06-May-2025

Orthofix Medical, Inc. (OFIX)

Q1 2025 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Thank you for standing by. My name is Keena, and I will be your conference operator today. At this time, I would like to welcome everyone to the Orthofix First Quarter 2025 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 will now turn the call over to Julie Dewey. Please go ahead.

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

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

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

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

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

Additionally, and unless otherwise stated, all net sales percentage changes discussed will be on a pro forma same sales day, constant currency, year-over-year basis, excluding the impact from the discontinuation of the M6 artificial disc product line, and all results of operations that we will refer to will be on a non-GAAP as adjusted basis.

Moving to today's agenda, Massimo will open with comments on our performance and business updates. Julie Andrews will then review the specifics of our first quarter results and our 2025 financial guidance.

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

Massimo Calafiore

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

Thank you, Julie. Good morning, everyone and thank you for joining us for our first quarter earnings call. I'll spend some time providing business updates and information about our key initiatives before I turn it over to Julie Andrews to cover the specifics of our Q1 results and 2025 guidance.

During the first quarter, we continued to execute the priorities that we outlined in our three-year plan to transform our business and deliver on our commitment to drive disciplined, profitable growth. On a same sales day basis, our first quarter pro forma net sales of $189.2 million represent year-over-year constant currency growth of 6%.

I'm also pleased to report that we delivered another quarter of excellent progress in adjusted EBITDA margin expansion that exceeded expectations. As we move forward in 2025, I'm confident we are well positioned for profitable growth as our efforts to further optimize our Spine commercial channel begin to bear fruit, and we continue to build on our financial foundation and prudently deploy capital to create long-term value for our shareholders.

Our excitement continues to build in our Orthopedics business, and the greenfield opportunity we have to redefine the category of Limb Reconstruction, which I'll discuss in more detail shortly, as well as prospects we have in our Bone Growth Therapies business to further capitalize on cross-selling opportunities and drive penetration in the traction market with AccelStim.

Now, I'd like to provide additional detail for each of our businesses. Our US Spine Fixation business grew 5.4% on a same sales day basis. We are successfully accelerating targeted distributor transition in a few US territories in order to maximize our growth opportunity and more closely align with our strategic focus.

As a result, we did experience some short-term incremental softness in Biologics and Spine Fixation. This transition won't be completed until later this year and will require some time to take full effect. But is expected to result in a stronger, more scalable commercial organization, as we shift into our next phase of growth. Once our optimization efforts are completed, we expect growth to return to historical levels.

During the quarter, we continue to gain share in product categories where we recently launched new products, including our ALIF, MIS, and Cervical Fusion portfolios, all of which significantly outperformed the market. Beginning in Q2, we have several product launches planned, including the full launch of Reef L Lateral Lumbar Interbody, an additional solution in our Meridian ALIF portfolios.

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This new interbody design features our proprietary advanced surface technologies and expand our portfolio of lumbar interbody fusion products to address varying surgeon preference and patient anatomies. In parallel, we will integrate our hardware products with access and navigation, creating a comprehensive procedural solution to enhance efficiencies and predictabilities in the OR.

At the same time, we continue to leverage our differentiated 7D FLASH Navigation platform to create longstanding relationships with our surgeon partners. With continued investment, we expect that our next-generation advancements in enabling technology and our hardware portfolio will build upon this unique foundation and establish us as the partner of choice for surgeons seeking real-time, data-driven, intraoperative solutions in the OR.

We believe that our comprehensive portfolio of spinal hardware, biologics, and enabling technologies and steady cadence of innovation will enable us to attract top sales talent, increase exclusive distributor relationships, and drive stickier relationships with surgeons and hospital accounts, which we expect to result in incremental product pull-through as well as ASP lift from mix benefits.

Now, turning to Bone Growth Therapies. On a same sales day basis, BGT net sales grew 7% overall in Q1, and investments in the Fracture market sales channel drove 8% growth in BGT fracture with AccelStim bone growth therapy device to continuing to outperform the market.

Our BGT business is focused on maximizing our market-leading position with the most comprehensive portfolio and the most indications on bone growth stimulation devices in the market. We will continue to focus on cross-selling with Orthopedics, Spine, adding new market channels with established sales representatives and driving penetration in the Fracture market with AccelStim.

Speaking of AccelStim, we received an earlier-than-anticipated FDA approval for our AccelStim 2.0 in the first quarter. This approval reinforces Orthofix's position as the market leader in bone growth simulation and represents a significant advancement in Low-Intensity Pulsed Ultrasound technology as the first and only such device to incorporate remote therapeutic visibility through integration with the STIM onTrack mobile app in physician portal. AccelStim 2.0 is expected to be available later this year. I continue to be impressed by the commercial execution of the BGT team.

Our global Orthopedic business had a strong start to the year, delivering a constant currency growth of 13% on a same sales day basis in Q1 compared to prior year. US Orthopedics benefited from strong execution and grew 12% also on a same sales day basis. Growth was led by the combination of our TrueLok and Fitbone products, as well as growth in the Galaxy fixation product family, and OSCAR bone cement removal products.

As we covered in our last earning call, Orthofix is redefining the category of Limb Reconstruction with a unique portfolio solution that empowers surgeons to excel in limb preservation, deformity correction, limb lengthening and complex fracture management. Together, these segments represent a market opportunity in excess of $1.7 billion, one of the fastest-growing categories in orthopedics.

We are particularly excited about the upcoming full market release of the TrueLok Elevate TBT System, which is indicated to correct non-unions and bony or soft tissue deformities or defects which could include non-healing wounds, ulcers and deep tissue wounds. According to the American Diabetes Association, over 160,000 amputation occur each year in the US as a result of diabetic-related complication, representing a sizable market

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opportunity of approximately $1.2 billion. The TrueLok Elevate TBT System is currently in limited market release at selected centers in the US and Europe.

Surgeons participating in the limited release are witnessing firsthand the transformative potential of this product in treating condition that previously would have almost certainly resulted in limb amputation, and drastically reduce patient's quality of life and their life expectancy. TrueLok Elevate is already making a real difference. We are continuing to prepare for a full market launch of TrueLok Elevate in Q3.

These include confirming reimbursement quoting and actively gathering feedback from surgeons involved in the initial rollout. This feedback will be crucial for successful full launch in the coming months. With over 90 TrueLok Elevate case completed so far, surgeon response has been overwhelmingly positive, and interest from the orthopedic community continues to grow rapidly.

TrueLok Elevate now enables surgeons to effectively address challenging condition in a patient's extremity by allowing for an efficient and reproducible method to create a bone segment in the tibia that can be gradually destructed over a period of several days. Published clinical research, as shown in this approach, improves blood circulation to the affected limb and promotes wound healing in diabetic foot, potentially reducing the need for an amputation, lowering associated mortality risk and alleviating the long-term healthcare costs linked to limb loss. Thus, TrueLok Elevate offers the potential to not only be a limb and cost-saving device, but most importantly, a lifesaving solution to a challenging patient population.

In addition to TrueLok Elevate, Orthopedics growth in 2025 will be fueled by a number of new product introductions that we expect to capture additional market share with existing and new customers. These include the Fitbone Bone Transport and Lengthening Nail, the only bone transport nail available in United States, and the Fitbone Trochanteric Nail. We expect all of this product to be in full market release in the second half of 2025.

Our focus on Limb Reconstruction is yielding significant results, particularly in the USA market, and we anticipate this will be a key growth driver for Orthofix for many years to come. Overall, we are in great positions to capitalize on our recent product launch successes and deliver meaningful innovation to improve outcomes and efficiencies for our surgeon customers and their patients. We have a healthy commercial pipeline that we believe is poised to deliver substantial revenue growth in the coming months. Importantly, the breadth and depth of Orthofix Spine and Orthopedic offerings provide multiple paths to grow the business sustained above market rates.

We remain the market leaders in Bone Growth Therapies have a comprehensive market-leading biologic portfolio, and differentiated products in several specialized orthopedic markets, such as complex trauma reconstruction and limb deformity correction. Additionally, our broadened Spine portfolio is world-class and is fully supported by a highly-differentiated and compelling enabling technology.

Looking ahead, we are focused on three strategic priorities. First, further sharpening our commercial execution to drive deeper market penetration through our comprehensive portfolio offering, including the adoption of our 7D FLASH Navigation system. Second, implementing projects to improve our gross margin. And finally, focus on a disciplined capital allocation, adjusted EBITDA expansion, and positive free cash flow generation, ensuring we are well positioned to create long-term value for our shareholders in 2025 and beyond.

At the same time, we are confident that our emphasis on responsible capital deployment within our businesses and deemphasizing area where we have less scale or share will also drive our transformation, support profitable growth and increase penetration of our technology and product platforms in areas where we can win.

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In summary, after one year with this new management team, Orthofix is operating with greater discipline, executing our priorities, and strengthening our balance sheet. I believe we are very well positioned to deliver on our commitment to drive profitable growth and innovation, while increasing long-term shareholder value.

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

Julie B. Andrews

Chief Financial Officer, Orthofix Medical, Inc.

Thank you, Massimo and good morning, everyone. As we get started, all net sales growth rates that I refer to in my prepared comments will be on a pro forma, constant currency, same sales day basis over the prior year quarter and exclude the impact of net sales related to the discontinuation of the M6 artificial cervical and lumbar disc that we previously announced. These pro forma comparisons are non-GAAP financial measures as described by Julie during the introduction of our call. As a reminder, this quarter had 63 selling days, which was one less selling day than Q1 2024.

Please refer to the non-GAAP reconciliations in our press release, and I strongly encourage you to review the information posted on our website. We have provided you with information to assist you with your modeling and to provide you with pro forma information to the first quarter of 2025.

During the first quarter, we continue to prioritize investment in innovation, rigorously allocating resources to high-return opportunities to further sustain our share capture in US Spine and US Orthopedics and focus on improving margins and cash, positioning the company for near-term and long-term profitable growth.

Global Spinal Implants, Biologics, and Enabling Technologies' first quarter pro forma net sales were $104.3 million, with year-over-year growth of 4% on a pro forma same sales day basis. These results were slightly below our expectations, primarily due to some incremental softness in Biologics and Spine Fixation.

In our US Spine Fixation business, procedure volume growth on a same sales day basis was 7%, which was partially offset by the outsized impact of a price decrease due to a joint venture between one of our largest hospital accounts in the Midwest and a large regional group purchasing organization that already had an Orthofix pricing agreement in place. We will be working through this for the remainder of the year.

Moving now to Bone Growth Therapies. BGT revenue grew 7% on a same sales day basis to $55.1 million in Q1, driven by above-market performance in both the Spine and Fracture channels. BGT Fracture growth was 8% on a same sales day basis, driven by investments in the Fracture market sales channel.

We do expect our BGT growth to remain above market growth rates, currently estimated to be 2% to 3% and continue to moderate somewhat as we move forward in 2025 due to our number one market position in the BGT Spine business and lapping the gains from surgeons acquired last year.

We will continue to focus on adding new surgeons and competitive surgeon conversions in BGT Spine and continue our commercial focus in the BGT Fracture market where we currently have a lower market penetration and see a substantial opportunity to drive new business with the orthopedic surgeons.

The Global Orthopedics business grew 13% to $29.8 million in the first quarter, led by 12% growth in the US as a result of strong performance across our portfolio, as well as distributor expansion and sales channel investments. The International Orthopedics business grew 14% versus prior year. As we've previously said, due to the nature

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of this business, particularly around the timing and volume of stocking distributor and tender orders, we expect to see variability from quarter-to-quarter in the growth rates.

Pro forma non-GAAP adjusted EBITDA, excluding the impact of the discontinuation of M6, was $11.4 million, with pro forma adjusted EBITDA margin expanding approximately 200 basis points compared to reported non-GAAP adjusted EBITDA for the first quarter of 2024. The discontinuation of M6, which has been a negative drag on our profitability in prior periods, drove the majority of the improvement in the quarter.

In addition, we continued our efforts to optimize our shared service functions, executing actions to deliver annual savings of $3 million. We remain encouraged by these results as we see our ability to drive leverage on sales growth materializing, as we continue to focus on disciplined, profitable growth.

From a cash standpoint, our total cash balance, including restricted cash at the end of Q1, totaled $60.5 million. As a reminder, the first quarter of each year is always a high cash outflow quarter, primarily due to the payment of the prior year's annual bonuses and Q4 commissions. In addition, we had higher-than-normal cash severance payments related to the discontinuation of M6 and the rightsizing of our shared service functions. Excluding these items, uses of cash were in line with normal business operations and slightly better than the company's projections.

As we said on our last earnings call, Q1 was expected to be the lowest cash flow quarter of the year. While we continue to expect to generate positive free cash flow, excluding the impact of restructuring charges that related to M6 discontinuation for the full year 2025, we do not expect to generate positive free cash flow in every quarter. As we announced on our Q4 earnings call, we are discontinuing the M6-C artificial disc and the M6-L artificial lumbar disc product lines.

It is important to note that the M6 product lines were a headwind to the company's top line revenue growth rate, gross margin, adjusted EBITDA and free cash flow. This product phase out is in line with our commitment to direct resources to more profitable growth opportunities. We have posted a pro forma P&L for M6 on our website to assist you with updating your models. We will update it on a quarterly basis for the remainder of 2025.

We expect to have one-time cash restructuring charges of approximately $8 million, primarily due to the closure of the dedicated M6 manufacturing facility in Sunnyvale, California. We expect most of the charges to be incurred during 2025. We will continue to support customer demand in the US market as we burn through remaining inventory.

In addition, we intend to fulfill all requirements related to post-market surveillance activities and meet our obligations with respect to pre-market approval of M6 devices, including completion of the IDE study in the United States, which we expect to have an annual cost in the range of $2 million. Overall, we continue to be confident in our ability to drive profitable revenue growth moving forward.

We remain focused on pursuing the vital few initiatives in our long-range plan and prudently deploying capital and resources to areas where we have a differentiated advantage, all of which we believe will support the achievement of our three-year financial targets and propel our business forward.

Moving on to 2025 full year guidance. First, regarding tariffs. Recognizing that this is still a fluid situation, we have exposure to tariffs in the EU, Canada, China and Taiwan. We now estimate our annual exposure to be approximately $3 million to $4 million, which is better than our original estimate of $5 million. This estimate includes currently applicable tariffs as well as the additional tariffs that were announced on April 2 by the US that

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would take effect following the 90-day pause and assume such tariffs remain in place. This exposure is very manageable, primarily reflected in cost of goods sold and are already contemplated in our guidance.

We now expect full year net sales of $808 million to $816 million, which excludes sales from the discontinued M6 product lines, representing implied constant currency growth of 5% year-over-year at the midpoint of the range. While we no longer expect foreign exchange rates to have a negative impact, our updated guidance reflects the anticipated short-term impact from the targeted distributor transitions that Massimo discussed earlier, which we believe will set us up for success and generate significant future returns.

Our guidance also assumes a $5 million negative impact from US funded non-governmental organization NGO business as compared to the full year 2024. This guidance range is based on the current foreign currency exchange rates and does not take into account any additional potential exchange rate changes that may occur this year.

We expect the majority of the impact from our revised net sales guidance to be reflected in the second quarter due to the timing of international stocking orders, the anticipated short-term effect of the targeted distributor transitions, and the quarterly impact from the reduction of US-funded NGO revenue.

We continue to expect full year 2025 non-GAAP adjusted EBITDA of $82 million to $86 million. This range includes the anticipated impact from the discontinuation of the M6 product lines that was previously announced in February 2025 and represents a 190 basis points of EBITDA margin expansion at the midpoint of the range compared to 2024. We also continue to expect to generate positive free cash flow for the full year 2025, excluding the impact of restructuring charges related to the discontinuation of the M6 product lines.

Now for some specifics on individual line items for the P&L for 2025. We expect our gross margins to be approximately 71% consistent with previous estimates and in line with 2024. We now expect our operating expenses to improve by 200 basis points this year versus 2024 compared to the 100 basis points of improvement we previously communicated. This improvement is expected to come from our continued focus on disciplined investments, as well as lower stock-based compensation and depreciation and amortization.

Stock-based compensation is now expected to be in the range of $29 million to $30 million, while depreciation and amortization is expected to decrease to $37 million to $39 million for the full year 2025. We still expect interest and other expenses to be approximately $5 million per quarter. Throughout 2025, we will maintain a heightened focus on disciplined, profitable growth and free cash flow generation to build on our financial foundation and prudently deploy capital to create long-term value for our shareholders.

Now, before we open the call for questions, let me turn it back to Massimo for concluding comments. Massimo?

Massimo Calafiore

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

Thanks, Julie. I want to thank our Orthofix team and our committed commercial partners for their effort in Q1. We believe our focused commercial strategy and broad differentiated technology, combined with our robust innovation pipeline and our pacesetting-enabling technologies, position us well to drive commercial execution and operational excellence, deliver on our financial commitments, and create long-term sustainable value for shareholders. I'm excited and energized about the path we have set for ourselves and the opportunities for the business to deliver exceptional value to our surgeons, their patients, and our shareholders in 2025 and beyond.

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

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QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] Your first question comes from the line of Ryan Zimmerman with BTIG. Please go ahead.

Q

Hi. Good morning, everyone. This is [ph] Izzy (00:31:57) on for Ryan. Thank you for taking the questions. So, to start out, Massimo, I was wondering if you could talk about the rationale for the optimization within the Spine channel. What prompted the decision to take this on right now? And if you could put a little bit of a finer point as to how long the process might take? This is a bit of a multipart here, so sorry about that, but are there any chance that these impacts could bleed into next year or any implications that we should keep in mind for the long-range plan as a result of the optimization?

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

A

No. Definitely not. To give you more color, we are entering -- when we enter the second year of our tenure, we believe that were much stronger footing than when we started. Our balance sheet is very strong. We're making a lot of progress on our EBITDA expansion. BGT keeps performing. We're redefining the Orthopedics and where we are, as you see, we are start to achieve sustainable growth.

So, for us, it was the moment to really think about our Spine business, and we want to start to be much more deliberate and intentional and how we see – how we go-to-market. So, given our strength, we realize that our current distribution network was already at capacity from the growth standpoint, so we are accelerating our transformation by investing larger, much more capital-efficient commercial partner to drive the long-term growth that we are expecting to create shareholder value.

And I can tell you that the commercial pipeline is already primed and ready to deliver substantial revenue growth starting later this year. It's coming with some pain point short-term, but, again, we believe that we can create higher growth business now investing in the right partner.

Q

That's helpful. Thank you. And, Julie, I heard your comments on the 2025 guidance, but I was curious what is enabling you guys to maintain your adjusted EBITDA, while lowering the top line?

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

A

Yeah. So, as we mentioned, we've been very focused on making sure that we're making investments that have a return. We did do some rightsizing of shared service organization at the beginning of the year as well, which was kind of delivering more on our synergies.

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As you remember, we had about $10 million going into the year remaining on synergies, and we've now taken actions for about an additional $6 million of that. And so, the combination of continuing to deliver on our synergies as well as looking in all of our costs and investing and what we're going to get the highest return on.

Q

Understood. Thanks for taking the questions.

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

A

Thank you.

Operator: Our next question comes from the line of Mathew Blackman with Stifel. Please go ahead.

Mathew Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Good morning, everybody. Thanks for taking our questions. Maybe to start, Julie, you mentioned one less selling day. I just want to make sure I get the simple math. Would that have amounted to something like a 0.5% growth headwind or about, call it $2 million or $3 million of a year-over-year drag in the first quarter? Is that the right ballpark? And then I've got some follow-ups.

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

A

Yeah. It was a little bit over a 0.5% of headwind on the quarter growth rate.

Mathew Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Okay. I appreciate that. And I guess, are there any other quarters this year that we should be sensitive to in terms of selling days versus last year?

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

A

No. The remaining quarters all have the same days as prior years'.

Mathew Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Okay. Thank you for that. And then, I just want to make sure I wrapped my head, arms, whatever you want to use, around the moving pieces on the updated guide as well as the first quarter. So, revenue for the full year comes down about $10 million at the midpoint, $5 million, I think very clearly federal funding being cut. The remaining $5 million, because you obviously mentioned the channel optimization initiatives, but then you also mentioned the pricing headwind in Spine from one particular customer. Can you just maybe put a little bit more detail against each of those buckets?

And I guess the last piece is, of all these disruptions you mentioned some in the first quarter in the Spine and Biologics business, and then there's the channel optimization and the pricing, did we see any of this impact in the

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first quarter? So, for instance, that $10 million, I know you said a lot of it's in the second quarter, but do we already absorb some of that $10 million headwind here in the first quarter? Those are my three questions. Sorry about all that.

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

A

No, that's fine. Yeah so let me try to unpack that. So, out of the takedown, yeah $5 million is related to the US-funded NGO business. The remainder is really Spine and Biologics, I would say, channel disruption. The price we primarily had included in our original guidance, it's a little steeper than we originally, but I would say that was in our original guide.

Yeah, we did take some of that in Q1, both the price and the softness in the distributor channel, we did see some of that in Q1, but we expect the majority of it to be in Q2. And then, if you think about the $5 million from NGO, that was -- they generally placed a quarterly order, so that's kind of spread evenly throughout the year. So, you had $1.5 million or so of that in Q1, and you'll see that throughout the remainder of each quarter of this year for that as well, as far as we are aware at this point.

Mathew Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Okay. And if I could just add, just to make sure I'm doing all that math right, I mean, it sounds like the first quarter, if you add back the selling days difference, which I don't think we had contemplated, and then some of those moving pieces, you're sort of excluding M6 still in the low 190s. Is that sort of the right way to think about it, if I just add back some of that stuff?

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

A

Yeah. That would be the right way to think about it, Matt.

Mathew Blackman
Analyst, Stifel, Nicolaus & Co., Inc.

Q

Okay. Thank you very much. I'll get back in queue.

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

A

Okay. Thank you.

Operator: Our next question comes from the line of Caitlin Cronin with Canaccord Genuity. Please go ahead.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

[indiscernible] (00:38:43) taking the questions. I guess just to start off, just a quick clarifying question for the NGO impact, where is that going to hit specifically within the different segments? And then just with the guidance change, really any thoughts on the longer-term guidance and the risk to that staying the same?

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

A

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Yeah. So, the NGO business is Ortho, so it will be in the International Ortho business is where you would see that. And then, we are not updating our long-term guidance at this point. We'll provide an update on our Q4 call.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

Okay, great. And then just a follow-up. Any more color on 7D this quarter and kind of the capital environment?

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

A

Yeah. I mean, we're still continuing to make progress with 7D. We're focused -- our focus is really on-earnouts as we believe that has the best return for us in the long-term with the pull-through to our Spine business. But no specific updates as it relates to the capital environment.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

Great. Thanks.

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

A

Thanks, Caitlin.

Operator: [Operator Instructions] And our next question comes from the line of Jeffrey Cohen with Ladenburg. Please go ahead.

Jeffrey S. Cohen
Analyst, Ladenburg Thalmann & Co., Inc.

Q

Good morning. Thank you for taking our questions. I guess two from me, and I guess, firstly, could you talk about AccelStim 2.0 a little bit? We're pretty clear on timing, but could you talk about some of the functionality that's available on the unit? And could talk about the bone fracture and manufacturing assembly? Thanks.

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

A

Yeah. Look, AccelStim 2.0, what it does, that pretty much it connects to our physician partner STIM onTrack, so it's going to do what all of the other system that we do, so give the opportunity to the surgeon to keep to follow the patient during the utilization of the – or the device to make sure that the patient is compliant and monitor progress.

So I think that this one is going to help us because, is give -- like it's something that also the physician can bill, can -- given that there is a [indiscernible] (00:41:18) called for it. So, a good opportunity for us to keep pushing into the specific market segment.

Jeffrey S. Cohen
Analyst, Ladenburg Thalmann & Co., Inc.

Q

So there won't be any changes towards functionality in the settings of the actual unit?

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

A

No. It's just integration with STIM OnTrack.

Jeffrey S. Cohen
Analyst, Ladenburg Thalmann & Co., Inc.

Q

Got it. Perfect. Okay. And then as following on that, look, you talk about the TrueLok System a little bit as far as the cases that's been done. What's being measured as far as data and outcomes? And how many SKUs would you envision having? I mean, now we're launched -- launching this year?

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

A

Yes. The SKUs of the TrueLok TBT is pretty much similar to all our other systems, so it's pretty much is one SKU with some accessories. And right now, we are in a limited clinical release that is doing very well. So, we are having a lot of interest of surgeons that are going to help us to collect data to demonstrate the benefit of this technique. There are already a good amount of literature available about the benefit.

But, of course, we want to make sure that we keep pushing this highly-differentiable procedure that can help us to enter a market segment that is pretty large. And as I said, there are 160,000 amputations that are happening in the United States because of diabetic foot, and we think that this procedure can be a game-changing. So, something that we are very excited about. And, like I said already, we did – [indiscernible] (00:43:12) cases just in a very limited market release. So, a great opportunity for us.

Jeffrey S. Cohen
Analyst, Ladenburg Thalmann & Co., Inc.

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Perfect. Thanks for taking our questions.

Operator: Okay. 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 and Communications Officer, Orthofix Medical, Inc.

Thanks, everybody for joining us today. We appreciate your time and interest. If you have more questions, please reach out, and we'll look forward to talking to you next quarter. This concludes our call.

Operator: Ladies and gentlemen, that concludes today's call. Thank you all for joining. You may now disconnect.

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