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Orthofix Medical, Inc. (OFIX)

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Thomas M. Stephan
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MANAGEMENT DISCUSSION SECTION

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

Okay, great. Good morning, everyone. Tom Stephan with Stifel medtech. Really excited to have Orthofix here with us today. Massimo, Julie, Julie, thanks for joining us.

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

Thank you for having us.

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QUESTION AND ANSWER SECTION

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

Q

Maybe I'll just kick things off and if you can sort of level set the audience, Massimo or Julie, start by quickly recapping the recent third quarter print and kind of what you view as some of the key highlights?

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

A

Yes, I mean, we I'll let Massimo follow up, but I'll start. You know, good Q3, our top line we beat, revenue beat consensus on revenue EBITDA and we're free cash flow positive in the quarter, $2.5 million, had an accelerating revenue growth rate. Our revenue growth was 6% for Q3 and around 230 basis points of EBITDA margin expansion, which was our seventh quarter consecutive quarter of EBITDA margin expansion. So, all around solid performance that we saw within the quarter.

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

A

Yeah, from the commitment that we made since the beginning, in all of the areas of all of -- on all of the focus areas for us, so we beat the market in a very significant way. So, you saw the growth that we had in United States in spine, which is actually speaking highly about all of the new strategy that we are developing, implementing about distribution, great growth in the orthopedics side in United States. BGT keep growing above market even if we are proudly the leader in the specific category. So, I was very pleased about how the company performed.

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

Q

That's great. Great recap and we'll certainly dive into some of those dynamics deeper. Want to jump into kind of revenue and some near-term questions. And Julie, I went down this road in Q&A on the call, I believe, but I wanted to revisit it and dig a little deeper. I think you mentioned it. You beat 3Q revs by about $3 million, but didn't raise the midpoint of the guide. So, Julie, maybe if you can talk about some of the factors that may have played into that sort of cadence and dynamic?

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

A

Yeah, I mean, the primary driver of our beat in Q3 was in stocking orders and international, and so just from a timing perspective, they came in a bit earlier from -- we expected them in Q4, they came in, in Q3. And so really that's why we're not raising guidance, it was timing of stocking orders. All of our US businesses are accelerating either maintaining growth rate or accelerating growth rate into the fourth quarter. And it was really just that timing of international stocking orders. And then in addition, that was US, our international spine, on the international ortho side last year had some stocking orders that will not repeat this Q4. So, there's some comparability there too, but it's really all around timing of international stocking orders.

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

Q

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Got it. Okay. So timing of stocking orders in 3Q 2025 for OUS spine, and then 4Q 2025, you face a difficult OUS Orthopedics comp, is that correct?

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

Correct.

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

Got it.

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

Yes.

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

Okay. Perfect. Super helpful. And Massimo, you mentioned US spine, so want to spend some time there. Procedure growth really strong at plus 10%, momentum seems to be accelerating, what you kind of view as durable US spine procedure volume growth moving forward?

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

Yeah, our goal is to keep growing above market. And I see that, you know, the floor that we have right now is something that we can achieve. Given that we need to remember that if you just see our spinal hardware, we're still subscale compared to many. There is a confusion between the size of the organization per se and how big is our spine hardware businesses. And we see each other as a market taker in the space for many years to come. The dislocation that is coming that in the marketplace is taking is a positive sign for us. We are we are a commercializing a product line that is very competitive, is very fresh.

We talk about our innovation, how we are investing in innovation would be rather to really close the circle and put [indiscernible] (00:09:48) on a product line that is let us attract the surgeon and commercial talent out there. But all of these still with in mind our philosophy of profitable growth. So, at the end, for us to create value, we need to connect the dots between like our customer on one side and the shareholder community on the other side. So, EBITDA positive free cash flow is going to be always our Northstar to drive growth.

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

Absolutely. That's great. Super, super helpful. So, you know, maybe floor on US spine procedure growth, think above market. And Julie, maybe for you, just the other side of that US spine growth equation being price, what about US price? You'll lap the ongoing price headwinds, I think fairly soon. So, how do we think about price contribution to US spine growth moving forward?

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

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So, I mean, overall, I think, you know, if you look at our long-range guidance, we assume about a 1% to 2% price erosion. I think really the reality is, though, I mean, our pricing has really been flat if you exclude the one account that we're in the process of annualizing now. But so it's been pretty flat as we've looked at it, but long range guidance, we kind of assume a 1% to 2%.

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

Q

Got it. Super helpful. And then, Massimo, you mentioned this earlier on the distributors, but the targeted distributor transitions seem to be, I'd say, already having a positive impact on the business. What inning are we in with these changes? Or I guess asked another way, like how long can this remain as an incremental growth driver for US spine?

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

A

Yeah, we are still in the middle of the road. The situation that we found when we start with Orthofix was a commercial organization that's very highly fragmented and has been a mandate for us to start to consolidate, creating -- start to invest and distributor can actually can scale, it's going to be always, let's say, an ongoing work that we have to do in the foreseeable future. I see this strategy divided, let's say in three pieces.

In one piece in areas where that is very highly fragmented, we consolidate and we are looking at geographic areas where we are not present to go and attract the talent that fits our profile. And we are very diligent on making sure that we don't rush on decision. And the other side now is going to be our goal to make sure that within this top 30, we're going to keep bring them up, help them to actually scale and to create a stronger partnership and loyalty with us.

So, I'm very excited, we are bringing the 20 plus experience in this space in order to leverage the relationship that we have. And as you said, is paying off.

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

Q

Got it. That's great. And then maybe to pivot a bit within US spine, just to capital. Massimo, can you talk a bit about 7D placement demand trends and notably kind of what the capital equipment purchasing environment looks like in the US, sort of from your perspective?

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

A

Yeah, we had a pretty good quarter, we didn't give any numbers, but we just said that we were up compared to last year. So, a good results there for us. What we are doing in order to be a little bit less, let's say, less sensitive from our overall change of the capital environment, since Julie and I started, we focus really on creating earnouts agreement with our hospital, we call Voyager program, so pretty much there is no capital outlay upfront for the enabling technologies, but the enabling technologies getting paid overtime with the utilization of all the implants or biologics.

It's very important to us for multiple reason. A, because we saw that historically the company that the companies that were able to leverage the capital equipment for earnout has been very successful in both, in orthopedics and in spine. So, hardware utilization is important. We believe in the quality of our product. So, we start to see that if the 7D and when we close an earnout contract, the overall utilization of our implants in the account increase. As

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we said that the in aggregate all of the accounts that have 7D available, they are 50% up from what their commitment purchase, so a great indication of the quality of both of the 7D and our implant.

And lastly, it's a good indicator for all of you because if the earnouts goes well for implant always means that is a new account for us. And now with biologic, if we have a strong presence in the account, we can add the biologic together to as a pull through, so 7D is [indiscernible] (00:15:52) strategy, I think that we can clearly say that it's paying off.

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

Q

Got it. Makes sense. And then last one here, just on capital equipment. Are hospitals kind of shifting their purchasing mindset to sort of those types of selling programs, maybe more with earnouts, are you hearing that from customers that that sort of preferred relative to outright purchase?

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

A

I think that it really depends from -- is twofold, it depends of the account. Of course, some of them -- it depends on the account and the experience that they had in the past. Within the Voyager program, what we offer for instance that is different from others, we have free software updates. We are very responsive, we don't charge for maintenance that we need to do on the machine. Other competitors actually do creating some kind of sour taste sometimes on the account where we try to go. So, I think that is a highly depend of the previous experience that they have and of course of their financial situation.

But what we have in our favor is what I just said, that knowing the experience that they had in the past is not just -- we are not just competing with their technology, but also we are competing with our ability to create a very smooth experience with our program for all the accounts. So, between the surgeon support and the fact that we are thinking also not just for this -- with the surgeon, also, we are seeing us about the administrators that they need to manage their programs, we are seeing a very good reception of it.

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

Q

Got it. That's great. Super helpful. Wanted to spend some time on VIRATA, and Massimo, maybe I'll stick with you, just to kick things off here. Maybe if you can briefly explain to us the value proposition of VIRATA and its and its key points of differentiation?

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

A

So first of all, VIRATA is the first product that we are launching that was fully designed with 7D with the experience with 7D in mind. So, as every enabling technology platform, 7D is an open platform, but with VIRATA in mind, we designed the system in a way to create a much, much smoother user experience in the OR. From the technical perspective, besides the differentiation in the screw design, VIRATA is like the sum of multiple areas of experience in the space on designing this kind of system. And that's been interesting to me to see that during the Alpha launch we targeted just new account.

And so, and we did that for obvious reason, A to start to make sure that we increase our surgeon pool. But from the alpha perspective, we want to make sure that the surgeon with different experience had a better experience with VIRATA. And then the results so far has been fairly positive.

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From the operational side, from the clinical side, during the merger between the SeaSpine and Orthofix, Orthofix said the specific patent -- specific IP around the screw heads and the pop on mechanism of the screw heads with the shank, and what it brings on one side in the OR let the surgeon to be -- to give the surgeon the ability to change and game plan during the case which kind of tool to use. But from the company perspective, from the hospital prospective, we shrunk the amount of screw and so the volume of offsets that we need to say in the OR.

So, I'm very excited because for these three reasons. A, the fact that it's going to keep validating the quality of the of 7D be the differentiation that we are going to give in the OR to the surgeon to game plan and make the real time decisions that are the best for the patient and see for the decrease of cost to serve that we're going to bring with an item that is the most widely used device in the OR, every time you have fusion -- lumbar fusion you always have...

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

Great. Got it.

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

Pedicle screw.

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

Got it. Super, super helpful there. And Just in terms of the launch roadmap, so currently in Alpha launch, what does that entail? And then, kind of where do you go from there to ultimately get you to the targeted 2H 2026 full launch?

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

Yeah, I think that the vast majority of the time is going to be just the waiting time to receive the instrument set. So, we're going to close the alpha end of this year, 30, 45 days to the design. And now it's going to be the time to place the order. So, it's going to be just a waiting time to make sure that we have the inventory available in house.

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

Got it. Okay. And so I guess with that in mind, do we think about VIRATA as more of a 2027 incremental driver? Or can it maybe start to help drive growth incrementally in the second half of 2026, maybe for you, Julie?

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

Yeah, so it will definitely drive growth in the second half of 2026. But 2027 will have the full year impact. And so, I think, it will accelerate into 2027.

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

Got it.

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

Also to think about VIRATA is a multiyear development program. Right now, what we are launching -- what the alpha launch, it just focused on the open market which is the lion's share of the overall spine market in beginning of 2026. While we are going to manufacture, expect to manufacturing the set for VIRATA open, we're going to start Alpha for the MIS version, which is going to be launched, if you can infer, in 2027. In 2027 we are going to start the alpha for the deformity version that is going to be launched in the following year. So, it's a big program, it's a great investment that is going to bring sequential growth, sequential catalyst for us in the spine side...

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

For multiple years.

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

... for multiple years, yeah.

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

That's great. Maybe to pivot to kind of 2026 or I guess sort of stick with 2026, Julie, I know you're not guiding, but maybe if you can talk about just kind of key puts and takes as we think about revenue next year?

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

Yeah, so I think, we see we're setting ourselves up for to have a positive year next year. I think the VIRATA launch mid-year, it'll be our first full year of TrueLok Elevate and our FITBONE nail. And then of course the distributor transitions that we did this year, you know, we'll have a full year impact from those as well. So, we see that we have a lot of tailwinds going into the year. I think it takes I'm going to say, you know, I think we've done as much as we can to de-risk the number, if there's external factors is priced or something like that. But beyond timing of product launches, but we feel good about going into next year.

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

Got it. That's great. And I wanted to kind of drilling deeper on one sort of new dynamic where we're getting more familiar with, but for Bone Growth therapy, I believe there were some CMS changes that potentially could have an early impact -- an impact early next year. Julie, can you explain what this is and maybe how we should be thinking about that in the context of BGT revenue next year, notably in the first quarter?

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

So, this Julie will take.

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

Yeah.

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

Q

Julie Dewey.

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

A

So, CMS is implementing a pilot program in January in certain episode of care categories, BGT being one of them. We expect, though, the annual impact for us will be immaterial based on what we've seen. And we don't -- Importantly, I think we don't expect it to change physician prescribing behavior at all, which would be a real impact for us. So no impact on physician prescribing behavior and hospitals will just manage the timing. CMS occasionally does these programs, hospitals have had to deal with this before, so immaterial impact on an annual basis for us next year.

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

Q

Okay, great. Super helpful. And then I want to move to kind of margins and profitability, and I'll start on gross margin. The 2027 financial targets included the goal of, I think, 300 bps of GM expansion. To kick things off here, talk about kind of key drivers of that?

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

A

Yeah, so there's three primary key drivers that we've talked about. One of those is supplier -- they're primarily targeted towards our spine margins is that's where we're below industry norms. And so from a spine perspective, supplier consolidation, I think, you know, as the organization has grown, has not necessarily been strategic in its supply base. And so we're working through that. It's been very transactional, just PO based. So, working through, you know, narrowing our supply base, going through contracting, getting volume commitments and volume discounts.

The second thing is in sourcing our warehousing and distribution, which has been outsourced for the spine business and really not the ability to leverage economies of scale there. So, we're in-sourcing that and consolidating that with our facilities in Dallas, Texas area.

And then the third is in-sourcing some screw manufacturing to our manufacturing facility that we have for our orthopedics business in Verona, Italy, and seeing some economies of scale and some reduced cost there. And then really kind of underlying all of that is some mix benefit we expect to see as well from growing the US business and particularly the international US business much faster than the ortho -- OUS business.

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

Q

Is there, as a follow up to that, between US and OUS, is there a rough way to think about kind of the gross margin differential there?

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

A

I mean, we don't necessarily break that out. But I would just say, generally speaking, you're probably going to have a 15 plus percent margin difference between the two.

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

Q

Got it. Got it. Okay, great. And then...

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

A

But given how we go to market to the cost to serve is still comparable.

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

Q

Got it. Okay. Okay. Makes sense. Maybe working my way down the P&L. Midpoint of 2025 adjusted EBITDA guidance, hopefully I have some numbers correct. I think implies 10.5% for full year 2025. You're targeting mid-teens by 2027. So, let's say that's 15% on the low end or at least 200 bps per annum. That's above this year, tracking toward I think 100 bps on a pro forma basis year-over-year. So, we just discussed gross margin, I think a lot of levers. But broadly speaking, talk about your level of confidence in achieving this 2027 target?

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

A

Yes, I mean, one on a pro forma basis, yes a 100 bps, but I think, you know, we took action in part of the discontinuation of M6 was to improve at our EBITDA profile. So, if you look at it kind of from that perspective and where we started, it's going to be around 200, a little over 200 basis point EBITDA margin expansion. And so I think, you know, again, we're going to see the flow through from the gross margin expansion will be a little less than 100 bps on that this year. So, that's going to be contributing as we go into 2026, 2027, a little above what we've seen this year, we're exiting it at 72%. So, 100 basis point improvement on our exit, but not for the full year print.

And then, we really believe that from a leverage perspective on our SG&A, excluding commissions, marketing costs, those types of things that we really have the organization that we need to be able to scale to a much larger revenue number. So, we expect that leverage to pull through as well.

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

Q

That's great. And as a follow up to that, Massimo, you know, we talked about the distributor transitions. I think there's a lot of top line benefits there and we've seen the top 30 distributors really, really performing strongly. Talk about the margin impact from the consolidation from your actions with the US kind of commercial footprint?

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

A

I don't think that we -- we don't talk about this.

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

A

Yeah, I mean, I would say it's generally less of a margin impact and more of...

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

Yeah.

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

Where you'll see efficiencies is on working capital and said deployment...

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

Okay.

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

Because they're much more efficient typically with your assets than having a lot of small non scale distributors. So, that's where you see the impact is more on the working capital and said utilization side.

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

Yeah because while I made the comparison with what we do internationally while internationally they buy instrumentation, the instrument set and the implants, our distributors in United States, the instrument set is proper -- is our asset that we give to our distributor to perform the procedure, this is why I think that the real -- the benefit for us and I keep talking about scale is because now you can do a higher amount of surgeries with the less asset that you pretty much mobilize it just for the specific distributor.

So what we like of this strategy that again is connect the dots and not just on growth but also on profitability.

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

Got it. That's great. And then maybe last one on margin. So, the 2027 adjusted EBITDA margin goal, Julie, how do we think about the path to getting there between 2026 and 2027? Is linear a reasonable assumption? Is it weighted more toward a certain year? Just curious, you know, as we kind of figure all these inputs, what's kind of timing of that pathway?

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

Yeah, I mean, we expect it to be weighted a little bit more towards 2027. We've said that kind of since the beginning. Just because some of the gross margin initiatives are a longer tail, you know, think about the supplier consolidation that'll be, you know, mid to late next year when we get that fully implemented. And so, again, that'll be a 2027 impact, so a little bit kind of back end loaded in the timing.

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

Got it. Makes sense. Maybe to pivot in the last couple of minutes, I'll try to try to squeeze one or two more in. Orthopedics, we haven't talked too much about. Massimo, your outlook for that business and I'll drill in with a more specific question. Do you believe a growth acceleration next year on the top line is within the range of

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outcomes as we think about TrueLok being more incremental, other new products, what's kind of let's call it the intermediate to long term outlook for the orthopedics business?

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

A

Look, I see that for sure the business is not decelerating from what I can tell you wholeheartedly. And mostly because of what you just said. I'm very bullish about what we're doing there, given that we identified a specific segment of trauma where we can actually have a meaningful product differentiation. We're the only company with internal external system to address all of these complex cases. We identified within this $2.6 billion opportunities, these segment of curing diabetic foot with our TL Elevate.

And so between the investment we're doing on Fitbone between all of the work that we're doing around this market creation, around Elevate and all of the work that's also we're doing there commercially, we are building up a team of leaders that actually manage a multi-billion dollar franchise in the past. I think that we have a great opportunity there.

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

Q

That's great. That's great. And this might be a good Segway into the last question I have and we have about a minute. But Massimo, just to wrap things up, I mean, what do you think is the most underappreciated part of the Orthofix story or parts if there are many in your view?

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

A

Actually, I think that the main -- I think what we are facing right now is this underappreciation of our company that coming out from a pretty difficult years was able to really change the foundation of the business. The improvement that we did on free cash flow is remarkable. All of that, the seven, you know, the continued beating our expectation on EBITDA, I think that the seven quarters that we keep delivering. The fact that our portfolio is built in a way that it can let us go in the account from a multiple point of access. And the fact that we can grow above market without a big depletion of our capital is kind of something that I think that is highly underappreciated.

But again, I think that I believe that we have everything available to show the market that our technology can win. Our focused strategy can win. And with that we can do everything with in mind is the profitable growth mantra.

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

It's a great note to end, Massimo, Julie, Julie, thanks so much.

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

Thank you.

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

Thanks.

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Massimo Calafiore

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

Thank you.

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