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Orthofix Medical, Inc. (OFIX)

Canaccord Genuity Growth Conference

CORPORATE PARTICIPANTS

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

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

OTHER PARTICIPANTS

Caitlin Cronin
Analyst, Canaccord Genuity LLC

MANAGEMENT DISCUSSION SECTION

Caitlin Cronin

Analyst, Canaccord Genuity LLC

Good morning and thank you for joining us at this year's Canaccord Genuity Growth Conference. My name is Caitlin Cronin and I'm one of the medical device analysts here at Canaccord Genuity. I'm here with Orthofix, a global medical device company specializing in differentiated orthopedic and spinal solutions. We're very pleased to be joined today by Massimo Calafiore, CEO and Julie Andrews, CFO, and Julie Dewey, Head of IR.

Before we begin, I want to remind everyone of any relevant disclosures, which can be found on our conference and/or from website. We'll begin with a brief presentation by management, followed by a fireside chat, and I'll try to leave a few minutes at the end for any questions from the audience.

And with that, I'll turn over to Massimo.

Massimo Calafiore

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

Good morning. Good morning. So for people that are not familiar with the story of Orthofix, we are a company, we're a medtech company focused on spinal solution and orthopedics. So how are we winning? In spine, we have a very comprehensive portfolio, pretty new, that we combine with a leading biologic portfolio. We are the second largest biologic company in the world and 7D, which is our enabling technology platform, our navigation system, which is highly differentiable in the marketplace.

On the orthopedics side, we are really focused on a market that is underserved. So we are the leading company on complex limb reconstruction, with a great success right now on entering the diabetics market, which is a $1.7 billion opportunities for us.

In the middle, we have bone growth therapy that help the healing of the bone for our patient that connects with both: in spine, where we have the market-leading company; and orthopedics, where we focus on trauma. We are the number two player in orthopedics and very focused on getting the leading position out there as well.

So the combination of all of this portfolio are creating us several opportunities to attract the market, to get opportunity within the market, and all of these with a laser focus on creating shareholder value. Like since this new management team has been together, the improvement we did on EBITDA creation and cash flow, together with innovation, has been very remarkable.

All of this is helping us to be very prescriptive, very strategic how we go to market. So, a lot of focus in the past [ph] 60s (00:02:44) months to upgrade our distribution network, creating loyalties. But all of these making tough choices along the way to create the long-term shareholder value. So, we are very pleased to be here. We're very pleased to tell our story and please.

QUESTION AND ANSWER SECTION

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

Maybe just starting with the Q2 results, which you announced recently, could you highlight for us what you want investors to understand coming out of the results?

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

A

Yeah. I think it was a very important quarter for us. We took very strong and tough decision, especially on the distribution side, that creates some temporary headwind that actually start to dissipate starting in Q2. So, I think what the investor like is the fact that we keep saying what we want to do very clearly in our calls and we keep executing very diligently.

And also has been a very important quarters because we start to really define the pillars that we're going to lever for, for our growth. I said innovation is very important. A lot of very – a couple of very important alpha and commercial launch for us. We are going in with our next-generation pedicle screw system in our [ph] FITSPINE (00:04:18) in orthopedics, as said, with our TBT device. We are taking advantage of this $1.7 billion market. So a great success there. And all of these keep creating, accelerating our value creation on EBITDA and cash flow. So I us finishing Q2, entering Q3 in a very strong footing.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

And you beat expectations but maintained your guidance across the P&L. I mean, why maintain guidance and any change to the cadence of your expectations in the second half?

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

A

Yeah. No, I mean, we expect to see an acceleration on our growth rate in the second half. I think we maintained our guidance. We said that at the end of Q1, and we're confident kind of in where we'll come in in that guidance range and feel like it's set appropriately.

Caitlin Cronin
Analyst, Canaccord Genuity LLC
Q

And you also unveiled your long-range plans last November. How are you feeling about these goals now halfway through this year?

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

Yeah, I think – I mean, we generally feel like we're on track. Again, we made a conscious decision to kind of do some distribution changes that impacted our growth rate in the first half of this year. But with the distributors that we brought on board, we feel like we've really set ourselves up well for going into next year and achieving our long-range growth plan.

Caitlin Cronin
Analyst, Canaccord Genuity LLC
Q

And just quickly walk through the current tariff assumptions and when you expect tariffs to impact the P&L?

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

Yeah. So, we have about $3 million to $4 million on an annual basis in tariff exposure. Manageable within our P&L this year, about $2 million. We already starting to see the impacts of that. But again, contemplated within our guidance and manageable within the P&L.

Caitlin Cronin
Analyst, Canaccord Genuity LLC
Q

Maybe just moving to spine, you just called out one of the headwinds that are impacting you and impacted you in the first half. Touching on the first, the distributor transitions that you mentioned in the US spine business. Maybe speak to why these transitions are necessary and how much capacity would these transitions bring once they're finished?

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

Yeah. We saw that this transition were necessary because we want to create a very sustainable network of distributor that can scale, distributor that can create a very strong loyalty with the organization. So we moved from an organization that was very opportunistic from the distribution perspective. So very an engagement of multiple, very small shop. And what we are doing, we are taking out all of this dollar, this distributor that we believe cannot scale to concentrate on a $5 million-plus distributor.

What is bringing – and you can see the effect, the multiple level. You can see the effect on a growth that can be sustainable in the future. You can see after the effect in our P&L. I think the creating density with this big distributor is increasing our asset utilization with, again, creates a free cash flow that flow through the company. And of course, like a safer and a more smarter use of our resources at innovation.

From the first headwind that you mentioned, it's pretty easily explainable, was a hospital that was purchased by GPOs where we're already in contract, so we had to honor the lower price. But it's going to go away by the end of this year.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

I believe you noted on the call accelerated distribute transitions versus your prior expectations. I mean, any chance that this process could finish earlier than you expected in terms of the transitions?

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

A

I think that, in general, for a company that are focused in orthopedic and spine and medtech, I think that you keep looking at your distribution network. So I see this as an ongoing process that's going to last over time. Of course, right now, there is a big acceleration on our side because we want to – because we are like in this phase of, let's say, on this building phase. And I think that in the future, you're going to go to maintain and keep looking at your distribution network.

But, again, this is an ongoing process. We are accelerating right now. What we want to do – look, what's happening in the industry is creating a lot of opportunities for us. You have many of the big players not focusing in spine anymore. You have already some of the big player that are going out and/or just the went out from the market. So distributors and doctor are looking for company that are focused on their market, that want to focus in innovation, too, for their patient. And we are being, let's say, a very good home for all of them. So I'm very excited about where we are today, but for what we can create in the future.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

And you touched on the other headwind, which was the price decrease given the joint venture between one of your largest hospital accounts and then a GPO that already had a pricing agreement in place with you. Is this dynamic something that could occur in the future with another GPO or another situation? Is there a risk to that happening again?

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

A

This is a consolidation. Also, hospital level is happening all the time. So I think we are ready. We always we are ready to absorb if something happen in the future, but this is very unpredictable. I think that this part of the world that we are – where we are competing.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

You discontinued your M6 business earlier this year. Maybe just introduced to the audience the rationale for that and how have you reallocated resources to other opportunities since the discontinuation?

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

A

Yeah. So M6 has been fundamental for the first – let's say, many years ago that the first phase of growth of Orthofix's spine. Where we came into the picture, the market is at the – was totally different for cervical disc arthroplasty. M6 was one of the oldest. And the surgeons start to move from – they didn't have any more, just a couple of choices. But they start to be much more prescriptive on how they were deciding to partner with – in function of patient condition.

So what we start to see, M6 was a declining product line for us, was absorbing a lot of our free cash flow. So we – given, again, the interest that we're seeing in the portfolio and given that is very expensive to maintain a PMA device, we decided to discontinue. And again, and you see that – you're going to see over time how this choice is going to pay off for us for a couple of reasons. A, because we're not wasting resources. B, because we can readdress the resources that we were using to maintain a losing product line on the innovation that you are seeing, especially in enabling tech.

So very excited about tough decision that we made. Just a testament to this organization to go through decision that can be seen as a short-term headwind to create the long-term growth and sustainable growth.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

And you've spoken about leaning more into deformity. Any more color on what innovations will help you leverage your business further to deformity?

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

A

Yeah. So when we start to build up our strategy, one of the highly differentiable platform for us is our enabling tech and navigation system 7D. 7D is state-of-the-art for open deformity. So for us, it was natural to say, okay, how – which kind of statement do we want to make to this market as a whole? And so, we decided to leverage 7D and start to build up our innovation around it.

I'm very excited about what 7D and the FLASH Navigation can do, especially because you see that moving forward, we will start to enter in the market technologies that are going to be unique for us. One of the areas that a big gap right now in spine or, let's say, in orthopedics in general when the surgeon goes in the OR, so you have a planning software that – like should tell you what is the potential best solution for the patient that you have. You have an enabling technology platform that lets you navigate interop, but nobody's telling the surgeon, okay, is what I'm doing today the same or what I plan?

So where we're looking for and what would be unique for us is bridging the gap between the information that you have at the beginning, what you doing in the OR, we would be able to tell the surgeon, okay, you are doing your plan or you are not doing your plan. So, excited about what is going to come in the future given that it's going to be unique to us.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

And talk about the new VIRATA system and what differentiates the platform going off of what you've been saying?

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

A

So VIRATA, like if we think about our spine portfolio as a whole, the excitement opportunity for us when we joined was that, especially on the SeaSpine side, the company went through a few years of almost 50 product launches. One of the system – the legacy system that with more longer – let's say, longer presence in the market was our old pedicle screw system, Mariner.

So we decided to invest on the next generation of pedicle screw system. Pedicle screw system are important in our industry at the end is what is widely used, is what we say is the currency of our market. So what VIRATA represent is pretty much – you imagine the history of spine. The history of all of the different successful system that we saw over time, where we combine all of this experience, all of the plus of everything out there – launching VIRATA, adding some technology that we had already in our suffix. So a system that is clinically focused on streamlining what the surgeon does from the inventory perspective, we are leveraging our proprietary technology for bringing the [ph] tool open to the head (00:15:54). What does it mean? That we are cutting the inventory that they needed in the OR to a quarter. And we are designing everything with 7D mind. So, we are creating a flawless experience for the surgeon in the OR.

We are just in alpha launch right now. 80% of the customers are new or brand new to the company or customer that were using other part of the portfolio, but not pedicle screw. So, I'm very excited about the opportunities. Opportunities that is going to evolve over time because right now, you're going to see that right now, we're in alpha launch for [ph] our open (00:16:37) beginning of 2026. We're going to start to focus on MIS and 2027 on the deformity.

So it's going to be a growth driver for the years to come with all of the different modules. So, excited about all of this.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

Maybe transition to enabling tech more broadly. It seems like 7D momentum is really continuing. I mean on the Q2 call, you noted a 66% increase in unit placements in the first half or $12 million in revenue commitments. How large is the total commitment number that you have across all of your 7D systems at this point?

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

A

So that's not something that we've shared publicly. But, I mean, we're very excited about the progress that we're seeing and the commitment that it's bringing to our customers. And what we saw in the first half of the year is that, in aggregate, we're seeing a 50% kind of over their commitment volume at the accounts. So, really good utilization of the system once it's in the hospital.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

And how are you viewing the capital purchase commitment environment for hospitals at this point and your pipeline?

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

A

Yeah. I think it's a great moment for us because a hospital or especially entering the second part of the year, they're very focused on their spending and how they're allocating resources for their fiscal year entering in the next. And one of the key question for administration and – is like are we investing in enabling technology with high ROI, that utilizing the OR? They want think that there is, again, a lot of excitement on other area of enabling tech, but we know that that the utilization is not there.

Where we are winning with the fact that surgeon actually are becoming big advocate for 7D. They realized how differentiable is there, and we can demonstrate to administration that it's actually the technologies used. The ROI is there because all of the data that we're getting from the other accounts.

So since I joined the organization, has been very excited about having access to the enabling technology platform, but mostly because it's not just highly differentiable, because every time I go to a hospital, actually seeing the OR, not on a corner.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

Any 7D innovations on the horizon that you want to speak to?

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

A

Yeah. So. We are like disproportionately investing right now in R&D on 7D. The again FLASH technology, that is the base of our system, is highly differentiable. And there is a lot of things that are going to come up from 7D from, I said, the ability to interop in a real time and give feedback to the surgeon about what they're doing, plus like second generation that we are working on that is going to have a much higher resolution, our proprietary camera. So you see that is going to become a staple of innovation for Orthofix in the near future.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

Maybe turning to the other part of your business, ortho, and you're looking to have a focused differentiated and specialized strategy in the US as it relates to the segment. Can you describe that strategy and how you believe it will lead to sustained growth in the ortho business?

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

A

Yeah. I think that is – so when we enter as a new management team, orthopedics was – we always believe that was our dark horse, because you had a product innovation that was coming on one side and a very established, let's say, knowhow in complex limb reconstruction.

We hired Patrick Fisher from Stryker, has been a great addition of the team, a person with a big Rolodex, a great understanding of the industry, and somebody can run a scale. And one of the first question that we asked to each others that where we can win. And we found – so we thought that we were trying to be too much – too little for too many surgeon in the United States. So first phase, we discontinued a lot of product line, more than 40 in United States. And second, really start to establish ourself as a market leader of this new category of complex limb reconstruction, limb deformity.

And why we're doing that? Because from the product perspective, we are the only company in the United States that right now is offering internal/external solution for bone transport with our Fitbone line, together with TrueLok. And on the opposite side, we found this opportunity on diabetic foot with our Transverse Bone Transport. So pretty much what we do with our device, we can create a temporary fracture that vascularize the area near the foot, and all of this drives a cure of the ulcer.

And again, as said before, is maybe one of the most successful launch in the history of Orthofix is giving us access to a lot of big institution. We start to see pull-through on – of our other product line. And again, we are very excited and – of taking full advantage of the opportunities. So far, the result that we are having is actually pretty compelling.

Caitlin Cronin
Analyst, Canaccord Genuity LLC
Q

And maybe let's just touch on bone growth therapies in the last couple of minutes. You plan to launch AccelStim. I was wondering when that will launch, and then do you see those as more of a meaningful or incremental driver to the BGT business?

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

Yes. So, yeah, we're going to launch AccelStim in the second half of the year. We see that it's going to be an immediate driver because it's going to be the only LIPUS device with Bluetooth enabled. What does it mean? That it's going to be able to connect to our winning platform that is going to let surgeon to monitor the healing of the patient, the utilization of the device. So, we are very excited to be the first on the market with this specific device.

As said, we are a market leader in spine. We want to become the market leader in fracture. So, I think that this one is going to give us the opportunity again to differentiate in the acute and in the malunion in the fracture space.

Caitlin Cronin
Analyst, Canaccord Genuity LLC
Q

And what are your longer expectations for growth here, both BGT overall and then within the channels that you mentioned?

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

Yeah. So what we're doing and the opportunities for us in BGT and why despite – especially in spine being the market leader, we keep beating the market, is the fact that we're taking full advantage of what came from this merger. What we noticed, I think that we are doing – our job is kind of goes in parallel. On one hand, we keep improving at converting competitive distribution into spine. But at the same time, we keep working on the market creation.

We have the leading company there. We have the eminence and the opportunity to keep talking about BGT with the surgeon community, that is still more than 50% our surgeon or spine surgeon in United States don't prescribe it. So, very excited about the opportunity to – we have there given that, like we are taking advantage of a business that is a scale for us right now.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Wonderful. We'll end it there. Thanks, everyone.

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

Thank you.

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

Thank you.