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Orthofix Medical, Inc. (OFIX)

Q2 2026 Earnings Call

CORPORATE PARTICIPANTS

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OTHER PARTICIPANTS

Caitlin Roberts
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Thomas M. Stephan
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MANAGEMENT DISCUSSION SECTION

Operator: Thank you for standing by. At this time, I would like to welcome everyone to the Orthofix second quarter 2026 earnings 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] Thank you.

I would now like to turn the call over to Julie Dewey.

Julie Dewey

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

Thank you and good morning, everyone. Welcome to Orthofix's second quarter 2026 earnings call. I'm Julie Dewey, Orthofix's Chief IR and Communications Officer. Joining me today are President and Chief Executive Officer, Massimo Calafiore and Chief Financial Officer, Julie Andrews.

Earlier today, Orthofix released its financial results for the second quarter ended June 30, 2026. A copy of the press release and supplemental presentation are available on our Investor Relations website and a replay of this call will be posted shortly after we conclude.

Before we begin, please note that our remarks include forward-looking statements. These statements involve risks and uncertainties, and actual results may differ materially. 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 may be included in our future filings with the SEC.

We will also reference certain non-GAAP financial measures during today's call, including certain growth rates presented on a pro forma constant currency basis and excluding discontinued M6 artificial disc product lines. Reconciliations to the most directly comparable US GAAP measures and additional information are included in our press release and supplemental materials. Here's today's agenda. Massimo will start with business performance and operational highlights. Julie Andrews will follow with their financial results and guidance. Then we'll open the call for Q&A.

With that, I'll turn the call over to Massimo to discuss our second quarter performance and the progress we're making across our strategic priorities. Massimo?

Massimo Calafiore

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

Thank you, Julie. Good morning, everyone. I appreciate you joining us today. Our second quarter results provide further evidence that the operational actions we have taken over the past year are showing up more clearly in the business. While that progress is encouraging, our transformation remains a work in progress, and we are staying disciplined in how we evaluate growth quality, commercial productivity and returns.

We delivered 5% pro forma constant currency net sales growth over prior year and saw encouraging trends across several areas of the portfolio, including double digit growth in global limb reconstruction and spine fixation. Sequential momentum in biologics and the restoration of medicare reimbursement for bone growth stimulators, which removes a meaningful headwind for our therapeutic solutions business as we enter the second half of the year. While we recognize that transformation are rarely linear and not every part of the portfolio will improve at the same pace, we believe Orthofix today is operating from a stronger position than it was a year ago. Our approach remains disciplined and focused. We believe the underlying drivers of our performance are becoming more constructive, supported by clearer execution priorities and better visibility in key parts of the business.

With that context, let me walk through our business performance in Q2, starting with spine. In spine, global spine fixation net sales grew 10% on a constant currency basis with US spine fixation net sales up 3% in the quarter. Our top 30 distributors, who represent approximately 80% of our spine fixation sales, continue to perform well. At the same time, we saw a steeper decline across the remaining smaller distributors, where productivity has been below our expectation for several quarters.

We are actively evaluating where we can generate the best long-term returns among this group. As part of the process, we are being disciplined about where we invest resources and where we make shoes to consolidate or exit relationships that are not delivering sustainable growth. This approach reflects our focus on profitable growth and strong returns.

We expect these challenges with our smaller distributors to continue through the balance of the year. Longer term, our objective is to build a higher quality, more productive distributor network that can support the sustainable growth, stronger adoption of new products, and better returns on future commercial investment. We are also preparing to bring new innovation into the channel. We completed our first clinical cases with our VIRATA minimally invasive system in Q2 and are continuing to prepare for the full market launch of our VIRATA spinal implant system later in the fourth quarter.

Importantly, the initial surgeon feedback has been encouraging and supports our continued focus on building an integrated procedural platform that combines VIRATA with our Interbody solution, surgical at-risk technology at 7D Enabling Technologies portfolio. Beyond spine, we believe early signs indicate that our focused execution is contributing to better performance in areas that had been under pressure. In biologics, we saw encouraging signs that this business is moving in the right direction.

Net sales were approximately flat year-over-year represented a market improvement from the contraction we experienced throughout 2025. This was the second consecutive quarter of improved year over year performance, moving from double-digit declines last year to approximately flat performance in Q2.

While we are encouraged by this progress, we believe more consistency is needed before declaring a sustained return to growth. Our priority now is converting this more constructive trajectory into durable growth supported by stronger account engagement, higher utilization, and targeted commercial focus around the key products such as our OsteoCove, bioactive synthetic bone graft.

To further support the long-term growth potential of the business, we're pairing improved commercial execution with targeted investments in clinical evidence generation for OsteoCove and [indiscernible] (00:22:10) and product registry for OsteoStrand Plus. This investment is intended to support a more durable recovery.

We saw a different, but equally important dynamic in therapeutic solutions where underlying demand remained resilient despite the reimbursement pressure it affected part of the quarter. Therapeutic solutions, formerly Bone Growth Therapies delivered 3% year over year net sales growth. Despite the impact from the Medicare reimbursement decrease that was in effect for a portion of the second quarter. That performance reinforces the durability of the franchise, which continued to benefit from steady demand, a strong margin profile and favorable cash generation characteristics.

We were also pleased with the CMS restored medicare reimbursement for bone growth stimulator to its prior level, following stakeholder feedback, including concerns we raised. This decision removes a meaningful headwind and supports improved second half visibility with utilization and prescribing trends during the quarter remaining constructive.

As we return to more supportive reimbursement environment, we plan to continue investing in elevating the patient and physician experience within the therapeutic solutions franchise. During the quarter, we launched AccelStim 2.0. This award-winning Bone Growth Therapy device was redesigned with a streamlined form factor to provide enhanced ease of use. It is now compatible with our STIM onTrack mobile app and STIM MD physician platform giving patient and physician greater visibility into device utilization and therapy progression. Further strengthening the value proposition of the franchise.

We view therapeutic solutions as more than a highly profitable franchise. It's established physician and patient reach provides a valuable channel for evaluating adjacent growth opportunities, where we see clear clinical relevance and attractive returns. Global limb reconstruction demonstrated solid performance during the quarter, supported by strong international momentum and sustained demand across key product families.

Net sales grew 11% on a constant currency basis, led by the Truelok, Elevate and Fitbone. In the US, growth was below our expectation, but the primary dynamic was not a lack of clinical interest. Rather, we are still building the commercial infrastructure required to more consistently convert net interest into revenue in what remains an emerging medical structural market. Our focus is on improving distributor productivity, expanding market development activities, increasing commercial consistency.

As those capabilities mature, we expect US performance to become more consistent over time. We also see opportunities to extend our limb reconstruction expertise into adjacent areas of unmet clinical need. One example is diabetic foot ulcers a large and underserved market where we believe our core technologies may have broader clinical applications.

Our near-term focus is on generating the clinical evidence needed to support a potential expanded indication, while maintaining a disciplined approach to investment and development. We view this as an important pipeline opportunity that could expand the reach of our limb reconstruction portfolio and support durable long term growth.

To recap, Q2 showed tangible progress in several areas of the business, while also reinforcing where continued execution is required. Our focus remains on improving quality of revenue, strengthening commercial productivity and building a more consistent path to profitability and cash generation. Just as importantly, we believe the combination of focused innovation, a more productive commercial organization and disciplined capital allocation position us to create sustainable long-term value for shareholders.

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

Julie B. Andrews

Chief Financial Officer, Orthofix Medical, Inc.

Thank you, Massimo, and good morning. For purposes of consistency, the growth rates I'll reference today are on a pro forma constant currency basis and exclude the impact from discontinued M6 product lines. From a financial perspective, Q2 results reflected improving revenue trends across several areas of the portfolio, while profitability was impacted by geographic mix and continued investment in priority growth initiatives.

Let me briefly review performance by business segment. Global spinal implants, biologics and Enabling Technologies generated $109 million in net sales and increase of 4% versus the prior year period. Growth was led by spine fixation, which benefited from continued international momentum and timing of international distributor orders.

Therapeutic Solutions generated $64.2 million in net sales, up 3% year over year. The business grew despite temporary reimbursement pressure, reinforcing our view that underlying demand remains resilient. With Medicare reimbursement restored, we expect therapeutic solutions to contribute more favorably in the second half. Global limb reconstruction delivered net sales of $37.7 million in the second quarter, an increase of 11%.

Growth was driven by strong international demand and continued adoption of key product families, including Truelok, Elevate and Fitbone. While growth in the US was more modest during the quarter, our second half assumptions reflect greater commercial productivity, the lapping of sunsetting product lines and continued prioritization of our highest return growth opportunities.

Moving down to the P&L non-GAAP adjusted gross margin was 71.7%, reflecting an unfavorable geography mix during the quarter. Adjusted EBITDA was $20.1 million, while net sales trends improved during the quarter. Profitability was impacted by geographic mix, credit losses in certain international markets, and continued investment in key launches, partially offset by ongoing cost optimization initiatives.

We remain confident that the resource alignment and cost actions underway will support our full year profitability outlook. We ended the quarter with $104.4 million in total cash, including restricted cash, providing us with flexibility to support both our operating priorities and strategic investment. Before turning to guidance, I want to provide context around our European MDR strategy for spine that is reflected in our updated net sales outlook and is important to understand and model appropriately. As background, Seaspine made the decision in 2022 to exit the European spine market and focus resources on the US. And that strategy remained in place following the merger. Accordingly, we had not been pursuing MDR compliance for the spine portfolio.

More recently, one of our largest European distributors expressed strong interest in continuing to sell some of our spine products in his territory. We entered into a strategic contractual arrangement under which the distributor is funding our MDR certification related work required to support continued market access for these spine products.

This allows us to preserve a targeted opportunity in Europe while maintaining our disciplined investment priorities. To support this arrangement, the distributor intends to purchase sufficient inventory in 2026 to maintain continuity of supply and ensure continued market access while MDR certification and related country specific market access requirements are completed. These purchases are included in our updated 2026 net sales outlook. The key takeaway is that we expect this arrangement to contribute approximately $15 million of incremental net sales in 2026, with the majority expected to be recognized in Q4.

We are calling this out explicitly because it would be a discrete timing benefit and should be distinguished from the underlying run rate performance of the business. As a result, the arrangement is also expected to create an approximately $22 million net sales headwind in 2027, while MDR requirements are completed.

Let me now turn to our updated full year outlook. Again, all measures are provided on a non-GAAP pro forma basis, are based on current foreign currency exchange rates, and do not contemplate any additional exchange rate changes during the remainder of the year. We now expect full year 2026 net sales in the range of $845 million to $855 million, representing approximately 5% pro forma constant currency growth at the midpoint and an increase of approximately $7 million from the outlook we provided in May.

The updated outlook reflects underlying business trends, plus several discrete factors that are shaping our expectations for the balance of the year. First, Medicare reimbursement for bone growth stimulators has been restored to its prior level, retroactive to May 18, 2026. Second, our strategic arrangement with our European distributor contributes revenue associated with inventory purchases tied to the MDR transition.

Third, we are seeing encouraging trends across several areas of the business, including stabilization in biologics and continued strength in portions of limb reconstruction. And fourth, those positives are offset by ongoing softness among smaller US spine distributors, who performance remains below our expectations and is reflected in our outlook for the balance of the year.

We are increasing our adjusted EBITDA guidance range to $95 million to $98 million, while the MDR related distributor revenue carries a different margin and timing profile than our core revenue. The restoration of Medicare reimbursement, ongoing cost actions and continued operational progress returns our profitability outlook to the level we expected before the Medicare reimbursement reduction was introduced in May. Our focus remains on balancing net sales growth, profitability and cash generation as we execute against our long-term value creation priorities.

As you think about the second half, we expect third quarter net sales to generally be consistent with Q2 as reimbursement restoration and improving trends in several businesses are expected to be largely offset by ongoing softness among smaller US spine distributors. Looking to the fourth quarter, sequential growth is expected to be by the timing of inventory purchases associated with the European distributor arrangement and normal seasonality.

We currently expect the majority of the approximately $15 million 2026 net sales benefit to be recognized in Q4. I also want to note that the European distributor arrangement creates the temporary free cash flow timing headwind in 2026, as some cash receipts are projected to occur in 2027 while inventory related cash outflows occur this year. Importantly, this timing dynamic does not change our view of the underlying cash generating potential of the business or the quality of earnings reflected in our outlook.

Taken together, we believe our updated outlook reflects more favorable performance indicators in key areas of the business, balanced by the timing of the MDR related net sales benefit and the continued softness among smaller US spine distributors. We remain focused on improving growth quality, expanding profitability and strengthening cash generation.

Now let me turn it back to Massimo for closing remarks. Massimo?

Massimo Calafiore

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

Thank you, Julie. Q2 was an important proof point in our transformation. We made progress in several parts of the business, but we remain focused on consistent execution, disciplined investment and improving the quality of our gross.

We believe Orthofix is entering the second half with greater clarity, more favorable trends across several businesses, and a focused approach to driving profitable growth and cash generation. Our priorities remain clear, improving commercial productivity, advancing differentiated innovation and generating the clinical evidence needed to support future growth opportunities.

Our objective is not growth at any cost. It is durable, profitable growth supported by better commercial productivity, disciplined investment, and stronger business fundamentals. Before we take your questions, I want to thank our team members and commercial partners around the world for their continued commitment and execution.

With that, let's open the call for questions.

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] And your first question comes from the line of Caitlin Roberts with Canaccord Genuity. Please go ahead.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

Great. Thanks for taking the questions. And I guess just to start on guidance, you increased the guidance again, but not as much as prior to the CMS changes. Maybe some more color on what's changed since that time, whether that's the partial quarter impact of the pricing change or if there's more in there from the small spine distributor challenges, any color on that would be great.

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

A

Yeah. Thanks, Caitlin. So the updated outlook reflects a combination of underlying business trends and several discrete factors that are shaping our expectations for the balance of the year. So first, on the positive side, we have the restoration of the Medicare reimbursement, which is approximately a $12 million benefit, as well as the European distributor arrangement, which is expected to contribute approximately $15 million of incremental net sales in 2026.

And we're also seeing stabilization across an encouraging trends across several areas of the business, including biologics and portions of our limb reconstruction business. At the same time, those factors are being offset by the ongoing softness among our smaller US spine distributors, where performance remains below our expectation. And that's what's reflected in our outlook for the balance of the year. We believe it was important to be transparent about both the progress we're seeing in the execution risk that remains. And those are the factors that are influencing our reset of our guidance.

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

A

Yeah. And like heavy transformation is not always linear. And we didn't change our main thesis to be very disciplined on prioritizing quality revenue. So what we see the softness on this, 20% of our smaller distributor is not related to demand is really related to spine channel. And we didn't feel to change how we operate in the business. But at the same time, I think that is very important to highlight the fact that we are maintaining our EBITDA target.

At the same time, we are doubling down on innovation. I'm sure that you heard about our investment that we're making in biologics. Biologics is the recovery very well. We strongly believe on our product and investing on clinical evidence for OsteoCove [indiscernible] (00:40:27) start a big registry for OsteoStrand Plus. In orthopedics, we see a great opportunity with this diabetic foot ulcer. And we are – we just submitted our IDE to the FDA and we are waiting for their feedback. All of this to open up a great, very great and potentially very lucrative opportunity for the organization.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

Understood. And then just any thoughts on reinstating an LRP now with the pricing decision reversed and the guidance for this year increased?

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

A

Yeah. I think we're still assessing where we are and looking at our actions, particularly related to the smaller spine distributors and how that may impact our LRP over the next year or so.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

Understood. Thanks so much.

Operator: [Operator Instructions] And your next question comes 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 wanted to start off excuse me on the Europe MDR kind of distributor order dynamic and sort of core growth. So basically as we think about apples to apples guidance on revenue compared to your previous outlook, we should be taking off that $15 million of sales that were not previously there. Like those are as incremental. Is that correct as we're trying to get to sort of core quote unquote, core growth? A, do I have...

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

A

Yes.

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

Q

...I guess, to start. Julie, do I have that correct? Okay. Got it.

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

A

Yes. That's correct.

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

Q

And so if we take out the $15 million tailwind in the back half, I mean, by my math that would imply core growth on revenue of 1% to 2% in the second half. Hopefully I have that right as well. So Julie or Massimo, why would growth slow to those levels in the core business just given 1H and 2Q or kind of in that mid-single digit range on a pro forma constant currency basis? And then I have a couple of follow-ups.

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

A

Yes, Tom. So I think when you're looking at it, I think you're in the range 2 percentage to 3 percentage core growth rate. Again, I think if you look at our smaller US spine distributors, we're seeing a decrease, a weakening there beyond what with our expectations. And that's what's really driving it in the back half of – at the back half of the year and again, we're going to be probably a little bit more discretionary about how we think about those distributors and what we may do with those distributors, whether we continue to consolidate or exit weaker distributors that are not delivering our sustainable growth.

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

Yeah. Look, we are – as I said before, we are intentionally prioritizing the commercial channel quality. We never changed our thesis. So we want productivity, a long-term value creation of our growth at all cost. So this is what we are today.

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

Got it. Okay. Great. And probably a good segue into my second question. Just on the declines from the smaller distributors. You talked about how – Massimo you talked about how these headwinds will persist rest of year. I guess a two parter here. One, can you elaborate on just why is this tracking weaker than expected, if you can sort of parse that out a little bit? And then two, as we think beyond this year, like, why won't this be a continued headwind or what specifically to resolve this issue?

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

It's just the increased percentage of revenue that is going to be concentrated to our top distributor. So right now, we're at 80% of our total revenue is in the hands of the top 30. So the exercise for us for the remainder of the year is within this 20% really pick and choose the partner to want to invest on. If you remember in earlier calls, we divided our overall commercial strategy in three frame part. One was focusing on a distributor that were already at [indiscernible] (00:45:16) scale. Two, existing distributor that can create scale and three, identify the smaller distributor in key areas that are of interest for us to invest on and that is what we've got to keep going.

I think that what is creating right now the headwind that we're seeing is mostly based on asset utilization. We're very disciplined about how we give asset in order to produce the revenue. If the asset downturn is not a good investment for us to keep feeding this smaller shop, because in order to do that, we should totally change our investment thesis, increasing cash spending for bad revenue. So naturally you see that the work that we are doing is going to adjust to the right state, the growth that we are seeing from our top partner over time, similar to what we did in biologics, you see, we were very disciplined despite the headwinds last year, we were very focused and now we start to see [indiscernible] (00:46:37) our strategy. So I'm not expecting this to change in despite.

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

Got it. That's great. I'll squeeze in one more quick one, if that's okay. And Julie for you, just I appreciate the free cash flow commentary and maybe some of the moving parts around the EU MDR order and timing around inventory. But any way you can help us kind of quantify where 2026 free cash flow may land, any sort of range would be super helpful. Thanks, everyone.

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

A

Sure. Thanks, Tom. I mean, we're not providing an updated outlook on free cash flow for the year. We haven't reinstated our guidance there. I think the value of the order, $15 million, you can kind of estimate and look at what our previous guidance was related to free cash flow and take those factors into consideration.

Operator: There are no further questions at this time. I will now turn the call back over to Julie Dewey for closing remarks.

Julie Dewey
Chief Investor Relations & Communications Officer, Orthofix Medical, Inc.

Thank you, everyone, for your questions and for joining us today. We appreciate your time and interest. If you need any additional information, please reach out. We look forward to updating you next quarter. This concludes our call today.

Operator: Ladies and gentlemen, thank you all for joining. You may now disconnect.