Medtronic

FINAL

Q1 FY23
Earnings call commentary

Ryan Weispfenning

Good morning and welcome to Medtronic's fiscal year 2023 first quarter earnings broadcast. I'm Ryan Weispfenning, Vice President and Head of Medtronic Investor Relations. I'm inside one of our Medtronic mobile labs, which is making a stop here at our operational headquarters in Minneapolis. These high-tech, mobile classrooms, will give about 5,000 US clinicians every year the opportunity to train on some of our most advanced, state-of-the-art technology, including our O-arm™ and StealthStation™. As you can see, it's on 18-wheels. Our fleet of mobile lab trucks allows us to play big... literally... as they traverse the United States. In fact, with over 200 stops planned this fiscal year, they're likely coming to a hospital near you.

Now, before we go inside to hear our prepared remarks, I'll share a few details about today's webcast:

- Joining me are Geoff Martha, Medtronic Chairman and Chief Executive Officer and Karen Parkhill, Medtronic Chief Financial Officer. Geoff and Karen will provide comments on the results of our first quarter, which ended on July 29, 2022, and our outlook for the remainder of the fiscal year. After our prepared remarks, the Executive VPs for each of our four segments will join us, and we'll take questions from the sellside analysts that cover the company. Today's program should last about an hour.
- Earlier this morning, we issued a press release containing our financial statements and divisional and geographic revenue summaries. We also posted an earnings presentation that provides additional details on our performance. The presentation can be accessed in our earnings press release or on our website at InvestorRelations.Medtronic.com.

- During today's program, many of the statements we make may be considered forward-looking statements, and actual results may differ materially from those projected in any forward-looking statement. Additional information concerning factors that could cause actual results to differ is contained in our periodic reports and other filings that we make with the SEC, and we do not undertake to update any forward-looking statement.
- Unless we say otherwise, all comparisons are on a year-over-year basis, and revenue comparisons are made on an organic basis, which excludes the impact of foreign currency and revenue from our recent acquisition of Intersect ENT.
- References to sequential revenue changes compare to the fourth quarter of fiscal '22 and are made on an "as reported" basis, and all references to share gains or losses refer to revenue share in the second calendar quarter of 2022 compared to second calendar quarter of 2021, unless otherwise stated.
- Reconciliations of all non-GAAP financial measures can be found in our earnings press release or on our website at InvestorRelations.Medtronic.com.
- And finally, our EPS guidance does not include any charges or gains that would be reported as non-GAAP adjustments to earnings during the fiscal year.

With that, let's head into the studio and hear about the quarter.

Geoff Martha

Hello everyone and thank you for joining us today. We reported our Q1 results this morning, and the quarter played out largely as expected. Our organization executed to deliver revenue ahead of our guidance, and EPS that was in-line with our guidance. Macro factors that we've discussed with you and forecasted over the past few quarters, like supply chain, inflation, and foreign exchange, along with difficult comparisons to the prior year, caused our revenue and EPS to decline. At the same time, there were several bright spots in the quarter across our businesses, including strength in Pacing, Cardiac Surgery, US Core Spine, Neurovascular, Diabetes in Europe, and strong overall growth in many emerging markets.

And as we look to the future, we have several near-term pipeline catalysts approaching that will accelerate growth. We're also making progress on our initiatives around quality and operating improvement. And in an uncertain economy, our business is well positioned with our robust balance sheet, strong and growing dividend, and leadership positions in many secular growth healthcare technology markets.

Q1 Results

So taking a closer look at our Q1 results, as expected, acute supply chain disruptions impacted our performance, most notably our Surgical Innovations business. We saw improvement in areas like packaging and resin supply as we progressed through the quarter. We also continue to manage semiconductor shortages across our businesses to minimize their impact on product availability, as well as our financial results, and we're expecting these chip shortages to linger throughout our fiscal year. Overall, our operations teams have executed and worked closely with our suppliers to minimize impact, improving our order backlogs as we exited the quarter. We expect our overall supply chain issues to continue to improve as we move through the fiscal year.

On the demand side, we're still seeing impacts to procedure volumes due to health professional labor shortages, and COVID is still causing procedure cancellations and deferrals in some pockets around the world. We see our hospital and physician customers are doing all they can to manage these dynamics. So while procedure volumes in most of our markets remain at pre-COVID levels, we do have certain procedures or geographies where volumes are still lagging.

Market Share

Turning to market share… This is an important metric at Medtronic and is part of our annual incentive plan, along with revenue growth, profitability, and free cash flow. And when we look at our quarterly market share performance, acute product availability challenges impacted our share capture opportunities in certain businesses, including Surgical Innovations and high-power CRM implants. We're also facing some competitive pressures in Pelvic Health and in Diabetes predominantly in the US. We're making good progress on the acute product availability issues and have pipeline plans in place to address competitive pressures over time.

Now, let me highlight some of our bright spots. In CRM, our Pacing business continues to outperform the market, as our Micra leadless pacemaker family is driving strong growth around the globe as we enter new geographies and expand penetration in existing markets. Micra grew 15% in the quarter, including high-seventies growth in Japan, mid-teens growth in Western Europe, and high-thirties growth in Emerging Markets.

In CST, we had a good quarter in US Core Spine, which grew 4%. We won market share on the strength of our overall portfolio, including our UNiD™ AI-enabled surgical planning platform and patient-specific implants, which had strong double-digit sequential growth in our US user base. In addition, our recently launched Catalyft™ PL spinal system, designed to target the TLIF and PLIF markets, drove meaningful results in Q1. And the breadth of our enabling imaging, navigation, and robotic technologies is a key differentiator.

In our Neuromodulation business, we are gaining initial implant share in both Pain Stim and DBS. In Pain Stim, the market continues to gravitate toward our Vanta™ recharge-free and Intellis™ with DTM™ rechargeable neurostimulators. And in DBS, customers value the differentiated sensing capabilities of our Percept™ PC system with our SenSight™ directional lead.

In Diabetes, we continue to see significant growth in markets outside the US due to the increasing user base of our MiniMed™ 780G insulin pump, combined with our Guardian™ 4 sensor. The increase in this user base over the past couple of years is now driving significant recurring revenue growth for our CGM sensors and other supplies. In markets outside the US where launched, the 780G and our Guardian 4 sensor has a very positive user experience, with no fingersticks and more time in range. Now this is due to its near real-time basal insulin and auto correction boluses every 5 minutes to address underestimated carb counts and occasional missed mealtime boluses.

Pipeline Discussion

Now, let's move to our product pipeline, where we're advancing several meaningful technologies that can create new markets, disrupt existing ones, and accelerate our growth. We continue to execute on our pipeline, having received over 200 regulatory approvals in the US, Europe, Japan, and China over the past 12 months. And looking ahead, we have several near-term pipeline catalysts approaching that we expect will enhance the weighted average market growth rate of Medtronic.

Starting with our Cardiovascular Portfolio and transcatheter valves, the limited US market release of our Evolut™ FX valve is receiving an overwhelmingly positive customer reception, and we're excited about the impact this next-gen valve can have as we move to full market release this fall. Evolut™ FX enhances ease-of-use and provides implanters with greater precision and control during the procedure. And it maintains all of the industry-leading hemodynamic and durability benefits of the Evolut platform. When you combine the FX launch in the US, Pro+ launch in Europe, and Evolut™ Pro launch in China, we feel really good about the opportunities in our TAVR franchise around the globe. TAVR is one of the largest growth drivers for Medtronic, and we expect the market, which is roughly $5 and a half billion today, to exceed $7 billion within the next 3 years and reach $10 billion in the next 5 years.

In Cardiac Rhythm Management, we're really looking forward to disrupting the single chamber ICD market with our Aurora™ extravascular ICD. Now as you may know, one of our competitors has had a subcutaneous ICD in the market for many years, but it's remained a niche device given its limitations compared to conventional ICDs. With Aurora, we've created a true gamechanger, where the electrophysiologist and the patient don't have to make tradeoffs. It will deliver the benefits of a traditional ICD, including having the same size, battery longevity, and ability to use proven anti-tachy pacing in lieu of delivering a painful shock to terminate life threatening arrhythmias. Aurora does all of this without having to place leads inside the heart. Our EV-ICD global pivotal data will be presented this weekend in a late-breaking session at the ESC congress in Barcelona. We're also awaiting CE Mark approval for Aurora, and we expect US approval next calendar year.

In renal denervation, our breakthrough procedure to treat hypertension, we're nearing completion of the six-month follow-up for the full cohort of patients in our SPYRAL HTN-ON MED study. We'll then analyze the data and plan to present the findings in the next few months. This data will complete the final piece of our clinical module submission to the US FDA, as every other module has been submitted, reviewed, and closed. The data on our Symplicity™ Blood Pressure Procedure is robust, including strong pivotal trial results and compelling real-world registry data from over 3,000 patients. And more recently, data has been presented that show RDN patients spend nearly double the time in target blood pressure range through 3 years than those who received a sham procedure. This could have a profound effect on public health through the reduction of cardiovascular events including stroke, heart failure, and CV mortality. And we expect to be a leader in this market, which we project to exceed $500 million by calendar year 2026 and $2-3 billion by 2030.

Moving to our Medical Surgical Portfolio, which includes Surgical Robotics, we continue to execute on the limited market release of our Hugo™ robot. We're installing new systems and collecting clinical data in approved geographies, enhancing the system based on surgeon feedback, improving supply chain resiliency, and scaling manufacturing production. Feedback and demand continue to be very strong. We've made progress over the last quarter, and we're nearing the start of the US IDE clinical trial for our urology indication. We also continue to increase our user base of Touch Surgery™ Enterprise, our AI-powered surgical video and analytics platform. With Touch Surgery™ Enterprise, surgeons can now easily review film from their surgeries to continuously improve and advance patient care. Overall, when it comes to surgical robotics, we're investing heavily to become a major player in the market for the long-term, leveraging our decades of experience and leadership in minimally invasive surgery.

Now turning to our Neuroscience Portfolio… In Neuromodulation, we've submitted our Inceptiv™ ECAPS closed-loop stimulator. We expect Inceptiv's™ closed loop therapy, which optimizes pain relief for patients, to revolutionize the SCS market. We're also continuing to ramp our commercial activities to go after the Diabetic Peripheral Neuropathy opportunity, with our first cohort of DPN market development reps now trained. We believe DPN is one of the largest opportunities in MedTech, and we expect the market to reach $300 million by FY26, with an annual total addressable market of up to $2 billion.

In Diabetes, we are in active dialogue with the FDA on our regulatory submission for the MiniMed™ 780G with the Guardian™ 4 sensor, and we remain focused on resolving our warning letter. We're making good progress on our warning letter commitments. We've completed more than 90% of the actions we committed to the FDA. This represents substantial progress toward resolving the warning letter and preparing for reinspection. In our CGM pipeline, we submitted our next-generation sensor, Simplera™, for CE Mark. Simplera™ is disposable, it's easier to apply, and it's half the size of Guardian™ 4. The Simplera™ file is ready to submit to the US FDA, and we're waiting to submit it as we're prioritizing the 780G/Guardian 4 review.

And with regards to our overall Diabetes pipeline, we're making considerable investments, well above our corporate R&D average. We have a comprehensive pipeline of multiple next-gen sensor and pump programs, including patch pumps. This pipeline gives us confidence that we can restore strong growth to our Diabetes business over the coming years.

With that, I'll turn it over to Karen to discuss our first quarter financial performance and our guidance. Karen?

Karen Parkhill

Thank you, Geoff.

Q1 Financial Recap

Our first quarter organic revenue exceeded guidance, decreasing 3.6%. Adjusted EPS of $1.13 decreased 17%, in-line with our guidance range. As we outlined on our last earnings call, we faced acute supply chain challenges in the quarter, particularly in our Surgical Innovations business. We also faced tougher underlying growth comparisons, including both strong ventilator sales and good procedure recovery following the third wave of COVID last year.

Looking at our results from a geographic perspective, our US revenue declined 9% and our Non-US Developed and Emerging Markets both grew 2%. Our Emerging Markets growth was impacted this quarter by China, which declined 9% given COVID lockdowns and volume-based procurement. However, our teams drove strong growth in many other markets, including high-teens growth in South Asia and Latin America, mid-teens growth in the Middle East & Africa, and low-double digit growth in Southeast Asia. And, when you exclude China, our Emerging Markets grew 13%.

Turning to our margins, our adjusted gross margin declined 230 basis points. The impact of the strengthening dollar drove 50 basis points of the decline, and the rest was primarily due to inflation on labor and materials, as well as freight, given fuel surcharges and increased expedited shipments. As we said at the beginning of the year, we expect the impact from inflation and currency to continue to negatively affect our gross margin in the quarters ahead.

I want to remind you when you look at our R&D line, we had a recast of last year's IPR&D that we told you about last quarter. Without that recast, adjusted R&D expense would have grown 4%, as we continue to prioritize investment into development programs across our businesses.

While our operating margin declined 320 basis points – on lower revenue and gross margin pressures – we do expect to show sequential improvement as our revenue growth accelerates through the year.

And our balance sheet remains strong, allowing us to invest in future growth and return capital to shareholders. We continue to target returning a minimum of 50% of our free cash flow to our shareholders, primarily through our strong and growing dividend. And we supplement these returns through opportunistic share repurchases. This past quarter, we repurchased $336 million, which is on top of the $2.5 billion we repurchased last fiscal year.

We also continue to put the cash on our balance sheet to work, investing in tuck-in acquisitions and minority investments that help fuel our near-term and future growth. We closed Intersect ENT in the quarter. And we also began the structured acquisition of the Acutus left-heart access portfolio, and expect to begin distribution by the first half of calendar '23. Their advanced transseptal access systems will be an important part of our broad offering to electrophysiologists and interventional cardiologists. Last month, we announced a co-promotion agreement and path toward acquisition with CathWorks. We're excited to partner with CathWorks and promote their innovative FFRangio™ system, which we believe can disrupt the traditional FFR market. We believe that Medtronic can add a lot of value to the technologies that we acquire. And we expect tuck-ins to supplement our organic R&D investment and long-term growth acceleration.

FY23 & Q2 Guidance

Now, turning to our guidance…

With one quarter behind us, we are maintaining our full year revenue guidance at 4 to 5% organic, which excludes currency movement and revenue from our Intersect ENT acquisition. If recent exchange rates hold, foreign currency would now have a negative impact on full year revenue of $1.4 to $1.5 billion, an increase of $400 million over the past quarter.

We expect organic revenue growth to improve each quarter, with the second half of our fiscal year much stronger than the first, driven by our expectation that many of the acute supply chain challenges subside and new products drive our growth. It's worth noting that we also face increasingly easier comparisons as we go through the fiscal year.

By segment and on an organic basis, we continue to expect Cardiovascular to grow 5.5 to 6.5%; Medical Surgical to now grow 0.75 to 2.75%, given increased volume-based procurement in many of the Chinese provinces; Neuroscience to now grow 4.75 to 5.75%, given a slightly lower outlook for the Neuromodulation market; and Diabetes to now decline 3 to 6%, given stronger growth in international markets.

On the bottom line, we continue to expect non-GAAP diluted EPS in the range of $5.53 to $5.65. Inflation and currency are still creating near-term impacts on our margins, and we've seen inflation on raw materials and freight become larger headwinds over the past quarter. We also continue to execute on initiatives to partially offset these macro impacts, as well as prioritize our R&D investments to drive future growth. Given these dynamics, and the fact that we are still early in our fiscal year, we would suggest you model closer to the lower end of our EPS guidance range. Our EPS guidance includes an unfavorable impact of foreign currency, which is approximately 17 to 22 cents at recent rates.

In the second quarter, we expect organic revenue growth in the range of 3 to 3.5%, implying a strong sequential acceleration, driven by improved product availability and the cadence of our launches. Assuming recent exchange rates hold, the second quarter would have a currency headwind between 365 and 415 million dollars.

By segment, we expect Cardiovascular to grow 5 to 5.5%, Medical Surgical to be down a quarter-point to up a quarter point, Neuroscience to grow 5.5 to 6%, and Diabetes to be down 3 to 6%, all on an organic basis.

And we expect EPS of $1.26 to $1.30, including an FX headwind of about 2 cents at current rates.

While our markets are facing challenges, we're focused on identifying ways to offset their impact to our financials. And we are optimistic about our future, as we prepare to create markets and realize new opportunities.

In addition, I want to take a moment to recognize and thank our employees at Medtronic, who are unwavering in their commitment to deliver lifesaving treatment to people around the world.

Back to you, Geoff.

Geoff Martha

Thank you, Karen.

Now this last quarter, we made a lot of progress on our aggressive agenda of underlying changes that are needed to ultimately accelerate our growth.

With supply chain, it's getting better… and our backorders are coming down. Not just because of the external environment, but because of the actions we are taking under Greg Smith's leadership, and I expect these improvements will continue. We've co-located our employees with suppliers, and are also working closely with sub-tier suppliers. We're managing through the acute issues and making progress on improvements that I'm confident can enhance the resiliency of our end-to-end supply chain.

On quality, we've been conducting a large transformation of our quality system over the past couple of years. We're advancing quality in innovative ways, working very closely with our regulators, and this is leading to important progress.

We're also making progress on our pipeline and portfolio, as these two strategies come together to create meaningful growth drivers. We're tucking new products into dependable, higher-growth businesses, like we did by adding Intersect ENT to our ENT business. We're also broadening the product portfolio of some of our businesses so they can become more meaningful growth drivers for the total company, like our strategy in Cardiac Ablation Solutions.

Overall, the path has not been easy. But I'm confident that these fundamental enhancements that we're making to the company… combined with our op model change, culture changes, and incentive changes… are positioning us to deliver a higher level of growth that can be sustained. And as we overcome the near-term issues and start to put points on the board with the pipeline, I believe the underlying transformation of Medtronic… all the work that we've been doing over the past couple of years… will become increasingly apparent, setting up a durable value creation engine to fully capitalize on the megatrends in the healthcare and technology markets, which will benefit all stakeholders.

So to close, I want to join Karen in thanking our employees. It's never easy going through change, especially in a challenging macro environment. But our teams have stayed focused and are playing critical roles in helping to alleviate pain, restore health, and extend life for millions of people around the globe.

Now let's move to Q&A. We're going to try to get as many analysts as possible, so we ask that you limit yourself to just one question, and only if needed, a related follow-up. If you have additional questions, you can reach out to Ryan and the Investor Relations team after the call.

With that, Brad, can you please give the instructions for asking a question?

Brad Welnick

For the sellside analysts that would like to ask a question, please select the "Participants" button and click "Raise Hand." If you're using the mobile app, press the "More" button and select "Raise Hand." Your lines are currently on mute. When called upon, you will receive a request to unmute your line, which you must respond to before asking your question. Lastly, please be advised that this Q&A session is being recorded.

For today's session, Geoff, Karen, and Ryan are joined by:

- Sean Salmon, EVP and President of the Cardiovascular Portfolio;
- Bob White, EVP and President of the Medical Surgical Portfolio;
- Brett Wall, EVP and President of the Neuroscience Portfolio; and
- Que Dallara, EVP and President of the Diabetes Operating Unit.

We'll pause for a few seconds to assemble the queue…

Ryan Weispfenning

Thanks. Geoff, please go ahead with your closing remarks.

Geoff Martha

OK. Thanks for the questions. We appreciate your support and continued interest in Medtronic. We look forward to updating you on our progress on our Q2 earnings broadcast, which we anticipate holding on November 22nd. So, with that, thanks for tuning in today, please stay healthy and safe, and have a great rest of your day.