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Orthofix Medical, Inc. (OFIX)

Q3 2025 Earnings Call

CORPORATE PARTICIPANTS

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OTHER PARTICIPANTS

Thomas M. Stephan

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Jeffrey S. Cohen

Analyst, Ladenburg Thalmann & Co., Inc.

Michael John Petusky

Analyst, Barrington Research Associates, Inc.

MANAGEMENT DISCUSSION SECTION

Operator: Hello and thank you for standing by. My name is Regina and I will be your conference operator today. At this time, I would like to welcome everyone to the Orthofix Third Quarter 2025 Earnings Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. [Operator Instructions] . We kindly ask that you please limit your questions to one and one related follow-up.

I'd now like to turn the conference over to Julie Dewey. Please go ahead.

Julie Dewey

Chief Investor Relations and Communications Officer, Orthofix Medical, Inc.

Thank you, operator and good morning, everyone. Welcome to Orthofix's third quarter 2025 earnings call. We appreciate you joining us. I'm Julie Dewey, Orthofix's Chief IR and Communications Officer. Joining me on the call today are; President and Chief Executive Officer, Massimo Calafiore; and Chief Financial Officer, Julie Andrews.

Before we get started, please note that our earnings release and the supplemental presentation accompanying this call are available on the Events and Presentations page of the Investors section of our corporate website at orthofix.com. Also, this call is being broadcast live over the Internet to all interested parties, and an archived copy of this webcast will be available in the Investors section of our corporate website shortly after the conclusion of this call.

During this call, we'll be making forward-looking statements that involve risks and uncertainties. All statements other than those of historical facts are forward-looking statements. We do not undertake any obligation to revise or update such forward-looking statements. Factors that could cause actual results to differ materially are discussed in our most recent filings with the SEC and maybe included in our future filings with the SEC.

In addition, on today's call, we will refer to various non-GAAP financial measures. Please refer to today's news release announcing our third quarter 2025 results for information regarding our non-GAAP results, including our reconciliations of these non-GAAP financial measures to our US GAAP results.

Additionally, and unless otherwise stated, all net sales percentage changes discussed will be on a pro forma constant currency year-over-year basis, excluding the impact from the discontinuation of the M6 artificial disc product lines, and all results of operations that we will refer to will be on a non-GAAP as adjusted basis. We have posted a pro forma P&L excluding M6 on our website to assist you with updating your models. We will update it on a quarterly basis for the remainder of 2025.

Moving to today's agenda, Massimo will open with comments on our performance and business updates. Julie Andrews will then review the specifics of our third quarter results and our 2025 financial guidance before we open it up for questions.

With that, I'll now turn the call over to Massimo.

Massimo Calafiore

President, Chief Executive Officer & Director, Orthofix Medical, Inc.

Thank you, Julie. Good morning, everyone, and thank you for joining us today. Orthofix delivered another strong quarter, reinforcing our track record of consistent execution and financial discipline. We achieved solid year-over-year and sequential revenue growth led by strong performance in our USA Spine and Orthopedics businesses. This marks our seventh consecutive quarter our adjusted EBITDA margin expansion and sustained positive free cash flow generation. Clear evidence of our disciplined approach to operational efficiency and cost management.

In our U.S. Spine Fixation segment, net sales increased 8%, with procedure volume up 10%, both ahead of Q2 and the prior year. This above market growth was fueled by the continued adoption of our 7D FLASH Navigation System and strong momentum across our Spine portfolios. Lateral grew 24% while Posterior Cervical and Anterior Lumbar both grew 17% and MIS Lumbar grew 18%. We're seeing encouraging momentum from recent distributor transitions, which are expanding our commercial reach.

Our top 30 U.S. distributor partners grew net sales 25% year-over-year in Q3 and 33% on a trailing 12-month basis. A clear validation of our go-to-market strategy and its ability to unlock accelerated growth. As we continue to optimize our channel, we are confident this trajectory will drive further market share gains and long-term value creation.

7D unit placements in the U.S. are up year-to-date compared to prior year, and our Voyager Earnout Program continues to outperform with customers surpassing their purchase commitments by over 50% on average. The 7D technology remains a key differentiator enhancing surgical precision and workflow efficiency and is central to our ability to win share in a competitive market.

Now, let's turn to one of the most exciting development in our Spine portfolio. The limited market release of our new VIRATA Spinal Fixation System. Every aspect of VIRATA from our proprietary pedicle screw design to intuitive instrumentation that integrates seamlessly with 7D FLASH Navigation is engineered to optimize the surgical workflow, both surgeon confidence and accelerate procedural adoption. All key differentiator that we fully intend to capitalize on to capture market share.

To put this into perspective, the U.S. pedicle screw market valued approximately \$2 billion in 2025, is projected to grow at a steady 4% to 5% CAGR through 2030, fueled by an aging population and increasing Spinal disorders.

Like our successful NorthStar Posterior Cervical system, we believe VIRATA will set a new standard in pedicle screw fixation, driven by its integration with 7D, we expect VIRATA will become a meaningful growth driver following its fully launch in the second half of next year.

And beyond VIRATA, we are advancing our data-driven deformity strategy with access to preoperative planning and patient-specific growth beginning in Q1 of next year, further strengthening our competitive edge.

Our Orthopedics business also had a standout quarter, with U.S. Orthopedics growing 19%, marking the fifth consecutive quarter of double-digit growth. This performance was driven by the successful global launch of TrueLok Elevate and supported by new product introductions, including the FITBONE Bone Transport and the FITBONE Trochanteric Lengthening Nails.

We are proud to be the only company in the U.S. offering a complete suite of internal and external limb reconstruction solutions. And our dedicated focus on this \$2.6 billion market is yielding strong results. Our Bone Growth Therapies, BGT teams continues to excel, delivering above-market growth of 6% by leveraging cross-selling opportunities and multiple access points to reinforce our market leadership position.

Looking ahead, we remain focused on three strategic priorities, sharpening commercial execution to drive deeper market penetration and adoption of our 7D FLASH Navigation System. Improving gross margin through targeted operational initiatives and maintaining disciplined capital allocation with a continued focus on adjusted EBITDA expansion and free cash flow generation.

As we look towards 2026, I believe we are well-positioned for our next phase of profitable growth with a streamlined, differentiated product portfolio, optimized Spine commercial channel and unique enabling technologies, we are ready to deliver transformative innovation that benefits both surgeons and patient.

With our healthy commercial pipeline, well-defined and transformative innovation roadmap and strong execution, we believe we have a clear path to sustained growth that outperforms the market, driving margin expansion, free cash flow generation and positive shareholder's returns. Thank you for your time and continuous support.

With that, I'll now turn the call over to Julie Andrews, to review our third quarter financial results and our 2025 guidance.

Julie B. Andrews

Chief Financial Officer, Orthofix Medical, Inc.

Thank you, Massimo, and good morning, everyone. Before we dive into the numbers, a quick reminder, all net sales growth rates I'll reference today are on a pro forma constant currency basis, excluding the impact of net sales related to the discontinuation of the M6 artificial cervical and lumbar disc.

These are non-GAAP financial measures as outlined earlier in the call. I encourage you to review the reconciliations in our press release and the supplemental materials posted on our website, which include pro forma results through Q3 to support your modeling.

In Q3, we remain focused on distributor transitions in Spine and Biologics and surgeon-driven innovation. Through disciplined resource allocation, we're prioritizing high return opportunities that support share capture in U.S. Spine and Orthopedics, margin improvement and free cash flow generation, positioning us for sustainable, profitable growth.

Total global net sales reached \$203.4 million, a 6% increase over the prior year, driven by strong performance in our U.S. Spine and Orthopedics segments. Our Spine Fixation business saw a meaningful step up from Q2, continuing to outperform the market. Orthopedics saw strong results from FITBONE products and the TrueLok Elevate launch.

I will now take you through the net sales results by product segment. Global Spinal Implants, Biologics and Enabling Technologies delivered a \$108.6 million in pro forma net sales, up 6% year-over-year. Growth was supported by targeted distributor transitions in key geographies, which is positively impacting both our U.S. Spine and Biologics businesses.

U.S. Spine Fixation saw increased procedure volume of 10%, partially offset by a price decrease at a major account as previously disclosed. Propelled by expansion into new markets and deeper penetration within established regions, International Spine Fixation net sales grew by 86% year-over-year.

Bone Growth Therapies achieved \$61.2 million in net sales, reflecting 6% growth, outperforming the market. We expect BGT growth to remain above-market rates of 2% to 3%, driven by new surgeon additions and competitive conversions, especially in the Fracture channel.

Global Orthopedics grew 6% to \$33.6 million in the third quarter, led by 19% growth in the U.S. as a result of the market release of TrueLok Elevate and the FITBONE Bone Transport Nail. International Orthopedics grew 1% consistent with expectations given variability and stocking distributor in tender order timing that can occur from quarter-to-quarter.

Moving down the P&L, pro forma non-GAAP adjusted gross margin reached 72.1%, up 80 basis points from Q3 2024, driven by the discontinuation of M6 and productivity improvements, partially offset by unfavorable geography mix due to increased net sales in the International Spinal Implants, Biologics and Enabling Technologies. Pro forma non-GAAP adjusted EBITDA was \$24.6 million or 12.1% of net sales, with year-over-year margin expansion of 230 basis points led by the discontinuation of M6.

As Massimo noted, this marks our seventh consecutive quarter of EBITDA margin expansion, underscoring the scalability of our model and operational discipline. We generated positive free cash flow of \$2.5 million, ending the quarter with \$65.9 million in total cash, including restricted cash, supporting continued innovation and financial flexibility.

Moving on to 2025 full year guidance. We are narrowing our full year pro forma net sales guidance range to \$810 million to \$814 million, with the midpoint of \$812 million, unchanged from prior guidance of \$808 million to \$816 million. This guidance range excludes revenue from the discontinued M6 product lines and implies fourth quarter pro forma net sales will be approximately \$219 million. These projections are based on current foreign currency exchange rates and do not account for any further changes to exchange rates for the remainder of the year.

We are raising the bottom end of our full year 2025 pro forma non-GAAP adjusted EBITDA guidance range to \$84 million, with an updated range of \$84 million to \$86 million and a midpoint of \$85 million, representing 200 basis points of adjusted EBITDA margin expansion at the midpoint versus 2024. We continue to expect to generate positive free cash flow for the full year, excluding the impact of restructuring charges related to the discontinued of the M6 product lines.

Now for some specifics on P&L line items for 2025. We expect gross margins to be approximately 72% for the second half of the year. We continue to expect operating expenses to improve by approximately 200 basis points

this year versus 2024. We now expect stock-based compensation expense of approximately \$28 million to \$29 million and adjusted depreciation and amortization of approximately \$38 million for the full year. And interest and other expenses of approximately \$5 million per quarter.

And keeping with our standard practice, we anticipate providing formal 2026 guidance on our Q4 call in February. Delivering long-term shareholder value will continue to be paramount in 2026 and beyond, driven by our heightened focus on disciplined, profitable growth, positive free cash flow generation and strategic capital deployment.

Momentum in the Spine, BGT and Orthopedics businesses is projected to continue, supported by a robust innovation pipeline, consistent commercial execution and ongoing margin expansion efforts. We remain confident in our ability to deliver strong operational and financial performance for the remainder of 2025 and believe our strategic positioning, disciplined execution and resilient business model provide a solid foundation for sustained value creation in the years ahead.

With that, I'll turn it back to Massimo for closing comments before we open the line for questions. Massimo?

Massimo Calafiore

President, Chief Executive Officer & Director, Orthofix Medical, Inc.

Thanks, Julie. I want to thank our Orthofix team and our committed commercial partners for their contribution in Q3. This was a strong and successful quarter, and I am incredibly proud of our team's disciplined execution and the way we are strategically positioning Orthofix for continued success in 2025 and beyond.

Our Spine, Bone Growth Therapies and Orthopedics businesses are demonstrating sustained momentum, reinforcing our confidence in a successful close to 2025 and positioning us well for 2026. With operational rigor, a solid financial foundation and a clear path for innovation-led growth, Orthofix is well-positioned to deliver long-term value for our shareholders and advance our strategic priorities.

Operator, let's now open the line for questions.

QUESTION AND ANSWER SECTION

Operator: We will now begin the question-and-answer session. [Operator Instructions] We kindly ask that you limit your questions to one and one related follow-up. Our first question will come from the line of Tom Stephan with Stifel. Please go ahead.

Thomas M. Stephan

Analyst, Stifel, Nicolaus & Co., Inc.

Q

Great. Hey, guys. Thanks for taking the questions. I want to start, I guess, two questions. One kind of near-term revenue, one long-term. Kicking things off with near-term. Just on 2025 revenue guidance, be 3Q on pro forma by about \$3 million. But the midpoint of guidance was unchanged.

And I think 4Q revenue implies a slight decel to about 4% growth from 6% in 3Q. So, Julie or Massimo, maybe if you can talk about some of the moving parts with the implied 4Q 2025 revenue figure and maybe what held back sort of a flush through of the 3Q top line be?

Julie B. Andrews

Chief Financial Officer, Orthofix Medical, Inc.

A

Yeah. Hi, Tom. Thanks for the question. We set our guidance where we feel it's appropriate for the year. I think we had a very strong Q4 last year and so we were up against a little bit of comparability. And so we feel like we've set it appropriately within the range of what we expect for the fourth quarter.

Thomas M. Stephan

Analyst, Stifel, Nicolaus & Co., Inc.

Q

Got it. Makes perfect sense. And then one bit more long-term, I guess. So as we think about the 2027 financial targets on revenue. Julie, maybe just stick with you, can you just help us a bit with sort of the path to the 6.5% to 7.5% CAGR, do we think about both 2026 and 2027 within that bands to get there? Or is growth maybe more weighted to either 2026 or 2027? And then maybe if you can talk about kind of key puts and takes for 2026 on the top line, that'd be great. Thanks for taking the questions.

Julie B. Andrews

Chief Financial Officer, Orthofix Medical, Inc.

A

Sure. Thanks, Tom. We're not providing 2026 guidance today, but in speaking about our long range plan, I think it will be a little bit more weighted towards 2027. Primary drivers of that, we will have a full launch of VIRATA in 2027.

So we're launching that mid -- we talked about launching that mid-year next year. So that will be a full launch. In addition, we've talked a lot about the TrueLok Elevate launch, which we are now in full launch of it, that is a market development type of launch. And so, we will see continued acceleration of that and deeper acceleration of that into 2027.

Massimo Calafiore

President, Chief Executive Officer & Director, Orthofix Medical, Inc.

A

Yeah, Tom, let me add some other -- some more color and you see the momentum that we're getting with the addition of our -- the new distributors and this is a -- this is ongoing, is very successful and we're going to still

going to get the benefit in 2026 and 2027. So, I think that the foundation of the company is much stronger, since we started two years ago. The pipeline is very strong, so I'm very optimistic about what we can achieve in the later year of our long range business plan.

Thomas M. Stephan*Analyst, Stifel, Nicolaus & Co., Inc.*

That's great. Thanks so much. Congrats on the progress.

Julie B. Andrews*Chief Financial Officer, Orthofix Medical, Inc.*

Thanks, Tom.

Operator: Our next question will come from the line of Mike Petusky with Barrington Research. Please go ahead.

Michael John Petusky*Analyst, Barrington Research Associates, Inc.*

Hey, good morning. So I guess I just wanted to try to drill down on the strength in U.S. Spine. Can you sort of talk about what you think are the most key drivers in that strong result? I mean, is it 7D pull-through, is it the distributor? Can you just talk about what's driving sort of above-average market growth in U.S. Spine? Thanks.

Massimo Calafiore*President, Chief Executive Officer & Director, Orthofix Medical, Inc.*

Thank you, Mike. Look, I think that is, there are three key points for us. One, we're seeing encouraging momentum from this recent distributor transition. If you think about -- if you drill down the top 30 of our U.S. distributor partners grew net sales 25% year-over-year in Q3 and 33% on a trailing 12-month basis.

And this is a clear validation that the tough decision that we took of starting our tenure, are start to paying off. And all of this, like it's we're bringing more capital-efficient commercial partners that can help us to drive the profitable growth that we want to achieve.

At the same point that, we want to be a company that lead with innovation, the commercial -- that our pipeline from the product standpoint is very exciting. There is a lot of support what we are doing so with VIRATA, a very successful alpha launch so far. And, of course, the -- our pinnacle of our strategy 7D, which keep driving a positive momentum.

Our placement are up year-over-year. Our Voyager Earnout Program is being a -- is still being a very -- a great success. And just remember that, on average, our customers are passing 50% or 50% of our customer are passing their commitment on usage of our implants. So a great foundation to build up our Spine business.

Michael John Petusky*Analyst, Barrington Research Associates, Inc.*

Okay, great. And then just a quick one for Julie. I would certainly expect, I guess, Q4 free cash flow to be strong relative to each of the first three quarters. I'm just curious though, you had a very strong free cash flow quarter last Q4, your last year's Q4. Would -- is there any chance that you could exceed that figure, this Q4 or should we model more conservatively? Thanks.

Julie B. Andrews

Chief Financial Officer, Orthofix Medical, Inc.

A

Yeah. I mean, I think what we've guided is that, we'll be free cash flow positive for the second half of 2025. We haven't specifically given a number for the quarters or specifically said what that number is. What I would say is, I think I wouldn't expect it to probably be at the same level as last year.

I think, we're forward placing some inventory to get a good start to next year. So I expect a little bit more in capital usage and inventory from a working capital standpoint. But I would expect that again, that we'll be free cash flow positive for the second half of the year.

Michael John Petusky

Analyst, Barrington Research Associates, Inc.

Q

Okay, great. Thanks. That's helpful. Thank you.

Operator: [Operator Instructions] Our next question will come from the line of Jeff Cohen with Ladenburg Thalmann. Please go ahead.

Jeffrey S. Cohen

Analyst, Ladenburg Thalmann & Co., Inc.

Q

Hey, good morning and thanks for taking our questions. I've one and a follow-up. Firstly, could you talk about distributor increases and transition, particularly domestically have you transitioned from existing ones to current ones or have the current ones expanded?

Massimo Calafiore

President, Chief Executive Officer & Director, Orthofix Medical, Inc.

A

I think it is a combination. So, we start to consolidate our distribution -- our distributor partner in some areas. So instead of having a multiple of -- multiple agent distributor in serving same account, we start to consolidate to the one that we believe can scale in the future.

And, of course, so we look geography-by-geography in areas where we want to win, and then we can add or add the new distributors to start to attract specific region of the country, where we saw we didn't have a good presence. So, I would say that it is a combination of the two, expansion...

Jeffrey S. Cohen

Analyst, Ladenburg Thalmann & Co., Inc.

Q

Got it.

Massimo Calafiore

President, Chief Executive Officer & Director, Orthofix Medical, Inc.

A

...and consolidation.

Jeffrey S. Cohen

Analyst, Ladenburg Thalmann & Co., Inc.

Q

Got it. And then as a follow-up, could you talk about this TBT or TrueLok Elevate as far as the one study that was published on increased peripheral vascularization, would you expect there to be more studies and publications that are currently being done or in the future? Thank you.

Massimo Calafiore

President, Chief Executive Officer & Director, Orthofix Medical, Inc.

A

Yeah, we believe in clinical validation of our product. So, is in the pipeline for us to participate. But at the same time, we see a lot of interest in the surgeon community around the procedure. So I would not be surprised if other centers are going to start to study the specific surgical technique. So, very excited about the opportunity. There is a specific focus of our organization and validate what we do with TrueLok Elevate and we are ready to build the great story around that.

Jeffrey S. Cohen

Analyst, Ladenburg Thalmann & Co., Inc.

Q

Perfect. Thanks for taking our questions.

Operator: And that will conclude our question-and-answer session. I'll turn the call back over to Julie for any closing comments.

Julie Dewey

Chief Investor Relations and Communications Officer, Orthofix Medical, Inc.

Thank you, everyone, for joining us today. We sincerely appreciate your time and interest in Orthofix. If you have any questions as usual, please reach out. We look forward to continuing the conversation next quarter. This concludes today's call.

Operator: This concludes our call. Thanks for joining. You may now disconnect.

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