Orthofix Q1 2021 Earnings Call

April 30, 2021

Operator: Good day and thank you for standing by. Welcome to the Orthofix Medical Incorporated Q1 2021 Earnings Conference Call. At this time, all participants are in listen only mode. After the speaker presentation there will be a question and answer session. To ask a question during the session, you will need to press star, one, on your telephone. Please be advised that today's conference is being recorded. And if you require any further assistance, please press star, zero. I would now like to hand the conference over to your speaker today, Alexa Huerta, Senior Director of Investor Relations. Please go ahead.

Alexa Huerta: Thank you, operator. And Good morning, everyone. Welcome to the Orthofix First Quarter 2021 Earnings Call. Joining me on the call today are our President and Chief Executive Officer, Jon Serbousek and Chief Financial Officer, Doug Rice. I'll start with the safe harbor statement and then pass it over to Jon.

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, including any earnings guidance we provide and any

statements about our plans, beliefs, strategies, expectations, goals or objectives. Investors are cautioned not to place undue reliance on such forward-looking statements, as there is no assurance that the matters contained in such statements will occur. The forward-looking statements we will make on today's call are based on our beliefs and expectations as of today, April 30th, 2021. We do not undertake any obligation to revise or update such forward-looking statements.

Some factors that could cause actual results to be materially different from the forward-looking statements made by us on the call, include the risk factors disclosed under the heading Risk Factors in our Form 10-K for the year ended December 31st, 2020, and Form 10-Q for the quarter ended March 31st, 2021, and filed this morning, April 30th, 2021, as well as additional SEC filings we make in the future. If you need copies of these documents, please contact my office at Orthofix in Lewisville, Texas.

In addition, on today's call, we will refer to various non-GAAP financial measures. We believe that in order to properly understand our short-term and long-term financial trends, investors may wish to review these matters as a supplement to the financial measures determined in accordance with U.S. GAAP. Please refer to today's press release announcing our first

quarter 2021 results for reconciliations of these non-GAAP financial measures to our U.S. GAAP financial results.

At this point, I will turn the call over to Jon.

Jon Serbousek: Thank you, Alexa. Welcome, everyone, and thank you for joining our First Quarter 2021 Results Conference Call. On today's call, I'll provide an update of our first quarter performance. I will then review the progress we've made against each of our strategic initiatives before handing the call over to Doug, who will provide our financial update. I'll close with our perspective on the balance of 2021 before opening the line for questions.

On this call and in the filings we made today, you will notice that we have changed how we refer to our Global Extremities business, reverting to the way this had historically been described within our company, as Global Orthopedics business. Although, there is not one label that exactly describes this business segment, we believe orthopedics is generally more descriptive of what we do and the products we offer in this business segment.

Moving on to our first quarter performance, we are very encouraged with how the business performed during the quarter. Total revenue of $106 million, which exceeded our previously issued guidance range of $95 million to $96 million. On a reported basis, revenue was up approximately 1% compared to the

prior year and down approximately 1% on a constant currency basis. While we experienced continue global headwinds associated with COVID-19 during January and February, a sooner than expected rebound in procedures occurred in March. This was due to COVID restrictions easing and rescheduling procedures from the weather delays in certain U.S. markets in February.

In addition, our team certainly executed well in many key areas. We increased adoption of our products within our expanded strategic channel, which drove a strong top-line performance in the quarter. We saw strong contributions from certain focus products, including our M6 artificial cervical disc, as well as the FITBONE lengthening elm. Complex cases, which we define as cases that require overnight stays or often multi-day hospital admissions, were up in our U.S. orthopedics and our U.S. spine fixation markets for the month of March. Which was in the shift from the decline we'd previously seen in Q4 of 2020 and the first two months of 2021.

Now, let us turn to the performance within each of our business units. I'll first cover our spine products category, starting with Bone Growth Therapies or BGT. Sales for the quarter were down $2.5 million or 5% versus prior year, largely impacted by COVID and the reduction in multi-level complex spine procedures during January and February, which are high utilizers of BGT products. Order volumes recovered in March to near pre-

COVID levels. However, this volume was partially as a result of catch-up orders related to the weather impacted geographies in the U.S. during February and rescheduling a case as previously postponed due to COVID restrictions.

Moving to Spinal Implants, we are happy to report that global revenue was up 12% on reported basis as compared to the first quarter of 2020. As a reminder, this category is made up of our Spine Fixation and Motion Preservation products. U.S. Spinal Implants grew 19% over prior year. And we saw growth in both Spine Fixation and Motion Preservation product categories, during this period. The primary driver of growth was the U.S. M6-C artificial disc sales, which grew over 100% in the quarter, as compared to the prior year. This was due to strong new surgeon adoption and increased procedure volumes among existing surgeon users.

We were pleased with our ability to attract new surgeon users of M6-C and continue to see improved growth within existing surgeon users. We hit $30 million in total global trailing 12-month sales of M6 discs at the end of Q1 2021, triggering our first revenue milestone from the Spinal Kinetics acquisition and bringing our estimated market share in the U.S. to over 10%. The remainder of the U.S. Spine Fixation saw growth this quarter due to increased adoption of new products with

existing surgeons and strategic distribution partners ramping up.

Turning to our biologic portfolio, revenue was down 2% compared to 2020, primarily as a result of COVID headwinds, combined with the anticipated channel disruption. Moving to our Global Orthopedics business, sales were up 3% on a reported basis versus prior year and down 3% on a constant currency basis. Continued COVID related headwinds and shutdowns in certain European geographies impacted procedure volumes, which were offset by a solid contribution from FITBONE, which generated $1.6 million in revenue during the quarter.

In the first quarter of 2021, there was approximately $1.5 million in one-time sales related to stocking orders across the portfolio that will positively impact future sales. Next, I would like to provide an overview of the progress we have made within each of our four focus areas. Starting with our first initiative to improve structure and leadership, we have a full executive management team in place and have effectively completed this initiative. But we will certainly continue to recruit and develop talent throughout the organization. We can now accelerate the execution of the rest of our initiatives.

Moving to our second initiative, operational execution. We’re focused on the refinement of our global supply chain to become more efficient and agile as an organization. This will

allow us to more rapidly introduce new products, integrate new distributors, focus on working capital management and deliver innovation to our customers and patients. We view this as an ongoing initiative. Our third initiative is product innovation and differentiation, but we have focused on developing and acquiring product and procedure solutions to meet unmet needs in the marketplace. We have developed a comprehensive portfolio roadmap to refresh our current products and bring new innovations to Orthofix. I'm proud of the team and our direction as we have been able to set good progress in 2021 with the introduction and early adoption of new products, launching 19 products in the last 12 months.

Looking ahead over the next 12 to 24 months, we anticipate contribution coming from both organic and inorganic strategies. As a reminder, our near and medium term priorities on the organic side will focus in key spinal procedures segments of anterior spine care, posterior cervical, minimally invasive surgery and deformity care. For the orthopedic business, we'll focus on organic and inorganic investments in our key markets of pediatric deformity and reconstruction, foot and ankle, especially trauma, as well as enhancements to our existing products and continue to pursue additional indications to expand to our addressable markets.

As we look deeper within each business, I'll share some key progress within spine. We recently received FDA clearance for the 3D-printed titanium CONSTRUX Mini Titanium Spacer System, as well as the FORZA Ti TLIF Spacer System, both with Nanovate Technology. Nanovate Technology is a service finish that differentiates us in the marketplace. The CONSTRUX Mini Titanium Spacer, which was developed to enhance ACDF procedures, is the first 3D-printed titanium inner body introduced into the market by Orthofix and adds an innovative technology to our ever expanding portfolio of comprehensive cervical spine solutions. The FORZA Ti 3D-printed Titanium TLIF Spacer System with Nanovate Technology was developed to enhance our TLIF Lumbar procedures. These launches are important to our near and long-term growth, and we are excited about their potential to impact the market.

Within the orthopedic business, we successfully launched the FITBONE lengthening nail in the back half of 2020 internationally. There have been over 3,500 cases completed using the system since its design inception, which validates the efficacy of the product. In Q1 of 2021, we did receive the first and only FDA pediatric 510K clearance for FITBONE, which includes smaller diameters, further demonstrating our commitment to the pediatric market. Late in the first quarter, we launched our OrthoNext surgical planning software platform for Juni Ortho

deformity plating system. The OrthoNext platform allows physicians to create 3D preoperative surgical plans to facilitate a more efficient procedure. Both the FITBONE pediatric 510K clearance and the launch of the OrthoNext planning software underscore our commitment to pediatric deformity correction. Our fourth and final initiative is commercial channel development, where we are continuously looking to invest to create a stable and predictable channel that is highly effective.

During the quarter, we continue to target, attract, onboard and strengthen our strategic partnerships. In March, we saw an increase adoption and usage of our products, including pull through from these strategic partners. In summary, I'm very proud of our performance in the quarter, during which we were able to exceed our own expectations and return to year-over-year growth. Many of the strategic investments we've made over the last 15 months are starting to payoff and we look forward to building off the momentum of the past few quarters during the balance of 2021.

With that, I'll turn the call over to Doug to review our financial performance. Doug?

Doug Rice: Thanks, Jon. And good morning, everyone. I will provide some additional details into our net sales and earnings results, and then discuss some of our other financial measures.

Because of the financial measures covered in today's call are on a non-GAAP basis, please refer to today's earnings release for further information regarding our non-GAAP reconciliations and disclosures.

Starting with revenue, as Jon mentioned, total net sales for the quarter were $106 million, up 1% on a reported basis, and down 1% on a constant currency basis, when compared to the first quarter of 2020. In the U.S. total net sales for the first quarter were flat to prior year and OUS total net sales were up 3% on a reported basis, and down 5% in constant currency, due primarily to the COVID related shutdowns in some European geographies, partially offset by increased stocking orders for new products. Gross margin in the first quarter of 2021 was 75.5% compared to 77.7% in the prior year period. The decline was primarily due to product mix, including the reduction in complex surgeries from COVID restrictions and increased expenses related to our FITBONE acquisition, integration, and manufacturing transition. For the full year 2021, we still expect gross margin to be in the range of 77% to 78%, in line with our pre-COVID historical averages.

Sales and marketing expenses in the first quarter of 2021 were 48% of net sales, an improvement from 52% in the first quarter of 2020. The decrease was primarily a result of lower travel, savings from decreased marketing events due to the

severe winter weather and events being held virtually as a result of COVID. In 2021, we continue to expect sales and marketing expenses to be approximately 49% to 50% of net sales as travel and event spending are expected to return to normal as the vaccine rollout continues throughout the year. And as we invest further in our commercial channel.

GAAP G&A expenses in the first quarter of 2021 were 16% of net sales, down from 17% in the prior year period. This decrease was mainly due to transition expenses in 2020 that did not recur in 2021. GAAP R&D expenses of 10% for the first quarter were up about 80 basis points over the prior year. This increase reflects spending to support new product development, as well as costs associated with our EU/MDR compliance efforts. We intend to continue to ramp up our efforts to drive organic innovation and differentiation, invest in clinical trials, such as our M6-C two level indication study in U.S. and build a robust product pipeline in both spine and orthopedics. As a reminder, this will cause our R&D spending as a percent of net sales to significantly outpace revenue growth in the near-term. We now expect 2021 GAAP R&D expense to be in the range of 12% to 12.5% of net sales, including an impact of about 250 basis points related directly to our EU/MDR compliance efforts, for which we are adjusting.

Adjusted EBITDA in the first quarter increased to $14 million, compared to $11.4 million in the first quarter of 2020. On a relative basis, adjusted EBITDA increased to 13% of revenue up from 11% of revenue in the first quarter of 2020, primarily due to the reduction in sales and marketing expenses. Now turning to tax. We had GAAP income tax benefit for the quarter of $200,000 or 3% of income before income taxes, as compared to income tax benefit of $20 million or negative 356% of income before income taxes in the same period of 2020. The effective tax rate for this quarter was negatively impacted by GAAP losses and our foreign operations that currently have no tax benefit, as well as acquisition related re-measurement expenses, not recognized for tax purposes.

For our non-GAAP results, we continue to use 27% as our adjusted long-term effective tax rate, which normalizes for acquisition related expenses and operating losses that have no GAAP tax benefit. For the first quarter of 2021, we reported GAAP loss of $0.30 per share as compared to GAAP earnings of $1.32 per share in the first quarter of 2020. After adjusting for certain items, and when normalizing for tax using our non-GAAP long-term effective tax rate, adjusted earnings for the first quarter of 2021 were $0.17 per share, compared to $0.09 per share in the first quarter of 2020. This increase was primarily driven by lower sales and marketing spend. Regarding

cash, we continue to maintain a strong liquidity position with $95 million in cash at the end of the first quarter of 2021, compared to $58 million at the end of the previous year's first quarter. We continue to have no borrowings outstanding under our $300 million senior secured revolving credit facility. In Q1 of 2021, we did trigger the first Spinal Kinetics revenue milestone by achieving $30 million in global trailing 12-month sales. And accordingly, we will pay the $15 million milestone amount in Q2 of this year.

As mentioned last year, we received $14 million in Medicare advanced payments as part of the CARES Act benefits during the second quarter of 2020, and repayment of that amount began in April of 2021. We expect the repayment to be phased over approximately one-year. Net cash provided by operating activities was $2.4 million in the quarter, down $10 million compared to $12.5 million in the first quarter last year, largely due to increased compensation expenses, product innovation and differentiation expenses, as well as payments made in 2021 related to transition expenses in 2020. Capital expenditures were $4.8 million in the quarter compared to $4.9 million in the prior year period. Capital expenditures are expected to be in the $23 million to $25 million range for 2021.

Consistent with our decreased operating cash flow, our free cash flow, which we define as cash flow from operations minus

capital expenditures, was $2.3 million outflow during the quarter, which was down from $7.5 million inflow in the first quarter of 2020. Our free cash flow levels are still expected to decrease significantly in 2021 compared of 2020 due to several items, including the repayment of the Medicare advance, which began in April of this year, the Q2 Spinal Kinetics milestone payment that I mentioned earlier, additional investments in our sales channels and in product innovation to support future growth and increased spending on EU/MDR compliance efforts.

I'll now turn the call back over to Jon.

Jon Serbousek: Thanks, Doug. Coming into 2021, we've completed our first strategic focus area of structure and leadership. We were highly focused on three key areas aimed at driving the business forward, operational execution, product innovation and commercial channel development. As a growth focused company, we wanted to provide more color on specific areas of the business that we believe represent primary growth drivers going forward. Our three near-term growth drivers are as follows. First, our most talked about product today, the M6-C artificial cervical disc. Since the 2019 U.S. launch of the M6 disc, we have seen triple digit growth as we continue to train the doctors as well as continue to drive growth coming from our existing surgeons, as they discover the ease and efficacy of the M6-C artificial cervical disc. The current U.S. market for

cervical disc replacements is approximately $250 million and anticipated to grow at low double digits per year, which is faster than the total spine market. Because of our premium artificial cervical disc, it’s the only disc on the market that mimics the natural motion of the spine, we expect to continue to take market share, as well as expand the overall size of the market.

The second key short-term growth driver is the FITBONE technology, a minimally invasive system, which enables full limb alignment and limb lengthening via an intramedullary nail. The current total served market is approximately $60 million and growing at high single digits annually and with only one main competitor in the market. The FITBONE system uses a precision German drive technology to provide precise deformity correction management utilizing a digital control system and can also utilize OrthoNext 3D preoperative planning. This acquisition expands our ability an already comprehensive deformity correction portfolio, and strategically fills our already robust pediatric offering.

The third key near-term growth driver is our technology leading interbody portfolio with the introduction of the 3D printed titanium, CONSTRUX Mini titanium spacer system, as well as the FORZA Ti TLIF spacer system, both with Nanovate Technology. The CONSTRUX and FORZA systems represent entry into

an estimated $500 million market that is growing over 3% annually. Orthofix has one of the most comprehensive interbody portfolios in spine with novel products utilizing the most comprehensive material and design selection, including Allograft PEEK, PEEK Titanium Composite known as PTC and 3D printed titanium with Nanovate. We are one of the few companies with a truly unique and comprehensive nano clearance for all titanium and PTC products. The nanoscale surface has been shown to increase proliferation of alkaline phosphatase activity, an early osteogenic differentiating marker in human stem cells in vitro. In addition to a number of exciting near-term growth opportunities, we also have a number of high priority segments of our business that we believe will drive growth.

Our long-term growth drivers are as follows. First, expanding our commitment to the bone growth stimulation market with the newly announced IGEA BGT partnership. This will provide new market segment and indication access for us and strengthen our market leadership in the U.S. Under the terms of this agreement, Orthofix has the right to pursue new FDA approvals and commercialize all of IGEA's products under the Orthofix brand. It will expand our Pulsed Electromagnetic Field or PEMF products and treatment modalities with indications such as low intensity Pulsed Ultrasound or LIPUS and Capacitive Coupling, CC for fracture management. We are also continuing to invest in the

ongoing rotator cuff clinical trial, which would be our initial entry into the soft tissue repair and protection market. This would be an indication with our existing PEMF mechanism of action. These investments show our continued belief in and our positive outlook for our BGT business in bone and tissue repair, as well as our post-surgical markets. These are important investments and initiatives as we maintain our BGT leadership.

The second long-term growth driver comes from our expansion of our FITBONE technology platform, from limb lengthening to spinal deformity. FITSPINE is an early intervention growth rod technology for non-fusion treatment of pediatric and adolescent scoliosis applications. The goal is to arrest or correct the progression of the scoliosis in order to significantly delay or eliminate the requirement for a definitive fusion procedure. There is currently only one other similar technology available on the market. We expect FITSPINE will further differentiate the Orthofix Spine portfolio to amplify our long-term commitment to both the deformity and pediatric markets with this highly innovative technology.

Now, shifting to revenue guidance. For the full year of 2021, we now expect top line revenue to be in the range of $455 million to $465 million. These ranges assume that current COVID restrictions and lockdowns in high-risk areas in the U.S. and Europe will continue through most of Q2 and begin easing in the

second half of the year, when procedure volumes should begin to return to 2019 levels. Through April, we have seen additional COVID-related lockdowns in Europe, as well as in select areas in the U.S., which we'll need to adapt to at a local level. We still believe the second half of the year will have mid-single digit growth over 2020, assuming no COVID-related impact exists. We now expect our adjusted EBITDA to be in the range of $52 million to $56 million. And our adjusted earnings per share is expected to be between $0.52 and $0.62 using a non-GAAP long-term tax rate of 27%.

We are very excited about the opportunities that lie ahead at Orthofix. As we continue through our transformation, we are now focusing our efforts on the execution of our long-term strategy to deliver growth by bringing innovative, high value solutions to physicians to improve patient mobility. We've already made great strides during the first quarter and I look forward to building on that momentum during the remainder of the year. As we've been saying, Orthofix is on the move.

With that, I would like to transition to the question-and-answer session. Operator, please open the lines.

Operator: Ladies and gentlemen, as a reminder, if you would like to ask a question, please press star, followed by the number one, on your telephone keypad. Please stand by while we

compile the Q&A roster. Again, that's star, one. And your first question is from the line of Mathew Blackman with Stifel.

Mathew Blackman: --for taking my questions. I've got a few here. But maybe to start, a bigger picture question for Jon. Jon, you were able to execute on a lot of your transformation plan in 2020, despite the pandemic. But now that we're seemingly and hopefully nearing a return to a more normal world, I was wondering if you were able to maybe step on the gas a bit more in 2021 in particular? Areas like commercial channels and sales force optimization, but also M6. Again, you're able to drive M6 adoption despite COVID. But just wondering if there's even more you can do in a post-COVID world? And then just a couple of follow-ups.

Jon Serbousek: Matt, thank you. And appreciate the comments. I think if you ask the team here, the pedals towards the floor. In fact, if I said here today that we're going to put this closer to the floor, they might just come back and have a different conversation for me. But to your point, actually we believe there is extra momentum we can get in these marketplaces. And we're just executing on a daily basis. M6 specifically, it's about training. It's bringing new surgeons to the technology, as well as taking the existing surgeons and getting them to grow their practices and become more comfortable with that procedure, as well as expanding the market from those

that are doing ACDFs and converting them to artificial cervical disc.

So there's opportunity there to expand the market. And we have a very robust team that trains on a local level every day. And so we look forward to them expanding their efforts as well. And as far as the commercial channel, we're making great progress there. Channels are always a process. And so we have people that are diligently pursuing those activities, not only from the existing channel, helping them to become more effective, but also bringing new members to the Orthofix family. So, we'll look forward to continue that process through 2021.

Mathew Blackman: Okay. And then a couple of follow-ups, I'll just throw them out at one time here. Jon, you mentioned pull-through, you see pull-through in the portfolio. Can you expand on that a little bit? Is that M6 driven? Is it something else in the portfolio that's pulling other things through? And was that through sort of any more significant this quarter than perhaps we've seen in prior quarters? And then the last follow-up is, the IGEA, I don't think I pronounced that, right. IGEA licensee, can you maybe just size the commercial opportunity that this portfolio addresses that may be incremental to your current portfolio? And maybe how should we think about the clinical and regulatory pathway ahead to get these products on the market? Thanks.

Jon Serbousek: Sure, Matt. Let me start with pull-through. Regarding pull-through and specifically towards spine, we do look for M6 as far as getting into new accounts and working with new surgeons, and then we have the opportunity to share the rest of our portfolio. And that's a strategy, basically a process that we're going through right now. So, we look forward to seeing our additional products within the Orthofix Spine product portfolio being utilized with new customers. It also includes bringing in new strategic distribution channel and our existing distribution channel. And sharing with them new products and also refreshes as we've highlighted with the titanium 3D printed interbody portfolio, as far as we get that into the market. So we'll look forward to more pull through in that regards.

Moving to IGEA. IGEA was a strategic move for us to reinforce our commitment and expanding our BGT opportunity. They have a very broad portfolio. They're in fracture management, they're in soft tissue modulation and also in cartilage. And so, we're going to work in primarily in the fracture management to start that. And it also broadens our overall portfolio. And there's 6 million fractures out in the marketplace today that we'll be able to expand our reach into with those new technologies and new approvals as we get them. Matt?

Mathew Blackman: That's all I had. Thank you.

Jon Serbousek: Thanks for the questions, Matt. Appreciate it.

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

Ryan Zimmerman: Good morning. Thanks for taking the questions. So, maybe just to start a couple questions from me. First on the spine, I mean, the motion preservation number was very impressive this quarter, given that triggered the milestones. And so, one, can you talk a little bit about, if I have this right, I think you did maybe over $17 million in sales just based on the trailing 12 months. I could be wrong on that. But talk about kind of what you're seeing in adoption there on the motion preservation side.

And then it feels like you've turned the corner on the legacy fixation business. You talk about whether that's coming from distributors or from new product adoption. And then as a as part of that question and then I do have a follow-up on bone growth therapies. But you did indicate that you are going to pursue a two level indication for M6. Can you talk about the timing, when you get there? And then I have a follow-up. Thank you.

Jon Serbousek: Sure. Thank you, Ryan. Regarding motion preservation, it is a key focus for our organization as I highlighted earlier. We will continue to train, we'll continue

to educate not only our distribution channel, but also our surgeon base and look at how they can basically expand their practice as well with motion preservation. It is a key driver for us as far as the overall business. And pardon me, it's a key driver for as far as overall business. And we look forward to having pull-through with the other products we go forward.

Let me jump down to your other question on two levels, since we're talking about motion preservation. We are actively recruiting sites right now and we expect to initiate that in the second quarter, as far as first cases. And so, it's a focus area for us, and we look forward to executing that study and bring it to level approval to the marketplace.

Doug Rice: Ryan, this is Doug. Your math was close, trailing 12 was $21 million for U.S. M6.

Ryan Zimmerman: Thank you. And maybe turning into bone growth therapies for a moment. I mean, it did decline about 5.5%, (INAUDIBLE) was an easy comp. So, maybe help us understand kind of how you think that can turn around? How much do you think that was kind of just the market in the first quarter versus broader market dynamics and kind of where the market is at in a normalized environment? And then maybe to Matt's earlier question, on IGEA, when we could expect potentially timing on that, if you're willing to share?

Jon Serbousek: Sure. Certainly. Let's start with the marketplace for BGT. One of the things about BGT is that it is used in cases that need additional biologic healing. And so they're usually come more complex cases. And with that, those are the cases that are oftentimes need a multi-day hospital stays. And so, those were the elective procedures that were actually really attenuated or minimized during January and February. So, we saw a really strong return in March in those areas. And also, there's a timing issue with BGT as far as how we recognize those revenues. They usually lag between four and six weeks of when they occur, actually during the application to the body. So, there's some timing issues there at BGT. We're still very positive and very robust as far as where the BGT business will go.

Ryan Zimmerman: Got it.

Operator: Your next question is from the line of Jeffrey Cohen with Ladenburg.

Doug Rice: Thanks, Ryan.

Jeffrey Cohen: Hi, Jon and Doug. How are you?

Doug Rice: Good morning. How are you doing, Jeff?

Jeffrey Cohen: Just fine. So, I was wondering if you could call out any more specifics on geographical strengths and weaknesses through Q2 and even over the past month from what you're seeing in some of the territory's out there?

Jon Serbousek: Sure. Let's talk U.S. versus Europe. Starting with Europe. We have certain regions that are basically been lockdown fairly heavily, and actually some have gone further into a lockdown, such as Germany, France, and Italy. There are still cases being done there, but some of the higher elective, some of the pediatric deformity cases are basically being minimized there as well. The good news is the UK is starting to open up. Their vaccination rates are high and so we're starting to see the UK open up as we've moved into March. And we look forward to that and remain productive through the out quarters. Regarding the U.S., we had great success in many regions in the U.S. There are still areas that are still slower to open up, California, New York, some of the Michigan area that's basically been minimized as far as some of the elective procedures. But we're seeing good return to elective procedures in the market, generally.

Jeffrey Cohen: Okay. Got it. Can you shed any further color on the biologics for the quarter? And how that looks regarding Trinity and other products and cross-selling current and future opportunities?

Jon Serbousek: We still view Trinity in a very positive light. It still has great access to the marketplace. We are focused on cross-selling as we bring in new strategic distributors, as well as cross-selling into our extremities

business. Here again, this product is used in some of the more complex cases where there's larger volumes of craft material required. And so, that follows that trend in the marketplace as well, as far as volumes. And we see Trinity doing well in the out quarters as well.

Jeffrey Cohen: Got it. And then lastly, for me, you made a comment about mid-single digit growth, I think that was for the balance of 2021. Is that on a constant currency basis? Because it looks like the midpoint of consensus is 12.4%, 12.5% approximately any commentary there?

Jon Serbousek: Right. It's on a reported basis, Jeff, is the way we think we're going to exit the back half of the year. I think there'll be pressure as COVID is still more of an impact in Q2 that we're experiencing. But as it eases, we expect back half of the year exit rate to be in mid-single digits.

Jeffrey Cohen: Got it. Okay. That's clear. Thanks for taking the question (INAUDIBLE)

Jon Serbousek: Thank you.

Operator: Your next question is from the line of Anthony Petrone with Jefferies.

Anthony Petrone: Hi. Good morning. I hope everyone's doing well. A few on cervical, and then we'll have a couple of follow-ups. On cervical, maybe just an update on how many surgeons are trained on M6? I think the last data point that was out there

was 650 surgeons are trained. And then, maybe any comments on the competitive dynamics, just considering the simplify medical transaction with invasive. Just anything of note in the competitive landscape following that transaction? And then I'll have a couple of follow-ups

Jon Serbousek: Thanks, Anthony. We continue to train surgeons on a monthly basis. We have monthly targets we put forward and we're training about the same rate and cadence that we have through 2020. So, we're adding a good volume of surgeons to the M6 product line, as far as our utilization. Regarding competitive nature, the great news is that M6 is the only disc that mimics the natural motion of the natural cervical disc. It's a very attractive technology to the surgeons. And so, it actually is very appealing. With that, we have great surgeon interests, and we also have good surgeon adoption.

It's early on for the other product coming on the marketplace, and we'll monitor it throughout 2021 and see how it goes. The good news about the surgical artificial disc market is it's very, very mature. There's plenty of room for the entire market to grow and we look forward to having really high end quality competitors to grow that market collectively together. So, that's a good thing for the market. And I think it's a good thing for the patients out there that need artificial cervical discs.

Anthony Petrone: That's helpful. A couple of follow-ups. One would be just sort of on procedure volumes. It sounds like certainly last quarter, your complex spine procedures were impacted by COVID and you started to see some reversal. And certainly, the numbers this quarter suggest the same. And so, I'm just sort of wondering if there's any way to sort of just provide, I guess, maybe March and April trends, how volumes are trending? How much backlog you still think is out there? And then the last question for me would just be any update on reclassification bone growth stimulators? I don't think anything has been updated of yet. And I know that process was also delayed by COVID. Thanks, again. I'll hop back in queue.

Jon Serbousek: Yeah. Regarding the current trends, we saw a greater reduction in elective procedures in January and February of 2021. And so, March was a very large rebound for us. And so, there was a fair amount of catch up in there as far as from the procedures that were delayed in January and February. And so, we're looking to normalize our go forward electives and we still do have, in April and beyond, we still do have this COVID restrictions in a number of the key marketplaces that we look forward to minimize. And we believe they're going to minimize. Some of them are starting to fall as we go forward. And so, we will look to see a more normal elective procedure in the out quarters.

Regarding reclassification, there's no new news there. The fact is the FDA is still doing their work. And we do expect that all the current environment that we don't expect to see a classification any time soon. But they'll do their work and let us know when they get their information completed and come back to us.

Anthony Petrone: Thanks again.

Operator: Ladies and gentlemen, as a reminder, if you would like to ask a question, please press star then one on your telephone keypad. Again, that's star, one. Your next question is from the line of Jim Sidoti with Sidoti & Company.

Jim Sidoti: Hi. Good morning. Can you hear me?

Jon Serbousek: Yes, we can, Jim. Good morning.

Jim Sidoti: Great, great. A lot of conversation around M6 today. Doug, can you just break out what the sales were for the quarter in the U.S. and outside of the U.S.?

Doug Rice: Yep. Let me get that for you here in just a second. They are in the back of the 10-Q that we filed, Jim. I'll look, I don't know those numbers off the top of my head.

Jim Sidoti: Okay. Okay. great. And then if you go by your R&D guidance here, R&D around 12% of revenue, it seems like you're expecting a pretty significant pickup of maybe $14 million, $15 million a quarter, the next few quarters. Is that

math correct? And is that for a specific trial or can you give us some color as to what the big uptake will be?

Jon Serbousek: Yea. This is Jon, I'll let Doug finish up after I gave a couple of color commentaries here. We are investing heavily. We are investing in clinical trials, IDEs trials. We also have a heavy lift of the EU/MDR, which is basically, not only just compliance to the regulation, but also collecting real-world evidence so that we can utilize on many fronts. And then we have this organic development that basically comes into refreshing the portfolio in the spine and also developing a broader portfolio in the biologics area. So, we're very active in the R&D area. And so, there's a very large incremental expense in R&D because we believe that's the future of building a high quality product portfolio that's innovative and differentiated.

Jim Sidoti: Correct there, Doug, you are expecting about $15 million and a quarter for the rest of the year?

Doug Rice: Yeah, just to complete the loop on your revenue question, in rough numbers $83 million U.S. and $22 million O.U.S., just to finish the story there. And then with regards to the uptick in R&D, I'd say the majority of it on a GAAP basis is related to our EU/MDR efforts. And in terms of cadence, I think you're generally in the right zip code.

Jim Sidoti: Okay. My first question though is specific to the M6. Do you have that breakout?

Doug Rice: The two level study in R&D. I don't have that right now (INAUDIBLE)

Jim Sidoti: I meant on revenue, the revenue in the quarter for the M6.

Doug Rice: Yeah. Roughly $8 million.

Jim Sidoti: And that's U.S.?

Doug Rice: $6 million U.S. and $2 million O.U.S.

Jim Sidoti: Got it. That's what I was looking for. Thank you very much.

Operator: Our final question comes from the line of Dave Turkaly with JMP Securities.

Dave Turkaly: Hey, good morning, guys. Just going back to the IGEA, if I'm saying that correctly. I'm just curious, so obviously you have a dominant position in the PEMF, spine, bone growth stem. It sounds like this is more ultrasound or CC. But I'm just curious, same patients or same cases? Or is ultrasound potentially better for soft tissue or I guess, any thoughts around sort of where you'll go with this first? Or how it's different than what you already have?

Jon Serbousek: Thanks, Dave. The IGEA license agreement, we couldn't be more pleased to be partnered with IGEA. That's a very high quality company with a very broad portfolio, not only

of technology, but applications. So yes, it does bolster the PEMF area, which we certainly will enjoy, but also it does bring into the LIPUS and the CC area that actually broadens the overall application we can go to. And both bone healing and soft tissue healing. So as we stated, our initial focus is going to be in fracture management in all three of those areas. But also expanding out in the future into the soft tissue area. We're looking forward to the our PEMF shoulder rotator cuff repair study coming to fruition, and having that in the marketplace, it opens up a very large market for us. And also IGEA has initiatives into cartilage and also pain management around joints.

So, from that standpoint, think of it as a technology platform play that basically, we also received a very large clinical database with as far as experience into Europe, as we've highlighted, they've treated over 500,000 patients since inception and about 20,000 patients a year. So, think about technology, think about clinical applications, and also think about clinical data as we go forward. And they're going to be a great partner. We're looking forward to seeing it come together.

Dave Turkaly: And just a quick follow-up when you say pain management, are you talking about like hips and joint pain? Or maybe stem for maybe delaying some of the joint procedures that are done today?

Jon Serbousek: They have technologies and applications in the market. They're looking at as far as pain as you described it, but also minimizing infusion or swelling as well as basically cartilage modulation. I'll leave it at that for right now.

Dave Turkaly: Thank you.

Jon Serbousek: Thanks, Dave, appreciate the question.

Operator: We do have a follow-up question from the line of Ryan Zimmerman with BTIG.

Ryan Zimmerman: Yeah, just one follow-up for me, we've talked a lot about Spinal Fixation and Bone Growth Therapies. But I do want to get your view of extremities a little bit. I mean, it's been somewhat dilutive to growth for the company for some time. And I know it's partly on the international distributors, but also from an EBITDA perspective, it does generate much less EBITDA for the company. So, Jon, what's your view of extremities just strategically and kind of it sounds like obviously, you're committed to it with everything you're investing. But at some point, is there a point where you do have to consider whether it should be part of the company.

Jon Serbousek: Thanks, Ryan. Extremities are, as we're now calling it, orthopedics. The key thing in that area is to narrow focus and that's why we're going into pediatrics. We're going into foot and ankles, and we're going into specialty trauma. And

so we're defining those areas in pediatrics and foot and ankle are two of the fastest growing markets in the U.S. today, as far as for application. It further amplifies our FITBONE investment, acquisition investment, and looking at how we're going to basically advanced pediatric deformity care, not only with FITBONE, but also with the balance of our products, whether it be from TL-HEX, eight-Plate and other technologies that we can do it basically, provide a very large portfolio, including our Orthofix preoperative planning system. So, we're committed to working in the pediatric space and also the foot and ankle space is a very high growing area that we actually have some key leading technologies in the cervical foot area. And so, we're looking to expand around that as well.

And outside the U.S., specialty trauma or the Ex Fix is, we're basically market leaders there. And we are expanding there as far as how to take TL-HEX and bring new technologies to advance that, not only planning, but also automatic deployment of those technologies for a procedural application. So, we're going to stay focused in those areas and not think as a broad portfolio. We're not going to become an orthopedics trauma company that's going to take trauma as far as in the 6,000, but we're going to be very focused in specialty trauma, the pediatrics and in foot and ankle area. So, we think there's some really good synergies.

And one last item, which we do, we acquired FITBONE, we also acquired FITSPINE. And so, that also is an opportunity for us to leverage that precision German technology to manage deformity care, not only on AIS or adolescent idiopathic scoliosis or early onset scoliosis. And that's an area where we've done very, very well. And lastly, it brings us to interact with a very different group of surgeons, whether it be an FITSPINE or FITBONE. And these are luminaries of the marketplace. So, we see that as a benefit as well. So, we're going to be committed to those three areas that I described.

Ryan Zimmerman: Understood. Thank you.

Jon Serbousek: Thank you. Appreciate the questions.

Operator: That concludes our Q&A portion. I'd now like to turn the call over to Jon Serbousek for closing remarks.

Jon Serbousek: Thanks, Operator. Thank you again for joining the call this day. We look forward to updating you on our progress at our next quarterly call. Have a great day and be well.

Operator: Thank you, ladies and gentlemen, that concludes today's conference call. We ask that you now disconnect your lines.