Q4 2014 Earnings Call

Company Participants

- Edward Joyce
- David M. Demski
- David C. Paul

Other Participants

- David Harrison Roman
- Robert Adam Hopkins
- Matthew O'Brien
- Kaila P. Krum
- Bill J. Plovanic
- Richard S. Newitter
- David L. Turkaly
- Jason H. Wittes
- Steven Lichtman

MANAGEMENT DISCUSSION SECTION

Operator

Welcome to Globus Medical's Fourth Quarter and Full Year Earnings Call. At this time, all lines will be on mute and a Q&A session will be held after the prepared remarks. I will now turn the call over to Ed Joyce, Investor Relations Director. Please go ahead.

Edward Joyce

Thank you for being with us today. Joining today's call from Globus Medical will be David Paul, Chairman and CEO; and Dave Demski, President and COO.

I will now read our required legal disclaimers. During this call certain items may be discussed that are not based entirely on historical facts. These items should be considered forward-looking statements and are subject to many risks, uncertainties and other factors that are difficult to predict and may affect our businesses and operations. As a result, our actual results may differ materially and adversely from those expressed or implied by our forward-looking statements.

A discussion of some of these risks, uncertainties and other factors is set forth in our Forms 10-Q and 10-K on file with the SEC. These documents are available at www.sec.gov. We undertake no obligation and do not intend to update any forward-looking statements as a result of new information or future events or circumstances arising after the date on which it was made.

The financial information discussed in connection with this call reflects estimates based on information available at this time and could differ materially from the amounts ultimately reported in our 2014 Form 10-K.

Our revenue, earnings, operating margins, cash flows and similar items are sometimes expressed on a non-GAAP basis and have been adjusted to exclude certain items, including among other things: interest income and expense and other
non-operating expenses; provision for income taxes; depreciation and amortization; stock-based compensation; changes in the fair value of contingent consideration in connection with business acquisitions and other acquisition-related costs; provisions for litigation and with respect to the computation of free cash flow, adjustment for the impact of restricted cash and purchases of property and equipment.

The comparable GAAP financial information and a reconciliation of non-GAAP amounts to their comparable GAAP amounts can be found in the tables included in today’s earnings release, which is available on the Globus Medical Investor Relations webpage at www.globusmedical.com.

I will now turn the call over to Dave Demski, our President and Chief Operating Officer.

David M. Demski

Thank you. And welcome to everyone on the call. We finished 2014 on a very strong note. Worldwide sales for the fourth quarter of 2014 were $128.8 million, an increase of 11.8% over the fourth quarter of 2013. Fourth quarter marked a second consecutive quarter of robust sequential growth with an increase of $11 million over the third quarter. Sales for the second half of 2014 were $19 million higher than the first six months of the year. Not only is this an impressive increase over the first half, it puts us in a very solid position entering 2015.

U.S. sales grew by 12.5% in the fourth quarter, while sales outside of the U.S. grew by 4.8%. OUS sales in the fourth quarter were negatively impacted by foreign currency exchange rate fluctuations of approximately $600,000. OUS sales growth in constant currency for the fourth quarter was 10.3%. Worldwide sales for the year were a record $474.4 million, up 9.2% over 2013. U.S. sales increased by 7.7% and international sales for the year grew by 24.9%.

Fully diluted earnings per share were $0.29 for the fourth quarter and $0.97 for the full year, both records. Part of the exceptional fourth quarter EPS result was due to the fact that the effective income tax rate was only 30% compared to 33% for the entire year, primarily due to the fact that the full-year impact of the R&D tax credit was recognized in the fourth quarter.

This had a positive impact of approximately $0.01 on the fourth quarter EPS. Adjusted EBITDA for the fourth quarter was 36.7% and 36.1% for the entire year. For 2014, we saw a 140 basis-point improvement over our 2013 adjusted EBITDA of 34.7%. We continue to achieve significant operating leverage in our business as a result of our growth and disciplined expense control.

For the fourth quarter gross margins were 75.7% compared to 76.8% in the fourth quarter of 2013, primarily due to certain year-end adjustments. For the full-year gross margins were very stable coming in at 76.6% versus 76.9% for 2013.

Research and development expenses for the fourth quarter were $8.4 million or 6.5% of sales, as compared to $6.4 million or 5.6% of sales for the same period of 2013. The increase in R&D spending was primarily due to expenses related to our robotics division along with additional investments made in our research department.

SG&A expenses showed significant improvement in the fourth quarter dropping to 37.0% of sales compared to 39.6% in the fourth quarter of 2013. The operating leverage we’ve consistently driven across our business in 2014 has been most pronounced in the improved SG&A performance of our OUS and Algea divisions, but also in the U.S. as well. We produced free cash flow of $78 million in 2014 and ended the year with $304 million in cash, cash equivalents, and marketable securities.

The overall spine market continues to be encouraging. The three Ps; pricing, procedures, and PODs remain relatively stable in our due. Pricing pressure remained in the mid-single digits in the fourth quarter, continuing the trend we saw beginning in the second quarter. Similar to last year, we did see a pronounced spike in procedures late in the fourth quarter as patients seemed to be adjusting to high-deductible policies. In addition, there is anecdotal evidence of strengthening overall procedural growth possibly associated with the improved employment picture in the U.S. Finally, we are seeing stability on the POD front with news of certain PODs disbanding and fewer instances of surgeons joining
new PODs.

As we announced earlier today, Globus intends to acquire the assets of Branch Medical Group, Inc., or BMG, for $52.9 million plus closing adjustments. BMG is Globus's largest third-party supplier and a highly efficient manufacturer of precision medical devices, generating $9.1 million in adjusted EBITDA on sales of $23.3 million in 2014. Globus intends to invest approximately $15 million to $17 million over the next three years to increase BMG's capacity and enable us to double our sourcing through BMG. This vertical integration opportunity has a potential to increase our adjusted EBITDA by up to $18 million annually by 2019. Thus, the total expanded investment of $70 million is only about four times the potential adjusted EBITDA from this acquisition. Not only is this a compelling value to Globus, because it lowers our overall cost structure, it also strengthens our control over our supply chain and protects our intellectual property assets.

As we indicated in January, our guidance for 2015 is for sales of approximately $510 million and earnings per fully diluted share of $1.01 per share. We expect pressure on our 2015 adjusted EBITDA margins and EPS related to increased investments in three strategic areas: one, the increased capacity we're building into our recent TTOT acquisition; two, accelerating commercialization efforts related to our robotics division, particularly in the second half of the year; and three, increased emphasis on and investments in basic and clinical research activity.

We expect the impact of the Branch acquisition to be neutral to our 2015 earnings as the benefit from reduced cost of manufactured parts will be delayed as Globus works through its inventory layers and will be offset by expected investments and additional operating expenses or increased capacity. However, we expect this acquisition to contribute $0.03 to $0.04 to 2016 EPS.

In summary, we are very pleased with the strong finish we had to 2014. Sales growth in the quarter was almost 12% even in the face of significant currency headwinds. We introduced 16 new products during the year. We consistently added to our sales footprint, both in the U.S. and abroad. We made significant progress in our robotics program. We completed the acquisition of TTOT in the fourth quarter, our most significant acquisition to-date, and we delivered record sales, exceptional adjusted EBITDA margins and record EPS for the fourth quarter and the full year.

I will now turn the call over to David Paul, Chairman and CEO for our closing remarks.

**David C. Paul**

Thank you, Dave, and good evening, everyone. 2014 was a great year for Globus Medical. Sales grew by 9.2% reaching $474.4 million and full-year adjusted EBITDA increased by 140 basis points to 36.1% of sales. We launched 16 new products during the year. We consistently added to our sales footprint, both in the U.S. and abroad. We made significant progress in our robotics program. We completed the acquisition of TTOT in the fourth quarter, our most significant acquisition to-date, and we delivered record sales, exceptional adjusted EBITDA margins and record EPS for the fourth quarter and the full year.

Over the next 18 months, we plan to launch another nine systems to complete this platform. This will make CREO the most advanced and comprehensive pedicle screw system in the world for treating a wide variety of complex deformity, degenerative and trauma pathologies through either an open or a minimally invasive approach. To-date, the CREO platform has been used in approximately 6,000 surgeries worldwide and we expect this to become our largest product in 2016. Surgeon feedback has been exceptional.
Second, another product I would like to highlight is our recently launched expandable TLIF spacer, ALTERA. Early feedback from the first 250 surgeries has been extremely positive. ALTERA is designed to maximize lordosis and sagittal balance from a posterior approach. Used in combination with our CREO midline cortical screws, ALTERA facilitates a simple MIS approach that minimizes soft tissue disruption and provides a powerful tool for minimally invasive posterior procedures.

Third, I would like to update you on our robotics program. We have made tremendous progress in commercializing this important technology over the past 12 months. We have built a multidisciplinary team dedicated to working on robotics, navigation and imaging in Boston. The first product is a robotic surgical aid for navigating and facilitating surgical access, implant sizing, positioning and placement. The system is being designed to enable surgeons to perform procedures more quickly and with greater accuracy, safety and reproducibility than is currently available in the marketplace today. We’re happy with the progress being made by our team and look forward to commercializing this first product as planned in 2016.

Fourth, we are investing significantly in the capabilities of our in-house research team. We are greatly expanding our existing research capabilities and laboratory space, including biomechanical testing, histology, histomorphometry, radiographic image analysis, particle analysis, videography, and post-market clinical research, all with a vision to create the best musculoskeletal research facility in the world.

Finally, our efforts to fortify our offering in regenerative biologics continued in 2014 and led to us having a very strong year with growth over 35%, primarily the result of our launches of KINEX and SIGNIFY, our Bioactive products.

The integration of TTOT is going well. As I discussed last quarter, we plan to leverage TTOT's current portfolio across our sales force and use the combined capabilities and expertise to bring new products to our existing customers. As mentioned before, we have an active pipeline of multiple new tissue-based products in various stages of development that are planned for launch this year and beyond. We are making significant investments in helping TTOT procure and set up high-precision manufacturing equipment and processes to bring advancements in allograft tissue offerings.

In closing, we continue to execute on our long-term growth strategy of rapid new product introductions and U.S. and international sales force expansion while maintaining a continued focus on profitability and cash flow. We remain excited about our prospects in 2015 as we continue to execute on our disciplined strategy of profitable growth. We’re now happy to take any questions.

Q&A

Operator

[Operator Instructions] And your first question comes from the line of David Roman at Goldman Sachs. Your line is open.

<Q - David Harrison Roman>: Thank you and good afternoon, everybody. First off, congrats on a nice finish to the year, given all the disruption we saw mid-year. But I wanted just to start on the Branch Medical acquisition. Could you just remind us of the nature of that relationship right now and any management involvement with Branch Medical that may have persisted post IPO?

<A - David M. Demski>: Sure, David. This is disclosed in all of our filings. The senior executive team here owns I think it's about 47% of Branch. So it's disclosed as a related party and has been since the IPO.

<Q - David Harrison Roman>: And I don't mean to be too cynical about that, but to what extent is it benefiting shareholders versus benefiting management? It in some ways seems like the shareholder capital is being put to work on a supplier side versus being put to work on the growth side?

<A - David M. Demski>: Well, it certainly is on the supplier side, but we think it's going to increase our operating margins, particularly over time. As we own it, we have the opportunity to follow more of our purchasing in that
direction, and as we outlined in the press release and in my remarks, it's a very efficient manufacturer. So, they did about $23 million of revenue last year, majority of that was sold to Globus. But on that they earned $9 million of EBITDA and eventually that EBITDA will go on to Globus shareholders.

So for roughly $50 million, we're picking up $9 million immediately of EBITDA. We think that we're going to double the amount we purchase from them over the next two years to three years. So, if we continue to operate at that same level of efficiency, and there's no reason that we shouldn't, we see that EBITDA benefit rising to about $18 million over the next four years to five years. So, I think it's a very compelling investment for Globus to improve our bottom line.

<Q - David Harrison Roman>: Okay. That's helpful. Maybe just one last one on the P&L. I was very impressed with the number on SG&A on the 37%. As I kind of think about the P&L algorithm going forward with international getting bigger as a percentage of total, should we think about gross margin as flattish to slightly down and adjusted EBITDA [ph] as leveraging your expenses (16:57)?

<A - David M. Demski>: You're breaking up a bit on the – David, I think I heard you. What we've been guiding to in the past is gross margins will continue to get squeezed a bit as we grow internationally and then also the biologics segment of the business typically has lower gross margins. And then the other theme that we want to remind you of is we use our highly efficient or bigger segments, the U.S. business with very strong EBITDA margin to fund some of our investment opportunities like the robotics platform, like Algea. So, as we improve in the U.S. and even now OUS, we're using those funds to invest in new areas, so that we're kind of projecting a more stable EBITDA margin going forward.

<Q - David Harrison Roman>: Okay. That's very helpful. Thank you.

<A - David M. Demski>: Sure.

Operator
And your next question comes from the line of Bob Hopkins at Bank of America. Your line is now open.

<Q - Robert Adam Hopkins>: Thanks and good afternoon.

<A - David C. Paul>: Good afternoon, Bob.

<Q - Robert Adam Hopkins>: So, just I want to start off with a couple more on Branch, just so I make sure I understand this transaction and also just understand Branch a little bit better, because Branch seems to have EBITDA margins as a contract manufacturer that are better than your EBITDA margins. So I don't think I've ever seen a contract manufacturer with margins that high, especially on that small of a revenue base, only $23 million. So just generally how is this contract manufacturer so profitable?

<A - David M. Demski>: I mean, this is a very efficient operation. It's about 50,000 square feet of 110 people or so. I think, a lot of their efficiency does come from the fact that they have one huge customer, so that can allow them to operate a little more efficiently than a business that has to spread their revenue over multiple customers just in terms of sales and marketing. I think it's one areas where they've been more efficient than some of the other companies might be. They're very automated facility, everything they do is high-tech in terms of getting the drawings in and getting the parts made, inspecting them even from those standpoint.

<Q - Robert Adam Hopkins>: And could you just explain how this isn't immediately accretive given that the cost to finance this is probably less than $1 million and you're bringing in this EBITDA and you mentioned some cost to expand, but I would think most of those would be capital expenditures. I'm just trying to understand why this isn't more accretive in 2015 and frankly in 2016?

<A - David M. Demski>: Well. Yes, I'll answer your question. It is a little tricky to understand particularly in 2015. So the EBITDA that they have recognized is on sales to us and other folks. When we buy that, it goes into inventory. So
we have layers of FIFO out there. So we're not going to see that part go through our costs of goods sold until it works its way through the FIFO layers, if that makes sense. So there is a delayed impact there. Even though they made the money, they've recognized the money from a GAAP standpoint, as part of Globus, it reduces our costs, but it has to work its way through the layers to hit the bottom line.

And then, yes, we're going to make some capital investments there, but we're also going to increase the manpower to get them trained and up to speed as we're going to move more purchasing towards them. So we think the impact in 2015 will be negligible. But going into 2016 that's about $7 million of pre-tax earnings that would translate into $0.04.

<Q - Robert Adam Hopkins>: Okay.

<A - David M. Demski>: So that is much more in line with their historical results. We're also trying to be conservative there.

<Q - Robert Adam Hopkins>: Yes, sounds like it. And then on the business, can we just talk a little bit about biologics and the opportunity there, and what specifically some of the launches are? And maybe just help us understand what the biologic revenue base was in 2014 and what you expected to be implicit in your 2015 guidance. So just maybe help us with what launches are happening this year and then what's the biological revenue base in 2015 versus 2014?

<A - David C. Paul>: Thank you, Bob. As far as the exact revenue of our biologics, as you know we don't share sub-segment revenue, but this is something we have been talking about for several quarters about a focus on biologics and we've introduced multiple new products, including KINEX and SIGNIFY. As I mentioned in the last quarter, this is an $800 million segment of biologics that we really don't get our fair share in the market. Biologic should account roughly for 10% to 15% of our sales and it doesn't at the moment, so you can do the math. And our goal is to get it there in the next three years that we can get our share of this market.

One piece is a synthetics, which we have very good progress now with KINEX and SIGNIFY. We have a few other synthetic products in the pipeline for this year. And also the regenerative biologics piece from our TTOT acquisition will also add to this. There's a $200 million, $250 million machine spacer market, another $300 million DBM market that we don't participate as much as we would like in today, and I think the TTOT acquisition will help us introduce all those products which are slated to be introduced in 2015, which will enable us to get more to that 10%, 15% of our sales with Biologics.

<Q - Robert Adam Hopkins>: Okay, great. Thanks very much.

<A - David C. Paul>: Thank you.

Operator

Your next question comes from the line of Matthew O'Brien of Piper Jaffray. Your line is now open.

<Q - Matthew O'Brien>: Afternoon. Thanks for taking the question. Hopefully you can hear me okay. I was hoping to start off with the first quarter here. I know back in 2014 you referenced a loss of about $2.5 million associated with some lost procedures because of poor weather. Are you seeing anything here, especially up in the Northeast region that's similar to what we saw back in 2014 so far? I know the quarter is not done yet, but just generally speaking.

<A - David M. Demski>: Not so far, thankfully, at this point, Matt.

<Q - Matthew O'Brien>: Okay. And then just thinking about the share-taking opportunities within the spine industry. The market is not growing very quickly, if at all. But can you just give us a sense for how difficult it is now or if it's been trending one way or the other as far as your opportunities for taking market share in the U.S. and internationally versus how it may have been a couple of years ago? Does the cycle take longer to get doctors to convert over? Is it shorter? Just any sense there for any challenges you may have above and beyond what you've seen recently.
<A - David M. Demski>: Yeah, I don't think there's a marked difference over the last couple of years. And if you go back even further, I think the overall market was much more favorable. So I feel like we're just well positioned. We've demonstrated we can continue to take share. It's really the levers that we've always emphasized in terms of product introductions and hiring more people. But we're still able to do both of those pretty effectively.

<Q - Matthew O'Brien>: So no aggressive competitive responses from the folks that have been losing share recently?

<A - David M. Demski>: I'm sorry, we're having a little trouble with the connection. I didn't hear the question.

<Q - Matthew O'Brien>: Yeah, my apologies. No real aggressive competitive response that you've seen thus far from the bigger companies that may be ceding some of the share?

<A - David M. Demski>: Nothing unusual. I mean, it's a very competitive market. They've always been great competitors. They have great product lines and they're highly professional. So it's always been a tough battle, but we enjoy the competition. We think it makes us better.

<Q - Matthew O'Brien>: Got it. And then if I may sneak one more in on the robotics system. Great to hear that it's on track for 2016. But can you just give us any sense for what that's going to do to the profitability profile of the business going forward? I know you're spending quite a bit in anticipation of that. I mean, I'm sure we're going to see somewhat of a drag next year as well. Is that the way that we should think about that product in 2016?

<A - David M. Demski>: Yeah, it's a little bit of a crystal ball right now. But we're going to continue to do the product development and get that to the FDA. And as we do that, we'll start to think about commercialization, which means hiring a sales force, doing the marketing around that. So you'll see drag on the P&L pre-launch.

And then post-launch it's really going to be a function of how quickly we can get adoption out there and that's, at this point, really hard to predict. So initially it is going to be a drag. And, in fact, I think it was David's question earlier about our model. So we're using the strong EBITDA performance that we have in our U.S. business, the improvements in that from the o-U.S., we're using that to fund these upside opportunities we have.


<A - David M. Demski>: Yes.

Operator

Your next question comes from the line of Ben Andrew at William Blair. Your line is open.

<Q - Kaila P. Krum>: Hi, guys. This is Kaila in for Ben. So after adjusting for our estimated contribution from the TTOT acquisition in 2015, we're estimating for your organic sales growth sort of in the mid-single digits. First off, is that a fair assumption? And then secondly, if that math is correct, that growth rate seems a little bit modest, especially given the improving market commentary that you discussed. So what really has to go wrong in order for you to not hit that organic growth rate target?

<A - David M. Demski>: Kaila, welcome to the call. And, yes, I believe your math is correct. We're just trying to be appropriately conservative. We're in the second month of the year and we're very bullish on our business, but it's a long year. And as we just talked about, it's a very competitive market. So...

<Q - Kaila P. Krum>: Okay. And then with respect to the core business, can you just elaborate on the runway for growth with the CREO system? You mentioned that this could be the most substantial contributor to sales, but could you just provide a bit more color on the size and the sustainable growth rate and opportunity with this platform?

<A - David C. Paul>: The biggest runway for us is we still have about 7% or 8% market share. And as we keep expanding our sales footprint, the biggest runway for our growth is expanding our geographical footprint. And pedicle screws account for about 40% of a surgeon's business, if you will. So really that's why CREO will end up becoming our largest product platform next year. So it's the offering of CREO as well as the fact that pedicle screws is the largest
sub-segment in spine. And as we expand our geographical coverage, that's going to translate to more sales for CREO.

<Q - Kaila P. Krum>: Great. Thank you.

<A - David M. Demski>: Thank you.

<A - David C. Paul>: Thank you.

Operator

And your next question comes from the line of Bill Plovanic from Canaccord. Your line is now open.

<Q - Bill J. Plovanic>: Great, thanks. Good evening. Can you hear me okay?

<A - David C. Paul>: We can hear you, Bill.

<A - David M. Demski>: Hey, Bill.

<Q - Bill J. Plovanic>: Thank you. So just on the manufacturing acquisition, $23 million gross. What percent of your metal business is that today? And is it 25% of the metal that you're making today and do you see that being 50%, 75%, where do you see that going over time?

<A - David M. Demski>: Yes. Roughly it's about a quarter of our purchases today and we expect to probably double that. I don't see it going beyond 50%. There is a lot of value in our, diversity of our supply chain, and we have a lot of folks that have been with us a long time. I think it helps level out the ebbs and flows that are associated with product launches and our demand. So we always want to have a diverse supplier base, but our target is to double the amount we buy from them over the next three years to four years.

<Q - Bill J. Plovanic>: Okay. And then, as I look at the OUS performance, even bringing back in the FX impact, not as much, but it looks like that international component for the year, if I look at each quarter was pretty flat nominally, up and down a little after a very strong growth rate in 2013, how should we think about that for 2015, are there new markets you'll be seeding, you've kind of hit the wall where you are, what should we think about the international?

<A - David M. Demski>: I think your analysis is right on. It is flattish as you look at it sequentially, have been focused on that and addressing it, so there are no big launches in terms of countries this year. We do have a lot of upside in all of the markets that we're in to be honest, even the U.S. but particularly OUS. So, we got a couple of little markets that we've had issues with and we're addressing. We're correcting.

Overall, I think Europe is not particularly strong in terms of procedural growth right now. Their economy is not the greatest, pricing pressure is pretty pronounced over there. You mentioned the currency. So, it is part of the reason that our overall guidance is where it is, I want to be conservative from that standpoint, but nothing in general, that's a problem. Nothing systemic from our standpoint, a few little spots that we need to address, but you're right in saying it's been flat and we need to get it accelerating again.

<Q - Bill J. Plovanic>: And then just lastly for me, every quarter you seemed to have a little litigation expense that hits the line. I know that's standard operating procedure for you but is there anything in the pipeline in terms of litigation that we need to be aware of that it's going to kind of come to a head in either 2015 or 2016? And that's it for me. Thanks.

<A - David M. Demski>: Nothing significant. It's the skirmishes that we're involving quite often, but there is nothing really big out there.

<Q - Bill J. Plovanic>: Thank you. Thanks, Demski.

<A - David M. Demski>: Thanks, Bill.
Operator

Your next question comes from Richard Newitter at Leerink Partners. Your line is now open.

<Q - Richard S. Newitter>: Hi. Thanks for taking the questions. Just on branch medical, you might have said this earlier on in your prepared remarks, but I was jumping between calls. Why the timing now? Maybe just answer that.

<A - David M. Demski>: Sure. We did not address that. Rich, thanks for bringing it up. It's actually been something Globus has wanted to do even pre-IPO. We've always thought that the benefit to us was significant in terms of lowering our cost structure. I think the answer to why now is that the branch owners have finally come around to that point of view and decided this is the best time for them to sell.

<Q - Richard S. Newitter>: Okay. And then just as we think about your use of cash going forward, the two deals that you've done in the last six months were not ones we would have expected and a little outside the box in our view. But maybe you can give us a sense of where kind of you think your holes are in the portfolio or where the kind of the value enhancing activity could be directed going forward? Thank you.

<A - David M. Demski>: We continue to look at opportunities in the metal space. We get approached quite often from people that have technologies or companies that they're looking to sell. I think we still have some upside in biologics. I think the tissue box has been checked and we have a great opportunity with TTOT, but there is also opportunities with synthetics that we would want to look at. And then just further down the line, I think we would want to leverage our engineering prowess potentially into areas that are still in orthopedics clearly but maybe not be in spine, but that's a little longer down the road.

<Q - Richard S. Newitter>: Got it. And on the robotics initiatives, are there any milestones or potential events where we might see a more formal presentation of what your robot is going to look at over the next 6 months, 9 months or 12 months?

<A - David C. Paul>: Not fairly, Richard. We're just still waiting to get the product developed, so we can get into the FDA with it. We're hoping to launch it in 2016 as we plan. It is a 510(k). So, it's a little bit more predictable process than PMA. So, we fully expect to launch it in 2016.

<Q - Richard S. Newitter>: Okay. Thanks a lot and congrats on the fourth quarter.

<A - David M. Demski>: Thank you.

<A - David C. Paul>: Thank you.

Operator

And your next question comes from the line of Dave Turkaly with JMP Securities. Your line is now open.

<Q - David L. Turkaly>: Thanks. And I may have missed it earlier in the call, but did you guys say the innovative fusion and disruptive technology breakouts?

<A - David M. Demski>: We did not. I think those numbers are in our 8-K, right? I don't have them right in front of me, Dave.

<Q - David L. Turkaly>: But it's in the filing from today?

<A - David M. Demski>: Yes, correct.

<Q - David L. Turkaly>: Okay.

<A - David M. Demski>: Yeah. It's in the 8-K.
<Q - David L. Turkaly>: All right, thanks. And you mentioned some increased capacity, I think you said even at TTOT and I was just curious, I mean I know it's pretty competitive out there for the cadaver space. And are you planning on investing in more machinery for them or is there actually like an expansion of that collection opportunity?

<A - David M. Demski>: It's more on the machinery side. Their donor base is very strong. It's actually one of the reasons that we were attracted to them, they have a really strong donor network. Did that answer your question?

<Q - David L. Turkaly>: Yeah, that's fine. And I guess just last quick then. You mentioned the Spacer in the DBM side, do they have a stem cell offering or is there any plan for one there?

<A - David M. Demski>: They don't have one right now and it is an area we have investigated and are looking at, yes.

<Q - David L. Turkaly>: Thanks a lot.

<A - David M. Demski>: Sure.

Operator

Your next question comes from Jason Wittes with Brean Capital. Your line is open.

<Q - Jason H. Wittes>: Hi, thanks for taking the questions. Just as a follow-up to that last question, when you say you get your fair share of biologics in three years, I guess my assumption would be that you would have some type of stem cell offering by then. Is that the right assumption?

<A - David C. Paul>: That's a fairly accurate assumption to get all our fair share in biologics. As we check off different boxes with synthetics, machine spaces, DBM, so we'll get most of it, but definitely adding the stem cell would then make us get all our fair share. As Dave mentioned earlier, we do have a program in place and we will be speaking more about it in the coming quarters.

<Q - Jason H. Wittes>: Okay. Thank you. And in CREO, I assume you are getting your fair share of pedicle screws, but you talk about share gain opportunities, I assume that's just penetrating more doctors and surgeons who aren't using Globus right now as opposed to potentially doing more deformity cases or things like that. Is that the right way to think about it?

<A - David C. Paul>: It's all of the above. I think we're going to be able to penetrate deeper into our current sales geographies with CREO because CREO adds some offerings that we did not have in the past, whether it's a modular screw or whether it was a threaded cap. So those are additions that will help us drive deeper into existing geographies, and the ease of use of the instrumentation. But then as we go to new geographies, it also helps us with converting competitive surgeons in new geographies. So it's a combination of all of the above that's going to make CREO keep growing.

<Q - Jason H. Wittes>: Fair enough. Thank you. And last year you lost a Gulf Coast distributor, but you recovered pretty quickly. I assume that was just the other geographies picking up some of the slack. Has that area been refilled? And are your expectations that that's catching up to where it was before at this point?

<A - David M. Demski>: I'm sorry, Jason, could you repeat it?

<Q - Jason H. Wittes>: Yeah, I was curious about the distributor that you lost last year. You bounced back pretty quickly from that distributor loss based, I assume, on rebound in other geographies. So I'm just curious, has that area been backfilled with new distribution? And has it largely caught up to where it was before?

<A - David M. Demski>: Yeah, we have been actively hiring in the area. It's a direct market for us now. And we're probably a little bit over halfway back in terms of their performance where they were a year ago.

<Q - Jason H. Wittes>: Okay, thanks. That's all from me. Thanks.

<A - David M. Demski>: Thank you.
<A - David C. Paul>: Thank you.

Operator

Your next question comes from Steven Lichtman of Oppenheimer Funds. Your line is now open.

<Q - Steven Lichtman>: Thank you. Hi, guys. I guess a first question on Algea and on the artificial disc market. Are these areas that you still think can be big drivers for you over time? Just want to get your latest outlook on the vertebral augmentation and disc market opportunities.

<A - David M. Demski>: Yeah, I think probably the best way to characterize those are single opportunities. As we've used the baseball analogy in the past, they're good niche products for us, but they're not going to be huge drivers is the way we look at the world.

<Q - Steven Lichtman>: Okay. So the investments – sorry, go ahead.

<A - David C. Paul>: Some of it has to do with the reimbursement challenges that are still out there with the disc replacement for physicians. And when the reimbursement changes, I expect a little bit more uptick in the disc replacement.

<Q - Steven Lichtman>: So you haven't reaccelerated investment on the Algea side? It pared back maybe a year or two ago, so you haven't reaccelerated that?

<A - David M. Demski>: We have not. It's more right sized now in terms of the opportunity and the investment are the right proportion.

<Q - Steven Lichtman>: Okay. Got it. And then lastly, what are your latest thoughts on potential launch in Japan? When should we start thinking about that expansion?

<A - David M. Demski>: We've started the process of trying to get into the market. So we've been counseled that that's up to a couple of years before we could see sales in the market.

<Q - Steven Lichtman>: Okay. Great. All right. Thanks, Dave.


Operator

And your next question comes from the line of Bob Hopkins with Bank of America. Your line is now open.

<Q - Robert Adam Hopkins>: Thanks. Sorry, I just had one follow up because I wanted to circle back to your guidance for organic growth. It's kind of in that mid-single digit range. When you guys went public a couple years ago you aspired to mid-teens growth. And, frankly, since I've been watching the company, you haven't had a quarter where you had 5% growth. So I think that that kind of result would be disappointing to investors and probably disappointing to you, too. And I understand it's a challenging marketplace, but you guys have a lot of momentum.

So I guess my question is, is there something that you're seeing in your business, something that you're seeing o-U.S. that makes you think that 5% is a reasonable way of thinking about the year in providing guidance? And just curious because, again, as long as I've been following the company, you've never had a 5% growth quarter, even when you had a troubled quarter earlier this year.

<A - David M. Demski>: Right. No, aspirationally we still want to be a double-digit grower, but we want to be prudent in how we look at the market going forward and not get ahead of ourselves, Bob. So we're very confident in our business. We have great momentum, but we're sticking with the guidance that we've given.
<Q - Robert Adam Hopkins>: No, I understand that. I don't expect you to change it on the fly here. But I guess my question is, are you seeing something in the business that's just a little bit different than what you've been seeing, say, over the last six months or nine months in terms of whether it's even incremental pricing pressure or more competition from the bigger players who have stopped bleeding relative to their troubles in the last couple of years? Just curious as to what you're trying to signal here with a mid-single digit guide and as to whether or not you're actually seeing something turn in the business that gives you a little bit of caution.

<A - David M. Demski>: We're not seeing anything turn in the business that's giving us more caution than we've ever had. I think it's an appropriate amount of caution and as we look forward.

<Q - Robert Adam Hopkins>: Okay. It's just you're much more conservative here than you've been in the past and I'm just trying to understand what the rationale for that is.

<A - David M. Demski>: I don't want to get ahead of ourselves, Bob. There is nothing else behind it.

<Q - Robert Adam Hopkins>: Okay. All right. That's all I had. Thank you.

<A - David M. Demski>: Great. Thank you.

<A - David C. Paul>: Thank you, Bob.

Operator
This concludes the questions. Now I'll turn the call to the presenters.

David C. Paul
Thank you, Ian.

Operator
And this concludes today's conference call. You may now disconnect.

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