Orthofix

Fourth Quarter Earnings Conference Call

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CORPORATE PARTICIPANTS

Jon Serbousek - *Chief Executive Officer*

Doug Rice - *Chief Financial Officer*

Alexa Huerta - *Senior Director of Investor Relations*

PRESENTATION

Operator
Ladies and gentlemen, thank you for standing by, and welcome to the Orthofix fourth quarter 2020 earnings call. At this time, all participants lines are in a listen only mode. After the speaker's 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 keypad.

I would now like to hand the conference over to your speaker today, Ms. Alexa Huerta, senior director of investor relations. Thank you. Please go ahead.

Alexa Huerta
Thank you, operator, and good morning, everyone. Welcome to the Orthofix fourth quarter and full year 2020 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 statement 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, February 26, 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 risks factors disclosed under the heading Risk Factors in our Form 10-K for the year ended December 31, 2020, and filed this morning, 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 fourth quarter and full year 2020 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 fourth quarter and full year 2020 results conference call. On today’s call, I’ll provide an update of our fourth quarter performance. I will then review the progress we’ve made against each of our strategic initiatives

throughout the year before handing the call over to Doug, who will provide our financial update. I'll close with a perspective on the business in 2021, before opening the line for questions.

Shifting to our fourth quarter performance. We are pleased with our performance for the quarter, delivering a total revenue of $118 million, which was down 3% on a reported basis and 4% on a constant currency basis compared to the prior-year quarter, largely driven by strong performance in our spinal Implants and a rebound of our BGT business, all offset by COVID-related elective procedure volume headwinds that impacted our entire business, including our Biologics and Extremities businesses.

Total revenue during October and November was flat to slightly up as compared to the prior year, but moving into December we did see a negative impact on revenues in various geographies based on the COVID slowdown in elective procedures. On a sequential basis, total revenue grew 6% over the third quarter of 2020. Despite the uncertain operating environment, we were very pleased with our performance during the quarter, which reflects continued execution throughout our organization.

Now, let's turn to the performance within each of our business units. I will first cover our Spine products categories ,starting with bone growth therapies. Sales were down 1% versus prior year, with performance at many of our legacy accounts continuing to be impacted by COVID-19, and closely tracking with the trends we are seeing in the elective case volume. These declines were offset by revenue contribution from competitive conversions.

On a sequential basis, Bone Growth Therapies was up 7% over third quarter. The sequential growth in this business demonstrates our ability to continue to work with our physician customers to identify patients in need of our products. Our team has truly adapted to the environment to provide flexible service solutions for these patients, including remote and virtual fitting when necessary.

Moving to Spinal Implants. We are excited to report that global revenue was up 9% as a reported basis over the fourth quarter of 2019. As a reminder, this category is made up of our spine fixation and motion preservation products, which are typically used in elective procedures. The primary driver of this result was an 11% growth in U.S. Spine Implants revenue, largely as a result of strong M6 disc sales.

Within Spinal Implants, was down 6% as compared to 2019, which was caused not only by the slowdown of elective procedures but a reduction in the number of complex cases being performed. As a reminder, complex cases typically require overnight and lengthy hospital stays. The COVID environment has limited these cases by hospital policy in many regions.

This softness was offset by continued strong performance in our U.S. Motion Preservation business, with sales growth of $3.7 million, up 129% over prior-year quarter. The demand for our marketing-led M6 artificial cervical disc has continued, with strong trends towards surgeon training, and revenue driven by new surgeon customers. This will be the last quarter that we will break out the Motion Preservation business from the rest of the Spinal Implants, as we will focus on our portfolio performance moving forward.

Turning to our Biologic portfolio, revenue was down 9% versus prior year, primarily as a result of a reduction in elective procedure volumes during the quarter, combined with channel disruption and continued price pressure in the market.

And now moving to our Global Extremities business, sales were down 15% on a reported basis versus prior year and 18% on a constant currency basis, primarily due to lower procedure volumes attributed to the COVID-19, particularly in our international markets and the non-reoccurrence of certain large stocking orders occurring in the fourth quarter of 2019.

Next, I would now like to provide an overview of the progress we have made within each of our four focus areas. Our commentary has previously focused on our accomplishments during the quarter, but given how chaotic 2020 was, I'd like to take a step back and review what we were able to accomplish during the COVID headwinds.

Starting with our first initiative to improve structure and leadership. At the beginning of 2020, we looked significantly different than we do today. In a relatively short period, we overhauled a majority of our organization. Structurally, we completed the realignment of our business units to focus on Spine and Extremities, which has improved our coordination and set up an opportunity to maximize revenue across the enterprise.

Along with that realignment, we also completed the integration of our Biologics and Spinal Implants products under a single sales management team, which has allowed us to better leverage our portfolio and our brand. One of the things that I am most proud of is the team we now have at Orthofix. Since becoming the CEO, we have brought an incredible amount of talent into the key roles throughout the leadership of the organization. This talent has complemented the solid foundation of legacy talent already with the organization.

Within Spine, we added a president of Global Spine, a managing director of International Spine, a vice president of U.S. Spine and Biologics Sales, and a senior vice president of Motion Preservation. Late in 2020, we brought a new global president of Extremities. On the corporate side, we added a global head of quality, regulatory, and clinical affairs, in addition to a head of global operations. Beyond the leadership team which is now fully in place, we have and will continue to add talent throughout the organization to support our long-term growth strategy.

Moving on to our second initiative, operational execution. During 2020, we made tremendous progress under the guidance of our new global head of operations. COVID surprised us early in 2020, but we managed to successfully operate through the uncertainty, while beginning some of our long-term initiatives. In early stages of COVID, we strategically realigned our facilities and operations to ensure that we met near-term demand to be able to deliver to our customers and patients while we kept the team and members safe.

For the last three quarters in a row we have been dealing with COVID, yet we've had no manufacturing or supply disruptions. Today, we are fully operational at our facilities in the U.S. and Europe, and will now be able to shift away from managing through uncertainty to beginning our longer-term initiatives to become a faster moving, more efficient organization.

Our third initiative is product innovation and differentiation, where we have focused on developing and acquiring products and procedure solutions to meet unmet needs in the marketplace. While COVID diverted some of our attention during the first half of the year, we were able to activate our product innovation and new product introductions in the back half of the year.

On the spine side, we announced the launches of FIREBIRD SI Fusion System, the O-GENESIS bone graft delivery system, and the AlloQuent Structural Allograft Q-Pack. In addition, early in the fourth quarter we announced a partnership with Neo Medical, where we are focusing on collaborating in the ASC space in the co-development of a cervical platform, including single-use sterile packed procedure solutions.

On the Extremities side, we acquired, integrated, and launched the FITBONE intramedullary lengthening system in some of our international markets, and now well positioned to make a positive revenue impact in 2021, as we just recently announced the launch in the U.S. With the recent 510k clearance for FITBONE, we are the first and only company in the market to have a pediatric cleared product. And this has bolstered our innovative commitment to the pediatric community.

We have initiated our global launch in the first quarter of 2021. We have also just received FDA clearance for our OrthoNext surgical planning software platform, and we are preparing to launch this for use within our JuniOrthopaedics portfolio of pediatric extremity treatment solutions.
In support of these innovative products, we continue to focus on and value our investment in clinical data as highlighted at NASS in October of 2020.

At the virtual event, we had a strong podium presence with five presentations. We recently announced a publication of strong, two-year data from our M6-C Artificial Cervical Disc IDE study in The Spine Journal, demonstrating that the M6-C disc had significant improvements in neck and arm pain, functional and quality of life scores, and verifying the benefits of this unique next-generation technology.

Our fourth and final initiative is commercial channel development. Our priority for 2020 is to invest in and begin transforming our commercial channels to create a stable and highly predictable distribution organization. One of our focus areas was to add or develop long-term strategic distribution partners.

A number of the structural changes and leadership additions we have made in the early part of the year positively influenced our ability to optimize our commercial channel, and I am very pleased with the initial progress we have made as we continue to add more high-quality distributor relationships and, continue to capture synergies across product lines and geographies.

In summary, I am incredibly proud of what our organization was able to accomplish during one of the most challenging years we, as a company, an industry, and as a society has ever had to endure. Rebuilding an organization during a global pandemic was not easy, but that's exactly what we did, which speaks to the dedication of our team and the excitement we have been able to build and generate, in order to retain and attract such high quality people. We have a solid foundation in place, and we are excited about what we can do and achieve in 2021.

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

Doug Rice
Thanks, Jon, and good morning everyone. I will provide additional details into our net sales and earnings results, and then discuss some of our other financial measures. 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 was $118 million, down 3% on a reported basis and down 4% on a constant currency basis, when compared to the fourth quarter of 2019. In the U.S., total net sales for the fourth quarter were flat to prior year, and O.U.S. total net sales were down 15% on a reported basis, due primarily to the timing of certain stocking orders in Q4 2019 that Jon mentioned earlier.

Gross margin in the fourth quarter of 2020 was 75% compared to 78% in the prior-year period. The decline was primarily a result of increased inventory reserve charges that resulted from lower sales, as well as increased depreciation expense related to the addition of new instrument sets over the previous 12 months to support new product launches. For the full year 2021, we 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 fourth quarter 2020 were 46% of net sales, down from 48% in the fourth quarter of 2019. The decrease was primarily a result of lower variable sales compensation during the quarter, and reduced spend on travel and marketing events in the COVID environment. In 2021, we expect sales and marketing expense to increase to approximately 49% to 50% of net sales, as travel and event spending are expected to return to normal and we invest in our commercial channel.

GAAP G&A expenses in the fourth quarter of 2020 were 16% of net sales, down from 18% in the prior-year period. This decrease was mainly due to reduced succession and transition charges when compared to the fourth quarter of 2019. For modeling purposes, because most of our stock-based compensation falls under G&A expenses, we wanted to give some color around it for next year. We expect stock-based compensation to be about $17 million to $18 million in 2021.

GAAP R&D expenses for the fourth quarter were 9% of net sales, up from 7% in the prior-year period. 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 M6C 2-level indication study, and build a robust product pipeline in both Spine and Extremities.

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. As a result, we expect 2021 R&D expense to approximate 12.5% of net sales, including an impact of about 250 basis points related directly to our EU MDR compliance efforts which we are adjusting for.

Adjusted EBITDA in the fourth quarter decreased slightly on an absolute basis to $22.1 million, compared to $22.5 million in the fourth quarter of 2019. However, on a relative basis, adjusted EBITDA increased to 19% of revenue, up from 18.5% of revenue in the fourth quarter of 2019. Jon will provide 2021 overall Adjusted EBITDA guidance in a few minutes.

Now turning to tax. We had income tax expense for the quarter of $15 million or 270% of income before income taxes, as compared to income tax benefit of $8 million or negative 180% of income before income taxes in the same period of 2019. The tax provision for this quarter was significantly impacted by the timing of earnings during the year. In addition, we recognized a reserve against certain foreign deferred tax assets, which was a non-cash charge in the quarter.

For our non-GAAP results, we will continue to use 27% as our long-term adjusted tax rate in 2021, as that reflects our expected adjusted earnings and eliminates certain non-cash impacts to our effective tax rate.

For the fourth quarter of 2020, we reported a GAAP loss of $0.48 per diluted share, as compared to GAAP earnings of $0.60 per share in the fourth quarter of 2019. After adjusting for certain items and when normalizing for tax using a non-GAAP long-term effective tax rate, adjusted earnings for the fourth quarter of 2020 was $0.44, compared to $0.51 in the fourth quarter of 2019. This increase (PH) was primarily driven by the lower net sales, as well as increased R&D spending to accelerate our topline growth.

Regarding cash, we continue to maintain a strong liquidity position with $97 million of cash at the end of the year 2020, compared to $70 million at the end of the previous year's fourth quarter. As previously mentioned, we received $14 million in Medicare advance payments as part of the CARES Act benefits during the second quarter of 2020. We will commence repaying those advances in Q2 this year. We continue to have no borrowings outstanding under our $300 million secured revolving credit facility.

During the fourth quarter, we announced a new partnership with Neo Medical to develop and market single-use spinal instrument solutions, focusing on improving patient outcomes. As part of the partnership, we invested $10 million in Neo Medical to support the ongoing partnership, through a combination of convertible term loan and an equity investment.

Net cash provided by operating activities was $22.3 million in the quarter, up $10 million compared to $11.9 million in the fourth quarter last year, largely due to strong collections on outstanding accounts receivable.

Capital expenditures were $4.4 million in the quarter, compared to $5.6 million in the prior-year period, due to decreased spending on new instrument sets due to the timing of new product launches. Capital expenditures are expected to be in the $23 million to $25 million dollar range for 2021.

Consistent with our increased operating cash flow, our free cash flow, which we define as cash flow from operations minus capital expenditures, of $18 million during the quarter was up from $6 million in the fourth quarter 2019.

Free cash flow for the full year 2020 was $57 million. However, in 2021, our free cash flow levels will decrease significantly due to several items, including the repayment of the Medicare advance mentioned earlier, the anticipated next Spinal Kinetics milestone payment, additional investments in our sales channels and in product innovation, and increased spending on our EU MDR compliance efforts.

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

Jon Serbousek
Thanks Doug. Before providing our outlook for 2021, I wanted to lay out our key focus areas for the year. At a high level, these will look similar to those we focused on in 2020. However, with the progress we have made over the last 12 months, we are shifting from a design and strategy phase into an execute phase. Our focus areas remain structure and leadership, operational execution, product innovation and differentiation, and commercial channel.

Starting with structure and leadership. There is still some work to be done to add talent in select areas within the businesses to finish building out certain teams, which we expect to be complete in the first half of 2021. I am very proud of our transformation that has occurred within the organization. And with the full team in place, we can accelerate the execution of the rest of our initiatives.

Our next focus area is operational execution. While COVID will likely continue to be a factor in the operating environment for some time, we have adapted to the situation and are 100% operational across the globe. In 2021, we will focus on the refinement of our global supply chain to become a more efficient and agile organization, while allowing us to more rapidly introduce new products, integrate new distributors, focus on working capital management, and deliver innovation to our customers and patients.

Our third focus area is product innovation and differentiation. We have spent a considerable amount of time reviewing our current portfolio, and we have developed a comprehensive, long-term roadmap to refresh our current products and bring new innovations to Orthofix. We started to see early progress towards that roadmap in late 2020, with several new product introductions, and we will continue to work to drive adoption of those in the marketplace.

Looking ahead over the next 12 to 24 months, we anticipate contribution coming from both organic and inorganic strategies. On the organic side, our near and medium-term efforts will focus on the key spine procedural market segments of anterior spinal care, posterior cervical, minimally invasive surgery, and deformity care.

For the Extremities business, we will focus on the key orthopedic markets of pediatric deformity and reconstruction, foot and ankle, and specialty trauma. We will also work to roll out enhancements to our existing products with line extensions, and continue to pursue additional indications of our expansion of efforts to open up new addressable markets in the years to come.

We have expanded our interaction with leading KOLs and global spine care institutions who will work closely with us and our teams to guide our thinking and our development of our portfolio broadly, and to help develop innovative and differentiated products. Our ability to attract this level of talent speaks highly to the excitement we have built around Orthofix and our recent innovation strategy.

On the inorganic side, we will look to be more active in bringing products and technologies into our portfolio to supplement our internal R&D efforts, all aimed at bolstering our portfolio and accelerating topline growth.

Our fourth and final focus area is our commercial channel. The playbook here remains the same as it did in 2020, invest to create a stable and predictable channel that is highly effective. As we have said in the past, we are looking to expand our network of strategic relationships, and we are agnostic to the model of these partnerships. We are looking to our quality people and organizations who can help us grow our business. We grew the number of these strategic relationships in 2020, and will continue to focus on developing these relationships in 2021.

Now shifting to guidance. For the full year 2021, we expect topline revenue to be in the range of $445 million to $460 million. This guidance assumes the COVID impact on procedures will continue throughout the first half of the year, with the first quarter being more heavily impacted than the second quarter, and that procedure volumes will pick up in the second half of the year as vaccines become more widely distributed.

We would also like to point out that from a quarterly cadence perspective, we continue to see headwinds associated with COVID during the first half of 2021, but expect the back half of the year to show low to mid-single digit growth over 2019.

In order to provide more clarity in the near term, we will provide revenue range for the first quarter only, and do not anticipate providing quarterly guidance ranges prospectively. For the first quarter, we expect revenue to be in the range of $95 million to $96 million due to continued COVID-related hospital restrictions.

We want to communicate that we are seeing additional pressure early in Q1 on current procedure volumes as compared to Q4 of 2020. In the U.S., we are seeing about a 15% decline in procedures in January and the first part of February, with most of this decline coming from more complex procedures that require multiple nights of hospital recovery and stay. The impact on this segment not only reduces our procedural ASP, but also delays the procedures where the patients would most likely be prescribed a bone growth stimulator to aid in their healing.

Last week, a national weather emergency created further disruption to our procedural volumes in all storm-affected areas. Our hearts and our thoughts go out those impacted, including many of our own employees. Although the storm has passed, it caused major challenges and disruption to our entire local community, state, and regions around the country. We are fortunate to have a great headquarters facility and staff that allowed us to get back to normal operations following the storm clean-up.

With regard to the U.S., we anticipate hospital restrictions to begin to ease in March, with improvement in elective and complex procedure volumes, as we believe this trend will continue into the second quarter of 2021. The third and fourth quarters are expected to show continued improvement in elective procedure volumes.

In our international markets, we continue to see country restrictions on elective procedures. We believe that markets will begin to open up in the second quarter, but timing of increased procedure volumes are country to country specific.

As we have mentioned, we will begin to ramp up our investments in product innovation and differentiation, EU MDR spend, operational execution, and our commercial channel developments in 2021. Our expense reductions from travel restrictions, hiring, and project delays in 2020 will not continue into 2021. We expect our adjusted EBITDA to be in the range of $50 million to $54 million, and our adjusted earnings per share will be $0.45 to $0.55, using a non-GAAP long-term tax rate of 27%.

Despite the backdrop of a challenging 2020, we are very excited about the future of Orthofix. We have assembled a world-class leadership team and organization, and worked tirelessly to implement a culture and strategy to drive this business forward into the future. We are no longer in planning mode. We are now transitioning into execution phase. There will no doubt be headwinds to navigate in 2021, but we are prepared to address any uncertainty as it comes. We will continue to work to bring high-value solutions to patients, surgeons, and hospitals around the world.

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

QUESTION AND ANSWER

Operator
Thank you. At this time to ask an audio question, please press star one on your telephone keypad. Your first question comes from the line of Anthony Petrone of Jefferies.

Anthony Petrone
Thanks, and good morning. I hope everyone's well and staying healthy. A couple questions on my end, one for 2021 on new product contribution. Just wondering, you know, how we should be thinking about the Q-Pack and FITBONE contributions for 2021, just considering the launches.

And then a follow-up on FITBONE would be it's focused on the pediatric space. I'm just trying to get a sense of where Orthofix currently is in pediatrics and how it views that market opportunity. And I'll come back with a couple of follow-ups.

Jon Serbousek
Thank you, Anthony. Let's start with FITBONE on that. Our position in the deformity--or in the pediatric area is regarding around deformity care and limb reconstruction. In that area, we basically focus on highly elective cases, predominately around our external fixation. With the addition of FITBONE, we now have internal fixation and correction methods.

This combined with our JuniOrtho plating system provides us a comprehensive portfolio to address this market. And we are positioning ourselves to execute more heavily in the U.S., as we already begin to execute in the international markets.

Regarding the Q-Pack, that product is basically being introduced into our interbody line, and we basically use it as a portfolio opportunity to basically address with not only our PEEK, our PTC, and also our titanium interbody devices. So it's a comprehensive portfolio for the surgeon to utilize.

Anthony Petrone
That's helpful. And then a couple follow-ups would be, one, is there a way to kind of quantify overall backlog just coming out of COVID, where we sit in terms of backlog? We were on a few orthopedic calls this week, specifically also in spine, and fourth quarter did see some deferrals, and I believe that has extended into early part of '21. So is there a way to quantify the deferral backlog?

And then the last one for me would be, what should we be expecting post the FDA Adcom meeting where it's recommending more data and post-market surveillance in order to down classify in the bone stim space? Thanks.

Jon Serbousek
Let's start with deferrals. Deferrals, as we looked at the dynamics in fourth quarter, electives continued to press into the early parts of December, but then decreased heavily towards the back part of December. We don't know how much of that was pulled forward, as far as--it depends highly on the segment we're talking about.

We saw in certain areas of cervical more push towards the ASC environment, and that kept further--kept procedures going further into part of December. However, in the highly elective complex procedure cases, those started to attenuate earlier in the December month. That trend has continued on into January and into the mid-February, where the highly complex procedures are being postponed because they require multi-day hospital stays.

And so it's hard to handicap how much of that is pushed forward. But the point about those patients is they are deferred. Those complex cases will not get better by themselves, and so we see them as deferred cases which will pick up in the months to come. But it's difficult to talk about when that might occur, because hospitals all have capacity issues right now. So there's a high capacity, full capacity currently today, and how we fit in those patients over the last six weeks will be determined by the hospitals, specifically.

On the FDA re-class, we don't know exactly the timing on that. We discussed the timing where October they closed their opening comment period. And typically, in a re-class, it takes 6 to 12 months for them to come and reaffirm their position or accept the panel's decision. So this is a little different situation, so we don't know whether it's going to be three months, six months, nine months, or 12 months from that close date. We're monitoring it closely.

The good news is that--regarding that is that even as re-classed as robust clinical data, we believe we are well-positioned in the way we operate that business. We have a very strong sales and service team. We have a strong order to cash. We have our very large contract basis, as far as to be in all accounts. And then we also have very robust clinical data, which further positions us in the marketplace. And so while there could be new entrants and there will be new entrants, we think we're well-positioned to address those.

Anthony Petrone
Thank you very much. I'll hop back in.

Operator
Your next question comes from the line of Matthew Blackman of Stifel.

Matthew Blackman
Good morning, everyone, and I hope everyone there is doing well as well. I've got a few questions. To start, can you remind us what percent of your Spine Implant business is skewed to complex procedures, even just in the roughest sense? And then I've got a couple of follow-up questions.

Jon Serbousek
Yeah. As we look at the numbers, we have a good portion of complex procedures. It balances out right now in our mix, because we have a higher percentage of M6 coming into the mix. So when we talk about spinal implants, that balances out some of that activity as far as overall revenue. So we're still monitoring that right now, as far as how much is complex versus simple. Much of the simple one level type of low back cases, we're still monitoring how that plays out between the ASC and the hospital environment. But we've basically captured--we've not lost any business as far as between account basis during this last period of time.

Matthew Blackman
Okay, great. A few questions on the profitability outlook. It sounds like there are very specific growth enhancing investments in 2021. I just want to make sure, though, that there isn't any change in your longer-term profitability trajectory.

And then the second part of that, can you talk through where some of these investments are going? You mentioned commercial channel. And also how much of this overall spend is new versus perhaps some catch-up on deferred or paused 2020 investments?

Jon Serbousek
Let's talk about the investments first. We've talked through 2020, and we'll continue to talk in 2021 about our channel, where we are basically continuing to onboard new distributors, train new distributors, and we spend time and energy working with them. But a good portion of it is in the new product innovations and differentiations initiative.

This initiative, we are basically building platform projects that are currently--that I referenced in my prepared remarks. And we're also looking for additional inorganic activities, which always have some type of spend falling on when you're bringing them on into the organization. So we look at that as well.

There, a side of the research and development spend is in this EU MDR, which Doug mentioned in his prepared remarks, that this is a heavy lift for all organizations in the company. And we think we're positioned at a percentage comparable to what others are spending to be in that European or the EU market.

Doug Rice
Matt, this is Doug. Just overall, I'll comment on profitability. You know, our investment and, you know, longer-term growth is not new. This time last year pre-COVID, the guidance that we did give at that time, not expecting COVID obviously, sort of midpoint was in the 14% range. And so the range that we gave for '21 is certainly COVID impacted here at the beginning of the year, but reflects sort of, you know, 11% to 12% EBITDA, which reflects both short-term and long-term investments that we've been chatting about for a while with regards to things like FITBONE and other investments.

But I would say in the short term, your question around expenses coming back, we certainly hope to be able to travel and meet with our customers and partners. And we certainly hope that they--full commissions on all of our sales plans that we didn't get to do in '21. So I'd say overall, it's a balance in terms of how we're investing and why we guided EBITDA and flowthrough the way we did.

Matthew Blackman
Okay, and then if I could just sneak one last one in. Jon, I'd just love to get your thoughts on the competitive environment. Do you--in particular, there are a couple of recent developments in BGT and now in cervical discs. Just any thoughts on how these new competitors may impact your growth outlook in those two franchises. Thanks so much.

Jon Serbousek
Yes, in the--let's start with cervical disc. We've been monitoring the latest entry into the market for years now, and we've been tracking it very closely in our selling activities for the last six months. And we look at this as cervical disc is at its infancy, as far as adoption. So we believe that additional competitors in that market, especially new innovative technologies that excite surgeons to want to try artificial cervical disc, is a benefit to us.

We're having great success with M6, and we're not only converting business from other disc companies, but we're also converting new surgeons to the disc market. And that latter category, I think, has benefited by having new high-tech innovations into the marketplace.

Regarding the BGT area, we spend a great deal of time developing our channel and also investing in this business. We have multiple investments that we're talking in BGT, such as STIM onTrack. And we're also looking at other ways of basically enhancing that product. Additionally, we have clinical trials invested in the area of shoulder repair, rotator cuff repair. That's an ongoing clinical trial.

And so we'll see new entrants come in. It's an exciting area that we'd want to invest in. But we think we're well-positioned, as I stated earlier, that we're pretty well-positioned to take full advantage of the marketplace and address any competitive entries.

Matthew Blackman
Thanks so much.

Operator
Your next question comes from the line of Dave Turkaly from JMP Securities.

Dave Turkaly
Great, thank you, and thanks for the guidance as well. Doug, maybe if I could maybe push you just a little bit. The revenue side, it looks like we get back to--you know, potentially back to where we were in '19. Obviously, we all know spinal implants is going to grow based on the disc product. And I would imagine you might think that the implants may come back, too.

But I'd love to get any color you might want to share, given that 2020 was so chaotic as you mentioned, for either Bone Growth Therapies or Biologics or Extremities. Like did they all return to growth? I mean, I know they'll have easy comps, but maybe any color on what you'd expect from them in this year that might be implicit in that 445 to 460 guidance. If you could help out, that'd be great.

Doug Rice
Yeah. No, good question, Dave. I'll start with some of the numbers, and I'll let Jon provide some of the color on the product categories. But overall, you know, we guided Q1, which is at its midpoint down, but versus '19 is up 12%. We think we've got more pressure in COVID-related activities going into Q2, obviously. But the back half of the year, you know, as you look at it will exceed growth rates in 2019, as Jon said in this script, low to mid-single digits as we exit the back half of the year. And that growth comes from a handful of different product categories, including Spine Implants.

And I'll let Jon provide color on the rest of it.

Jon Serbousek
Certainly. Let's start with Spine Implants and we'll get to the other ones. The Spine Implants went through a low period in the--let's call it 2012 to 2017 period. And it started to come back as far as the interest and innovation in new products, new procedures. And there's an excitement among the surgeons out there as far as they want to innovate now. They want to bring new technologies in.

And if you take that combined--if you follow the demographics of what's called the U.S. population to start with, we're in the middle of the Baby Boom basically in the post-65 right now, and that's a high--it's a large area for doing spinal procedures. And also the millennials are coming in to the 35, 40 age group, which is also another predominate area where spine conditions present themselves.

So we think were well-positioned not only from product innovation and surgeons wanting to advance, but also demographics. And we think we are well positioned in that space, as demonstrated by artificial discs and other minimally invasive approaches that are being rewarded in the marketplace.

Regarding the Extremities business, we see a good position for us, especially with FITBONE. It rounds out our portfolio, and it allows us to be--provide a comprehensive approach to providing deformity and reconstruction in the pediatric space. And it also will augment our foot and ankle space going forward.

We also didn't mention about our FITSPINE initiative, which will come into play, which is a growing rod which allows a procedure to be done in a pediatric environment where there's no second surgery to correct a deformity presentation. So we're quite excited about that.

And on the BGT area, I think I already highlighted about the new area for advancing in. But this is an area which is now starting to be recognized and has been recognized for its efficacy in these cases that are slow healers or non-healers. And that provides great value to the healthcare environment when you basically are allowed to do a nonoperative repair of a nonunion--or a slow healer versus having a secondary surgery. So we think we have a great value position going into that, and our expanded indications in shoulder will basically pay dividends in the future as well.

Dave Turkaly
Great, and maybe just as a quick follow-up. You know, if you looked at your Biologics and then let's say your fusion spinal implants, I would imagine that in some procedures you're getting both of those sales. I don't know what percent that is, if there's anything--that you could share that. But over time I would imagine that you would think that those would track maybe closer together.

And if not, maybe any color there as to how much of your Biologics business is used with your implants. And as we move forward, should we expect them to sort of--not with M6, I'm saying just with the other part of the spine. Should we expect them to sort of be more closely aligned in terms of growth?

Jon Serbousek
Yes, we would expect them to be more closely aligned going forward, and that was the fundamental reason why we put the spine and biologics sales management under one individual and one direction, to align those businesses and get the leverage in that area. So we would expect that. We are very pleased with our Trinity product line and our MTF Biologics partner. You can't find a better partner than MTF. And so we're looking to expand that portfolio as well.

We have also the fiberFUSE program coming into that, which is another product. So we are continuing to expand the portfolio, and also have better collaboration between the biologics and the spine fixation sales organization.

David Turkaly
Thank you.

Jon Serbousek
Thanks, Dave.

Doug Rice
Thank you, Dave.

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

Ryan Zimmerman
Hey, thanks for taking the questions. Good morning, everyone. So Jon, I think you mentioned a little bit within BGS, you won some competitive conversions. And I was just wondering if you could expand kind of where you're taking share or who you're taking share from on the BGS side. And then I have one follow-up.

Jon Serbousek
You know, we--throughout the 2020 year, we focused on not only growing the business organically, but also tracking the distribution in that area. So we really haven't mapped as far as where it came from. I mean it's a (INAUDIBLE) people opportunity share take in that regard. When you look for the opportunity, it's on the street. And so we don't particularly work on one specific area.

And the reality is we've been successful in a couple of areas, and we'll continue to work on that because we have a very talented sales management team and we have a very good reputation in the marketplace for sales reps who want to come and work.

Ryan Zimmerman
Okay. Doug, for you, just--you know, you've got that $300 million revolver sitting out there. I'd love to just get your comments on kind of your comfort level from a leverage standpoint and just, you know, as it relates particularly to M&A.

Doug Rice
Yeah. No, good question, Ryan, in terms of our ability to invest and grow. We're really happy with our capital structure and our firepower. As you mentioned, we've got a revolver that can scale up to $300 million that we are able to tap. You know, during the lowest of the lows last year to get us through COVID and make sure that we knew we were going to come out on top.

As we end the year with almost $100 million in cash and with the cash flow that we do have, you know, it puts us in a really good position to be able to invest. We'd like to draw down. We're certainly not afraid to use leverage and recognize the pre-acceleration that business development can provide organically.

And then in terms of comfort level, you know, I'd say it's deal specific or--you know, we'd have to look--2 to 3 times would be fairly common, I think, and comfortable. And beyond that, we'd have to look at how quickly things would pay down and be able to rationalize our investments. But we're certainly not afraid of leverage.

Jon Serbousek
Ryan, I would add to this is that we are ramping up our business development team, and we're basically screening more deals than we've ever screened right now. And I'm certainly motivated

to basically put new technologies and new products and programs into this company, and we'll take full use of our financial ability to do that.

Ryan Zimmerman
Got it, okay. And then just lastly for me and I'll hop back in queue. The $23 million to $25 million in capital spend that you're targeting this year, Doug, maybe you could just elaborate. Is that--a lot of that on instrument sets? There's manufacturing expansion. Just kind of help us understand kind of where that--where those dollars are going specifically in Capex for the year. Thank you.

Doug Rice
Yeah, I'd say probably a third of our spend is related to instrument sets. We've got technology investments as well that works into our Capex, and then we've also got some new products and tooling and molding and things that we're investing in. So I hope that answers your question.

Ryan Zimmerman
Thank you.

Operator
Your next question comes from the line of Jeffrey Cohen of Ladenburg Thalmann & Company.

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

Jon Serbousek
Great, Jeffrey.

Doug Rice
Hey Jeff, how are you today?

Jeffrey Cohen
Just fine. I was wondering if you could share any further color on any change or modifications on your distributor channels, as far as upgrades and exclusives, at least domestically?

Jon Serbousek
Domestically, we're--as I stated, we're agnostic to how we move forward. So if we get exclusive, that's great. If we don't--you know, our channel has been heavily populated by nonexclusive relationships. We're looking for strategic partners that want to create a stronger and stronger relationship with us and could commit more and more of their time to us.

And it's a work in process. We'll go from where we're at today and we'll build to stronger and stronger. The goal is ultimately to have an exclusive relationship someday. You know, everybody would like that, but that's a longer-term--a longer-term objective, and we'll take nonexclusive along the way to make that happen.

You know in building channels, it's time and it's basically find the right partner. And we're more interested in the right talent and relationship, and so we'll create a business around that talent.

Jeffrey Cohen
Okay, got it. As a follow-up to Dave's question earlier, specifically on O-GENESIS, could you talk about the specific approaches that are being taken there? And is that helping drive

Biologic? I know that you're also selling prefilled, so are you seeing your Biologics being used in a larger and larger percentage there, and how is that going on that front?

Jon Serbousek
Yeah. On O-GENESIS, it can be used anywhere you want to basically, minimally invasively or percutaneously deliver a graft, and that's the beauty of the system. As far as where we're at, we're early days in the launch of that. We launched it in the fall.

Part of the dynamic that's going on with COVID is also many hospitals and surgeons are less apt to bring new technologies in during that period of time. So we're making headway in that area, but we're looking forward to 2021 to really driving that product forward. And we adopt it into all of our procedures when we go out and sell, and so we're looking for the leverage there.

Also, we are still working on pre-fills right now. You mentioned pre-fills. That's part of the pipeline we're working on, especially around Trinity, because Trinity has certain characteristics that go with it. So we're looking forward to Trinity pre-fills in the future, but they are not prefilled right now.

Jeffrey Cohen
Got it. And then lastly for me, could you talk about your outlook a little bit as far as U.S. versus international sales, and provide us a little more color there if you're able to? Thank you.

Jon Serbousek
We'll need to break it between Spine and Extremities to do that. On the Extremities business, we look forward to building our U.S. sales. We're very strong OUS right now. That's where the business was founded. And we have a high-quality channel put together there, and they are working diligently to grow that business. And they are very excited about the new technology, such as FITBONE, will bring into it.

In the U.S. area, we're basically continuing to build that channel, and we're diversifying it to basically make a better impact in both foot and ankle, and pediatrics.

On the Spine side, it's kind of the reverse of that. The U.S. distribution is stronger, and we're building the international business. We've hired key talent in the international markets, both in the Continental Europe and emerging markets, in Australia. And we look forward to them executing in the 2021 year.

Jeffrey Cohen
Got it. Okay, thanks for taking the questions.

Jon Serbousek
Thank you.

Doug Rice
Thanks, Jeff.

Operator
Your next question comes from the line of Jim Sidoti of Sidoti & Company.

Jim Sidoti
Good morning, can you hear me?

Jon Serbousek
Hey, Jim. Yeah, we got you.

Jim Sidoti
Great. I hope you're all well. I hope you survived that bit of weather a couple weeks ago. Were you able to keep the facility open, or did you have to shut down then?

Jon Serbousek
We ended up closing the facility. Not that the facility didn't have power and heat; it's just we didn't want to put the team in harm's way to travel to the office. Dallas on a storm like that doesn't do well for transportation. So we just elected to take the conservative way and protect our team.

Jim Sidoti
Yeah, I think that was probably wise. Just one for me, because a lot of the questions--my questions have already been answered. The additional cost to update the product registrations in Europe, can you just give me a ballpark figure on what that is? And is that something that should go away by 2022?

Jon Serbousek
Yeah, it's a good question, Jim. It's a significant investment for us. And in 2020, you saw us spend just over $4 million already, primarily towards the back half of the year as we deferred as much as we could during the uncertainty. But this year, we guided that about 250 basis points of our top line is going to be invested in those efforts. That's both in Europe and in the U.S.

And we would expect, you know, next year is going to be significant spend in terms of our '22 level of compliance efforts. You know, it's a robust and thorough review and compliance effort that we have, complete with people and professionals and systems. But I would expect that the majority of the spend would be this year and next year. And as we engage in the clinical trials and underlying supporting things that we need, and then it would taper from there.

Doug Rice
Jim, if I might add just--add a note on that, is that it was a strategic decision to do this. Because our Extremities business is highly European-based, we had to do it for that. But some of our peers and competitors that don't have European businesses, they don't have this spend. And so when you--if they're U.S. focused, you won't see this type of spend. And so you have to look at that when comparing company to company.

We decided we're going to be a global company and we're going to invest in Europe. And also, the CE mark is required for certain other regions outside of Europe to be able to sell your products. So that was a strategic decision, it's an expensive decision, but we think it's a great long-term decision.

Jim Sidoti
All right, thank you.

Jon Serbousek
Thanks, Jim.

Operator

Thank you. There are no further questions at this time. I would now like to turn the call back over to management for any closing or additional comments.

Jon Serbousek
Thanks, operator, and thank you again for joining us today. We look forward to updating you on our progress on our next quarterly call. Have a great day.