Orthofix Q2 2021 Earnings Call

August 6, 2021

8:30 A.M.

Operator: Good day and thank you for standing by. Welcome to the Orthofix Medical, Inc. Q2 2021 earnings call. At this time, all participants are in a listen-only mode.

After the speakers' presentation, there will be a question and answer session. To ask a question during the session, you'll need to press star-one on your telephone. Please be advised that today's conference is being recorded. 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. Please go ahead.

Alexa Huerta: Thank you, operator, and good morning, everyone. Welcome to the Orthofix Second 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, August 6th, 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 June 30th, 2021, filed this morning, August 6th, 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 second 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 on our second quarter 2021 results conference call.

On today's call, I'll provide an update of our second quarter performance. I will then review 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'll close with our perspective on the balance of 2021 before opening the line for questions.

Starting with our second quarter performance, given the massive disruption caused by COVID during the second quarter of last year, we will be giving comparisons to both 2020 and 2019 in order to provide better context for our performance.

Total revenue was $121.4 million, growing approximately 66% over 2020 on a reported basis and 63% on a constant currency basis. When compared to 2019, total revenue was up approximately $5.5 million or 5% on a reported basis and 4% on a constant

currency basis. Total revenue grew 15% sequentially over the first quarter of '21.

We are very proud of what we accomplished during this quarter. While we still saw some procedural headwinds due to COVID in our international business and, to a lesser extent, in certain pockets in the U.S., we also saw a benefit in Q2 from procedures that were delayed in Q1 of '21. Our strong topline performance was driven by contributions from a number of key new products, including the M6-C artificial cervical disc and the FITBONE limb lengthening system, as well as contributions from new strategic commercial channel partners.

Now let's turn to the performance within each of our product categories. Starting with our bone growth therapies, or BGT, sales for the quarter were $50 million, up 75% over second quarter 2020. Compared to 2019, BGT sales were relatively flat. Sequentially over the first quarter of '21, BGT sales grew 16%.

Performance in the quarter was largely as a result of a continued sequential rebound in volumes, particularly in multilevel complex spine procedures. These complex procedures, which are high utilizers of our BGT products, continued to improve throughout the quarter, and we expect to see a return to growth over levels of 2019 during the back half of the year, barring any significant setbacks and hospitals pulling back on complex procedures due to a surge in COVID cases.

Moving to spinal implants, this includes spine fixation and motion preservation, revenue was up 62% on a reported basis compared to 2020 and, more impressively, was up 30% over second quarter of 2019. This growth was primarily due to solid performance in our U.S. spinal implants business increasing 37% over second quarter of 2019. Revenue for spinal implants grew 17% sequentially when compared to first quarter of '21.

U.S. M6-C artificial cervical disc sales grew over 105% compared to the second quarter of 2020, driven by our continued success in attracting new surgeon users as a result of our ongoing marketing, education, and training efforts. In fact, our revenue from new surgeons performing their first M6-C procedure in the U.S. continues to strongly perform.

Our U.S. spine fixation business increased significantly when compared to 2020, but fell slightly versus 2019 as we continue to see procedural volumes somewhat below 2019 levels. Overall, our surgeon base in the U.S. spine fixation has increased modestly versus 2019, despite still being impacted by COVID.

During the second quarter, although sequentially improving, we continued to experience a negative impact on complex multilevel procedures due to COVID factors. Our strategy within the next generation M6-C disc continues to be focusing on training new physician users, working with current surgeons'

practices to broaden their adoption, introducing new physician users to the entire Orthofix spine portfolio, and strengthen our global M6 clinical evidence, including our recent initiation of the M6-C two level IDE study.

I also mentioned the success we experienced in Q2 related to our spine channel partners. Our new sales leadership structure, which includes a very experienced and respected team with strong interrelationship, has focused on attracting new strategic distribution partners to strengthen our performance. This strategic group is very important to our growth plan as we work together to provide mutual value in meeting surgeon and patient care needs.

Turning to our biologic portfolio, revenue was up 34% when compared to 2020. Compared to 2019, revenue was down 11%, primarily driven by an overall decrease in multilevel complex procedures and previously anticipated channel disruption. We did experience growth of 8% sequentially over the first quarter of 2021.

Our biologic portfolio is a key piece of our growth strategy. We are investing in additional technologies and products to expand this portfolio, along with clinical evidence investments, to support the long-term success of our biologics business.

Lastly, moving to our global orthopedics business, sales were up 78% on a reported basis and 66% on a constant currency basis over 2020. When compared to 2019, sales were up 4% on a reported basis and were relatively flat on a constant currency basis. Sequentially, sales increased 15% for the first quarter of '21, despite the continued impact to procedure volumes from COVID related headwinds and shutdowns in certain key European geographies.

These headwinds were offset by a solid contribution from the FITBONE limb lengthening system, which generated procedural growth during the quarter as we just completed our second quarter of our global launch. The surgeon feedback on this new technology has been very positive and confirms our investment in this platform.

As we're providing an update of our key initiatives, I want to highlight changes to our Board of Directors. I am pleased Cathy Burzik was elected by our shareholders to the board and by our directors as our new chair. Cathy is already highly engaged and providing great leadership, and I am personally enjoying our partnership.

Cathy's nomination followed the announcement that our former chair, Ron Matricaria, and Maria Sainz both opted to not stand for reelection this year in order to focus on personal commitments. In July, Alex Lukianov resigned from the board to

pursue a business opportunity outside of the company that Orthofix and he agreed presented a conflict of interest. We are very appreciative of the years of leadership and the contributions of Ron and Maria and Alex, and look forward to maintaining our friendship going forward.

Looking ahead, we are very excited about Cathy joining the organization. She brings an incredible wealth of knowledge and experience in the healthcare space, having been part of some very successful medical device and diagnostic companies.

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. I want to specifically highlight a few products that we launched during this quarter.

First is our fiberFUSE Strip, which is a preformed allograft that consists of mineralized cancellous bone and demineralized cortical fibers, providing an ideal matrix for bone healing. This addition to our fiberFUSE portfolio, in partnership with MTF Biologics, provides procedurally focused solutions for cervical and lumbar spine procedures.

FiberFUSE Strip maintains its shape after being hydrated, conforms to the surgical site, and is 100% allograft. Our

initial cases have received very positive surgeon feedback on this technology.

A second new product added to our biologic portfolio in the third quarter of this year through a recently completed license agreement. This will provide a procedure specific, magnesium-based, settable synthetic to aid in fracture care and trauma, providing immediate compressive strength post implantation.

This new bone void filler, which we've marketed as Opus MG Set, is moldable and injectable to the surgical site, providing a versatile handling for clinical applications. These new biologic products further demonstrate our commitment to this space and our focus on expanding the Orthofix biologic portfolio.

In addition to these new regenerative technologies, we launched multiple products within our FORZA Ti family a 3-D printed titanium interbody devices that leverage our unique Nanovate technology. In April, we launched the FORZA Ti TLIF, designed to help optimize transforaminal lumbar interbody fusion procedures. In June, we launched FORZA Ti PLIF, developed to enhance posterior lumbar interbody fusion procedures. Both these products feature our optimized design porosity and surface that allows bone to grow into and through the spacer.

The introduction of these products into our leading interbody portfolio accelerates our penetration into this fast-

growing interbody market, and is an important part of our growth strategy. I am proud of our recent progress within the development and introduction of new products. Having launched 22 spine and orthopedic products since January of 2020, the continued cadence of new product launches further demonstrates our ability to operate through COVID with the transformational plan we put in place in early 2020.

Our second initiative is commercial channel development. Our BGT channel is tenured, clinically sound, and a key strength of our organization. It is comprised of dedicated Orthofix distribution partners and direct sales representatives. We are focusing our efforts on building a similarly committed and predictable U.S. channel for our biologics, spinal implants, and orthopedic product lines.

While this investment is ongoing, we are pleased with the progress we've made to date. In Q2, our U.S. strategic channel partners, which we define as distribution partners that are committed to Orthofix and carry both hardware and biologics, made up 37% of our spinal implants, biologics, and orthopedics U.S. revenue.

This same strategic group grew 30% in that time period compared to 2% growth for the remaining distributors' network selling the same products, which really validates our strategy.

We will continue to drive higher growth within our current and our new strategic partners that will be added in the future.

Our final initiative is operational execution. We continue to be focused on a refinement of our global supply chain to become more efficient and agile, allowing Orthofix to rapidly innovate and deliver our products while our structure and process improvements continue.

One unique example of this in the second quarter was the adaptability of our supply chain to secure a future supply of microchips for our bone growth therapy devices in the current environment of microchip shortages. Operational execution across the organization is an ongoing initiative, and we will continue to successfully execute our plan and adapt when and where necessary.

Overall, I am very excited about our performance during the quarter. We've continued to work through our transformation, build out the foundation for our long-term accelerated growth, while delivering innovation in the near-term and continuing operational execution. We look forward to leveraging that momentum throughout the end of the year and beyond.

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 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 in the quarter were $121 million, up 66% on a reported basis and 63% on a constant currency basis when compared to the second quarter of 2020. When compared to 2019, total revenue for the quarter was up approximately 5% on a reported basis and 4% on a constant currency basis.

In the U.S., total net sales for the second quarter were up 4% over the second quarter of 2019, led by the strong recovery in spinal implants that John mentioned earlier. O-U.S., international total net sales were up 7% as reported and up 2% in constant currency over the second quarter of 2019, reflecting the growth from our FITBONE limb lengthening system as well as strong sales from stocking distributors.

Gross margin in the second quarter of 2021 was over 77% compared to 68% in the prior year period. The increase was primarily due to the easing of COVID restrictions and the return of case volumes over the prior year. The second quarter gross margin indicates a return to our pre-COVID margin level.

For the full year of 2021, we now expect gross margins to be in the range of 76% to 77%, which reflects 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 second quarter of 2021 were 47% of net sales, an improvement from 59% in the second quarter of 2020. The decrease was primarily a result of the increased sales in 2021.

The second quarter of 2021 reflects lower travel expenses, including delays in the timing of industry events and trade shows. Spending in these areas is expected to increase in the third quarter and beyond. We are excited to get back to more normal travel volumes and participate in three major trade shows in the third quarter.

In 2021, we now expect sales and marketing expense to be approximately 48% to 49% of net sales as travel and event spending are expected to return to normal and we invest further in our commercial channel.

GAAP G&A expenses in the second quarter of '21 were 15% of net sales, down from 21% in the prior year period. The percentage decrease was mainly due to the significantly increased net sales in the second quarter of '21 versus the prior year, even though the absolute dollar spending increased about $3 million.

As a reminder, spending levels in the second quarter of 2020 reflected several cost savings measures, including short terms salary reductions, 401(k) match suspension, a travel freeze, and a pause in investment spending.

GAAP R&D expenses for the second quarter decreased to 11% of net sales, down from 12% in the prior year period. However, the absolute dollar spending increased approximately $4 million. The dollar 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 intend to continue to ramp 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 percentage of net sales to significantly outpace revenue growth in the near-term. We now expect 2021 GAAP R&D expense to be approximately 12% of net sales, including an impact of about 200 basis points related directly to our EU MDR compliance efforts, for which we adjust within our non-GAAP financial metrics.

Adjusted EBITDA in the second quarter increased $18.4 million, 15% of sales, compared to a loss of $5.6 million in the

second quarter of 2020, driven primarily by the 66% increase in net sales over the second quarter of the prior year.

Now turning to tax, we had GAAP income tax expense for the quarter of $2.2 million, or 48% of income, before income taxes as compared to income tax expense of $1.6 million, or negative 9% of income, before income taxes in the same period of 2020. Tax expense and the resulting effective tax rate in 2020 were significantly affected by the impact of COVID on global earnings.

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 second quarter of 2021, we reported GAAP earnings of $0.12 per share as compared to a GAAP loss of $0.96 per share in the second 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 second quarter of 2021 was $0.32 per share compared to an adjusted loss of $0.59 per share in the second quarter of 2020. This increase was primarily driven by increased net sales.

Regarding cash, we continue to maintain a strong liquidity position, with $81 million at the end of the second quarter of 2021 compared to $95 million at the end of the first quarter of

2021. We currently have no borrowings outstanding under our $300 million senior secured revolving credit facility.

In Q1 of '21, we triggered the first M6 revenue milestone payment of $15 million to the Spinal Kinetics sellers by achieving $30 million in global trailing 12 month sales, which we paid out during the second quarter of this year.

In addition, we commenced repayment of the $14 million Medicare advance that we received in 2020 during the second quarter of 2021, leaving the balance at $11 million as of June 30, 2021. We still expect the repayment to be substantially complete by early Q2 of 2022.

Net cash provided by operating activities was an outflow of $2.2 million in the quarter, down $19.8 million compared to an inflow of $17.6 million in the second quarter of last year, primarily due to the $18.5 million that we received in Q2 of 2020 as part of the CARES Act benefits.

Capital expenditures during the quarter were $5 million compared to $4.4 million in the prior year period, due primarily to the investment in instruments to support our future growth plans. Due to an increase in instrument set demand for our new products and to support our new strategic partners, we now expect capital expenditures to be in the $24 million to $26 million range for 2021.

Consistent with our decreased operating cash flow, our free cash flow, was which we define as cash flow from operations minus capital expenditures, was a $7.2 million outflow during the quarter, which was down from $13.2 million of inflow in the second quarter of 2020.

Our free cash flow levels will decrease significantly in 2021 compared to 2020 due to several items, including the repayment of the Medicare advance, the Q2 milestone payment to the Spinal Kinetics sellers mentioned earlier, additional investments in our sales channels and product innovation to support our future growth, as well as increased spending on EU MDR compliance efforts.

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

Jon Serbousek: Thanks, Doug. Looking to the back half of 2021, we remain highly focused on our three near-term growth drivers, including the M6-C artificial cervical disc, the FITBONE limb lengthening system, and our leading spine interbody portfolio. I'd like to provide a quick update on each of these growth drivers starting with the M6-C artificial cervical disc.

Since the 2019 U.S. launch of the M6-C disc, we have been consistently delivering triple digit revenue growth as we continue to attract, educate, and train new doctors and see increased utilization within existing surgeon users.

To date, we have trained over 900 surgeons, and we expect to see more new surgeon conversions as we continue to take share and expand the overall size of the artificial cervical disc market. We continue to develop our growing set of clinical data on the long-term outcomes of the M6-C artificial cervical disc.

At this year's ISASS conference in May, data was presented from our IDE study demonstrating the long-term clinical efficacy of the M6-C disc, with the retention of benefits in disability and neck, shoulder, and arm pain scores at three and four years post procedure. We believe the ongoing compilation of high-quality data like this will continue to attract new surgeons with patients that this device will benefit.

To this end, I am pleased to announce that we have enrolled our first patient in the M6-C two level study. Although COVID slowed the initiation of study, we anticipate the enrollment of patients in this area to accelerate quickly into this multiyear study.

A second key near-term growth driver is our FITBONE technology, which enables full limb alignment and limb lengthening via an intramedullary nail. This acquisition expanded our already comprehensive deformity correction portfolio and strategically filled our robust deformity pediatric offering.

Early interest in the FITBONE product has been strong, particularly given that we completed our acquisition and integration of the technology during what turned out to be a massively disruptive macroenvironment in 2020. In a relatively short timeframe, we secured the only U.S. FDA clearance for pediatric use, launched a smaller nine millimeter nail that is well-suited in this patient population, and ramped our commercial innovation of the FITBONE system, seeing approximately $3 million in sales during the first half of 2021.

Since acquisition, over 140 surgeons have been trained on the FITBONE procedure, mostly outside of the U.S. There is strong enthusiasm for this patient solution, given the current limited options available for pediatric surgeons and the clinical performance of the FITBONE system, and 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. With the introduction of the 3-D printed titanium lumbar and cervical interbody systems, all with Nanovate technology, we are the--we are one of the few companies with truly unique and comprehensive nano clearance for all titanium and PTC products. With the introduction of titanium interbody products during the second quarter, we expect to see positive impact to our topline during the balance of 2021 and beyond.

In addition to a number of exciting near-term growth opportunities, we have high priority segments of our business that we believe will drive growth over the long-term. The first is expanding our commitment to the bone growth stimulation market. The second is the expansion of the FITBONE technology platform from limb lengthening to spinal deformity, and last is the focused expansion of our biologic portfolio offerings.

Beginning with our bone growth therapy portfolio expansion, as announced during the first quarter, we entered into a partnership to commercialize a portfolio of stimulation devices in the U.S. from IGEA, an innovative medical technology company based in Italy.

This agreement will expand our current bone stimulation product and treatment modalities with a number of new technologies, such as low intensity pulse ultrasound, or LIPUS, and capacitive coupling, CC. We anticipate our first U.S. regulatory approval for one of these new technologies' indications in 2022, and go to market plans are actively in development.

Beyond the IGEA investment, we have continued to invest organically to promote the expanded utilization of our existing industry-leading technologies. In July, we announced the publication of data indicating that the efficacy infusion rates generated by our SpinalStim bone growth therapy system, when

used in three and four level fusion surgery patients, was the same efficacy rates demonstrated in patients with one and two level lumbar procedures.

These results reconfirm the benefit that PEMF therapy can provide patients when utilized in multilevel lumbar fusion surgery. The study results showed a 92.7% fusion rate in patients with and without risk factors such as diabetes, obesity, tobacco use, advanced age, and osteoporosis, all conditions that have been linked to higher rates of nonunion or bone healing complications.

We also continue to invest in our ongoing rotator cuff IDE clinical trial, which will be our initial entry into the soft tissue regeneration market. With the successful trial results, this could be the first of its kind therapy to enhance patient care for those undergoing rotator cuff reconstruction.

To consider the opportunity of this market, over 650,000 patients receive rotator cuff repair surgery in the U.S. every year. These investments show our continued belief in and our positive outlook for the BGT business in bone and soft tissue regeneration in postsurgical markets.

The second long-term growth driver comes from our expansion of our FITBONE technology platform from limb lengthening to spinal deformity. This expansion, called FITSPINE, is an early

intervention growth rod technology for non-fusion treatment of pediatric and adolescent scoliosis application.

We expect FITSPINE will further differentiate Orthofix Spine and amplify our long-term commitment to the scoliosis and pediatric markets with this highly innovative technology. The project was initiated in 2021 with the engagement of a global surgeon thought leaders group to outline clinical approaches, and will be developed over the next several years.

Lastly, as highlighted by the planned commercialization of our Opus MG Set bone void filler and, in partnership with MTF Biologics that just launched fiberFUSE Strip, we are focused on expanding our biologic portfolio. We are building on the market leading Trinity ELITE allograft with the goal of having a comprehensive offering of biologic products and solutions for surgeons to use with our spine and orthopedics products and associated procedures. We believe this will support the topline growth not just with our biologic products but also our spine and orthopedic offerings.

During the first half of 2021, we also initiated four major development projects to create spine product solutions in the areas of interior column support, lumbar minimally invasive spinal platforms, posterior cervical systems, and a deformity correction system. These organic innovation products are supported by key surgeon opinion leaders, and we expect the

resulting products will help differentiate Orthofix in the market and drive topline growth in the long term.

Now shifting to revenue guidance, for the full year of 2021, we are now expecting topline revenue to be in the range of $468 million to $474 million. These ranges assume minimal COVID restrictions and lockdowns in high-risk U.S. areas, and Europe will be open in the second half of the year when procedure volumes should begin to return to 2019 levels, despite the COVID environment.

Assuming minimal COVID related impacts, we still believe the second half of the year will have mid single-digit growth over 2019 and occurring fairly ratably each quarter. We now expect our adjusted EBITDA to be in the range from $58 million to $61 million, and our adjusted earnings per share is expected to be between $0.74 and $0.82 using a non-GAAP long-term tax rate of 27%.

I am very excited about the future of Orthofix. We will work to continue to execute on our near-term impact initiatives and our long-term strategies to drive growth by delivering innovative, high-value solutions to physicians to improve patient mobility.

On a closing note, and as a proud sponsor of Laura Wilkinson's Olympic training journey in pursuit of another Olympic appearance, we would like to congratulate her for

advancing to the finals in the recent U.S. Olympic diving trials. Laura is an Olympic gold medalist diver, and is also an Orthofix bone growth therapies, biologics, and spinal implant patient and an inspiration to all patients seeking to return to their everyday activities. She just happened to take a little further than most of us.

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

Operator: Ladies and gentlemen, at this time if you would like to ask a question, please press star followed by the number one on your telephone keypad. Again, it is star-one. We'll pause for just a moment.

Your first question comes from the line of Mathew Blackman with Stifel.

Mathew Blackman: Good morning, everybody. Thanks for taking my questions, and congratulations on another nice quarter. I had a couple questions to start for Doug and then, you know, maybe one for Jon.

Doug, how should we think about the shape of the second half revenues, in particular 3Q? I think Jon just mentioned sort of expect ratable. I wanted to make sure that ratable was growth as opposed to absolute dollars. So, any color there would be a helpful way to start.

Doug Rice: Thanks, Matt. Yep, appreciate it and good question. We had a strong--stronger than expected Q2, very pleased with our performance there. And like Jon said in his prepared remarks, we expect to exit the year in mid single-digits in Q3 and Q4 as compared to '19. We really tried to focus a lot of our feedback on comparisons to 2019. So, that's the way I would look at it.

And yes, in terms of cadence, Q3 and Q4 should be similar.

Mathew Blackman: Okay. And then I wanted to push a little bit. You know, I know it's probably too early to ask, but as we think about 2022 and we see you doing this sort of in the back of the year, in fact in the--sort of the final three quarters of the year, this mid single-digit growth, is that sort of a good starting point as we think about our models for 2022, sort of a mid single-digit topline growth? And then just one final question after this.

Jon Serbousek: Yeah, Matt, this is Jon. Thanks for the question. That's a reasonable way to look at it. You know, we're executing on all of our initiatives, rebuilding the--you know, the pipeline, the product pipeline, the channel. And so, we're seeing good traction, you know, coming out of this COVID, and we'll continue to execute on that horizon.

Mathew Blackman: And then I guess the final question, you know, M6 continues to perform really, really well. I'm just

curious, what kind of pull-through are you seeing on the rest of the portfolio, whether it's in, you know, existing customers or when new customers are on-boarded with M6? Do you see that pull-through for the rest of the portfolio? Any sort of color there would be helpful. Thanks so much.

Jon Serbousek: Yeah. Thanks, Matt. Pull-through is a key area of focus for our team. It's early, Matt. There are the-- everyone is focused on M6 right now. The surgeons are focused on the M6.

As we continue to develop and enhance our channel, we'll get better pull-through in those areas. But right now, it's a-- we're basically getting minimal pull-through on the M6--or on the Spine Fix, but it is a key focus area for us going forward.

I think we lost Matt.

Mathew Blackman: No, I'm good. Thank you so much.

Jon Serbousek: All right.

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

Anthony Petrone: Hi, and I hope everyone's doing well. Maybe just a high-level sort of view on the backlog, just checking in there. Obviously, in ortho across the space, whether it's large joint or spine, there is still talk this quarter of at least some of that tailwind coming in in the second quarter,

but certainly there's still a large pool out there of backlog patients. So, maybe just the view from Orthofix on the backlog.

And then in terms of the M6 in cervical, you know, obviously NuVasive is out there with Simplify and, you know, they have views on obviously level two surgeries. They got that clearance. Just wondering if the cervical--if you're hearing anything competitively now that that asset is new hands. And then I'll have one follow-up. Thanks.

Jon Serbousek: Yeah, Anthony, thanks for the question. On the large joint, I followed just some of the press activities that are going on. And we don't directly participate in that area, but we've talked about where we're headed in spine.

We saw good activity in the second quarter. We did see some attenuation as far as from the COVID activity, so we still think there's still some of the channel that's happening. We're still a little below 2019 levels as far as some of our spine fixation growth. And so, we see a little bit back--it's back loaded.

But the good thing about--or the thing about this marketplace is that our patients don't necessarily get better without surgical care or intervention. So, those patients are there. And as soon as they're--the hospitals or physicians or--and they decide to seek care, we believe those cases will come into the marketplace. We don't see a sizable volume sitting out

there that's going to flow in, but it's all COVID impacted in that regard.

Second, on the M6 side, you know, as I highlighted, we've trained over 900 surgeons. And we continue to do the--we'll continue to focus on training, education, and talking about the differentiation of M6. M6 is truly the only artificial disc--cervical disc out there that mimics the natural motion of the native disc. And so, we're going to focus on that and we're really going to drive that.

And that is actually one of the things that attracts these surgeons to us and also helps them consider switching off of a fusion procedure to a motion procedure. So, we're seeing movement in that regard as well.

Regarding competitive activities, we're focused on where we're going in training and education. And we really haven't see any significant impact to date from our sales.

Anthony Petrone: And last one for me and I'll get back in. So, when you think about cervical fusion versus a motion procedure, you know, on average, what--you know, where is the penetration on motion right now? But over time, as the education continues to improve, where do you think motion can go versus fusion across, let's say, a high user account? Thanks.

Jon Serbousek: Yes. The--one of the key things to focus on is that, when you're talking about a fusion procedure and

cervical spine, it's one of the most predictable procedures that spine surgeons do and have done. It is--moving to motion is a logical progression. Those discs were made to move, and so it's logical to do that.

But when you're taking the most--one of the most successful procedures that the surgeons do and transitioning, it's a slower transition for some. Once surgeons start doing it and they see how their patients react to that and benefit to it, they see a bigger pull from their practice to doing more motion.

Also, there's a push from the patient community to want to go towards motion once they hear about the opportunity with motion. And once again, we focus on training and basically educating not only the patient but also the community.

Anthony Petrone: Thank you.

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

Your next question comes from Jeffrey Cohen with Ladenburg and Thalmann.

Jeffrey Cohen: Oh, hi, Jon, Doug, and Alexa. How are you?

Jon Serbousek: Morning, Jeff.

Doug Rice: Morning, Jeff.

Jon Serbousek: We're doing great.

Alexa Huerta: Morning, Jeff.

Jeffrey Cohen: Hey, I was wondering if you could run through some thoughts as far as the energy space and your relationship with IGEA and talk a little bit about the PEMF technology and how pulse ultrasound may find some different utility, particularly as it is on different skeletal such as cartilage as opposed to bone. Thanks.

Jon Serbousek: Jeff, thank you for the question. That's a fair amount in there. I'll start and then you can redirect me as we get through it.

The--yeah, what we--what attracted us to IGEA is that we have a strong view that electrical stimulation has many positive effects as far as for soft tissue and bone healing. And what we--you know, we obviously are--have robust data in the PEMF area for bone healing, not only for acute surgical but also nonunion.

On the IGEA front, what attracted us to it was an alternative signal of ultrasound which is really focused towards fresh fracture areas. So, it comes down to that's a key area that they have data in and that we like and that we're exploring, and also getting--going to utilize.

When you take a jump to the soft tissue area, clearly we have a focus in that with our PEMF on rotator cuff and we're in the middle of that IDE study. So, we believe there's a--we know there's a positive effect there, and the clinical data will bear out how positive as we come forward.

Moving towards cartilage, IGEA has data that says it affects cartilage and that it has a positive effect on cartilage. That is an area that is--has a great deal of research going into it. And it's very early days, so to basically make a--you know, a directional statement as far as how efficacious it might be or not be is--really that wouldn't be prudent. However, there's positive signals of indication that it has a strong effect in cartilage generation.

Jeffrey Cohen: Okay, perfect. And I just wanted to talk a little bit about FITBONE and FITSPINE. So, walk us through SKUs on the FITBONE side. It sounds like you're adding a second one in nine millimeters. And then talk about FITSPINE as far as clinical work going forward and how you're thinking about SKUs there.

Jon Serbousek: Sure. Certainly. On FITBONE, when we acquired the asset in March of 2020, it had a very strong portfolio. One area that they were working on was a smaller diameter nail that had not been perfected by anyone in this industry. So, we focused on getting that nine millimeter--excuse me, nine millimeter nail in place, and we did that.

Also, we focused on getting a pediatric indication or clearance because no one had taken the time to get that clearance. So, we got not only the nine, but we also got the

pediatric clearance, which was key for where we wanted to go with this marketplace.

It's also to remind you that FITBONE is also used in pediatrics but also adult deformity correction as well. So, from that standpoint, it made a robust opportunity for us in basically a broad application of FITBONE.

Now, on FITSPINE, it is a similar mechanism we're going to use in FITSPINE. One item--one area of use will be in early onset scoliosis. These are very young patients which have different needs. And we've assembled a global group of surgeon key opinion leaders, and they're helping us map the best way to create clinical procedures.

We know how to basically make the rod work, and they're going to tell us how to make the rod work in clinical applications not only for those early onset, but also for adolescent idiopathic scoliosis cases as well.

And I must say that the--that with the sheer attention that we got, we have the--from the key opinion leader standpoint, we have the who's who of who's in the early space of scoliosis care. And we couldn't be more proud of the team internally that put together the group for external guidance.

Jeffrey Cohen: Perfect. Thanks, Jon. Thanks for the strong readout. Have good day.

Jon Serbousek: Thank you, Jeffrey.

Operator: There are no additional questions at this time.

Jon Serbousek: So, operator, thanks for everyone that joined the call and appreciate hearing more about Orthofix and the progress we're making. And with that, we'll close the call. Thank you very much.

Operator: Ladies and gentlemen, this does conclude today's conference call. You may now disconnect.