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Orthofix Medical, Inc. (OFIX)

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CORPORATE PARTICIPANTS

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

OTHER PARTICIPANTS

Caitlin Roberts
Analyst, Canaccord Genuity LLC

MANAGEMENT DISCUSSION SECTION

Caitlin Roberts

Analyst, Canaccord Genuity LLC

Good morning, everyone, and thank you for joining us at this year's Canaccord Genuity Growth Conference. My name is Caitlin Roberts, and I'm one of the medical device analysts here at Canaccord Genuity. I'm pleased to be joined this morning by Orthofix, a global medical device company specializing in differentiated orthopedic and spinal solutions. With me today are Massimo Calafiore, CEO; Julie Andrews, CFO. Thank you for joining us.

And before we begin, I want to remind everyone of any relevant disclosures which can be found on our conference and/or firm website. We'll begin with the fireside chat and I'll try to leave a couple of minutes at the end for any questions from the audience.

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QUESTION AND ANSWER SECTION

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

Let's start off with Q2. So, you guys raised guidance on the Q2 call, and this comes after having lowered expectations and removing your long range targets inter-quarter for post the CMS bone growth stimulation reimbursement changes, which have since been reversed. So, guidance while raised was – it was lower than it was prior to the bone growth stim noise. So maybe if you could walk us through the pieces of the updated guidance, including the CMS impact and some newer pieces of that guidance change.

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

A

Yeah. Thank you, Caitlin, and happy to be here again. Before I let Julie answer the question, I want to step back and remind everybody the progress that we made in just two years. Since the beginning, we more than doubled our EBITDA since the inception. We moved from more than $100 million of use of cash to almost breakeven last year. And we arrived today with – after we made the very deliberate choice about how to strengthen our business, how to make our commercial organization more predictable and with a very clear path of innovation moving forward. And all of this drive the decision that we just made.

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

A

And I'll answer your question regarding guidance. So, our updated guidance reflects several moving pieces. On the positive side is the reimbursement restoration, as well as a European MDR-related inventory purchase in the back half of the year and strengthening that we're seeing in both our biologics and limb reconstruction business. That's partially offset what we've talked about in the spine business on the smaller US spine distributors, where we're seeing a steeper decline than we had originally anticipated for that business. So that kind of makes up, kind of the pieces behind the guidance reset.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

And then, how are you thinking about the cadence of growth and then profitability through the remainder of the year just given that updated guidance?

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

A

Yeah. So, on our call last week, kind of our comments around that was Q3 we expect to be really in the same range as Q2 from a revenue perspective. Profitability will kind of follow that. We expect a little bit of expansion versus prior year EBITDA margin. And then, Q4 is where we expect the majority of the European MDR inventory purchase will be in Q4.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

And anything to call out here from a procedural volume demand standpoint?

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

No. I mean, I would say we see procedural volumes being relatively consistent. We were encouraged by what we saw with – in our therapeutic solutions business with really showing resilience there in spite of kind of the reimbursement noise in the quarter. But overall, pretty consistent procedural volumes.

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

Yes. And then, the 80% of the distributors now, just our top 40 distributors, they kept growing above market. So, no noise from this point of view.

Caitlin Roberts
Analyst, Canaccord Genuity LLC
Q

And turning to therapeutic solutions, maybe a little bit more color on the segment. I think there's been a lot of noise the past few months, as you guys mentioned, with the down classification of the products by the FDA to the CMS pricing decrease and reversal of that decision. Can you speak to what really drove the reversal of that initial decision?

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

Yeah. I think that was a very concerted effort that we spear, being the market leader in the space. So, a lot of work that we did internally with our team, driving up very positive interaction with CMS and we were able also to connect with MDM and some of our competitor in the space to create unified voice about the decision that was made. So, if you think about there was a lot of skepticism, but what we did was pretty unprecedented for CMS. So very pleased that we rectify a decision that clearly was made, let's say, a little more abruptly from the government decision. So, good.

Caitlin Roberts
Analyst, Canaccord Genuity LLC
Q

And then, anything in that about a month where that pricing change had occurred, that there was an impact in the Q2 or nothing that you really saw?

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

Yeah. So we saw about $1 million impact over that six-week period. So we will actually be able to recoup that revenue in Q3 as well as the proceeds from the billing. So...

Caitlin Roberts
Analyst, Canaccord Genuity LLC
Q

And the FDA down classification remains in place, how does this down classification change the market dynamics or your own approach to the segment going forward?

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

Well, actually, if you – if we step back thinking about the down classification, it was there for a while. So, we're pretty ready on what to do next. So, for any new comer is not going to be, let's say, so linear to get the same

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indication is to go through specific request from the FDA. And from our point of view now is opening up the opportunity to leverage our commercial organization to go to other markets. Being a Class III device, there was a lot of constrain for us in order to make any changes at every level. So, now, we can start to really think about how we can innovate in this space is something that we couldn't do before.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

And then, moving to spine. Last year, you implemented efforts to concentrate the business in larger and higher quality distributor partners, which I think you noted you done about 80% of revenues now really concentrated in these partners. But on the Q2 call, you also noted that the remaining 20%, the smaller distributors have been performing under your expectations for a few quarters. And then, these impacts really indicated in your revised guidance. How are you approaching management of these smaller distributors and when do you expect to see this headwind ease?

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

A

Look, we're going to keep being deliberate on our choices. Within the 20%, there are let's say, we're going to identify the group that we want to keep participating with. And we're going to keep moving resources from the 20% to the 80% in order to keep driving this – the profitable growth that we promised our investors since the inception of our leadership. So, we stay the course. It's very, let's say, transformational, not linear. So, I believe that we still going to have some noise moving forward. But I'm very optimistic about what we can achieve now with this concentrated effort that we are making.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

And, Julie, you called out the EU dynamic is one of your legacy distributors is planning to fund your EU MDR cost in the region. Can you speak to this year and then next year kind of expected impacts and just why strategically it makes sense to remain in the region and supplying this distributor?

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

A

Yeah. So I'll start with the impact. So, we expect $15 million stocking order from this distributor. Most of it we'll see, we believe, in Q4. And then, next year, the headwind is $22 million. The reason it's more than the $15 million is there was a base business, right, of about $7 million. The $15 million is really to bridge them until kind of the expected timeline of when all of the approvals would be back in place again.

I think for us, strategically staying in the market when the distributor came forward and offered to fund it, it gives us a pathway eventually to stay in the market, maybe to even expand in the market, it just seemed to make sense. I think on a – us funding it, I think the decision was rightfully made to not fund it based on again really focusing on markets where we had higher growth opportunities as well as more profitable growth opportunities. But certainly, if someone is willing to fund it, they were really – they wanted to stay in the market, they saw our portfolio as something that they wanted to continue to carry. So, it seems to be a win-win for both of us.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

Great. And then just from a cash flow perspective, what are your expectations for that?

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

A

Yes. So there will be a little bit of near-term headwind on cash flow in 2026 as we have to pay for the inventory purchase. And then most of the cash receipts will be into next year. So, it's timing. It's not – it's a profitable sale and it will generate cash. But just timing between quarters, which happened to be between years in this case.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

And then just turning more broadly to spine leadership. I think you eliminated that leadership earlier in this year. And, Massimo, you're now more directly overseeing this business. How has that structure change been going and any plans to add leadership back?

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

A

No. The idea is that, first of all, I think that being more directly involved help me to drive the strategy that we implemented. So I'm very pleased. But also I have to recognize the fact that we have a lot of talent around the spine business. And I don't foresee to bring anyone from the outside, but actually we are working – I'm working personally with the person that right now is helping me to manage the business, which I believe has a lot of potential to take over in the near future. So, great impact for me right now, and I'm very optimistic of a smooth transition of leadership given the talent that we have.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

Great. And spine is always a competitive segment. Anything to call out from a competitive dynamic standpoint or maybe your place within the competitive landscape as you look to really shape your business going forward?

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

A

Yeah. Look, for us, the thesis didn't change. Actually, we have a lot of request from partners of our competitors that we really analyze on weekly basis. I think that being very deliberate, especially with the 20%, is helping us to free up capital in the future to keep adding big shop. It's interesting that I still see the spine market very dynamic. We've – I feel that we are very well-positioned in this space because, A, the quality of our technology, B, the fact that we have access to 7D, and that give us a big differentiator out there. So the demand, that the interest at our surgeon level and the distributor partner level is out there, is as usual on us making sure that we make the right choices to keep managing our resources.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

And then just touching on 7D quickly, could you update us on your installed base and if any signs of VIRATA helping out through some demand in helping pull through for 7D?

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

A

Yeah. So from an installed base perspective, we don't give those numbers we have been giving kind of metrics on what we're seeing in terms of performance. Last updated those, I think, at the end of the year and that's kind of our cadence. But Massimo can speak to VIRATA, but we are seeing kind of some encouraging news with

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VIRATA. It's early days, of course, we haven't fully launched VIRATA yet, but certainly VIRATA is the first system that's custom – purpose built, I would say, to be used with 7D. So we're seeing encouraging things there.

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

Yes. With VIRATA, we are ready for commercial launch for open procedure. And the early feedback has been very, very encouraging. So, a lot of excitement out there. And on the MIS side, we're going through alpha right now. Even on the alpha's launch for the MIS system, a lot of great support. We actually recently did the first MIS case together with the new software update on 7D that has been a great success. So I'm very optimistic about what we can do with the two system combined. But what is also important now, having a competitive pedicle screw system, we can go back and start to really create proceduralize all of the different approach that we have. So, you're going to start to see in the outer year a very systematic approach of proceduralization with access, VIRATA or interbody 7D.

Caitlin Roberts Q
Analyst, Canaccord Genuity LLC

And then just turning to biologics, I think they were somewhat impacted by the spine distribution changes you made last year. Maybe talk about why this business was impacted from the distribution changes and if there could be risk to further disrupted performance with the management of these smaller distributors.

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

No, I think we accelerated what we were doing in spine and biologics. All of this [indiscernible] (00:14:22) favor, like our 80%, so, the noises around, let's say, distribution, I believe that right now is much lower, if not gone. Very good, encouraging signs of – that we got from the business. The last two quarters were the best two quarters in a while. And now for us, we have a pretty much brand-new commercial team, very strong leadership in the vertical. We are investing heavily in the business. In the last – during the last call, I reminded the market that we are clinically – start to create clear clinical evidence for the entire portfolio from our synthetic OsteoCove to Virtuos to Strand Plus. So, very optimistic about this space and very optimistic about a segment that is very important for us from value creation.

Caitlin Roberts Q
Analyst, Canaccord Genuity LLC

And you brought the business under limb reconstruction leadership. How important is driving usage of biologics in the limb recon portion of the business vital to the overall success of biologics?

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

It's giving us two opportunities right now, besides the – if you focus just on biologics, of course, a new channel, but also help us implement similar strategy that we had in spine into the limb reconstruction segment, where we can engage a more – let's say a more – a larger distributor, given our ability to offer bigger amount – bigger bag, combining the limb reconstruction bag with biologics. So, we are in the right track there. Very pleased.

Caitlin Roberts Q
Analyst, Canaccord Genuity LLC

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And then what's your timeline for returning the business to market growth and then your confidence in your ability to execute within this timeframe?

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

A

So, I mean, we're not guiding 2027 yet, but we feel like, if you look at the underlying pieces in our business, we feel really good about where those are headed. Again, limb reconstruction, really strong quarter. Biologics is stabilizing. The therapeutic solution business really, if you adjust for the $1 million impact really at market growth, there. And so really the piece left that we're continuing to work on is US spine and working through kind of that smaller distributor network and feel good about our ability to execute in that area.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

And then maybe just touching more on financials, Julie, with the free cash flow guidance for the year removed, how long could it be for the free cash flow inflection to occur?

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

A

Yeah. Well, so just – I guess to step back and remind everyone, we've had quite an inflection already, right, from $108 million use of cash in 2023 to near breakeven in 2025. And this year, I would say, is timing more than anything between 2026 and 2027? We don't see a change in fundamental underlying cash generation of the business. And when we had guidance earlier in the year, we said we'd be positive, excluding kind of the impact of settlements with our three former executives. We have made those payments now in Q2. So that's kind of that noise is out of the cash flow numbers. And so, again, I see inflection just with some timing on working capital in the next few quarters.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

Great. And with a lot of that progress, how are you thinking about your capital allocation priorities over the next several years?

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

A

Yeah, I mean, I think we'll continue to try to strengthen the balance sheet, invest in organic R&D or organic R&D pipeline are kind of our two biggest priorities as we move forward.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

And you also removed your LRP earlier this year. How are you thinking about potentially reinstating this LRP and what needs to happen before that occurs?

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

A

We don't have a timeline at this moment for reinstating the LRP. I think we want to really be thoughtful and deliberate and intentional about the actions that we're going to take in the US spine business before we do that, to

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make sure that we have stability in that. And so, as we work through that over the next couple of quarters, we'll be considering when is the appropriate time to reinstate our long range guidance.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

And then, just with M&A, what are your thoughts on that and what a potential M&A candidate could be for you?

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

A

So I think right now our focus is on growing organically. If we saw an opportunity for something that made sense in our bag, we would consider it. But at the moment, we're focused on organic execution of the business.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

Any questions from the audience?

Q

[indiscernible] (00:19:35-00:19:50)

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

A

Yeah. So, our growth really was organic volume-driven growth, not price growth. Generally speaking, our guidance is that we have about a 1% to 2% price pressure annually kind of baked into our number, and that's generally what we're seeing. So, our growth is really driven by volume and market acceptance of our products. We don't break down the international US margin difference, but you can generally assume international is going to be a little lower than the US, depending on – in some markets in international, we're direct. So they're going to have a little higher than a stocking distributor. But generally stocking distributors don't pay commission. So, you'd probably want to look at the contribution margin which are relatively similar.

Caitlin Roberts
Analyst, Canaccord Genuity LLC

Q

Awesome. In the last few minutes, anything you guys want to leave with the audience about the business and the trajectory going forward?

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

A

Yeah. Look, just to reiterate what I said at the beginning, we are today a much stronger business. I believe that we have a clear strategy that we keep executing since day one and not deviating. And we are entering in this next chapter of our leadership with a stronger commercial organization, with an organization that can use resources much more wisely and have a very clear path for innovating in all of the markets where we compete. So, very excited about the opportunities that we have limb reconstruction, excited about the progress we've made in biologic. OTS is driving – which is our STIM business is very resilient. And spine, we have a clear path to be – to create real responsible growth that, given the share that we have, is pretty dramatic, et cetera, the progress that we are making. So, very pleased with where we are and a big believer of what we can do in the future.

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Caitlin Roberts

Analyst, Canaccord Genuity LLC

Great. We'll leave it at that. Thank you, both.

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