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Orthofix Medical, Inc. (OFIX)

Q4 2024 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Thank you for standing by. My name is Jeannie, and I will be your conference operator today. At this time, I would like to welcome everyone to the Orthofix Q4 2024 Earnings Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. [Operator Instructions] Thank you.

I would now like to turn the call over to Julie Dewey. 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 fourth quarter 2024 earnings call. We appreciate you joining us. I'm Julie Dewey, Orthofix's Chief IR and Communications Officer. Joining me on the call today are President and Chief Executive Officer, 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'll 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 fourth quarter and full year 2024 results for information regarding our non-GAAP results, including our reconciliations of these non-GAAP financial measures to our US GAAP results.

Additionally, all revenue percentage changes discussed will be on a constant currency year-over-year basis, 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 fourth quarter results and our financial guidance for 2025.

With that, I'll 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 fourth quarter earnings call. 2024 was a year worth celebrating for Orthofix. We executed against our guidance, strengthened our market position, and accelerated innovation across the business. We continue to invest in our most important differentiators, our people, to support our ability to best service our surgeons' need and deliver excellence, and our technology to advance our portfolio pipeline and fuel our growth.

We put a new leadership team in place that define a cohesive, long-term, profitable growth plan for our company and aligned our organization with our go-forward strategy. Throughout 2024, this team capitalized on Orthofix competitive advantages to advance our strategic initiatives, taking advantage of significant cross-portfolio commercial opportunities and profitably growing our business.

In spine, we grew our US spinal fixation business, more than doubled the market growth rate, including 24% growth in our top six implant systems, twiced the market growth rate in thoracolumbar fixation and tripled the market growth rate in interbody and cervical fusion. Demand for our enabling technology was strong and included a record number of 7D FLASH Navigation System placements.

2024 was a record setting year for our Bone Growth Therapies business. We generated more revenue, manufactured more devices, and support more surgeons and patients with our life-changing technology than any year in the company history with BGT. Collectively, we continued to expand our capabilities and build upon our best-in-class status, market share leading position and market expander in spine and orthopedics.

Our Orthopedics business also had an excellent year, setting a record for both global and US sales. We are redefining the category of limb reconstruction with a unique portfolio of solutions addressing the most challenging orthopedics conditions in patients of all ages. Under our new business unit leadership, we are executing towards an exceptionally focused strategy that optimizes the impact of our innovative portfolio and enables Orthofix to meaningfully gain traction in the USA market, while growing our position internationally.

Across the business, we continue to transform our commercial organization and strengthen relationship with our surgeon partners and their patients. Additionally, we are delivering on an exceptional pace of innovation with a number of key new product introductions across each of our portfolio areas, and leveraging our strength in enabling technologies to continue to differentiate our products in the market.

Organizationally, we sharpened our focus and launched new project teams to tackle our vital few initiatives, the most essential priorities that will enable us to strengthen our market position, equip us to explore new growth opportunities and win in 2025.

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With our focus on innovating technologies, a commercial organization dedicated to delivering an unrivaled customer experience and disciplined planning and execution strategies to guide our effort, we have significantly improved our operating and financial position and paved the way for sustainable growth.

During 2024, we made significant strides in improving our financial strength, including $21 million in positive free cash flow in the second half of 2024 and negotiating a new term loan with extra capacity, lower rates and increased flexibility to further optimize the company's capital structure.

Finally, we set long-term financial targets that reinforce our commitment to long-term profitable growth. And we are just getting started. Looking ahead, we will continue to focus on our vital few initiatives in our long range plan that we believe will fuel profitable growth and propel our business forward.

This includes an innovation focus and continued development of differentiated products to meet diverse surgeon preferences, a commercial strategy enhancement to drive deeper market penetration through comprehensive portfolio offerings, a technology leadership that harness advanced systems for improved surgical outcomes and efficiencies, emphasis on high-quality revenue streams and operational excellence for growth sustainability, and disciplined cash flow management and strategic financial planning to sustain positive free cash flow.

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.

Now, on to the numbers for the fourth quarter of 2024. Our fourth quarter net sales of $215.7 million represents year-over-year growth of 8% on a constant currency basis and reflect the record above-market performance across all three major product lines, providing further evidence that Orthofix balanced and complementary product mix offer a differentiated advantage across multiple markets.

We had another quarter of strong adjusted EBITDA margin expansion with positive free cash flow of $15.2 million, far exceeding our original expectation that we set at the beginning of last year. I can confidently say that the business fundamentals are excellent and we have positive momentum to continue leveraging our strategic advantages in 2025 and beyond.

US Spine Fixation grew 12%. Revenue growth was driven by continued strong market demand of the recently launched Reef and Waveform Interbody products, along with the strengthening of our distributor network. More specifically, our lateral portfolio grew 33% and our ALIF and MIS portfolios both grew at over 19%, all significantly outperforming the market due to increased focus on procedural selling, the addition of new, larger, more dedicated distributor and expanding our relationship with our top distributors.

Growth within our Spine segment has been supported by a 30% increase in our global 7D FLASH Navigation System placement in 2024, including 150% year-over-year increase in the number of earn-out agreements. We are leveraging this differentiable platform to create longstanding relationship with our surgeon partners.

With continued investment, our next-generation advancement in enabling technology and our hardware portfolio will build upon this unique foundation and establish us as a partner of choice for surgeons seeking real-time, data-driven intraoperative solution in the OR. At the end of the fourth quarter, we received FDA clearance for our FLASH EVD or external ventricular drain cranial navigation product.

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EVD is a common neurosurgical procedure, but can result in a higher rate of catheter placement errors using the standard freehand technique, as well as high rate of infection.

FLASH EVD is designed to address these drawbacks. Although the cranial market is not a strategic focus for us, this clearance supports an increased footprint and presence at the hospital for our 7D system.

As our enabling technologies strategy continues to evolve, we are more confident than ever in its increasingly significant role in our portfolio. New product introductions are a driving force and continue to open doors to new surgeon. Beginning in Q2, we have several product launches planned, including the full launch of Reef L Lateral Lumbar Interbody and additional solution in our Meridian ALIF portfolio.

This new interbody design features our proprietary, advanced surface technologies and expand our portfolio of lumbar interbody fusion products to address varying surgeon preferences and patients' anatomies. In parallel, we will integrate our hardware products with access to navigation, creating a comprehensive procedural solution to enhance efficiency and predictability 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 the top sales talent, increase exclusive distributor relationships and drive stickier relationships with surgeons and hospital account, which we expect to result in incremental product pull-through as well as ASP lift from mix benefit.

Now, to Bone Growth Therapies. Even as we continue to own the number one market share position in spine, BGT net sales still grew an impressive 9% overall in Q4. We continue to take share with more than 50% of the growth coming from new customer conversions, validating our strategy of capitalizing on multiple access points.

In addition, investment in the fracture market sales channel drove 10% growth in BGT fracture with the AccelStim bone growth therapy device continuing to outperform the market. As a reminder, the fracture market represents an opportunity of more than $200 million, and we are still in the very early innings of building our position in the market, with a clear goal to become the number one player.

Our BGT business is focused on maximizing our market-leading position with the most comprehensive portfolio and most indication of bone growth stimulation devices in the market. We will continue to focus on cross-selling with Orthopedics and Spine, as the new market channel with established sales representatives and drive penetration in the fracture market with AccelStim.

Later this year, we anticipate FDA approval for our AccelStim 2.0, which we expect to redefine the recovery experience by engaging patients and surgeons with their prescribed treatment through the STIM onTrack mobile app. Our global orthopedics business delivered record net sales in Q4, representing constant currency growth of 18% compared to prior year.

USA Orthopedics benefited from strong execution and grew a record 21%. Growth was led by the combination of our TrueLok and Fitbone products, as well as growth in the GALAXY fixation product family. We are in the very early stages of expanding into the USA Orthopedics market, which presents incredible growth opportunities, given our unique and innovative product lines.

Our focus is on areas where we can win, specifically in redefining the category of limb reconstruction, an underserved market that includes limb preservation, deformity correction, limb lengthening, and complex fracture

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management. As the only company solely focused in limb reconstruction, we have a growing unique portfolio solution to address the most challenging condition in patient of all ages.

I am excited to announce that we received FDA clearance and CE Mark registration for the TrueLok Elevate Transverse Bone Transport or TBT System, the latest addition of Orthofix flagship TrueLok family of external fixators. TrueLok Elevate is the first FDA cleared device for TBT and is indicated to correct non-unions and bony or soft tissue deformities or defects, which could include non-healing wounds, ulcer and deep tissue wounds.

According to American Diabetes Association, over 160,000 amputations occur each year in the United States as a result of diabetic-related complications, representing a sizable market opportunity of approximately $1.2 billion. In addition, published studies have shown that patients with diabetic foot ulcer who received an amputation have a five-year mortality rate of [indiscernible] (00:25:42) and are bundled with lifetime health care cost of just over $640,000 for carried directly related to their amputation.

Thus, TrueLok Elevate offers the potential to not only be a limb and cost-saving device, but most importantly, a life-saving solution to a challenging patient population. The TrueLok Elevate TBT System is currently in limited market release as direct centers in USA and Europe. Orthopedics growth in 2025 will be fueled by a number of new product introductions that we expect to capture additional market share with these existing and new customers.

These include the TrueLok Elevate TBT System, the Fitbone bone transport and lengthening nail, the only bone transport made available in United States, and the Fitbone trochanteric nail. We expect all of these products to be in full market release in the second half of 2025.

Underpinning our business strategies are significant cross-portfolio commercial opportunities.

The breadth and depth of the Orthofix Spine and Orthopedics offering provide multiple paths to growth the business as sustained above-market rates. We continue to take advantage of opportunities to cross-sell our BGT products into spine accounts, as well as introducing spinal hardware, biologic and navigation to our spine BGT surgeon. We also have additional opportunities with our biologic and fracture stimulation products through our orthopedics channel.

Overall, Orthofix is in a great position to capitalize on our recent product launch success and delivering meaningful innovations to improve outcomes and efficiencies for our surgeon customers and their patients. We remain the market leaders in bone growth therapies, have a comprehensive market-leading biologics 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 the highly differentiated and compelling enabling technology. In summary, it's clear that Orthofix focus on our main strategic pillars and executing a clear strategy for profitable growth is delivering compelling results and I remain optimistic about the opportunities ahead.

At the same time, we are confident that our emphasis on disciplined capital deployment within our business and de-emphasizing areas we have less scale or share, will also drive our transformation, support profitable growth and increased penetration of our technology and product platforms in areas where we can win.

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As we look to 2025 and beyond, we plan to build on our progress by: number one, further sharpening our commercial focus and discipline for margin expansion; number two, continue to innovate our enabling technology platform to support our renewed procedural focus on spine, in particular, deformity; and number three, ensuring we are well-positioned to create value for our shareholders over the long term.

Our full year 2025 financial guidance reflects our confidence in sustainable growth trends, the strength of our differentiated and expanded portfolio which continues to win share and our commercial strategy and focused execution. I believe we are very well-positioned to accelerate our positive momentum and deliver on our commitment to drive disciplined, profitable growth and innovation, while increasing long-term shareholder value.

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

Julie B. Andrews

Chief Financial Officer, Orthofix Medical, Inc.

Thank you, Maximo; and good morning, everyone. We delivered record fourth quarter and full year results in 2024, well above the guidance we set at the beginning of the year and fortified our business for the future. We continued 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- and long-term profitable growth.

As we look ahead to 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.

I'll now review financial results for the fourth quarter for each of our business units and then discuss our full year 2025 guidance. Global Spinal Implants, Biologics, and Enabling Technologies' fourth quarter revenue was $116 million with year-over-year growth of 4.5%. US Spine Fixation revenue grew 12%, over twice the market growth rate driven by deeper penetration of existing accounts and expansion of our customer base.

Moving now to Bone Growth Therapies. BGT revenue grew 9% to $63.9 million in Q4, driven by above-market performance in both the spine and fracture channels. BGT fracture growth was 10% in the quarter, driven by investments in the fracture market sales channel. We do expect our BGT growth to remain above-market growth rates, but should continue to moderate somewhat as we move forward into 2025 due to our number one market share position in the BGT spine business and lapping the gains from [indiscernible] (00:33:16) 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 are significantly less penetrated and see a substantial opportunity to drive new business with orthopedic surgeons.

The Global Orthopedics business grew 18% to $35.8 million in the fourth quarter, led by 21% growth in the US as a result of strong performance across our portfolio, as well as distributor expansion and sales channel investment. The international business grew 17% versus prior year. As we've previously said, due to the nature 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 rate.

Non-GAAP adjusted EBITDA of $23.9 million was driven by leverage on sales growth and represented growth at nearly 3 times revenue with 130 basis points of margin expansion. We remain encouraged by these results as we

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are seeing our ability to drive leverage on sales growth materialize, as we continue to focus on disciplined profitable growth.

From a cash standpoint, our total cash balance, including restricted cash at the end of Q4, increased to approximately $85.7 million. Our free cash flow generation was $15.2 million in the fourth quarter and $21.1 million in the second half of the year, a significant improvement over the negative $30 million in free cash flow in the first half of 2024. This was a result of higher EBITDA as well as improvements in working capital usage.

As part of our commitment to prudently deploy capital, we are continuing to actively evaluate and manage our portfolio to ensure that we remain focused on our most profitable growth opportunities. In line with this process, we wanted to highlight a couple of updates that we believe will positively impact our results.

First, as we align our orthopedics product portfolio with our focus on redefining the category of limb reconstruction, we are sunsetting non-core products in the US that do not align with this strategy. This impact has been included in our 2025 guidance. We will also be discontinuing the M6-C artificial cervical disc and the M6-L artificial lumbar disc product lines. This product phase-out is in line with our commitment to direct resources to more profitable growth opportunities.

And as Massimo mentioned, it is another milestone in our transformation and supports our strategic focus on driving profitable growth in areas where we have a differentiated advantage. It is important to note that the sales of the M6 disc have been a headwind to the company's top line growth rate for the past few years, which also factored into our decision to discontinue the product.

Global net sales for the M6 artificial discs were $23.4 million in 2024. We plan to provide a full update on the accounting treatment and financial impact for the discontinuation of the M6 product lines on our first quarter 2025 earnings call.

I also want to point out that we plan to file an automatic shelf registration statement today. We are putting the shelf on file merely as a matter of good corporate housekeeping and do not have any plans to issue additional new equity at this time. As a reminder, with a debt facility that we put in place in November, we are adequately financed for our current operations.

We currently have approximately $83 million in unrestricted cash on our balance sheet, along with an additional $115 million in available capacity in our debt facility. We remain focused on pursuing the vital few initiatives that we outlined in our long range plan that we believe will fuel profitable growth before achievement of our three-year financial targets, as we outlined in November and to propel our business forward.

Overall, we are very pleased with our fourth quarter results and our performance in 2024, where all key financial metrics exceeded our expectations. We delivered above-market growth across all business lines, demonstrating the strength of our portfolio. We sequentially improved adjusted EBITDA every quarter, became free cash flow positive well ahead of our plans and significantly strengthened our balance sheet, all of which underpin our confidence in our ability to deliver long-term profitable growth.

Moving on to 2025 full year guidance. We expect full year net sales of $818 million to $826 million, which excludes sales from the discontinued M6 artificial disc product lines and includes the negative impact from foreign currency of approximately $4 million or 50 basis points on a reported basis as compared to the full year 2024.

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These expected net sales represent implied constant currency growth of 6.5% year-over-year, at the midpoint of the range. 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 full year 2025 non-GAAP adjusted EBITDA of $82 million to $86 million. This represents 180 basis points of EBITDA margin expansion at the midpoint of the range compared to 2024.

We also 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 artificial disc product line. With regard to our long-term financial targets, we are pleased to increase our long-term net sales CAGR from 2025 through 2027 to 6.5% to 7.5%, up from the 6% to 7% net sales CAGR target that we provided on our last earnings call. This increased growth rate reflects the discontinuation of our M6 artificial disc business.

All of our other three-year financial targets are unchanged, including mid-teens non-GAAP adjusted EBITDA as a percentage of net sales for the full year 2027 and positive free cash flow generation from 2025 through 2027, excluding the impact of restructuring charges related to the discontinuation of the M6 artificial disc product lines which we expect to be a headwind to 2025 free cash flow.

We believe these targets build on the positive momentum we've generated and put us on an accelerated path to profitability with a stronger financial profile to maximize value creation. While we are not providing quarterly guidance, I do want to provide you with some directional comments on the expected cadence of our business to assist you in modeling our quarterly performance.

Generally, we expect normalized procedure volume and seasonality throughout 2025 and more pronounced impact from the newly launched products as the year progresses. We expect Q1 to be slightly below the low end of our full year net sales growth guidance range due to the timing of international stocking orders in 2025. In addition, the $4 million foreign exchange impact is expected to be more heavily weighted in Q1 and Q3 of this year. Also note that M6 revenue was highest in Q1 of last year.

Now, for some specifics on the individual line items on the P&L for 2025. We expect gross margins to be approximately 71%, in line with 2024. We remain on track to deliver approximately 300 basis points of gross margin expansion over our long range plan period and achieve mid-teens adjusted EBITDA as a percent of net sales for the full year 2027. We expect operating expenses to decrease approximately 100 basis points through leverage on incremental sales and a continued focus on disciplined investments.

Before we move to line items below the operating income line, to assist you with modeling EBITDA, I want to provide you with an outlook for depreciation and amortization expense, which for the full year 2025, is in the range of approximately $38 million to $40 million as compared to $37 million in 2024. Stock-based compensation expense is expected to be in the range of $33 million to $34 million.

Now, let's touch briefly on the items below the operating income line. Our expectation for interest and other is approximately $5 million per quarter. We expect our adjusted EBITDA margin improvement of 180 basis points to be weighted more towards the back half of the year due to the timing of revenue and R&D investment.

As a reminder, Q1 always experiences a disproportionate amount of annual expenses due to industry conferences and certain other Q1 heavy expenses such as payroll taxes and 401(k) matching that reset in the new calendar year. In addition, this year's Q1 expenses will include our US national sales meeting which occurred in Q2 last year. As a result, we don't expect to see operating expense leverage in Q1 of this year versus Q1 of 2024.

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With regard to free cash flow, please keep in mind that while we expect to generate positive free cash flow, excluding the impact of restructuring charges related to M6 discontinuation for the full year 2025, we do not expect to generate positive free cash flow in every quarter.

Q1, in particular, has historically been the lowest cash flow quarter due to the payment of the prior year's annual bonus and Q4 commissions, among other items. With a compelling combination of profitable above-market growth and a stronger financial profile, we believe our focused commercial strategy and broad differentiated technologies, combined with a robust innovation pipeline and our pacesetting enabling technologies, position us well to enhance operational excellence, deliver on our financial commitments, and create long-term sustainable value for shareholders.

Now, before we open up 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. At the beginning of this call, I said that 2024 was a year worth celebrating. As I reflect on the past year, I'm incredibly proud of the progress we have made. I want to express my appreciation to our entire Orthofix team and our committed commercial partners whose contributions have been instrumental in driving our record performances in Q4 and 2024.

Together, we are working towards our vision to be the arrival partner in medtech, delivering exceptional experiences and a life-changing solution. We enter 2025 with great promise and momentum and to integrated organizations that are moving forward as one team. We are building a culture where we take ownership, innovate boldly and win together.

I look forward to leveraging our unique portfolio platform to drive profitable growth and building the long-term value for surgeons, patients, and shareholders in 2025 and beyond. Thank you for being part of our journey.

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

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QUESTION AND ANSWER SECTION

Operator: Thank you. We will now begin the question-and-answer session. [Operator Instructions] And your first question comes from the line of Caitlin Cronin with Canaccord Genuity. Please go ahead.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

Hi. Good morning, everyone. Congrats on a great end to the year. Just a few questions for me. So, starting out with the discontinuation of M6. Appreciate that this exit will help improve the overall growth rate, but would love some more color on why the exit to the business at this time, given your work on the two level M6-C study. Was it the increased competition in the space or other reason?

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

A

Yeah. Look, Caitlin, we – I'd say, good morning. We look at our product portfolio overall and we start to think about where do we want invest in 2025, beyond. And we saw that with the decrease of demand on M6, was not, let's say, worth to invest anymore, given our focus – renovated focus in deformity thinking about spine.

So, we wanted to start 2025 and beyond from a much cleaner slate and M6 become one of the decision that we made together with other products within the Orthopedics. We didn't believe that just having a two-level indication with a few additional demand. So, this is why the tough decision.

But again, our goal, given all of the progress that you saw in 2024, was to start 2025 with a much solid footing and a potential, let's say, higher growth rate moving forward.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

Got it. And then with the M6 and other portfolio updates and with others in the industry [ph] where throwing (00:48:43) their hats in the ring with M&A, what are your current thoughts on M&A? What would be your investment hurdles and what areas would you look to bolster and add to?

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

A

Yeah. These are great questions. We work very hard to improve our balance sheet in 2024. So, between the strengths that we have right now there, the new credit facility, I think that is creating the opportunity for us to look at the market, be patient and take advantage if something that fits our portfolio comes up.

So, it's not, let's say, something that we are going to be focused on this year. We are really focused and executing. But compared to 2024, let's say that we are creating the basis to be ready in case opportunities in the market that fits us, are going to be available. So, I feel very good about where we are as of today. We keep making the tough decision and keep generating the free cash flow that we need in order to be more competitive at this level.

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Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

Great. And then just one more quick one on 7D. Any color on the installed base or even the net adds in 2024 as you continue to see traction in earn-out agreements?

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

A

Yeah. We don't give specifics, but what I can tell you that is a record – is a record year for 7D. The demand stay very strong. If you see at the beginning when we started with this new management in 2024, we decided to be focused on creating earn-out agreements with different partners around United States and the team executed very well.

What is very important is that we keep monitoring how these earn-outs are performing in the marketplace. And what I can tell you that the vast majority of everything that we've done is exceeding our expectation. And you understand the fact that we are exceeding our earn-outs, the hospital exceeding the earn-outs agreement, commitments are creating higher stickiness between our device, our product and the enabling tech.

So, we are very, very pleased about the performance. It has been under 50% higher year-over-year. So, 7D is one of the pillars of our strategy moving forward and I can clearly say that is delivering.

Caitlin Cronin
Analyst, Canaccord Genuity LLC

Q

Awesome. Thank you.

Operator: Your next question comes from the line of Ryan Zimmerman with BTIG. Please go ahead.

Iseult Mcmahon
Analyst, BTIG LLC

Q

Hi. Good morning, everyone. This is Izzy on for Ryan. Thank you for taking the questions. Just to start out, I wanted to continue on with the M6 update. I was curious if there's any margin impact that we should be aware of from exiting these product lines.

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

A

We will provide more details in terms of the impact that it had on our historical financials on our Q1 call, but we have contemplated the impact in our guidance that we've provided in terms of our EBITDA margin that we've provided this morning.

Iseult Mcmahon
Analyst, BTIG LLC

Q

Got it. Thank you. And then, do you guys feel that there's going to be any gaps in the US Spine portfolio and how do you feel about that as a whole?

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

A

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No. I think that we – first of all, we are not discontinuing. We are phasing out the product. So, it's going to be available for a little while. But in general, I don't think that is going to create a big gap for us. Actually, it's freeing up the resources that we need to double down on the pillars of our future strategy, starting with deformity.

So, we felt very hard about this decision and we believe that is the most – it makes sense long term for what we want to accomplish here in Orthofix.

Iseult Mcmahon
Analyst, BTIG LLC

Q

Helpful. And then, last one for me. Massimo, you outlined several upcoming product launches throughout 2025. I was curious if there's any one in particular that you're excited for or which you expect will provide the most impact to top line growth. Thanks for taking the questions.

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

A

Yeah. Look, I think that if you see our portfolio as a whole, I think that in every single our business unit, we're going to have some strategic new initiatives and new products this year. Of course, I think that – thinking about Spine, the introduction and the full commercial launch of our new Interbody product is going to create a very good leverage for us.

If you see, 2024 has been a great year for adoption of our [ph] cages (00:54:24). So, I see this will keep continuing. In Orthopedics, the launch of our new Elevate system that augment our TrueLok is already creating just in the clinical phase a lot of positive demand. So, a very good lever that we're going to have in orthopedics.

And of course, in BGT, even being the number one player in the market, we keep delivering new solution to our surgeon. So I see, with AccelStim 2.0, a good boost in the structural side to keep fueling our race to be the number one also in the three markets. So, I'm very positive and bullish about 2025 and beyond for all our business.

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

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

Q

Good morning, everybody. Thanks for taking my questions. I got a couple. Maybe, Julie, to start with you on the 2025 guide. Could you just give us a sense of the total revenue headwinds baked in to 2025? I think $20 million roughly from M6 is a $4 million FX headwind. You mentioned some ortho franchise sunsetting.

And I guess, also the last question. Did you bake in any dislocation into that guide to the extent there may be some, I don't know, call it backlash from still existing high volume M6 users? And then I've got a follow-up on that.

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

A

Okay. Thank you, Matt. Yeah. So our guide, the $818 million to the $826 million, it assumes again 6% to 7% kind of growth, 6.5% at the midpoint. Last year, 2024, M6 revenue was $23.4 million and then also assumes about a 50 basis point or $4 million impact from FX.

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Those are the base assumptions in the guide. We don't expect any significant disruption or dislocation from M6 just in terms of the way that it's sold in the market [ph] versus often (00:56:47) different distributors and then we feel confident in the numbers that we put forward.

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

Q

Okay. And then, I know you hadn't guided to 2025 EBITDA, but I think you still landed roughly with all of those aforementioned revenue headwinds in 2025. You roughly landed in the same spot where you're modeling and consensus was modeling.

So I guess, the question there is, should we read that as M6 maybe being less profitable than we perhaps thought or are we actually seeing your ability to offset some of that EBITDA dilution with underlying margin outperformance you may be seeing elsewhere?

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

A

Yeah. So, the EBITDA guide for the year was $86 million. I think consensus out there was just over $80 million, a little under $81 million. And again, yeah, I think this shows the progress that we're making on expanding our EBITDA margins above expectations as well as some of the headwind that was in the M6 profitability.

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

Q

Okay. And then, Massimo, just hoping to get a little bit more out of you on 7D adoption and what you're seeing on that front. I guess, are there any common themes of who is adopting? Are these Orthofix portfolio users today? Are these accounts that perhaps are under-indexed to the broader Orthofix portfolio?

And I guess, really the most important piece I want to ask is, are you starting to see any sort of portfolio pull-through or step-up in utilization of 7D at these sites? Really just trying to gauge the long-term portfolio of pull-through opportunity as you place more 7Ds. And I can't help, but notice the Spine business has been really strong in the last couple of years. Are we seeing that sort of tailwind from the 7D pull-through or is that opportunity really still all in front of us? And that's all I had. Thank you.

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

A

Thank you, Matt. Good morning. The opportunity that we have is very large for us. So the under 50%, the year-over-year increase in earn-outs agreement is driven by all new account. So, for us it's all pretty much. The vast majority is in new revenue.

And I've said earlier, what is very encouraging for us is that all of these earn-out agreements are performing well above where the agreement is set. All of these translates on a high utilization of our 7D technology with our implant. So, the farther we go with 7D, it's clear for me that the larger the number of implants that we're going to sell.

The larger is the opportunity with our implant and the bigger is our opportunity to convert surgeon. So, I saw for you for every quarter every time we talk about earn-out is an indication of customer conversion.

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

Q

Okay. And so, I can put words in your mouth here, but it would seem like the growth rate in the spinal implant business is sustainable here at least over the next 12, 24 months, given the power of the portfolio but also what you're seeing with 7D and your ability from an earn-out standpoint to potentially grab share. Is that a fair statement?

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

A

Yeah, it's 100%. And it's going to be a combination between the 7D, the investment that we are doing on the technology, our focus on proceduralizing 7D with access with our products. So if you see, we are making bold decisions because we want to make sure to over index our investment in areas that is going to drive profitable growth.

And the combination of 7D with our implant let us go deeper and keep increasing, let's say, not just our sales but also our margins. So, I'm very pleased about where we are today and where we can go in 2025 and beyond.

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

Q

All right. Thank you so much, everybody.

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

A

Thanks, Matt.

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

A

Thank you, Matt.

Operator: Due to time constraints, that concludes our Q&A session. I will now turn the conference 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 look forward to talking to you next quarter. This concludes our call.

Operator: Thank you, everyone, for joining. You may now disconnect.

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