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Orthofix Medical Inc.

First Quarter 2023 Earnings

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CORPORATE SPEAKERS:

Alexa Huerta
Orthofix Medical Inc.; Senior Director, IR
John Bostjancic
Orthofix Medical Inc.; Chief Financial Officer
Keith Valentine
Orthofix Medical Inc.; President, Chief Executive Officer & Director

PARTICIPANTS:

Mathew Blackman
Stifel, Nicolaus & Company, Incorporated; Analyst

PRESENTATION:

Operator^ Thank you for standing by. My name is [Brennan] and I'll be your conference operator today. At this time, I would like to welcome everyone to the Orthofix Medical Inc. Quarter 1 Earnings Call. (Operator Instructions)

Senior Director of Investor Relations, Alexa Huerta, you may begin the conference.

Alexa Huerta^ Thank you, operator, and good afternoon, everyone. Welcome to the Orthofix First Quarter 2023 Earnings Call. Joining me on the call today are President and Chief Executive Officer, Keith Valentine; and Chief Financial Officer, John Bostjancic.

During this call, we will be making forward-looking statements that involve risks and uncertainties. All statements other than those of historical facts are forward-looking statements, including any earnings guidance we provide and any statements about our plans, beliefs, strategies, expectations, goals, or objectives. Investors are cautioned not to place undue reliance on such forward-looking statements as there is no assurance that the matter contained in such statements will occur. The forward-looking statements we will make on today's call are based on our beliefs and expectations as of today, May 9, 2023.

We do not undertake any obligation to revise or update such forward-looking statements. Some factors that could cause actual results to be materially different from the forward-looking

statements made by us on the call include the risk factors disclosed under the heading Risk Factors in our Form 10-K for the year ended December 31, 2022 and Form 10-Q filed this afternoon, May 9, 2023, as well as additional SEC filings we make in the future.

In addition, on today's call, we will refer to various non-GAAP financial measures. We believe that in order to properly understand our short-term and long-term financial trends, investors may wish to review these matters as a supplement to the financial measures determined in accordance with U.S. GAAP. Please refer to today's news release announcing our first quarter 2023 results for reconciliations of these non-GAAP financial measures to our U.S. GAAP financial results.

At this point, I will turn the call over to Keith.

Keith Valentine^ Thank you, Alexa. And thank you everyone for joining us this afternoon. I am pleased with our strong financial and operational performance in the first quarter following the combination of Orthofix and SeaSpine on January 5th. The merger of these two companies creates a leading global spine and orthopedics company, and the new leadership team has remained focused on continuing to execute on our growth strategies and cross-selling opportunities across all portfolios.

Revenue for the first quarter was $175 million, representing reported growth of 65% and pro-forma growth of 11% year-over-year. Our strong quarter is indicative of our commitment to deliver consistent, above-market growth through innovative products via our expanded commercial reach. Since January, our team has worked tirelessly to integrate the two companies, and I believe we're already starting to see some of the benefits of our complementary portfolios throughout this stronger and more aligned organization.

For today's call, I'll start my remarks with some commentary on each product category, including any product innovation initiatives, followed by operational highlights and commercial channel updates. Then I'll ask John to provide a more detailed look at financial performance and guidance for full-2023 year before we open the call for your questions.

Our Bone Growth Therapies division, or BGT, enjoyed a solid start to the year with 14% year-over-year revenue growth totaling $48 million in the first quarter. We generated double digit growth in both the spine and fracture management channels. In 2022, we invested in a realignment of the BGT sales and sales management teams to expand the organization and to

bring more dedicated focus to each of the spine and fracture management channels. This positioned us well to take advantage of the anticipated cross-selling opportunities in spine following the merger and to accelerate market share taking in the fracture market share following the launch of AccelStim, our most recent solution which adds a fresh fracture indication to our already expansive portfolio of indications. Within the spine channel, we generated growth from both SpineStim and CervicalStim, the only PMA approved cervical BGS device in the US market.

While we're pleased with the significant inflection in sales growth in the first quarter, we believe that annual growth rates will normalize to mid-single digits throughout the remainder of 2023 to account for the fairly low comp in the first quarter of 2022.

As for spinal implants and enabling technologies, which includes both legacy companies' technology portfolios, we reported global revenue of $61 million, reflecting 13% year-over-year growth on a pro-forma basis. More specifically, in the US market, where we generate the substantial majority of that revenue, we reported 21% growth in the spinal fixation franchise, and mid-single digit growth in the M6-C motion preservation product line, as we continue to focus on stabilizing that franchise.

Overall, US sales growth was driven by the more exclusive, high-volume distributors we onboarded in recent years, who are leading the efforts to take market share generated by increasing surgeon interest in the multiple products we launched within the past couple of years. We remain committed to continuous product innovation and have made critical decisions on rationalizing the spinal implants portfolio by leveraging the best of both companies' spinal implant systems to enable above market revenue growth with a more streamlined product offering that we expect to increase overall asset utilization and therefore the efficiency of our revenue.

In Q1, we announced the full commercial launch of the Mariner Deformity Pedicle Screw System, an extension of our foundational Mariner technology platform, which will address the unique clinical requirements of complex adult deformity in spine cases. In addition, we expanded our access solutions for the $1.8 billion MIS procedures market with the full launches of the Lattus Lateral Retractor system, which optimizes the lateral procedure to provide access to challenging anatomy during surgery, and the Fathom Pedicle-Based Retractor System, which allows the surgeon to control the precise length of each blade and dial in a customized lateral medial tilt, providing a rigid construct to address each patient's unique anatomy.

In early February, we announced the new US sales leadership team for spinal implants and biologics, and we defined smaller, more focused territories to increase our presence in those markets. We are excited to bring that sales leadership team and our key distributor partners together for our inaugural combined company global sales meeting next month.

Within the enabling technologies franchise, the first quarter marked the sale of our 50th 7D Flash System unit outside the United States. This comes on the heels of having announced the 100th global placement of a 7D Flash System unit in late 2022. To date, we have placed 7 units under active earnout arrangements that are expected to generate an average of $4 million of revenue per year over the respective earnout periods. This machine-vision technology is providing significant value to the institutions that are utilizing its capabilities and we look forward to expanding our market reach across the world through the expanded global distribution network. In the first quarter, we launched four new tracked tools to be used in our navigated percutaneous model, and we also completed our first fully integrated 7D Flash System case utilizing a legacy Orthofix spinal implant system, which signals the flexibility and ease of use of the 7D Flash System.

And finally, we were pleased with the publication of a study in a recent Journal of Pediatric Orthopedics that highlights radiation and time savings benefits when using the 7D Flash System in complex pediatric cases. The study noted that the system reduced operative time by approximately 64 minutes and reduced interoperative radiation exposure and time by 66% and 68% on average, respectively. We are excited to now be able to leverage our enabling technologies platform to support growth across all product lines of the combined company and to service the full continuum of care with this novel technology. We have seen a shift in the sector as more and more cases are relying on navigation and planning systems and we believe this creates an opportunity for us to accelerate share gains.

In biologics, we generated global revenue of $41 million, representing 7% year-over year growth on a pro forma basis. In the US, where the substantial majority of that revenue is generated, we also reported 7% revenue growth on a pro forma basis, which was driven primarily by recently onboarded distribution in the US. The biologics franchise provides surgeons with a full spectrum of biologic solutions, led by our flagship Accell-based demineralized bone matrix and Trinity cellular bone matrix solutions, to enhance the fusion process and promote bone repair and growth in a surgeon preference market. There are significant cross selling opportunities across

the entire Orthofix portfolio in conjunction with the use of biologics for improved patient outcomes.

In global orthopedics, sales grew by 14% at constant currency over the first quarter of 2022, with revenue totaling $26 million. This performance was driven across our diverse portfolio and was led by solid commercial execution in both the U.S. and international markets, and continued acceleration from 2022 product launches. The investments in U.S. sales leadership and our European direct sales channels over the last 12 months are bearing fruit, and we are enjoying continued pick up from the 2022 launches of the TrueLok EVO and Galaxy Gemini systems. These single-use sterile pack products are a simple and efficient solution for surgeons and hospitals, reducing complexity in the OR.

In 2023, we intend to continue our investments in product innovation, targeting end of year to introduce the next offering from the Fitbone platform. Our investments in product innovation, sales channel, and our market leading medical education programs are all designed to continue our current higher than historic growth in the Orthopedics business.

While we are still in the early stages of identifying and leveraging cross selling opportunities between all of our highly complementary portfolios and business segments, we believe that we are making good progress to be able to realize many of these opportunities to generate accelerated revenue growth later this year and to carry that growth momentum into 2024 and to help us further expand our commercial reach.

And finally, we believe that the announcement of our new US sales management responsible for spinal implants and biologics was an important first step in removing the uncertainty paralysis that can result from a merger like ours, and that certainty is now supporting our efforts to attract more strategic distribution. To date, we have not experienced any meaningful revenue dis-synergies in the spinal implants business, as our first quarter results would support, and we remain cautiously optimistic that we can successfully navigate through any remaining dis-synergy risks to the business.

Looking ahead, we are encouraged by the momentum we have coming out of the first quarter. That momentum, and the confidence we have in our teams to continue to execute, was a major factor in raising our revenue guidance to between $750 million to $756 million for the full-year 2023.

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The integration of the two companies is progressing smoothly and we are pleased to report that we are ahead of plan with respect to realizing the many operating expense synergies outlined in prior communications. We're seizing on the opportunity to capture market share and expand our commercial footprint on a global scale with our combined portfolio, and we have plenty of runway for a balance of further growth and scale.

From a macro perspective, we've seen procedure volume trends rebounding and some expansion and developments within the spine market that I believe Orthofix is in a great position to capitalize on. Competitive pressures across all our markets will reward innovative organizations like Orthofix, and we have the robust portfolio to meet the needs of patients and surgeons across the continuum of care. With initiatives like increased product utilization and offerings, higher revenue per case, and effective cross selling, our commercial team is ready to leverage the steady underlying market demand we're experiencing, and I can't wait to see what else 2023 brings.

With that, I'll turn the call over to John to provide a more detailed look at our financials in the first quarter and to provide more robust financial guidance for the full year.

John Bostjancic^ Thanks, Keith, and good afternoon, everyone.

As Keith noted earlier, total revenue for the first quarter of 2023 was $175 million, a 65% increase over the prior year as reported and an 11% increase over the prior year, on a proforma basis.

In the U.S. total revenue was $146 million, or 83% of total revenue, and revenue outside the US totaled $29 million, or 17% of total revenue.

The 14% growth from BGT came from both the spine and fracture commercial channels, with AccelStim revenue growing in the high teens sequentially compared to the fourth quarter of 2022.

On a proforma basis, U.S. spinal implant sales, which include motion preservation, were up 18% over the prior year, while international spinal implant sales were down 10% due to legacy SeaSpine's exit from the European market in the third quarter of last year.

U.S. biologics revenue grew 7% on a proforma basis driven by onboarding new, high-volume distributors, with significant growth coming from our DBM portfolio. We will continue to see new opportunities in biologics with our broad portfolio that allows for a targeted approach to meet surgeon needs.

This quarter is the last quarter we will be showing biologics as a stand-alone product category. Beginning in the second quarter of 2023, we will consolidate biologics into the same product category as Spinal Implants and Enabling Technology, since those products are typically sold through the same US distribution channel as spinal implants, are predominantly used in spine procedures, and are part of the enabling technologies earnout opportunity.

In Orthopedics, we saw double digit growth in both the U.S. and international when measured at constant currency rates, with that growth driven by sales channel investments and new products.

GAAP gross margin for the first quarter of 2023 was 63% compared to 73% for the first quarter of 2022. Adjusted gross margin was 71% for the first quarter of 2023, compared to 74% for the first quarter of 2022. On a pro-forma basis including the financial results of SeaSpine for the first quarter of 2022 revised to conform to the Orthofix presentation, we estimate that adjusted gross margin increased by 300 basis points to 71%.

The decrease in GAAP gross margin was almost entirely driven by the following merger-related factors, an $11.6 million non-cash, purchase accounting fair value step up charge attributable to SeaSpine acquired inventory that was amortized during the quarter; $700,000 of excess and obsolete inventory and instrument impairment charges related to spinal implant system rationalization decisions directly attributable to the merger, for which we expect to record similar charges in the next two quarters, and likely at a greater dollar amount, as we finalize those product discontinuation decisions; and the dilutive impact of the acquired legacy SeaSpine business on legacy Orthofix's overall gross margin, which we estimate to be approximately 500 basis points. Recall that legacy SeaSpine's financial results for the first quarter of 2022 are not reflected in Orthofix's GAAP results.

Likewise, the year-over-year decrease in adjusted gross margin is entirely due to the dilutive impact of the acquired legacy SeaSpine business on Orthofix's overall adjusted gross margin. We expect adjusted gross margins to increase over time as we recognize additional efficiencies from spinal implant set utilization and other economies of scale that we expect to generate from the merger.

GAAP sales and marketing expenses in the first quarter of 2023 were 54% of net sales, up from 51% in the first quarter of 2022. Adjusted sales and marketing expenses were 51% for the first quarter, compared to 50% for the first quarter of 2022. The increase in GAAP is primarily driven by integration-related severance and retention costs associated with the merger, as well as costs related to a national sales meeting for the BGT organization in 2023. That meeting was cancelled in 2022 for COVID-related reasons.

GAAP G&A expenses in the first quarter of 2023 were 28% of net sales, up from 18% in the prior-year period. Adjusted G&A expenses were 13% for the first quarter, compared to 14% for the first quarter of 2022. The increase to GAAP G&A expenses was driven by $5.9 million in higher stock-based compensation as a result of a larger employee base post-merger and from accelerated vesting of certain equity-based awards directly as a result of the merger, as well as other merger related costs, including more than $9 million of financial advisor and other professional fees, and approximately $6 million of accrued severance and retention costs. We expect to record additional severance and retention expenses throughout the remainder of 2023, albeit at lower dollar amounts per quarter, as those affected employees work through their respective end dates.

GAAP R&D expenses in the first quarter of 2023 were 13% of net sales, up from 11% in the prior-year period. Adjusted R&D expenses were 10% for the first quarter, compared to 9% for the first quarter of 2022. The increase to GAAP R&D was primarily driven by spend related to EU MDR compliance, accrued severance and retention costs associated with the merger, an MTF development milestone payment, and higher stock-based compensation expense. Our focus in R&D continues to be on bringing innovative and differentiated new products to the market.

Adjusted EBITDA for the first quarter of 2023 was $3.2 million, compared to $7.1 million for the first quarter of 2022. On a pro-forma basis including the financial results of SeaSpine for the first quarter of 2022, we estimate that adjusted EBITDA increased by $4.1 million compared to a loss of $900,000 in the prior year period. We expect adjusted EBITDA to increase in subsequent quarters in 2023 as we begin to realize an increasing amount of merger-related operating expense synergies through the remainder of the year.

Adjusted EBITDA is a non-GAAP financial measure that we believe provides valuable information on our operating results that facilitates comparability of our core operating performance from period to period and against other companies in our industry. A reconciliation of GAAP to

adjusted gross margin and adjusted EBITDA is presented in the financial tables of the news release we issued this afternoon. A reconciliation of pro-forma adjusted gross margin and adjusted EBITDA is at the back of our updated investor presentation that was posted to our website today.

Cash and cash equivalents on March 31, 2023 totaled $50 million, and we currently have $51 million of outstanding borrowings under our $300 million credit facility.

Our free cash flow, which includes operating cash flows and capital expenditures, was an outflow of $46 million for the first quarter of 2023. The significant items that generated the heavy cash spend in the quarter included the following, more than $15 million of cash spend related directly to the merger, including the success fees paid to each company's respective financial advisors, professional fees to facilitate the closing of the merger as well as post-closing integration assistance, and employees severance; $13 million paid for 2022 employee cash bonuses; and a $17 million cash spend related to inventory to support future revenue growth and upcoming product launches.

In terms of financial guidance, as Keith previously indicated, we expect our revenue for the full year 2023 to be between $750 million and $756 million, which represents 7% to 8% reported year-over-year growth compared to the approximately $701 million of pro-forma combined company revenue for full-year 2022 after giving effect to anticipated reclassifications to conform SeaSpine's revenue reporting to that of Orthofix.

Also, I'd like to remind everyone that any revenue generated by SeaSpine for the pre-merger period between January 1 through January 4, 2023, is not included in the combined company's GAAP or pro-forma first quarter revenue results nor in the full year 2023 revenue guidance.

For the full year 2023, we expect our adjusted gross margin will be in a range of 71% to 72% and for our adjusted EBITDA to be in a range of $40 million to $45 million, with more than 70% of that adjusted EBITDA generated in the second half of the year as we increase revenue and more fully realize anticipated operating expense synergies.

We still anticipate generating more than $40 million of operating expense synergies by year three post-merger, with the bulk of those synergies coming from redundant corporate overhead included in G&A, redundant headcount and program spending in spinal implants R&D, Sales and Marketing, and from a meaningful reduction in IT system related costs as we integrate a

portfolio of very common, and in many cases, overlapping IT systems. We expect to realize more than $15 million of those synergies in 2023 alone.

Costs to achieve those synergies are still expected to total $40 million. We anticipate spending more than $30 million of those costs in 2023, with remaining amounts in future quarters largely related to severance and retention costs for headcount synergies.

Given the large non-recurring cash spend related to the merger in 2023, we expect our free cash flow burn to be approximately $100 million for full-year 2023. However, we remain confident that, as we gain P&L leverage throughout the year as we increase our revenue and more fully realize those operating expense synergies, we will have sufficient borrowing capacity under the credit facility to finance all of that spending and to maintain a very healthy cash balance.

As we get further into the integration process, we will continue to provide additional reporting and guidance metrics.

At this point, I would like to turn the call over the Keith to wrap up.

Keith Valentine^ Before we open the line for questions, I would like to thank all of the employees of Orthofix for their loyalty and commitment during this time of transition. I am very proud of what our combined organization has been able to accomplish during the 4 months since closing on the merger. I would also like to specifically thank our field sales teams for continuing to place the patient first as we expand and strengthen our market presence. I am extremely excited about the future of Orthofix and look forward to continuing our momentum from the first quarter into the rest of 2023 and beyond.

At this point, operator, please open the line for questions.

Operator^ (Operator Instructions) Your first question comes from the line of Matthew Blackman.

Mathew Blackman^ Maybe to start, Keith and John, it's been about 5 months since you closed the deal and call it about 8 months since you first announced the transaction and provided what we'll call it an aspirational 3-year outlook, which I think was something in the neighborhood of $1 billion in combined revenues and mid-teens EBITDA margins. Just looking at consensus and our numbers, frankly, in '25, I think we're both coming in closer to the low $900 million range,

which is still a near double-digit CAGR. So I guess my question is really any updated thoughts now that you've been in that seat for the last several months on how we should be thinking about the longer-term outlook relative to those admittedly very initial financial mileposts you provided back in September?

John Bostjancic^ Hi, Matt. Yes. It's John. Thanks for the question.

And so now that we've had time to dive deeper into both companies' organizations, right, looking at the collective distributor bases, the collective product portfolios and geographies. We're definitely going to take a more targeted and balanced approach to revenue growth that's accompanied by increasing P&L leverage. So I mean, growth at all costs in the current market environment, we don't think is a winning strategy, and we think our stakeholders are going to benefit more longer term from this balanced approach to growth and an increasing P&L leverage.

So our goal is to still grow above market, right? We want to grow at a level that demonstrates we're still taking market share through innovation, through a focus on meeting our customers' evolving needs, but accompany that with a strategy that's got a little bit more focused on the operational and financial efficiency of the revenue that we're generating from those products and that we're launching to the market because we're just much more cognizant of making sure the ROI on those investments exceeds the cost of the capital.

So we're going to look at some low-margin product lines and try to minimize our exposure there and only keep those alive to the extent that they're helping meet the evolving clinical needs of our customers. But our overall goal, too, is to help reduce the complexity of the organization, right? We have very comprehensive product portfolios and the more products you're managing, the more complexity you have to manage.

So there's a lot of hidden costs, hidden opportunity costs that come with sustaining those older product lines with diminishing revenue and contribution margins. So we're definitely going to focus on minimizing our exposure there and really look at the portfolio so that we're generating higher margin, more efficient revenue as we go forward. So it will be a more balanced approach because we've all learned particularly in the spinal implant market, all revenue is not created equal, right? So I think we're going to be a bit more selective in how we grow. Again, we still want to demonstrate an above-market growth rate that shows we're absolutely taking market

share, but in a more disciplined approach that ultimately translates to more P&L leverage on the bottom line.

Mathew Blackman^ So if I translate that, I think it makes a ton of sense maybe that $1 billion aggressive on the top line and maybe mid-teens could prove conservative, whether it's in ‘25 or ‘26, but we should be thinking about leverage more so than revenue growth. So it's profitable growth, that's the focus.

John Bostjancic^ Yes. Definitely a more balanced approach. That’s (inaudible).

Mathew Blackman^ And then on the first quarter, I just wanted to dig into a couple of the franchises. First, really solid spinal implant performance despite what I think was a tough year-over-year comp. So hoping you could help on a couple of items. First, and this one is going to be tough if I appreciate it. But our work suggests the US spine market probably accelerated sequentially. Is there any way to tease out qualitatively or quantitatively how much of the 1Q Spinal Fixation upside was market versus better Orthofix portfolio performance like M6 being less of a drag or maybe some of those early portfolio synergies. And then I'll just throw this other one out there, it's related. The biologics still lagging hardware growth, is that complex headwinds that are still manifesting or something else?

Keith Valentine^ Yes. Thanks, Matt. So a few details on the spinal implant side. I think we did see a benefit of both, as you mentioned. I think the market has had a nice recovery. Part of that recovery, I think, as you can remember, is a more consistent quarter this quarter versus last year, where we still had some headwinds, if you will, from COVID and related issues with hospitals being able to be at full surgical capacity. And so I think that both of those things are going on.

One -- a couple of nice things, as you saw over the past few weeks, us being able to go into full launch with a couple of products as well. We got good momentum in the first quarter with especially the retraction side, retraction systems create an ability for us to have a more procedural sell, meaning the ability to be able to have not just the pedicle screw, but also the interbody opportunity as well as the [orthobiologics].

And so I think that we're seeing a more complete procedural selling opportunity, and we're seeing uptick in momentum because new distributors are excited about that procedural sell. We've even had the ability to cross-sell. We've had 7 cases that were done with Firebird pedicle

SKU systems. So we're seeing the integration just as we had anticipated and hoped and seeing the field get excited about the broader product portfolio that they're able to help move.

Now your question on the orthobiologics, it is interesting. I think the DBM franchise is still quite robust. We're still seeing good uptake. We've seen the ability to continue to drive that not only in larger buying group hospital systems, but also seeing it across the country having nice growth rates. I think what you see is some puts and takes when it comes to the higher-priced cell-based allograft opportunity. I still feel it's a very strong opportunity. We're fortunate to have the best product in Trinity as the offering. But I think there is some puts and takes across the United States when you take a look at hospital systems and what they're doing with their pricing and ability to sell that broadly.

John Bostjancic^ Thank you again for joining us this afternoon. We are excited to leverage the momentum we have coming out of a successful first quarter and appreciate your interest in Orthofix.