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WMGI - Q3 2018 Wright Medical Group NV Earnings Call

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OVERVIEW:

Co. reported 3Q18 results. Expects 2018 net sales excluding impact of Cartiva acquisition to be $825-828m.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Q3 2018 Wright Medical Group N.V. Earnings Conference Call. (Operator Instructions)

As a reminder, this call is being recorded.

I would now like to turn the call over to Julie Dewey. Please go ahead.

Julie D. Dewey - *Wright Medical Group N.V. - Senior VP & Chief Communications Officer*

Thank you, and good afternoon, everyone. Welcome to Wright Medical's Third Quarter 2018 Conference Call. We appreciate you joining us. I'm Julie Dewey, Wright's Chief Communications Officer. With me on the call today are Bob Palmisano, Wright's President and Chief Executive Officer; and Lance Berry, Wright's Chief Financial Officer.

We issued a press release this afternoon regarding our third quarter results, and a copy of that press release is available on our website, at wright.com. The agenda for this call will include a business update from Bob, a review of our financial results from Lance, a question-and-answer session and then conclude with closing comments from Bob.

Additionally, the company has posted a slide presentation highlighting Cartiva historical revenue and preliminary combined non-GAAP pro forma revenue, including third quarter of 2018, on our Investor Relations website, at ir.wright.com.

Before we begin, I would like to remind you that this call includes forward-looking statements, including statements about our outlook for 2018. Each forward-looking statement contained in this call is subject to risks and uncertainties that could cause actual results to differ materially from those projected in such statements. Additional information regarding these factors appears in the section entitled Cautionary Note Regarding Forward-Looking Statements in the press release we issued today. More information about risks can be found under the heading Risk Factors in Wright's most recently filed annual report on Form 10-K and subsequent quarterly reports on Form 10-Q, as supplemented by our other SEC filings. Our SEC filings are available at www.sec.gov and on our website, at wright.com. The forward-looking statements in this call speak only as of today, and we undertake no obligation to update or revise any of these statements.

Our earnings release and today's discussion include certain non-GAAP financial measures. Please refer to the reconciliations which appear in the tables of today's press release and are otherwise available on our website. Note further that our Form 8-K filed today provides a detailed narrative that describes our use of such measures.

Unless otherwise noted, today's discussions refer to results from continuing operations. Also note that unless otherwise noted all growth rates discussed today are on a non-GAAP constant currency basis compared to the prior year quarter.

With that introduction, it is now my pleasure to turn the call over to Bob Palmisano. Bob?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

Thanks, Julie, and welcome to our third quarter earnings call. Our team produced outstanding results across the board in the third quarter, including over 14% constant currency net sales growth fueled by our new product launches, increased contributions from our sales organization and continuing strength in our underlying businesses. We also had a strong quarter of adjusted EBITDA, with 330 points of EBITDA margin expansion.

These results include continuing strong performance in our U.S. upper extremities business, which grew 19% in the third quarter driven by a 21% growth in our U.S. shoulder business. We had excellent growth from our SIMPLICITI shoulder and our PERFORM Reversed glenoid this quarter, which both grew faster than our overall shoulder growth.

We also set new records in Q3 for the number of surgeons planning on saving cases in BLUEPRINT, and registration of new BLUEPRINT users was strong and continued to grow. As of Q3, approximately 30% of our shoulder customers and shoulder cases are using BLUEPRINT, which is a significant acceleration from approximately 20% last quarter. BLUEPRINT has proven to be integral to our ability to convert competitor surgeons, and we believe that impact will increase as we execute our plans to make the system easier to use and release additional enhancements.

We anticipate that continued penetration of our SIMPLICITI shoulder system, our ongoing PERFORM Reversed launch and accelerating adoption of our BLUEPRINT enabling technology will continue to drive market-leading shoulder sales growth.

Our U.S. lower extremities growth accelerated to 12% in the third quarter, driven by accelerating growth of 22% in our total ankle and a return to market growth in our core lower extremities business. Additionally, the launch of AUGMENT Injectable is off to a strong start and provided an excellent boost to our U.S. biologics business, which grew approximately 11% this quarter, up from 5% in the second quarter of 2018.

We continue to see new products and improving sales force execution drive improved results in our core foot and ankle business, resulting in core growing at market rates of growth for the full third quarter. We expect the Cartiva acquisition as well as the ongoing launch of our PROstep Minimally Invasive Surgery System and other recent new product launches to support our growth prospects in our core lower extremity businesses for the remainder of the year and throughout 2019.

With the Cartiva acquisition now closed, we significantly strengthen our market-leading lower extremities portfolio by adding Cartiva's highly differentiated CSI (sic) [SCI], synthetic cartilage implant, the first and only PMA product for the treatment of great toe osteoarthritis, supported by compelling clinical performance and the only product of its kind backed by Level 1 clinical evidence. Cartiva is experiencing rapid commercial adoption and is well positioned for future growth, as it addresses large markets with significant unmet needs and strong patient demand. We expect this acquisition to support our growth prospects in our core lower extremities businesses throughout 2019 and beyond.

As we begin the integration process, our guiding principle is, first, do no harm. Our top priority is to protect and grow revenue, and our integration is off to a great start. There will be some disruption to Cartiva sales in Q4, which was anticipated, as we finalize the go-forward sales organization. We will be in a great position to hit the ground running on January 1. We are confident of our ability to deliver $47 million in 2019 sales for Cartiva, which we forecasted at the time we announced the acquisition. Over the next several months we intend to evaluate additional opportunities for the development of the Cartiva platform and determine investments needed for long-term growth.

In summary, everything went right in Q3. Third quarter net sales growth improved significantly, with upper extremities continuing to grow more than double the market rate of growth and lower extremities and biologics and international all significantly accelerating their constant currency growth rates. Additionally, we had a very strong adjusted EBITDA margin expansion. As a result, we are increasing our full year guidance to reflect both the overperformance of our existing business as well as the addition of Cartiva.

This couldn't be a more exciting time to be at Wright. I believe we are set up well for the next several years. Our upper and lower extremities, biologics and end markets remain healthy and fast-growing. Our gross margins are expanding, and our specialized sales forces are executing well. Additionally, with BLUEPRINT, our total ankle portfolio, including PROPHECY, AUGMENT Injectable and now Cartiva, we have unique differentiated and protected technologies in all parts of our business.

With that, I'll now ask Lance to provide further details on our third quarter results. Lance?

Lance A. Berry - *Wright Medical Group N.V. - Senior VP & CFO*

Thanks, Bob. As we get started, please note that unless otherwise stated all of today's discussions regarding our sales growth rates refer to our constant currency growth rates compared to the prior year quarter and our results of operations refer to our as-adjusted results, which are non-GAAP financial measures as described by Julie during the introduction of our call. Unless otherwise noted, today's discussions refer to results from continuing operations. Please refer to the non-GAAP reconciliations in our press release.

Globally, our net sales grew 14%. We saw a strong sales performance in all segments of the business, with continued exceptional growth in U.S. upper extremities and above-market growth in our U.S. lower extremities business. We also saw an acceleration in the U.S. biologics business, driven by the first quarter of AUGMENT Injectable sales. International also had a strong quarter, growing 13%. Over all, Q3 net sales came in better than we anticipated.

Moving on to some detail below the sales line. Beginning with our Q3 adjusted gross margin, we achieved gross margins of 77.9% for the quarter. As we have discussed previously, our gross margins fluctuate from quarter-to-quarter and Q3 is often the lowest gross margin quarter of the year. We remain on track for the full year guidance for gross margins in line with prior year and approaching 79%.

As for the line items making up our Q3 operating expenses, selling, general and administrative expenses as adjusted totaled 71.4% of net sales for the second quarter, compared to 76% in the prior year period, a 460-basis-point improvement.

R&D expense as adjusted was $13.8 million in Q3 of 2018 and $11.9 million in Q3 of 2017.

And finally, amortization expense was approximately $5.9 million in Q3 of 2018, compared to $7.2 million in the prior year period.

Below the operating income line, net interest and other expense was $7.6 million for Q3 of 2018, compared to $8.5 million in the prior year period.

For share count, our Q3 per share results as adjusted are based on average diluted shares of 113 million for Q3.

All together, this resulted in adjusted EBITDA of $20.6 million and 10.6% of net sales for the quarter, a 330-basis-point improvement over the prior year period. Over all, year-to-date for the first 9 months of 2018, we have seen EBITDA margin expansion of approximately 260 basis points, slightly ahead of our expectations, driven by sales overperformance.

From a cash standpoint, our total cash balance at the end of Q3 was approximately $695 million. The increase in this balance from Q2 was driven by our equity offering to fund the Cartiva acquisition. The $435 million purchase price was dispersed in October upon close of the acquisition.

I will now discuss our 2018 full year guidance. Consistent with Wright's past practice, please note that our guidance ranges and assumptions for 2018 exclude any consideration for the effect of potential future acquisitions or any other possible material business developments.

Additionally, it is important to note that we'll be using a number of non-GAAP financial measures to describe our outlook for the business. In particular, unless stated otherwise, all of today's discussions regarding our financial guidance refer to our as-adjusted results of continuing operations. Our press release issued today notes those items that are excluded from our as-adjusted results.

We are raising our full year 2018 net sales guidance, excluding the impact of the Cartiva acquisition, to approximately $825 million to $828 million, from our previous guidance of approximately $812 million to $822 million. This is a fairly narrow range, but with a little more than a month left in the year this is realistically where we expect the year to land.

This guidance range assumes foreign currency exchange rates for the rest of the year that are generally in line with current rates.

In addition, this range implies full year 2018 constant currency net sales growth of 11% to 12% and fourth quarter 2018 constant currency net sales growth of 10% to 12%, excluding the estimated $9 million impact of the 4 fewer selling days in the fourth quarter of 2018.

This guidance implies a slight growth rate deceleration in the fourth quarter due to tough comps on shoulders and an expected lower growth rate for international in the fourth quarter than we saw in Q3. International had an excellent third quarter, at 13% constant currency growth and well above our full year expectation for that business of high single digits.

Also, I want to remind everyone that we did not provide line item estimates for the impact of the 4 extra selling days in Q4 of last year. So it will be challenging to try to compare individual product line performance to previous quarters. One thing we know for sure is that the extra days had a greater impact on the U.S. business than international.

Additionally, the company is providing guidance on the impact of the Cartiva acquisition. From the date of closing, which was October 10, 2018, Cartiva is anticipated to provide approximately $7 million of net sales in 2018, resulting in an as-reported net sales guidance of $832 million to $835 million. This guidance implies a year-over-year decline for the standalone Cartiva business in the fourth quarter. This was anticipated, as we knew that from announcement through the end of the year we would be working with the existing distributor group and until they had certainty about the future sales would be negatively impacted.

The vast majority of Cartiva's revenue is with a little over 20 distributors. We have informed those distributors that there is a role for them going forward with the SCI product, and we are currently in the process of negotiating their ongoing contracts. The goal for these territories is to keep the momentum that they have with the product and supplement that in 2019 with our sales force where it can be beneficial.

The remaining slightly less than 20 distributors have been notified that we will not be renewing their contracts. Our direct sales force will be taking over those territories on January 1, and we will be training our sales force this quarter.

As Bob said, we expect to be in a great position on January 1 with our sales force trained and ready to go and clarity for the distributors that we will be retaining.

As previously announced, we expect Cartiva to contribute approximately $47 million of sales in 2019.

We are also raising our full year 2018 non-GAAP adjusted EBITDA from continuing operations guidance to a range of $110 million to $116 million, from our previous guidance range of $106 million to $113 million. Cartiva is estimated to be roughly neutral to 2018 non-GAAP adjusted EBITDA on an as-reported basis.

As you may recall, we have a headwind on EBITDA margin expansion this year from the lower levels of incentive compensation in prior year, all in the second half of the year. We estimated this is a headwind of a little over a 1-percentage-point impact for the full year of 2018, or approximately a 260-basis-point impact in the back half of 2018. At the midpoint, our guidance implies EBITDA margin expansion in the second half of the year of approximately 140 basis points, or approximately 400 basis points, excluding the incentive comp headwind.

The company estimates approximately 112.6 million diluted shares outstanding for Fiscal Year 2018 and 127.2 million non-GAAP adjusted diluted shares outstanding for the fourth quarter of 2018.

The last item I would like to cover is some directional comments on 2019. As is our normal mode of operation, we will provide formal 2019 guidance on our Q4 call in February. However, I wanted to provide you with some thoughts to keep in mind as you begin to develop your 2019 models.

We expect the extremities and biologics markets to continue to be high growth, in the range of 7% to 10%. From a modeling standpoint, all quarters in 2019 have the same number of days versus the prior year quarter.

We are confident in our ability to grow revenue on a constant currency basis in the double digits in our base business, plus the $47 million for Cartiva that we previously announced. At current rates, foreign currency is a headwind, in the range of 1%, as we head into 2019, and we typically include some currency cushion in our as-reported guidance.

From a profitability standpoint, we have been consistently expanding EBITDA margins in the range of 200 to 300 basis points each year and expect the addition of Cartiva to increase this to 300 to 400 basis points of expansion in 2019 over the midpoint of our current 2018 guidance, excluding Cartiva.

As we have stated previously, we expect to have 20% EBITDA margins towards the end of 2019, and that is still the case. Specifically, we now expect to achieve our goal of 20% adjusted EBITDA margins for the full fourth quarter of 2019.

In closing, we delivered a strong quarter in Q3 that was driven by our enabling technologies, new product launches and strong sales force execution across the business. Our increased guidance reflects the strong underlying business performance and the recent close of the Cartiva acquisition. We are confident in our ability to deliver a strong close to 2018 and are set up well for next year.

With that, we would now like to open the call to take your questions.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question comes from the line of Matt Blackman, with Stifel.

Mathew Justin Blackman - *Stifel, Nicolaus & Company, Incorporated, Research Division - Analyst*

First, for Bob and/or Lance, you just posted your fourth consecutive quarter of sequentially stronger sales growth, and you've touched on this a bit in your prepared remarks, but I was hoping to get your take on just the health of your end markets. Are the upper and lower extremities market do you think getting a little stronger here in 2018? Or do you think the acceleration we're seeing is really largely specific to Wright? And then I've got 1 follow-up.

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

I think that the end markets are continuing in the growth rates that we have seen previously, in that 7% to 8% area. So the overage is more related to what we're doing in terms of our new products that we talked about, sales force execution, enabling technologies, those kinds of things.

So I think that both things are good: the markets are strong and healthy and growing nicely and that our position in them is very strong. Our upper business is better than 2x, almost 3x, market, and our lower business is about 150% of market. So I think that that's all good and puts us in great shape now and for the next foreseeable future.

Mathew Justin Blackman - *Stifel, Nicolaus & Company, Incorporated, Research Division - Analyst*

Thanks for that. Appreciate the color. And my follow-up, just shift to AUGMENT Injectable, obviously it's still early, but we can already see some modest monthly acceleration since the launch. So first, do you think your reps have hit their stride yet? Or do you think growth should continue to accelerate from here? And can you give any flavor as to the early uptake? Is it largely increasing penetration in existing AUGMENT classic users? Or are you also seeing new account openings, as well? Our survey work suggests meaningful opportunities for both those avenues of incremental growth.

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

I think that AUGMENT Injectable is off to a good start. We got approval I believe in June but really didn't have a full supply and everything going until sometime in July. So I think that we're very happy where we are. We've always commented that where we launched AUGMENT Injectable in international markets we saw about a 30% increase, and I think we're on a trajectory to get there. We're not there yet, but I think that is very doable for us.

I think that the AUGMENT Injectable has opened some new doors for us, but the vast majority of it is cannibalizing the, what we call, the Augment classic. And I think that we still have some of that out in the field that is being used up, but I think that it won't be long before 90-plus-percent of all AUGMENT sales will be AUGMENT Injectable. I think it's only about 60% right now, I believe.

So we're off to a great start. The product performs well. It doesn't seem that we're going to have to go back to any VAC committees again. That was something that we thought might be possible, but we haven't been notified of that. So it's just all positive from AUGMENT Injectable from getting the approval until now.

Operator

Our next question comes from the line of Larry Biegelsen, with Wells Fargo.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Analyst*

Bob, just wanted to ask you about international and Cartiva. So international, you've seen a nice improvement there. Can you talk about why you think you've seen that improvement this year and the sustainability of that? And I had 1 follow-up.

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

Regarding international, as we've always said, international is a little bit choppy: one quarter is really strong and then the next quarter isn't so strong. And that's what -- international third quarter just had a very good year. Everything just kind of went right there also.

The above performance results in my opinion came mostly from distributor markets that are strong biologic markets also, which is a good thing. And whereas I think that our direct markets grew in the high single digits, which is where we thought that they should be growing at and had forecasted that, but the real uptick came from our distributor markets.

Lawrence H. Biegelsen - *Wells Fargo Securities, LLC, Research Division - Senior Analyst*

That's helpful. And then on Cartiva, thanks very much for posting the standalone sales. And I think when people look at them they might be surprised to see sequential declines in 2018. I know I was, given all the positive feedback we've heard from physicians and the numbers you've provided. So can you talk about why maybe there's been sequential declines in 2018 for Cartiva and why you're so confident in $47 million in 2019?

Lance A. Berry - *Wright Medical Group N.V. - Senior VP & CFO*

Larry, this is Lance. I'll take a shot at that, and Bob can jump in. As we were looking at the deal, we saw that as well. And a lot of that had to do with you had a management team that spent most of this year working on a sale process for the company and not really driving sales. And you really could see the slowdown coincide to when they really started their process.

And we looked at that very closely in our diligence and were very confident that really when we were able to get highly focused on this and really probably roughly double the number of active reps selling this product, that we would be able to get that going strongly in a positive direction.

So we were obviously well aware of the results up until we announced, and then we were not surprised at all that following announcement that sales have slowed down as all the distributors really wait to see what the future holds from them, which we're working through with them now.

Operator

Our next question comes from the line of Jeff Johnson, with Robert W. Baird.

Jeffrey D. Johnson - *Robert W. Baird & Co. Incorporated, Research Division - Senior Research Analyst*

Bob, just wondering maybe any update on your presence in the ASC channel. I know it's only been a month with Cartiva. PROstep I think has been out there since July. Those are 2 markets I think that are going to help lead you into that market in a more robust way, going forward. But just kind of what are you seeing so far on the ASC side?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

This has been a growing partner of the business for several years. We trailed a little bit and had some catch-up to do, and I think we started in earnest about a year or so ago when we formed a team to go attack this. And we've learned a lot and we've gotten significantly better results, which I think will just keep on getting better.

Specifically, a couple of things that we learned are that this is more -- our group before had traditionally sold to physicians and their whole mentality was selling to physicians. This is more selling to an institution or an ASC site, and the sales process is different. The billing is different. They like to be billed for a procedure, not each piece of the procedure. The inventory on hand is different. And the actual product mix is different.

So I think all that was learning that we learned, and I think that's one of the reasons I think that we're seeing some improvement in our core business, core lower extremity businesses, that we're getting much better at it, and I think we will continue to get better at it.

Cartiva is a product that really is made for ASCs, and that along with the other stuff and the other learnings that we had I think will make us increasingly more important to ASCs. I'd also put our minimally invasive PROstep into that category also, that has helped our presence in the ASC.

So whereas we were in not a great position a year ago at this time, I would say, in ASCs, I think right now our business is strong and is accelerating. And when we get Cartiva really going, I think it will actually be one of the stronger parts of our distribution system.

Jeffrey D. Johnson - *Robert W. Baird & Co. Incorporated, Research Division - Senior Research Analyst*

Thank you. That's helpful. Maybe Lance, I don't know if you could provide more color there on what percentage of your business currently goes through ASC, where you think that might go over time. Just any help there. And then, same kind of clarifying question on AUGMENT Injectable as that goes from 60% to 90% over time. Just remind me, is there a pricing differential on Inject versus the classic version?

Lance A. Berry - *Wright Medical Group N.V. - Senior VP & CFO*

So I'll take the AUGMENT first. So we're generally pricing that the same, and that was intentional, partly to avoid having to go back through the VAC committee. If we'd have put through real (inaudible) price increase of consequence, that would have put a lot of -- in a lot of accounts having to go back through the VAC committee and delayed that entry. So our choice was, you know what, we held good pricing on AUGMENT, the original, so let's just maintain that and get Injectable into these accounts.

We don't break out what percentage of our business is ASCs. I'll say at a high level the way you can think about it is things like total ankle and complex hind-foot surgeries, those are generally being done in a hospital inpatient setting. And then your forefoot and mid-foot procedures, for the most part, unless they're being done in conjunction with one of the more complicated procedures, are being done in an outpatient setting, which is a mix of hospital outpatient and ASC but trending over time more towards the ASC.

So that's really how the business kind of shakes out. We haven't broken out what percentage is which, but both parts of that are very important to us in our ability to grow our lower extremities business.

Operator

Our next question comes from the line of Travis Steed, with Bank of America.

Travis Lee Steed - *BofA Merrill Lynch, Research Division - VP*

Appreciate the comments on 2019, but from where I sit you've got several tailwinds: new products in lower; good growth in shoulder; AUGMENT Injectable; you just posted 2 quarters of mid-teens growth. So can you just remind us some of the headwinds we should consider in 2019 that could keep you from achieving mid-teens growth next year in your underlying business?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

Well I think that mid-teens growth is something that we would strive to hit, but I think it's a little bit unrealistic for every quarter. And so particularly when you look at this quarter, the Q3 that we're reporting on, is that everything went right, as I said. You've always heard the story about the perfect storm. The perfect storm is usually a negative storm. There was bad weather, regulatory problems, supply chain problems, et cetera. This is something that we believe everything went right on, and I just don't think you can count on that all the time.

So I think that we will continue to put up very strong numbers. We will be -- we consider ourselves to be as -- what we said, I think it was about a year ago at this time, is you could look at us to be a double-digit growth company. And hopefully we can do better than that, but I think that's something that we're willing to sign up for.

We do have some very difficult comps when you look at this compounding year-over-year, particularly in our upper extremity business where our PERFORM Reversed product line has been over 20% for the last year, growth. And at some time, I think that would slow down some. But our

SIMPLICITI business is extremely strong and growing even more than our PERFORM Reversed business. So it's just hard to see that you can continue that on ad infinitum.

On our lower extremity business, I think that this has 2 aspects to it that I do think provide some really good headwinds for us. We've launched a lot of good solid new products. We talked a lot about minimally invasive in the past, and that is now launched. As we expected, there's a pretty steep learning curve on that. And that's just going to get better and better and really accelerate our business, our lower extremity business, as well as our ASC business. AUGMENT Injectable again is something that I think is really going to help grow that business, and we're looking for about a 30% increase over where we were with just the classic formula there.

And I think all the kind of issues we had with sales force last year as we went away from the Tornier lower extremity sales force into the new sales force that created problems, those are behind us. So I think that that business is getting stronger and stronger.

And so I think that our lower -- the way I see it is our upper extremity business will de-accelerate some, in that it's just too hard to maintain that kind of 20% growth, but our lower extremity business I think has the potential to increase some. Our biologics business I think is going to -- should be able to increase some.

So I think that we'll give you a much better insight in 2019 in February, but directionally we think that we're very comfortable with people thinking about the out years as double digit at this time.

Travis Lee Steed - *BofA Merrill Lynch, Research Division - VP*

That's very helpful. And last quarter, I think you said SIMPLICITI grew 31%. So just curious if you'd be willing to give that growth rate again this quarter and also how we should (inaudible).

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

Travis, I think it's roughly the same.

Travis Lee Steed - *BofA Merrill Lynch, Research Division - VP*

Okay. Helpful. Then the shoulder INVISION product launching in Q4, is that a material impact to revenues? Or how should we think about the ramp there?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

What we learned, and we knew this when we launched our revision product in ankle, is that there's not a big amount of new business that comes. But what it does though is it gives surgeons the, I don't know how to usually say this, the courage, I guess, to do these procedures knowing that they have a bailout. Our INVISION product in ankle is growing triple digits, quite frankly, but it's off a low base. And I think that eventually the revision product in upper will have some type of a meaningful effect. But the more important thing is that physicians will be doing these procedures more than maybe they would have done them without having a revision option if something happens downstream. That's really what that product is for.

Operator

Our next question comes from the line of Matthew O'Brien, with Piper Jaffray.

William George Inglis - *Piper Jaffray Companies, Research Division - Research Analyst*

This is Will, on for Matt. I guess, starting off with the U.S. upper extremities, the shoulder business was still very strong, 21%. You anniversaried the PERFORM Reverse glenoid launch. So just kind of trying to deconstruct the growth there, what's driving that. Is it SIMPLICITI? PERFORM? And then the 30% customer base using BLUEPRINT, was that obviously a factor, I assume?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

I think you hit on all of them. The PERFORM Reversed continues to be strong. And as I said, we had over 20% growth in that; it was higher than that. And SIMPLICITI is around 30%.

But I think a really driving force is the acquisition of new surgeon customers, and that has a lot to do with the adoption of BLUEPRINT. We have now about 30% of our cases that are done are using BLUEPRINT, and I think that would continue to accelerate. And once you actually demo this to a surgeon, no matter how skilled they are, and some of the most highly skilled surgeons use it all the time, are just wowed and bowled over with what this can help them do.

And we're just at the beginning of this. We have a lot more modules, if you will, that we're working on, everything from augmented reality, artificial intelligence, interoperative guidance that are being worked on now. We have a -- we've made a big investment and I think it's paying off. We have 25, or so, software engineers working on these things full time. So it's not insignificant.

But this is what's driving our growth more than anything, I believe. Or at least I would put it this way: it's driving our acquisition of new surgeons away from competitors. And I think that as the additional modules get ready and are rolled out, this will even become more -- have a more profound effect.

But the hardware itself, the PERFORM Reversed and SIMPLICITI, are doing their jobs extremely well: 20%, 30%. And then BLUEPRINT is just really pushing everything forward really well.

William George Inglis - *Piper Jaffray Companies, Research Division - Research Analyst*

Great. That makes sense. And then shifting to the U.S. lower extremities, with core still at market growth, when do you think that you can be back in a share-taking position, given some softness with your competitors?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

We're striving to do that. And I think that our organization is a thousand times better than we were a year ago when we went through the transition. And so I can't give you a time period, but I do think that that is in the cards. I think that there's no reason that with our organization and the strength of our organization and the competency that they exhibit that we should not be taking share.

But don't forget, in total, when you look at the market, that includes total ankle and what we call technically advanced products, Charcot systems as well as AUGMENT. Taking just the hardware piece of it, is that we're growing well above market now.

Operator

Our next question comes from the line of Mike Matson, with Needham & Company.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Just wanted to kind of follow up on that last question about the lower extremities growth. Stryker called out some supply issues in their extremities business, and Integra seems to have some sort of self-inflicted issues going on in their extremities business. So do you think you've benefited from these competitors' issues in the quarter, at all, (inaudible)?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

I don't know. We certainly didn't see a slowdown in the market, if that's what you're asking. The people that were gaining some share last year and the year before were not the big players, I would say. There were a bunch of smaller companies and distributorships that were spawned out of the Wright-Tornier merger, when that 50 or so distributor sales reps were displaced and got their own business. Those are the people who gained share.

So I don't know specifically what's going on with those competitors, but it seems like the growth in these smaller players has waned some, for sure. And the reason it has, I think, is that our sales force has got much more traction behind it and that customers, surgeons realize that they need more than just a cheap product; they need medical education, they need support and everything that we strive to give them.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay. Thanks. And then you went through this big sales force expansion in the lower extremities business last year and you've seen some tremendous growth in the upper extremities business. So just wondering where things stand there with the size of the sales force. Are you going to need to expand that, as well? Or have you been doing that kind of on an ongoing basis?

Lance A. Berry - *Wright Medical Group N.V. - Senior VP & CFO*

Mike, this is Lance. So one, we have been just adding in territories as needed through the normal course on the upper extremity business. I will also say that the sales per rep in the upper extremities business if you go back, say, 1.5 years ago was pretty low compared to lower extremities business. And we moved that business into our hub network, which created a fair amount of capacity for the reps, as well. So I think just natural adding where we needed to but then also giving them some extra capacity has allowed us to handle that very significant increase in volume over the past 2 years.

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

I would add to that, Mike, that we don't see, like, a big (inaudible) of additions like we did in lower. We think that, as Lance said, is that we're adding people pretty much all the time, but it's one-sies, two-sies in different areas so we don't get that big disruption that we had in our lower extremity organization a year ago.

Michael Stephen Matson - *Needham & Company, LLC, Research Division - Senior Analyst*

Okay. Great. That's kind of what I was getting at. I just wanted to make sure we weren't going to see a risk of something like that happening in the other side of the business.

Operator

Our next question comes from the line of Craig Bijou, with Cantor Fitzgerald.

Craig William Bijou - *Cantor Fitzgerald & Co., Research Division - Research Analyst*

I want to start with the total ankle business. Obviously, you guys had a strong quarter this quarter on a relatively tough comp. And I know, Bob, you've talked about it before, but maybe just is there anything that you saw within the total ankle market maybe in terms of penetration? Anything that could be signaling an inflection point where total ankle starts becoming a larger portion of the market?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

I think it's just pretty much steady growth. For me, it's hard to believe that everybody that has an ankle fusion doesn't have a total ankle replacement, but that's still the case, although we're making progress on it.

The big driver here that differentiates us than any of the other players is PROPHECY. It's just like BLUEPRINT affects in a pretty dramatic way our upper growth; PROPHECY is what affects our lower growth. So what it does is it makes it easier for physicians to do total ankles than just freehand surgery like they have to do with most of the competitive products.

So I think that the enabling technology philosophy is key and I just think that it'll continue to grow. And hopefully it will continue to grow 20% and 20% and 20%, and at some point in time ankle fusions will go the way of knee fusions that used to be in effect a while ago. But we're making great progress. The team is very motivated. We do a lot of Med Ed, and we continue to develop our portfolio to have even better hardware. But PROPHECY I think is really the differentiator.

Craig William Bijou - *Cantor Fitzgerald & Co., Research Division - Research Analyst*

Great. Thanks for that. And just a couple of follow-ups on AUGMENT. Lance or Bob, I think you guys said that you expected $3 million in additional revenue in the second half from Injectable. So just curious as to if that's still a good number. And then a little maybe longer term or bigger picture, I know there were some other indications that you guys were looking for with AUGMENT when you originally did the deal. So just maybe your thoughts on where -- what the next indication could be for AUGMENT.

Lance A. Berry - *Wright Medical Group N.V. - Senior VP & CFO*

Craig, we raised guidance when we got approval. And so we were trying to give people a little color on how much that was attributable to Injectable. So no real intent to update that and how we're performing against that. We had 2 pretty meaningful upticks in our guidance since then. So over all, the business is obviously doing well. And if you just look at the U.S. bio business, we have a pretty significant improvement in growth rate from Q2 to Q3. So I think all good signs that Injectable is doing well, but we're not going to give any hard specifics on that.

And then as far as other indications, we're still evaluating are there any nearer-term opportunities, which is a little more challenging, and then still working through the process to decide do we want to do a full-blown PMA, which could potentially be very meaningful if approved, but obviously a very long time frame to get that done.

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

I'd just add that I think that we're looking at both things, what short-term things -- and so the regulatory path that we would have to go through is dictating how we're going to proceed. Short term, if we could get an indication for maybe our mid-foot or forefoot, that would be something that we may be able to have a much sooner regulatory path. If we're going to get out of foot in total, go to some other part of the anatomy, that's a real big investment, but it may be worthwhile.

Operator

Our next question comes from the line of Robby Marcus, with J.P. Morgan.

Robert Justin Marcus - *JP Morgan Chase & Co, Research Division - Analyst*

Lance, I was hoping, and excuse me if someone asked this, I was jumping between calls tonight, but hoping you can talk about the good EBITDA performance in the quarter. Cartiva is going to start hitting next quarter. You reiterated guidance for greater than 20%, probably exiting next year. How do you -- seeing the good performance you've had to date, does this increase your confidence you could get there? And then help us think about over the next few years as the business continues to grow where you think this can trend beyond the 20%, which doesn't seem that far from being achievable at this point.

Lance A. Berry - *Wright Medical Group N.V. - Senior VP & CFO*

Sure. So first of all, I'd say we've always had a pretty high level of confidence in getting to that 20% number by the end of '19. We posted pretty steady 200 to 300 basis points of EBITDA margin expansion every year since the merger. And that's really pretty much the same formula that we've been talking about, which is the actual sales force and our R&D we're not going to look to get any leverage out of that. We want to reinvest in that at the rate of sales because that, really differentiated technologies and specialized sales forces, is how we think we can win.

But then the other parts, sales management, medical education, marketing, those things are things that we can continue to invest in but not fully at the rate of sales and we can get some leverage.

And then when you start looking at more our distribution network and our G&A, which honestly are pretty high for what you would expect for a company our size, due to our unique history, we have everything we need there. And there's a great opportunity to hold that as flat as possible and, if we can grow double digits, drive quite a bit of leverage.

And so that's really been the formula for the past couple of years, and we see that ongoing. And we certainly have a 20% objective that we laid out at the merger, and we're getting pretty close to that if you look toward the end of next year. And we're not ready to give formal guidance beyond that, but we are confident in our ability to continue to drive leverage beyond the 20%. We're certainly not going to stop once we hit that number.

Robert Justin Marcus - *JP Morgan Chase & Co, Research Division - Analyst*

Got it. Thanks. And at AOFAS over the summer, PROstep was a product you talked a lot about. Can you help us understand maybe in the good numbers you put up in lower tonight how much was driven by PROstep and other new products and how much was just improved productivity from the base business.

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

I think all our new products performed at expectations or greater. PROstep is a very important product for us for 2 reasons. First of all, it's a market share gainer for us, is that it's a better procedure for bunions, which are the largest surgical procedure that we have. And the recovery times are much -- the operating times are much less, the recovery time is much less and there's less of a scar. And so it's a better procedure, which helps drive that.

Secondly, it's a product that is really made, in a way, for the ASCs, and we talked a little bit earlier about how important that is and how much of a trend I think that we're in an uptick on that.

What I will say is that the learning curve is pretty steep, in that it's one of these things that if a doctor seems to do 1 or 2 of them they get discouraged. And we have a whole process that we have and we're working to refine that encourages doctors to do a lot of procedures under supervision, if you will, a lot of help there so that they get comfortable doing this procedure more quickly than they would have if they just do a couple and then stop.

So it's kind of a breakthrough product, we believe, for a very large surgical procedure. And so that's a lot of it.

Our other new products, our cross-check and revision systems that we talked about, are all performing at or above expectations. The reason that we had such good growth is a lot to do with the new products and will continue to be that as we exit '18 into '19, when we have a lot of other stuff that will be hitting the market.

Operator

Our next question comes from the line of Richard Newitter, with Leerink Partners.

Richard S. Newitter - *Leerink Partners LLC, Research Division - MD, Medical Supplies & Devices and Senior Analyst*

I have 2, and I apologize if 1 of them was asked. I'm jumping between calls. But Bob, you've talked in the past and you mentioned again on this call the procedural sell versus kind of individual product sell. Maybe I hesitate to use the word "bundle," but it sounds like that's what that is. Can you talk, in the ASC, what is the impact to gross margin and ASP from that kind of new selling process?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

Rich, I'm going to turn it over to Lance, actually, because he was the one -- he led the team on our ASC expansion. So I'm going to let him talk about that.

Lance A. Berry - *Wright Medical Group N.V. - Senior VP & CFO*

Rich, as we really tried to dig into this we found that it's not just a price thing with ASC. They're obviously trying to -- they're much more profitability focused, but that profitability really entails a lot of things. The cost of the product is part of it, but it's also, how do they keep their O.R.'s full? That's their biggest cost. And how do they attract the type of procedures and patients that they want to fill up the O.R.? What can you do to help them with their efficiency? And then they want options, and they're willing to pay fine gross margins for the different options, but they may want a lower-cost option and a higher-cost option that they will make some decisions around. So it's not as simple as price; it's a lot more nuanced than that. And I think that something we've learned as we've gotten into it.

So this can be a really good healthy part of our business, but we have to be more attuned to the customer and know that the customer is not just the surgeon; it's the surgeon and the account. And that's what we've really been working on over the past year. We've made a lot of progress, but I still think there's a lot of progress we can make and do a lot better on this as we roll into 2019.

Richard S. Newitter - *Leerink Partners LLC, Research Division - MD, Medical Supplies & Devices and Senior Analyst*

Okay. That's helpful color. Thanks. And maybe just a follow-up on Cartiva. Bob, just in the past you've done a number of deals over the past few years, and occasionally some -- the unanticipated happens and some things take you by surprise, whether it's distributor workouts or sales productivity ramps and what not. Can you maybe just describe what you learned from those in the past and how you've approached kind of getting to the numbers you've provided for '19 and what you can say to give us confidence that you've got this one entirely right?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

Well I wish I could guarantee that, but what I would say is that I think most of the acquisitions that we've made turned out just great. But there is a learning around when you really disrupt the sales organization and the relationship of that rep with that customer, which is usually a physician, is that you're in some jeopardy.

So what we've done here is -- let me just say Cartiva had about 40 distributors. And it's really the 80/20 rule: about 80% of the revenue comes from the top 20 distributors. So we are not messing with that. We have offered all these distributors new contracts, and we're in the process of finalizing those and negotiating the terms and the accounts, et cetera. The other 20 distributors, we have notified that we are not going to be using them in the future. And we will be supplementing our sales force with them, and we think that's a low-risk deal.

So what we've tried to do is protect revenue and, in doing that, protect the relationship between who was selling it to them and that account. And I think that I can't be sure that everything will work 100% as planned, but I think that this is a good plan.

And the distributors that we are keeping that we've offered new contracts to are thrilled. Now there was a little bit of anxiety between the announcement of the deal and the close, and even after the close until we were able to get to them and talk to them, each one specifically. But I think that right now I think that we're seeing just lately their business picking up. And I think that as we go into next year and all these things are behind us, 80% of the revenue is going to be with the same sales rep, the same distributor. The other 20% that didn't do much, we think we could better with, with our direct organization.

Operator

Our next question comes from the line of Chris Pasquale, with Guggenheim.

Christopher Thomas Pasquale - *Guggenheim Securities, LLC, Research Division - Director and Senior Analyst*

Bob, I wanted to start just following up on Rich's question about Cartiva. The $47 million guidance for next year implies over 30% growth. That's obviously pretty healthy. Is that actually net of some assumed friction as you make that transition? Or are you guys really assuming that the handoff is going to be pretty smooth and we should think about that as being a clean number for the product?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

I think that we think that as we get into next year is that handoff will be pretty smooth, and the addition of the Wright sales reps selling this product in addition to the current distributors will drive a lot of upside. We will have probably one-third more reps selling than...

Lance A. Berry - *Wright Medical Group N.V. - Senior VP & CFO*

We're getting close to double.

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

Double the reps selling Cartiva next year as are selling it this year.

Lance A. Berry - *Wright Medical Group N.V. - Senior VP & CFO*

Chris, 1 thing on that. For the distributors that we notify that we won't be renewing their contracts, they still have the territory through the end of the year. So our sales force can't really get in there until January 1. So I think there will be some ramp-up period over the first quarter as we get the much bigger sales force in there. And as we've discussed, we expect the fourth quarter to certainly be much less than it would have been if there hadn't been a transaction, for the reasons that Bob had discussed, with uncertainty the distributor network had until we could get to them and explain the ones that had a role, going forward.

Christopher Thomas Pasquale - *Guggenheim Securities, LLC, Research Division - Director and Senior Analyst*

Thanks. And then on BLUEPRINT, I thought the jump in utilization there was an interesting data point. You've had that software for a while. I know you've been adding functionality over time. Was there anything, in particular, that you think drove the step-up in adoption this quarter? And where do you think that penetration could go over the course of, let's say, the next year?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

One of the things, we've made it a lot easier recently. The software now is a Cloud-based software. Whereas before we had to physically take the CT scans disks to the surgeon, now it's all in the Cloud. So we've made it a lot easier.

So I just think that in addition to that doctors are getting much more comfortable with it. One of the things that is unique and is kind of surprising in a way is that it's really the leading physicians that are using it all the time. They use it all the time. And I think then other doctors who are kind of dabbling in it are talking to these other physicians and are now converting to using it all the time.

So I think that the combination of making it easier, plus the momentum of the leading KOLs, is driving that. So I think it's going to continue to grow. I'm not sure it's going to -- next quarter it's going to be up to 40% and then after that 50%, but I think it's going to accelerate. And I think that the vast majority, the vast majority of cases in the next couple of years will be done using the BLUEPRINT technology. It's so much better than doing it the other way, and there's so much more help for a physician to plan and execute a case that, as I said, they love it and the leading KOLs are using it more than anybody.

Operator

Our next question comes from the line of Joanne Wuensch, with BMO Capital Markets.

Matthew Donald Henriksson - *BMO Capital Markets Equity Research - Associate*

This is Matt Henriksson in for Joanne. I'd like to follow up on Robby's question on PROstep. You talked about the steep learning curve. You talked about how doctors need more than 1 or 2 cases to kind of get up to speed. What is kind of the average number of cases that doctors need to do before they say, "Okay, I feel comfortable with this."

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

I don't have a specific number, but it certainly is double digits. And the quicker that -- so what we try to do is ask a doctor to line up a bunch of cases and make sure that all the help that we can throw at the doctor is there when they're doing a whole bunch of cases. This is contrary to a lot of other procedures where doctors like to do 1 or 2 and then wait a couple of months and see how the patients do and then start up again. This is a high-volume procedure. Physicians, DPMs do a lot of these. And using PROstep is a pretty big change in their technique. But once they get it, they get it and they never go back.

Matthew Donald Henriksson - *BMO Capital Markets Equity Research - Associate*

That's helpful. And then just my follow-up, now that the holders of the 2021 notes can convert those notes in the upcoming quarter, what's your strategy to address investors who decide to convert those notes?

Lance A. Berry - *Wright Medical Group N.V. - Senior VP & CFO*

Well we've had this situation on and off in the past. It would be to their economic detriment for them to redeem the notes. They honestly could get -- just because of the mechanics of how converts trade, they could get more money just selling the convert in the open market than what the redemption price would be from us. So we've had that in the past. No one has ever redeemed, because it's really -- it's detrimental to them to do that. And so we would not expect that to occur.

Operator

Our next question comes from the line of Steven Lichtman, with Oppenheimer & Co.

Steven Michael Lichtman - *Oppenheimer & Co. Inc., Research Division - MD and Senior Analyst*

You talked about the strong performance outside of the U.S. Bob, you gave a little color on where the strength came from. I'm wondering geographically has that growth been broad-based? And are you expanding your reach outside the U.S.? Or has this just been accelerated growth within the current countries?

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

Sometimes we have a not-so-good quarter internationally and we say, well, it's choppy internationally. And that's what it is, is that in 1 quarter you can have a good growth, because these are stocking distributors. And so both in -- (inaudible) these in the emerging markets; specifically, China and South America. And it seems like 1 quarter is really strong, and the next quarter is not so strong, and it just goes on like that.

And I say is that a lot of the growth is in our bio portfolio, particularly in China, which is a good thing because we like the margins and we like the lack of capital intensity that goes with bio.

So it would be great if we could have that type of growth every quarter. I would more look at a normalized international growth rate in the high single digits as we go forward. Hopefully, we'd like it to do better than that, but I think that's realistic.

Steven Michael Lichtman - *Oppenheimer & Co. Inc., Research Division - MD and Senior Analyst*

That's perfect. And you actually answered my second question on the underlying sales growth ahead.

Operator

This concludes our question-and-answer session for today. I would now like to turn the call back to Bob Palmisano for closing remarks.

Robert J. Palmisano - *Wright Medical Group N.V. - President, CEO & Executive Director*

Thanks, Operator, and thank all of you for joining us today. I want to express my appreciation to our team for their efforts in Q3, and I am also delighted to welcome Cartiva employees to the Wright Medical family.

I look forward to speaking with you again in our next quarter earnings call. We appreciate your interest and your continued support. This concludes our call.

Operator

Ladies and gentlemen, thank you for participating in today's conference. This does conclude today's program. You may all disconnect. Everyone, have a great day.
