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Orthofix

Third Quarter 2021 Earnings Call

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PRESENTATION

Operator

Welcome to the Orthofix Third Quarter 2021 Earnings Conference Call.

Please be advised that today's conference is being recorded.

I would now like to hand the conference over to Alexa Huerta, Senior Director of Investor Relations. Please go ahead.

Alexa Huerta

Thank you, Operator, and good morning everyone. Welcome to the Orthofix Third 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 will 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 make on today's call are based on our beliefs and expectations as of today, November 5, 2021. We do not undertake any obligation to revise or update such forward-looking statements. Some factors that can cause 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 31, 2020, and Form 10-Q for the quarter ended September 30, 2021 filed this morning, November 5, 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 third 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 third quarter 2021 results conference call.

On today's call, I'll provide an update of the third quarter performance. I will then review each of our strong progress we've made against each of our strategic initiatives before handing the call over to Doug, who will provide our financial update. I will close with our perspectives on balance of 2021 before opening the line for questions.

Starting with our third quarter performance, total revenue for the quarter was $112.4 million, growing about 1% over 2020 on both a reported basis and constant currency basis. During the quarter we experienced the negative impacts of hospital restriction on a elective and complex procedures and hospital staff shortages in each of the U.S. key geographies, namely the Southeast, MidAtlantic and South Central region. However, despite these COVID-19 challenges, we were able to grow relative to 2020, highlighted by double-digit growth in both our global spinal implants and orthopedic businesses.

Our performance in the quarter was aided by our diversified portfolio that includes therapies and sites of service less impacted by COVID, as well as our international footprint that includes areas beginning to recover from COVID restrictions.

Despite these disruptions in the third quarter, we made solid progress against all of our growth initiatives and remain confident in the investments we've made and will continue to make in product development, commercial channel and operational excellence.

Now let's turn to the performance of each of our product categories.

Starting with bone growth therapies, or BGT, sales for the quarter were $45.2 million, down 4% compared to the third quarter of 2020. The decrease in the quarter was largely a result of increased COVID-19 related restrictions affecting complex overnight procedures which are a large part of the patient population receiving BGT spine therapies. These restrictions were a reversal of the positive trends we saw in the last quarter. The decline in the quarter for spine procedures was offset by somewhat by 13% growth in our PhysioStim, our bone healing therapy for nonunion of long bone fractures. Our commercial channel investments are yielding benefits in these nonelective trauma segments.

Moving to spinal implants, which include spine fixation and motion preservation, revenue was up over 10% on both a reported and constant currency basis compared to 2020. This growth was primarily driven by U.S. M6 artificial cervical disc and international spine fixation sales. In the U.S., gains were led by the M6 disc revenue driven by our continued success in attracting new users and a result of our ongoing education and training efforts. Internationally, growth was driven primarily by a mix of new distributors coming online and existing stocking distributors reinvesting following COVID delays.

Turning to our biologics portfolio, revenue was down 16% compared to 202. The decrease was not surprising given that a large percentage of the procedures where our biologics products are used are complex elective procedures requiring multiday hospital stays and these procedures were impacted by the restrictions in key U.S. COVID-affected geographies mentioned prior. This decrease was partially offset by the increase of new customers driven by new distribution and strong early adoption of new technologies.

Lastly, moving to our global orthopedics business, sales were up 14% on a reported basis and 12% on a constant currency basis over 2020. The increase was primarily due to the rebound in the international markets from COVID restrictions and reorders from international stocking distributors following COVID elective delays. During the third quarter we also saw a solid contribution from the FITBONE limb-lengthening system with over a 30% sequential growth over the second quarter of 2021 and encouraging physician training trends with over 180 surgeons trained since the acquisition of this technology platform.

Before providing an update on our key initiatives, I want to share how excited we are to have Wayne Burris join our Board of Directors. He brings over 35 years of experience in U.S. and international finance from various diagnostics, pharma and orthopedic businesses. Mr. Burris spent much of his medtech career at Roche Diagnostics where he served in a number of executive roles including CFO of North America from 1996 through his retirement in 2019. We were excited to add someone with his financial and business leadership experience, and we look forward to working with him for years to come.

Now moving to our first initiative, product innovation and differentiation. During the quarter, we made solid progress in our efforts to develop and acquire products and procedure solutions to address unmet needs in the marketplace. Since January 2020, we have launched 23 spine and orthopedic products, which include expansions into key product categories during the quarter. Within spinal implants, we expanded our FIREBIRD SI 3D offering by launching new implant and instrument additions in this high-growth market segment, further improving our differentiated MIF solution designed to compress and stabilize the sacroiliac joint.

Within biologics, we expanded our portfolio with the full market launch of our Opus MG Set, an osteoconductive injectable scaffold to fill nonstructural bony voids or gaps during orthopedic fracture care or trauma surgery applications.

I will now touch on our second initiative underway, commercial channel development. For this initiative we are focused on our U.S. channels for biologics, spinal implants, orthopedics and working to make these channels as dedicated and predictable as our BGT channel.

In Q3, our U.S. strategic channel partners, which we define as distribution partners that commit to Orthofix and carry both hardware and biologics, generated over one-third of our spinal implants, biologics and orthopedics U.S. revenue. Revenue related to these strategic distribution partners has grown 9% when compared to the current third quarter as compared to third quarter of 2019, despite being mostly in the heavily impacted COVID regions. While investment in these channels is ongoing, we have made steady progress in this initiative to date.

Our final initiative is operational execution. Given the recent regional reoccurrences of COVID-19, our global supply chain remains our top priority. Our goal is to make our company as nimble as possible with efficient structures and processes that encourage product innovation. Our success in securing a future supply of microchips for our bone growth therapies devices in light of the continued disruption of global supply chain highlights the improvements we have made in our operational execution. There will always be continuous improvement in operational efficiency and we intend to adapt as needed to keep with the changing macro environments and build value within Orthofix.

I am very pleased with our results in the quarter. Despite the return of COVID-19 in certain geographies, we've kept moving forward with our transformation, laying the groundwork for long-term growth and innovation while maintaining operational execution. We are excited to build on that momentum as we approach year end.

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 measure. Because many 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 $112 million, up 1% on a reported basis and on a constant currency basis when compared to the third quarter of 2020. In the U.S. total net sales of $86 million for the third quarter were down 4% over the third quarter of 2020, mainly due to hospital restrictions on elective procedures, offset by U.S. M6-C growth that Jon mentioned earlier. International total sales of $26 million were up 25% as reported over the third quarter of 2020, reflecting the growth from our FITBONE limb-lengthening system as well as strong sales to stocking distributors.

Gross margin in the third quarter of 2021 was 75% compared to 76% in the prior year period. The decrease was primarily due to sales mix and a short-term increase in electrical procurement costs due to the global microchip shortage, offset somewhat by decreased noncash inventory reserves. For the full year 2021, we now expect gross margins to be approximately 75% to 76%, which reflects the continued impact of the changes in our sales mix as well as an expected short-term increase in microchip costs as a result of the global microchip shortage.

Sales and marketing expenses in the third quarter of 2021 were 50% of net sales, up from 48% in the third quarter of 2020. The increase was primarily a result of the timing of three major trade shows in the third quarter of 2021 that did not take place in person in 2020, as well as an increase in travel expenses. As anticipated, spending in the third quarter was more in line with our pre-COVID levels. In 2021, we still expect sales and marketing to approximate our year-to-date average of 48.5% of net sales as travel and event spending have seen a return in line with historical spend and as we invest further in our commercial channel.

GAAP G&A expenses for the third quarter of 2021 were 15% of net sales, right in line with the prior year period. As a reminder, spending levels in the third quarter of 2020 reflected several cost savings measures including 401(k) match suspension, a travel freeze and a pause on investment spending, offset by succession related expenses in 2020.

GAAP R&D expenses for the third quarter increased to 11% of net sales, up from 9% in the prior year period. The increase reflects spending to support new product development, clinical studies, FITBONE integration expense, as well as costs associated with our EU MDR compliance efforts. We will continue to

ramp up our efforts to drive organic innovation and differentiation, invest in clinical studies such as rotator cuff and our M6-C two-level indication study, and continued spend to build a robust product pipeline in both spine and orthopedics. As a reminder, this is causing our R&D spending as a percent of net sales to significantly outpace revenue growth in the near term. Due to the timing of certain expenses, we now expect 2021 GAAP R&D expense to be approximately 11% of net sales, including an impact of about 175 basis points related directly to our EU MDR compliance efforts, for which we adjust within our non-GAAP financial metrics.

Adjusted EBITDA in the third quarter decreased to $11.9 million or 11% of sales, compared to $19.7 million in the third quarter of 2020, driven by the investments we have made in R&D related to product development and clinical trials, as well as increased spend in marketing trade shows as they return to in-person. Our COGS have also increased with the changes in our sales mix and the expected short-term increase in microchip costs. We mentioned all of these investments and temporary increases during our second quarter call so the reduction in Adjusted EBITDA is in line with our expectations.

Now turning to tax, we had GAAP income tax benefit for the quarter of $400,000 or 14% of loss before income taxes as compared to GAAP income tax rate of 12% of income before income taxes in the same period of 2020. The primary factors affecting tax rate for the third quarter of 2021 were the financial expenses not recognized for tax purposes related to the acquisition related remeasurement, as well as losses in certain foreign subsidiaries for which we do not recognize a tax benefit.

For our non-GAAP results, we continue to use 27% as our adjusted long-term effective tax rate, which normalizes for acquisition related expenses, certain law changes and operating losses that have no GAAP tax benefit.

For the third quarter of 2021, we reported GAAP loss of $0.11 per share as compared to GAAP earnings of $0.24 per share in the third 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 third quarter of 2021 was $0.10 per share compared to an adjusted earnings per share of $0.31 in the third quarter of 2020. The decrease was primarily driven by the increased short-term expenses due to the global microchip shortage, increased R&D spend to drive organic innovation and differentiation, and increased travel and marketing trade show spend.

Regarding cash, we continue to maintain a strong liquidity position with $83 million at the end of the third quarter of 2021, compared to $81 million at the end of the second quarter of 2021. We currently have no borrowings outstanding under our $300 million senior secured revolving credit facility. We commenced repayment of the $14 million 2020 Medicare advance in the second quarter. The balance as of September 30, 2021 is about $8 million. We still expect the repayment to be substantially complete by early Q2 next year.

Net cash provided by operating activities was an inflow of $6.4 million in the quarter, down $15.5 million compared to an inflow of $21.9 million in the third quarter of last year, primarily due to the recoupment of the 2020 Medicare advance, inventory investments this quarter and the savings in 2020 related to the cost reduction initiatives such as the 401(k) match suspension, travel freezes and conferences only being held virtually.

Capital expenditures were $3 million in the quarter compared to $3.4 million in the prior year period, due primarily to the timing of spend for instruments to support our future growth plans. We now expect Capex to be in the $19 million to $21 million range for 2021. The decrease over prior guidance is due to the timing of the deployment of instrument sets and the implementation dates of certain projects.

Consistent with our decreased operating cash flow, our free cash flow, which we define as cash flow from operations minus Capex, was a $3.4 million inflow during the quarter, which was down from an $18.5 million inflow in the third quarter of 2020. As anticipated, our free cash flow has decreased significantly in 2021 compared to 2020 due to several items including the repayment of the Medicare advance, additional investments in our sales channels, and product innovation to support our future growth, and the Spinal Kinetics milestone payment as well as increased spending on the EU MDR compliance efforts.

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

Jon Serbousek

Thanks, Doug.

Looking to the remainder of 2021, we remain highly focused on our three near-term growth drivers, including M6-C, FITBONE, and our comprehensive spinal interbody portfolio. I'd like to provide a quick update on each of these growth drivers.

Starting with M6-C artificial cervical disc, demand for M6's innovative motion preservation technology continues to grow as evident by over 1,000 U.S. surgeons we have trained since the launch in 2019 and the recently surpassed milestone of 60,000 global M6-C implants. We remain confident that our ability to attract and onboard new surgeons, as well as support expanded utilization by existing surgeons, will allow us to expand the market and take market share to drive growth for the foreseeable future.

From a U.S. indication expansion perspective, we are progressing the M6-C two-level clinical trial which remains on track; sites are actively enrolling and we expect to continue to initiate additional sites for both the M6-C investigational and concurrent ACDF control study arms. We also recently kicked off a real world evidence study that will access over 3,000 patients and bolster our body of clinical evidence in support of M6.

A second key near-term growth driver is FITBONE. We have made quick progress in commercializing the FITBONE System with a third quarter revenue contribution of $2 million as compared to $800,000 in the third quarter of 2020. Early demand has been strong with over 180 surgeons trained since the acquisition, the majority of whom are located outside the U.S. A key differentiator and growth opportunity for FITBONE is its adult and pediatric labeling, which no other intramedullary limb-lengthening solution has. In early September, we announced the first U.S. pediatric patient implanted with FITBONE for the femur and tibia. Given the current limited options available for pediatric surgeons and the clinical performance of the FITBONE System, we expect to see accelerated adoption and use as more surgeons are trained.

The third key near-term growth driver is our technology-leading interbody portfolio. Overall, we believe we have one of the most comprehensive interbody portfolios in the industry with technology offerings spanning PEEK, PTC and now 3D printed titanium materials. All 3D printed titanium designs incorporate our innovative Nanovate technology and optimized design, porosity and surface that allows bone to grow into and through the device. We are seeing accelerated adoption of these technologies with strong performance of our FORZA XP expandable PLIF TLIF cage and our new CONSTRUX Mini titanium 3D printed cervical interbody product, which we expect to see continued focus in the future.

In addition to the number of exciting near-term growth opportunities, we also have select high priority segments of our business that we believe will drive growth over the medium and long term periods. First is expanding our commitment to the bone growth stimulation market. The second is expansion of the FITBONE technology platform from limb-lengthening to spinal deformities. Third is our spinal fixation platform expansion in the areas of posterior cervical, MIS, anterior column support and deformity correction.

And last is the focused expansion of our biologic portfolio offering. I want to highlight two key updates on these initiatives: the progression of our BGT portfolio as part of our IGEA partnership and the launch of new biologics products. As announced during the second quarter, we entered into a partnership with IGEA to commercialize a portfolio of stimulation devices in the U.S. As part of this, we recently submitted a PMA application to the FDA for the approval of AccelStim bone healing therapy, a low-intensity pulse ultrasound product for the healing of fresh fractures and nonunion fractures. Upon approval, this will expand our bone growth therapies portfolio and complement our current PEMF technologies that focus on nonunion fractures and spinal treatments, positioning us as a leader in regenerative bone healing technologies. The initial market release is expected during the second half of 2022.

Within biologics, our goal is to have a comprehensive offering of biologic products and solutions for surgeons to use with our spine and orthopedic procedures.

With the recent additions of Opus MG Set bone void filler and fiberFUSE strip, which we launched in partnership with MTF Biologics, we have meaningfully bolstered our portfolio, which we believe will not only support both top line growth of our biologics segment, but will also help drive incremental pullthrough of our spine and orthopedics hardware offerings.

Now shifting to guidance, for the full year of 2021 we now expect top line revenue to be in the range of $460 million to $464 million, which includes approximately $1 million in FX rate headwinds since our last guidance update. This range assumes modest seasonality disruption due to the continued COVID impact throughout portions of the U.S. and certain European markets. We now expect our Adjusted EBITDA to be in the range of $57 million to $58 million, and our adjusted earnings per share is expected to be between $0.71 and $0.75 using a non-GAAP long-term tax rate of 27%.

Despite an increase in COVID-19 pressure on procedures across the business that we have experienced, we continue our transformation, concentrating on executing against not only our short-term but long-term goals of providing physicians with innovative products and solutions to care for their patients. We have made significant progress already and expect to continue to do so in the last quarter of this year and beyond.

In closing, and with enduring gratitude, I would like to thank our worldwide team for all their hard work, resiliency, adaptability and commitment to delivering our patient-centric mission.

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

Operator

Thank you.

Your first question comes from Mathew Blackman with Stifel.

Mathew Blackman

Good morning, everybody. Thanks for taking my questions.

I have three questions. Maybe to start, reflecting on the quarter, is there a way to quantify how much COVID impacted 3Q results, and is there also a way to maybe tease out how much of that headwind was volume-based versus mix headwinds?

Jon Serbousek

Yes, Matt. This is Jon. Thank you very much for the question.

What we look at as far as the volume-based is we're seeing the same macroenvironment that everyone else is in the marketplace, and those volumes are basically in the mid-single—mid to high-double-digit range. Single digit-rate, excuse me. With that, we bring our technology forward in that area and we adapt as far as whether—the site of application for those procedures. We saw restrictions greater in the hospital on large multi-level procedures, which impacted not only our biologics but our BGT business in the long-term, but on the ASC or the same-day surgery activity we saw more volume increase there. So it's a mix story between type of procedure and the COVID impact.

Mathew Blackman

All right, I appreciate that. I don't know if you're willing to comment on sort of how October played out, but if so, how does that fit with what's sort of baked into the 4Q guide as we think about COVID headwinds and sort of the persisting staffing headwinds?

Then, how should we think about deferred procedure recapture cadence? Is it fourth quarter? Will it bleed into the first half of 2022? Just help us think through that.

Then just one follow-up on a product.

Jon Serbousek

Let me start with the COVID impact.

We saw COVID impact August and September. We believe it peaked toward the back half of September and started to become—reside into October. We're still with it and we're going to see it through the fourth quarter and how it impacts our sales. We've taken those in accommodation with our views forward.

When it comes to procedural reallocation, we know that those larger cases, those multi-level cases, those more revision cases are out there. Those patients want to be cared for. The surgeons want to do those cases and care for those patients, and the hospitals want to provide those cases. We know they're out there. How they come back in will be dependent upon how open the hospitals are and that's also a regional discussion because there are—we've highlighted there are certain regions of the U.S. that are being more heavily impacted in the third quarter. We're also seeing some other dynamics as far as lifting in some of the northern states, some more re-emergence of COVID, so it's going to be a region-by-region case-by-case basis. The good news is the international markets that we've seen more of a level setting, more of a stability of those COVID cases and so we're seeing a little bit more predictable business in international markets.

As we look forward in the quarter, we've accommodated for those dynamics in our view.

Mathew Blackman

I appreciate that. I'll sneak this last one in. Can you just remind us of the opportunity? Maybe addressable opportunity with AccelStim and as we think about primarily 2023 and beyond. What kind of impact could it have on segment growth? Thanks so much. Appreciate it.

Jon Serbousek

Thank you, Matt.

AccelStim, we book that—we look at that market in the U.S. at around $100 million of market opportunity, and we'll launch this in the second half of 2022 based on all the variabilities as we deal with the FDA; that's our prediction. You know as the FDA works, but I think we have a good submission going in.

So how we look at that as far as it's a portfolio for us, we have a very strong distribution channel with BGT and as we highlighted in our remarks, we saw an uptick in PhysioStim of 16% in the quarter, dealing with nonunion care. We look at that as far as a portfolio and it's another piece of that activity where we can go after fresh fracture as well as nonunion care.

Mathew Blackman

Thank you so much.

Operator

Your next question comes from Anthony Petrone with Jefferies.

Anthony Petrone

Thanks. Hope everyone is doing well.

First question would be just sort of a macro question then I'll go into a couple of product-specific questions. Maybe just kind of going through, Jon, the themes of this quarter, which certainly is still Delta but also staffing shortages at hospitals, and then supply chain. If we could just kind of go over those three headwinds. You spoke on Delta. Maybe a little bit deeper on staffing shortages. We're hearing a lot about that this quarter. Then anything on the supply chain of note that may or may not be impacting Orthofix? Then I'll have a couple of product-specific questions.

Jon Serbousek

Sure. Thanks, Anthony.

We talked about the Delta side of it, and we're still in Delta. I mean, COVID Delta. We see even more hospitals opening up and they're gradually coming back. The key thing is that the surgeons are there, the patients are there and the hospitals want to basically care for these patients, provide care for these patients. That will come. Those people do not go away. They're not getting better on their own, so they're out there. How they come back in over the next month, two months and into 2022 will be dependent on how those dynamics play out.

Regarding the staffing shortages, we believe they're real. I'll give you a real-life point. We had a very high-volume surgeon in visiting us and he said, "I am back to doing the number of cases I was before, however I don't know how long that's going to last because I'll start at 7 AM in the morning and where I typically would end at 3 in the afternoon, it now takes me until 8 PM to finish those." So he essentially burns through two shifts of staffing to do what he used to do. That's an anecdotal, but the fact is those are the type of things we are hearing that the cases are there and the patients are there and there's a willingness to do those.

The staffing shortage also comes into that many of the—there's transportability in some of that staff. Those nurses can go locum tenens and basically go to different parts of the country where they can make money and basically lead a different lifestyle. We're seeing that as well play out in different parts of the country as well.

Regarding supply chain, we focus on that as far as for not only microchips we highlighted but all the other materials we deal with and always make sure we have adequate supply. And so we've actually increased our inventories a touch to make sure that when the cases come back we'll have all the adequate products to basically address any needs that are put in front of us. We've also spent time working with our sales teams, basically mapping out where those might occur so the supply chain can adapt and make sure the correct products are there and appropriate for those surgeries.

Anthony Petrone

That's helpful. Maybe just a quick follow-up on staffing. I mean if there's any—if you could use your own crystal ball, how long do you think that particular headwind lasts and is it transient or is it maybe perhaps a couple of quarters?

Then on product-specific questions, M6, it looks like another record quarter. Maybe just a little bit on the specific Q-over-Q dynamics with M6 in terms of adoption, and then anything you can share as it relates on the IDE for the two-level indication. Then I'll hop back in queue. Thanks.

Jon Serbousek

Crystal ball and staffing as far as it's so regionally variable, I will tell you that we track it. There's also, we saw—we've been hearing from some of the hospital systems that some of the people have taken early retirements and those will have to fill the funnel with new nurses and hospital staff. It's not just nurses either though, because it comes down to turnover and rooms and things of that nature that basically have to find staffing for. They're struggling with it. They're doing a great job trying to accommodate for it, for sure. I can't tell you whether it's a quarter or two quarters. I'll give you a point that we have in the U.K. It was published that they're looking for 70,000 new nurses over the next four years. They're trying to basically refuel that and that's an educational process. We map all those things and we look at them, but right now the cases are being done and I think that that's part of the reasons why some of the systems are being a little stressed out there.

Regarding M6, we stayed on a continual cadence as far as M6, and what it looks like is that we continue to track new surgeons. We continue to track surgeons that basically want to do M6 for all its features. It's the only device out there that has 6 degrees of natural motion compressionability, and so what it comes down to is it's unique and it's naturally appealing to a surgeon because it looks like a natural disc. We track those surgeons.

Additionally, we also—once a surgeon uses them, we track whether they become users, and the fact is on multi-cases we track that as well, and so we're seeing a good lift in those that become not only first-time users but also continue to use that product.

M6 has been nice because we've been able to use it not only in the hospital on same-day surgery but also in ASC environment and that's helped us basically continue through a COVID environment.

On the two-level study, we're making good progress in adding really key sites to that. It's a focus for us and so we'll continue to add sites and we'll continue to basically enroll not only the study patients with the M6 but also the ACDF patients that we're doing to collect a database that we'll have and be able to use in the future.

Your next question comes from the line of Jeffrey Cohen with Ladenburg Thalmann.

Jeffrey Cohen

Good morning. Thanks for taking the questions. Just a follow-up to Anthony's question on timing of the M6 study. What's that look like or what's your current anticipation as far as a filing and a commercial launch?

Jon Serbousek

Thanks for the question, Jeff.

We initiated that study in late July and it's a traditional prospective randomized study, it's in a four- to five-year window. If we accelerate on our enrollment, which we are basically putting good energy behind, so as we map it out we can look at it in that range as far a four- to five-year horizon before there. I will note that we do multi-level cases throughout Europe and that's part of our real-world evidence plan that we put together and have highlighted, so we're going to track those patients in Europe and also bolster our IDE with the real-world evidence because we have great results in Europe as well.

We look at it on a standard basis and this is one of those items that we want for future benefit, and we're going to continue to put M6 in the market with the current indication we have and do well with it there.

Jeffrey Cohen

Fantastic. Some of that starting, some of the enrollment is coming out of outside the U.S. as opposed to the U.S. What's the breakdown?

Jon Serbousek

All of the enrollment for the U.S. IDE two-level is coming from the U.S. We have bolstered a second study of real-world evidence where we're going out to collect data of patients that have already been treated with M6 outside the U.S. The FDA allows us to bolster that IDE study with real-world evidence and it doesn't impact our study, the two-level study per se, but it just bolsters our overall portfolio of clinical evidence for M6.

Jeffrey Cohen

I got it. That's helpful.

Then for AccelStim, you did submit the PMA for that. What does that look like as far as timing?

Jon Serbousek

Yes, we did submit a PMA submission to the FDA. As we highlighted, we project to be in the market in 2022. That's typically PMA submissions have anywhere from 180-day window to basically be reviewed and approved, or basically reviewed and a date set for questions. Avoiding any secondary questions it could be six, seven months from now to have the approval. Putting it to a second round of questions, it could be three months longer than that.

Jeffrey Cohen

Got it. Then lastly for me, could you talk about external fixation and specifically how those channels look for Europe and how the outlook looks there?

Jon Serbousek

Jeff, on external fixation, it's one of the real strong points for our orthopedics business and specifically in the U.S.—I mean in Europe. I will tell you right now there's 12 surgeons being trained on external fixation in our building, in our skills lab today (inaudible).

There's a keen interest in external fixation in a couple of different areas. One in the foot and ankle area, specifically for Charcot. Most of those Charcot patients get external fixation. In Europe, it's a little different. It's used not only in those patients but also in a broader trauma application, and so we'd use our TL-HEX for rings and lengthening deformity activity. We also use our Galaxy product for external fixation and we've proceduralized those, so there's a Galaxy shoulder and a Galaxy ankle. Those are very attractive procedures for surgeons in Europe and other parts of the world. The team in Europe this year is really exceling in that external fixation area.

Jeffrey Cohen

Got it. Thanks for taking our questions.

Jon Serbousek

Thank you, Jeff.

Operator

Your next question comes from Jim Sidoti with Sidoti & Company.

Jim Sidoti

Hi, good morning. Thanks again for taking the questions.

First one is in regard to distribution. You did a really good job today laying out all the new products you have in the spine fixation and biologics and stimulation, but can you talk a little bit about what changes you've made over the past 12 to 18 months on distribution and how that's been impacted by COVID, and where you think that's going over the next couple of years?

Jon Serbousek

Jim, thanks for the question.

Distribution channel is one of our key investment areas and drive areas. Let me break it down a little bit as far as U.S. and O.U.S.

In the U.S., we're looking to bring in strategic distributors and we're looking to bring them in not only in our spine business but our orthopedics business. Strategic distributors are those that commit to Orthofix to use both our fixation products and our biologics products. In doing so, we invest in specific regions initially, but we are going to go broadly for all regions of the U.S. for strategic distributors. Those people we build an organization where we want to build more and more of their volume being committed to Orthofix. We track it. We track it by a daily basis. We've had two of them in here this week that we're looking to basically engage, and there's a continual effort for not only the spine leadership but also the orthopedics leadership in the U.S.

Outside the U.S., we use a combination of distributors and also our subsidiaries, and so we continue to invest in our subsidiaries. Those are our Company-managed areas, and those are the large areas in

Europe and so we continue to invest in distribution sales reps in those areas as well as distributors to go to different parts of the world that we may not want to set up a subsidiary.

Distribution channel is an area where we have our sales management keenly focused on it and bringing talent that can basically fill a broader array of our products.

Jim Sidoti

Has COVID helped you add or has that been more of a headwind for you? In regards to distribution.

Jon Serbousek

COVID has been I would say neutral; it's plus and minus. Distributors that are having ongoing business that may not be 100% satisfied with where they're at, it may be a little bit slow to change as far as in a COVID environment because they have a situation and don't want to jump to a new situation where they'll have to bring in new products and convert their business. But at the same time, it gives us more time to talk to those individuals and to build a relationship and to build trust with those individuals because this is a—it's a long-term process of bringing a distributor into your organization.

We have a seasoned and experienced team. They have great relationships throughout the industry, and so we are working on building those relationships and making those conversions on a daily and monthly basis.

Jim Sidoti

Then the last one from me is on strategic investments. You call them out, several million dollars a year on strategic investments. Can you just remind me exactly what that is? Is that you shopping for new deals? What else is involved in that?

Jon Serbousek

We have both an organic and inorganic strategy and I highlighted some of the key features on the organic side as far as building in the spine business and also in the orthopedics business. On the external side as far as inorganic, we look at technology. We look at tuck-ins. I have stated previously that we were not looking for bigger deals because we couldn't consume them, but actually we are expanding our view to basically looking for midsize deals that could basically complement our existing portfolio and bring channel with it as well.

Jim Sidoti

A similar question: with COVID, has that process been hindered or is possibly more people likely to sell as a result of COVID?

Jon Serbousek

I think in the first year there were people that may have panicked a little bit and wanted to sell. I don't think that's the case right now. I think that the valuations are quite high and people are very proud of it. I think it does allow you time to work with these companies and basically get to know them and see—and they actually want to mature their companies a little more right now before they transact, but at the end of the day it's variable. We have a great team that looks at these deals and does diligence on these deals, and so we combine that with our commercial teams and also our in-house product teams and we have a good process going here. We look forward to be active in that space.

Jim Sidoti

All right, thank you.

Operator

Your next question comes from David Turkaly with JMP Securities.

David Turkaly

Thanks, good morning. The $100 million you mentioned for AccelStim, I was just curious, is that fresh fractures and nonunions? Can you segment that at all?

Jon Serbousek

It is fresh fracture and nonunion, and it's with LIPUS, with ultrasound.

David Turkaly

So that's your view of sort of the ultrasound market as it sits today, correct? So the addressable market is probably much larger, but that's sort of your guess of maybe what Exogen is doing?

Jon Serbousek

Yes. David, thanks for raising that.

We think that the whole BGT market is actually—has areas to—has the potential to expand. That's the reason why we're investing here.

AccelStim is focused ultrasound, fresh fracture, nonunion, but we think that market as I highlighted is $100 million, will expand. If you think about the dynamics in today—and part of the reason we had the lift in our PhysioStim is that it's nonoperative. It's done in the office, and so where some of those cases may have gone back to be revised in the OR, now it's a good opportunity to go ahead and try the ultrasound before you go back into operative. So, I think we're seeing some traffic there.

From a fracture standpoint, it avoids a second surgery for a patient and it's good opportunity for them to seek a firm fusion in that fracture.

David Turkaly

When you think about PEMF versus ultrasound, I just guess, will your PMA—will there be data that you could—maybe not apples-to-apples but look at sort of how those devices work? I mean maybe they're very similar; I don't know the answer to that, but what are your thoughts there?

Jon Serbousek

The energy source is very different and PEMF is a very proprietary process that we basically developed over decades. It is our mainstay. We have all of our clinical data in spine. We have our nonunion data. So, we're not going to steer away from that at all. That is part of that robust portfolio we have.

AccelStim with ultrasound is going to be focused at fresh fracture and basically put us in that market to expand our portfolio, not only AccelStim and there's other technologies out of IGEA license agreement that we have opportunities to explore as well.

David Turkaly

All right, thanks a lot.

Jon Serbousek

Thanks, Dave.

Operator

At this time there are no further questions. I will now turn the call back over to Jon Serbousek for closing remarks.

Jon Serbousek

Thanks, Operator. Thanks everyone for joining the call. I appreciate your interest in learning more about Orthofix and the progress we're making.

With that, I'll close the call and thank you very much. Have a wonderful day.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.