

Operator

Our next question coming from the line of Matthew O'Brien with Piper Sandler.
Matthew Oliver O'Brien Piper Sandler & Co., Research Division - MD & Senior Research Analyst

One for Raul and then probably one for Fred. But relative for starters, the gross margin adjusted in the quarter was really good, but you're sticking kind of with the full year outlook for that metric. So can you talk about some of the benefits that you saw there? And then why would we kind of go back to the midpoint of the range you provided versus kind of the higher end based on what we saw in Q1?

Raul Parra Merit Medical Systems, Inc. - CFO & Treasurer

Yes. Look, I think as we noted, product mix was -- I'm looking at it more sequentially, quite frankly, Matt if you look at kind of where we came out of the fourth quarter, but the reality is we have good product mix. Our obsolescence expense was less. And then obviously, with the volume that's helping also. So I think we feel comfortable with our guidance for the year and our -- I think the gross margin, quite frankly, was kind of where we expected it. So...

Matthew Oliver O'Brien Piper Sandler & Co., Research Division - MD & Senior Research Analyst

Okay. Okay. Sounds like you're being somewhat conservative, which is understandable. And then, Fred, the peripheral business, I know we all want to talk about the different segments here. But if you go back to '19 and the Q1 performance there, you grew nicely in the peripheral business off of '19. I know '20 is a little bit more challenging to look at. But that chunk of the business is doing quite well. Can you just talk about some of the dynamics that are assisting that business and how we should think about the trajectory for peripheral over the course of this year and even the next couple of years?

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Yes. I don't have that -- the numbers, Matt, in front of me to -- but I will just say, generally, as you know, in our research and development, we focused on that market which is highly fragmented and one that we've invested in for years. So if you look at products like the Surfacer, you look at products like the WRAPSODY, you look at embolics, you look at all these things, the SCOUT, You Take a look at microcatheters, those are the areas that a lot of interest. And those are the areas that Merit continues to invest in probably heavier than some of the other areas, just simply because of the opportunity. So I think it's been more of a company focus. Now all of that being said, as these markets open back up, we have a lot of electrophysiology products and other things that will be coming to the marketplace that would go over on the cardiac side. But clearly, peripheral has been an area of interest in development and investment for quite some time and will continue to do so.

Operator

Next question coming from the line of Mike Matson with Needham.

Michael Stephen Matson Needham & Company, LLC, Research Division - Senior Analyst

I guess, first, I wanted to ask about WRAPSODY. The -- just curious if you had an estimate of the cost of the PMA trial in the U.S. and kind of the timing of that, that will be incurred in and what that sort of means for your R&D spending as a percentage of sales.

Raul Parra Merit Medical Systems, Inc. - CFO & Treasurer

Yes. So if you remember our guidance at the beginning of the year or last quarter, Mike, we actually included that and it's one of the reasons why our R&D expenses is going up. So I won't talk to the actual dollars of the actual study, but it is baked into our guidance. Some of that was delayed, I guess, in Q1, so we'll start to see additional expense in Q2 for it. But again, I'll just keep it high level and just say that it is included in our guidance, and it's part of the reason why our R&D expense is growing.

Michael Stephen Matson Needham & Company, LLC, Research Division - Senior Analyst

Okay. All right. And then very strong quarter from operating margin perspective and some of that, I guess, is due to the continued savings from reduced travel and conferences and things like that. So how should we think about the ramp-up in OpEx over the next few quarters? And do you think you'll get back to full kind of precoded levels there? Or is there any kind of permanent savings we could see

Raul Parra Merit Medical Systems, Inc. - CFO & Treasurer

Yes. So we do expect an uptick in operating expenses. for Q2. I think we talked about that in our opening statements. But as far as our non-GAAP operating expenses, we do expect modest increases year-over-year. Obviously, there is some savings that we plan on keeping, but there's also investments we're making, such as the WAVE study, as we talked about.
Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

And Mike, I think you asked when you go back to normal, and the answer is partially. There are going to be things -- in fact, we've met several times this week in terms of some office issues and consolidation and things like that. And in those issues, we will continue to have a number of people continue to work at home as an example, I think we discussed this in the conference we were in, but our entire customer service department is working at home. Interestingly enough, at higher levels of efficiency, the customer satisfaction, the surveys we've done have shown us that these are things that are continuing to be helpful. And in fact, what we did this week is reallocated that space for other areas and moving to make it more efficient internally for departments to meet. I won't go into all the details, but we're reallocating. And the reason I'm saying this is your question was do you expect to go back to normal. And the answer is nothing at Merit is going back to normal.

There are modifications and efficiencies and businesses and SKU rationalization, all the things we've talked about as part of our Foundations for Growth. I mean those things are a high priority. And some of those are now just beginning. Remember, we worked all of last year, a good portion of the year, at least 6 months of that evaluating and assessing and planning, and those things are starting to go, and that plan is for 3 years. So I think that momentum and the things we're doing there would tell us that things are not going to go back to what would be considered normal and past performance. So we believe that we'll continue to improve the business across the board as we have promised to do so. And you've seen that in our plan, of course. So I don't want to get too much on the soapbox, but it's pretty important to us.

Michael Stephen Matson Needham & Company, LLC, Research Division - Senior Analyst

That's helpful. And we'll all be happy if the costs are lower than normal in the revenue and EPS are higher than normal. So

Raul Parra Merit Medical Systems, Inc. - CFO & Treasurer

I think we agree

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Anything else, Mike?

Michael Stephen Matson Needham & Company, LLC, Research Division - Senior Analyst

Okay. I'll stop.

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Okay. All right.

Operator

The next question coming from the line of Larry Biegelsen with Wells Fargo. 

Shagun Singh Chadha Wells Fargo Securities, LLC, Research Division - Senior Equity Analyst

This is Shagun in for Larry. I was hoping you about the impact from new product launches, I believe, a number of products, you could launch a number of products during COVID. So how significant is that backlog of new products? And then Fred, you recently hired a Chief Strategy Officer that you mentioned briefly on the call. That's a new role. So can you talk a little bit about why you added that role, what Rob brings to the table and how you're thinking about succession plan.

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Yes. Thank you. So let's go back to the new products. I think one of the encouraging signs of what we believe is kind of the early stages of recovery of the industry is some of the products that we introduced essentially stalled. You introduce them and then hospitals locked down, elective procedures locked down. But what we've seen is those products come back to life. And by that, I mean, we're getting orders with increased access that we talked about just previously to a comment a few minutes ago. We're starting to see that those products are good products, interesting and are things that fill into the areas, again, that we talk about, peripheral and cardiac and so on and so forth. So -- but it's still very, very early. in all of these products and more to be launched. But I think the key part to all of this is the fact that we didn't stop our development of new products and that we will continue to see the benefit of that as we go forward as part of
our overall growth strategy.

Let me go to the individuals. I think you can read in there -- in the parts that are in the press release, this is really good people, experienced people. It's part of our succession planning. It's part of being able to build a base of experience of talent going forward in our business. These are guys that have experience or helping us, for instance, in the HR or in recruiting and in compensation and benefits and helping to prove and make sure that we're competitive and so on and so forth globally.

And again, on the operations side, let's say, on the sales, marketing and strategy, it's -- I've been doing a lot of this myself for many, many years. I've got people that help me. But I think that it's been helpful to have Rob here and to be able to bounce ideas off of him. And I think this is just part of what we had talked about. This isn't -- we had talked about this in our Foundations for Growth. We had talked about this and we think it's necessary. This is something the Board is engaged in, and that's the structure and part of our Foundations for Growth. So we're pleased. We've seen a difference. The experience -- at the same time, it's been kind of interesting because, in many cases, they're pleased with things and the culture of agility and things that we've talked about that maybe they didn't experience in other places. And then we get the benefit of their wisdom, their experience and looking at things and giving us things to consider. So I think when you add all that together, you have a stronger company, you're able to attract even more talent down the road as the company grows, and we think that's essential for both succession planning and just for the well-being of the business. So I think it's been a good process. And over time, we'll fill in other places that we think are necessary for continued growth support. So talent development is an important part and talent acquisition is an important part of our strategy in Foundations for Growth. So it's planned. It's not haphazard. It's well planned and thought out, and we have a schedule and 3 years to execute that plan that we delivered.

Operator

(Operator Instructions) Our next question coming from the line of Jim Sidoti with Sidoti Company.

James Philip Sidoti Sidoti & Company, LLC - Research Analyst

Fred, can we stick on that new products subject for a little bit? Can you give us a little color on what you have in the pipeline? And are you able to start launching those now? Or do you think they'll be significant by 2022?

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Well, Jim, it's a good question. Listen, Merit has always been known as a company of innovation. We've incorporated the new products into our guidance. And again, when appropriate, if appropriate, we'll discuss that down the road. But listen, if you take a look at the business, we got here and built this business on the foundation of innovation and meeting customer needs and we've been doing a long time. It is a cultural thing that we do all the time. So again, whether it be in the area with SCOUT and -- or in the peripheral area from your toe up to your head or whether it be in the cardiac area with our electrophysiology products, Merit is building a foundation of complex and needed products for continued growth in the future.

What also, I think, is very pleasing is to see that as things start to come back and procedures is the fact that people want these products. You can -- products sometimes sit on a shelf. But as this thing is starting to come back together, people want these products. And that, for me, is -- things were dark a year ago. Jim, you never know if you get a chance to show people these great innovations. But we're showing them and I think going back to the WRAPSODY, just in this BSI thing, symposium I told you about. I mean, we have 130 physicians spend 1.5 hours or whatever on a Zoom, Teams meeting is terrific in the evening. I mean they've been working all day, they're tired, but that's how exciting that technology. So I'm not concerned that anything has changed despite the foundations of growth on the innovation side. In fact, it's the thing that we have really, really spent a lot of time making sure it's preserved and passed on to the next generation.

James Philip Sidoti Sidoti & Company, LLC - Research Analyst

All right. And then on working capital, I mean, it's just -- your working capital management improved quite a bit in the last 12 months. If we look a year ago, sales are higher now, receivables are flat. The inventory is quite a bit lower. What's changed there? And is that change sustainable?
Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Yes. Well, listen, I've got my Chief Operating Officer in the room. I've got my financing staff here properly spread out. And listen, when we announced our initial plan 18, 20 months ago, Raul talked about what we were going to do with some facilities and the products we were going to move. This was really just the beginning. And then we looked at all the other things. You get so busy sometimes that there are some things right in front of you. We -- I mean, I don't care whose business we're talking about. There are nuggets all over the so-called low-hanging fruit. So we're looking at that and then the stuff that's in the midrange and the stuff that maybe is a little bit more difficult. So it's how we get compensated, Jim, And humans respond to incentives and the incentives are -- these are the goals, and we meet weekly, sometimes daily, to talk about are we on track. And some we're ahead on, some we're behind on.

But again, if there were measures to leave today, it's -- I don't want anybody to misunderstand or underestimate our commitment to completing our Foundations for Growth. It's not foundations for being cheap. It's not foundations for lower cost. It's foundations for growing the business and growing it more profitably. And it's -- I think we've done a good job, and I think you will see them -- continue to see the benefits and the fruits of our labor going forward. So I'm maybe being too assertive, aggressive here. But we're engaged and we continue to be, and we'll hit those goals. That's yes.

Raul Parra Merit Medical Systems, Inc. - CFO & Treasurer

And there's targets every year.

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

And it's fun, yes.

Raul Parra Merit Medical Systems, Inc. - CFO & Treasurer

There's targets. We keep track of them. Ron and I, we're close contact almost on a weekly basis. Actually, on a weekly basis, we get an update where the inventory stands. Receivables, we're just -- we've got a good handle on it. We're keeping an eye on it.

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

And what I would call is still a difficult -- you're talking about the goals and forecasts. Listen, there's a lot of stuff out there. Let's not forget this storm that's out there. I'm sure on other medical device calls, you guys have picked things up like shortages that people have and transportation and Suez Canal and I mean all these things that are going on out there. There's stuff -- it's a constant battle, but the staff and everybody have committed working hard. And I just have to say because you left his wide open for me, I am really pleased with the results of this quarter. And I'm pleased, not just by looking backwards but looking as to what everybody is committed to do and how we're working together. I think I don't know if we've surprised people. It hasn't surprised me to see the things. Now the question is always, well, why didn't you do it before. And I think we should all ask ourselves that same question on almost every aspect of our life, right, why don't we do this and why didn't we do that? Well, we're doing things, and I think you're seeing the results of that, Jim. So I better stop because I could go on another half an hour and I committed to keep this call to 1 hour. So Jim, anything else?

James Philip Sidoti Sidoti & Company, LLC - Research Analyst

No. I think It sounds like the -- the focus on improving cash management and working capital management and cash flow, it sounds like that's something that's not going away in the.

Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

No. No. Watching that debt go down and watching the sadness in bankers' eyes because they're not getting as much as absolutely one of the most pleasing things that can never happen. And maybe more importantly, the flexibility it gives to us. I mean I've seen grown men bankers and women weeping because we won't take their money and don't need it.

Operator

And I'm showing no further questions at this time.
Fred P. Lampropoulos Merit Medical Systems, Inc. - Chairman, CEO & President

Well, listen, everybody, thank you. I know it's a busy day. We'll take no more of your time. We appreciate you taking the time to listen this. So Raul and I will be around for the next 2 or 3 hours. Looking forward to your calls. Thanks again. We look forward to coming back to you when appropriate to do so. See you soon. Thank you. Bye-bye.

Operator

Ladies and gentlemen, that does conclude our conference for today. Thank you for your participation. You may now disconnect.