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WMGI - Q3 2016 Wright Medical Group NV Earnings Call

EVENT DATE/TIME: NOVEMBER 02, 2016 / 8:30PM GMT

OVERVIEW:

Co. reported 3Q16 results. Expects 2016 net sales from continuing operations to be $677-683m.

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Wright Medical Group N.V. third-quarter 2016 earnings conference call. (Operator Instructions). As a reminder, this conference may be recorded.

I would now like to introduce your host for today's conference, Ms. Julie Tracy. Ms. Tracy, you may begin.

Julie Tracy - *Wright Medical Group N.V. - SVP, Chief Communications Officer*

Thank you and good afternoon, everyone. Welcome to Wright Medical's third-quarter 2016 conference call. We appreciate you joining us. I'm Julie Tracy, 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 released 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 and updated 2016 guidance from Lance, a question-and-answer session, and then conclude with closing comments from Bob.

Before we begin, I would like to remind you that this call includes forward-looking statements, including statements about our outlook for 2016, our beliefs and expectations regarding the outcome of pending litigation, the completion of our metal-on-metal hip settlement, the completed merger with Tornier, 2017 cash flow; and new products, including AUGMENT Bone Graft.

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 annual report on Form 10-K for the fiscal year ended December 27, 2015, and quarterly report on Form 10-Q for the fiscal quarter ended September 25, 2016, filed or to be filed by Wright with the SEC, 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.

In addition, as a result of the completed sale of our large joints business to Corin, all current and historical operating results for the large joints business are reflected in discontinued operations. Unless otherwise noted, today's discussion refers to results from continuing operations.

Also note that unless otherwise noted, all growth rates discussed today are on a combined, pro forma basis compared to third quarter of last year.

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

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Thanks, Julie, and welcome to our third-quarter earnings call. In the third quarter, global extremities and biologics pro forma constant currency net sales growth of 9.3%, adjusted EBITDA from continuing operations of $5.7 million, and adjusted gross margins from continuing operations of 78.2% reflect the strength of our markets and our unique position in them.

As anticipated, our third-quarter results were impacted by revenue dis-synergies which we estimate to be approximately 3% for the third quarter.

The underlying drivers of growth in our business remain strong as we continue to see excellent growth from new products, in particular our SIMPLICITI and ASCEND FLEX shoulder systems, our INFINITY total ankle replacement system, and ongoing commercial activities for our AUGMENT Bone Graft and SALVATION limb salvage system.

Although dis-synergies did impact our third-quarter results, our current expectation is that the impact of dis-synergies of 2016 will be significantly less than we expected at the beginning of the year.

One year post-close the merger of Wright and Tornier, we are a stronger and more focused Company. With the closing of the sale of European large joints business, we are now completely focused on extremities and biologics markets. We have completed the integration of our salesforce globally with less revenue dis-synergies this year than we originally anticipated. We are ahead of schedule on our integration activities and associated benefits.

We have improved our balance sheet and reached a settlement agreement for a substantial percentage of our metal-on-metal hip litigation. Also, the guidance we are providing today is for sales and adjusted EBITDA, well ahead of our expectations we provided at the beginning of the year. I am very pleased with what we have accomplished in our first year as a combined company, and believe we are positioned well for future success. However, we are nowhere close to meeting our full potential, and we continue to have great opportunities for improvement.

Highlights in the quarter include strong contributions from our ongoing rollout of our SIMPLICITI and ASCEND FLEX shoulder systems, which drove [13%] sales growth in US shoulders, and ongoing penetration of the INFINITY Total Ankle Replacement system which drove 19% sales growth in US total ankles.

In addition, net sales of our US biologics business grew 45% in the quarter, driven by the ongoing commercial activities for AUGMENT Bone Graft. We expect all these products to continue to be growth engines during the remainder of 2016 and beyond.

Let me now provide some additional color on the business results for the third quarter. As anticipated, we continued to see the impact of revenue dis-synergies in the third quarter. As expected, the US lower extremities business was most affected by dis-synergies, evidenced by 4% sales growth this quarter. We believe US lower extremities sales growth was impacted by dis-synergies in the range of 5% to 6% this quarter.

Our underlying business continued to perform well, led by continued strong growth in our US total ankle business, as well as nice contributions from the launch of our SALVATION limb salvage system for treating Charcot foot.

I also want to highlight the strong performance of our US biologics business, which grew 45% in the third quarter, once again the fastest-growing segment in our business. This growth was driven by the ongoing launch of AUGMENT Bone Graft as well as good performance from our other biologics products.

With regard to AUGMENT, we continue to convert new accounts in the quarter. We saw value analysis committee approvals pick up as we exited the quarter, as we anticipated. We expect AUGMENT to continue to grow steadily as we continue to work through VAC approvals, add new customers, and further penetrate top-decile accounts.

In terms of pipeline, we are finalizing our options with regards to the regulatory pathway with the FDA to bring an injectable form of AUGMENT to the US market. We hope to have more clarity on this by our fourth-quarter call in early February.

Our US upper extremities grew 11.2% this quarter, driven by our innovative shoulder product portfolio, including ASCEND FLEX shoulder and the ongoing launch of the SIMPLICITI shoulder system. Although well above market rates of growth, this is a de-acceleration as compared to the second quarter, driven by the annualization of the 2015 SIMPLICITI launch.

We have important new product launches on the horizon. And we are focused on improving the utilization of our inventory and instrument kits, both of which we expect to benefit -- to be beneficial to the shoulder business as we move into 2017. Overall in the third quarter, our innovative products in upper, lower, and biologics continue to drive growth. And the timing of dis-synergies has played out better than originally anticipated.

Now moving on to our progress in the merger integration. We have made tremendous progress in the first year of integration. We have completed over 80% of our approximately 300 integration milestones; and, most importantly, we have completed the integration of our salesforces globally. The integration of the US lower extremities salesforce was completed on schedule at the end of Q2. And the integration of our US upper extremity salesforce was completed this quarter, ahead of schedule.

The consolidation of the two companies in our direct international markets has been particularly complex, as in each market we had to merge two organizations. And in three of our top five international markets, we had to co-locate those organizations and consolidate them into one ERP system. This is now behind us.

It is important to note that the timing of our sales dis-synergies has played out better than we originally anticipated, and we now have good visibility into the revenue dis-synergies that we expect. Lance will cover the expected amount and timing of those dis-synergies in more detail in his prepared remarks.

From a cost synergy perspective, we have continued to track ahead of schedule, which contributed to the adjusted EBITDA over-performance we have delivered year-to-date. We are continuing to work on our balance sheet initiatives, where we have significant opportunity to improve inventory, instrument set utilization, and DSOs, with our first focus on our legacy Wright business.

We have started to see the impact of these initiatives, as evidenced by the reduction in gross inventory days on hand for the legacy Wright business of over 100 days so far this year, which underscores our conviction about fundamentally changing the way we do business, so that we can have both a well-managed balance sheet and still deliver high growth.

We have already made some early progress in integrating the US upper extremities distribution into our existing inventory hub network, and this work will continue into 2017. This represents a substantial opportunity to increase instrument set utilization, decrease inventory and DSOs, enhance our balance sheet, and ultimately increase rep productivity and sales time. This initiative was highly successful in our lower extremity business, and we look forward to the benefits we believe it can deliver in our upper extremities business, as well.

In summary, we have made an incredible amount of progress in just one year. Our salesforce integrations are complete and ahead of schedule. Cross-synergies have materialized earlier than anticipated. The dis-synergies have played out better than originally anticipated. Additionally, we have materially improved our balance sheet and improved a great deal of uncertainty related to our metal-on-metal hip litigation.

We also completed the sale of our European hip and knee business. And while we accomplished these significant initiatives, we continue to grow our core businesses well above market rates of growth.

Our work is not complete, and much potential still remains. We now believe the integration has been significantly de-risked, and we are now focused on executing the next phase of opportunities.

Before I turn this call over to Lance, I did want to comment on the metal-on-metal hip litigation and insurance settlement agreements that we announced today in a separate press release.

First, I encourage you to read to the disclosures in our SEC filings, including our previously filed 10-K and the 10-Q for the third quarter that will be filed shortly. Today we announced that we have entered into an agreement to settle a substantial portion of our legacy Wright metal-on-metal hip litigation, resulting in net cost to Wright of approximately $180 million, which is right in line with the range we've previously disclosed in Q2. We have also completed a settlement with three of our insurance carriers to resolve the litigation regarding the extent of insurance coverage.

We are pleased to have reached this settlement agreement; in particular, the population of claims that the settlement covers, as well as the required 95% opt-in rate for those claims. This settlement addresses approximately 85% of the known US revision claims that do not have potential statute of limitation issues; that removes a great deal of uncertainty that has been associated with this litigation.

It is important to note that these agreements do not include any additional recoveries from the additional insurance carriers that the Company is still litigating and negotiating with. Lance will provide additional commentary later in the call, but please refer to the separate press release issued today and the disclosures in the third quarter of 2016 10-Q, when filed, for more information.

With our attractive combination of products and people, I continue to believe Wright Medical is a unique company that has the ability to drive mid-teens growth, gross margins in the high 70% range, and achieve adjusted EBITDA margins of approximately 20%, 3 to 4 years post- the close of the merger. I believe we have demonstrated our ability to leverage strong sales growth and increase our size and scale, and to even faster EBITDA growth than originally planned.

With that, I'll now ask Lance to provide further details on our third-quarter results, 2016 guidance, and our settlement agreements. Lance?

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

Thanks, Bob. As we get started, all sales growth rates that I refer to in my prepared comments will be on a pro forma, constant currency basis over the prior-year quarter. In addition, all results of operations that I'll refer to in my prepared comments will be as adjusted, and comparisons will be on a pro forma basis. These are all non-GAAP financial measures, as described by Julie during the introduction of our call.

In addition, as a result of our completed sale of our large joints business to Corin, all current and historical operating results for the large joints business are reflected in discontinued operations. Unless otherwise noted, today's discussions refer to results from continuing operations.

Please refer to the non-GAAP reconciliations in our press release. And I also strongly encourage you to review the information posted on our website. Similar to last quarter, we have provided you with information to assist you with your modeling, and to provide you with pro forma information and EPS through the third quarter of 2016.

Bob covered the highlights of our underlying revenue growth in his earlier comments. I will focus my comments on dis-synergies, specifically how they impact the year and the quarter, as well as the ultimate amount that we estimate. At this point, our salesforce integrations are complete, and we believe we have good visibility on where dis-synergies will land.

We anticipate that dis-synergies will negatively impact 2016 in the range of $15 million. The dis-synergies have increased throughout the year, and we now estimate the annual run rate for dis-synergies to be approaching $25 million, or towards the low end of our original range. Therefore, we expect the negative impact to 2017 will be an incremental of roughly $10 million, as we will have a full-year impact to the business that was lost over the course of 2016.

As anticipated, these dis-synergies have been heavily weighted to the lower extremities business. We have also seen some dis-synergies in the international business, and, to a lesser extent, the US upper extremities business.

Globally, the extremities and biologics business grew 9%, and we estimate was impacted in the range of 3% by dis-synergies this quarter. The combined US lower extremities business grew 4% in Q3. The US lower extremities business was most impacted by revenue dis-synergies, which we estimate were in the range of 5% to 6% for Q3. At this point, we do not anticipate any meaningful increase in the US lower extremities dis-synergies.

Our international extremities and biologics business grew 4% in Q3 and was also somewhat impacted by dis-synergies as we combined operations in certain of our international markets. We anticipate some incremental impact of dis-synergies in the international business in Q4.

The combined US upper extremities business grew 11% in Q3, and had minimal impact from dis-synergies. We estimate a small, incremental increase to dis-synergies in Q4.

Now, moving on to some detail below the sales line. Please note that all of my discussions will refer to our continuing operations results. Beginning with our Q3 adjusted gross margin, we achieved 78.2% for the quarter, an increase of 150 basis points over the same prior-year period, driven by mix, leverage, and lower levels of excess and obsolete inventory reserves.

As to the line items making up our Q3 operating expenses: selling, general, and administrative expenses totaled 78.5% of net sales for the third quarter compared to 82.7% in the prior-year period. The decreased as a percent of sales was driven primarily by our ability to drive leverage in the cost structure and the capture of cost synergies. R&D expense was $12.3 million in Q3 of 2016 and $14.1 million in Q3 of 2015. And, finally, amortization expense was approximately $7.5 million in Q3 of 2016 compared to $6.9 million in the prior-year period.

Below the operating income line, net interest expense was $16.8 million; and other income, net, was $400,000 of income for Q3. Finally, for share count, our Q3 per share results, as adjusted, are based on average diluted shares of 103.1 million for Q3 of this year, and average diluted shares of 102.9 million for Q3 2015. Altogether, this resulted in adjusted EBITDA of $5.7 million and 3.6% of net sales for the quarter.

From a cash standpoint, our total cash balance at the end of Q3 was approximately $314 million. Overall, our third-quarter results demonstrate the powerful leverage opportunity we have as we drive strong growth in extremities and biologics.

As Bob mentioned earlier, we have entered into a settlement agreement in the previously disclosed metal-on-metal hip litigation. We also entered into a settlement agreement with three of our insurance carriers. I will provide some additional color on the settlement, and a summary of what is and is not included. However, you should refer to the disclosures in our 10-Q, which we expect to be filed shortly, for a complete discussion of these matters.

Under the terms of the metal-on-metal settlement agreement, the parties agreed to settle approximately 1,300 revision claims for a total settlement amount of $240 million, of which approximately $180 million will be funded from cash on hand, and $60 million will be funded from insurance

recoveries from the three settling insurers. It does not include any additional recoveries from the three additional insurance carriers that the Company is still litigating and also negotiating with.

The metal-on-metal settlement agreement includes a 95% opt-in requirement, meaning that we have the right to terminate the settlement agreement payment if greater than 5% of the claims in the settlement pool elect to opt out of the settlement. No funding of any individual plaintiff settlement will occur until the 95% opt-in requirement has been met or waived.

The approximately 1,300 claims covered by the metal-on-metal settlement agreement represent approximately 85% of the known US revision claims that do not have potential statute of limitations issues.

There are a significant number of claims that are not included in the settlement agreement, and here is some additional color on those claims. As of September 25, 2016, we estimate there were approximately 700 non-revision claims and approximately 300 revision claims, with possible statute of limitation issues. Of the remaining approximately 250 US revision claims, there were approximately 200 revision claims with implant durations of more than eight years; approximately 20 revision claims that would be eligible for inclusion in the settlement, but for the participation limitations contained in the settlement agreement; and approximately 30 revision claims pending in US courts other than the multi-district litigation, or MDL, and the Judicial Council Coordination Proceedings, or JCCP.

From an accrual standpoint, in Q2 we reported a range of probable loss to settle a substantial portion of the revision claims of $150 million to $198 million; and in accordance with GAAP, recognized as a charge within discontinued operations in the second quarter of 2016; the $150 million low end of the range of probable loss to resolve these matters.

The final resolution we announced today was right in line with our range. As GAAP required us to book the low end of the range in Q2, we are now recording a charge of $30 million to bring the total accrual in-line with the final agreement.

Additionally, we accrued approximately $9 million for claims that would be eligible to be included in the settlement, except for the participation limitations in the agreement, or because they are pending in US courts outside the MDL or JCCP. We are unable to estimate and, therefore, have not accrued any amounts for the US revision claims that have possible statute of limitations issues or have implant durations of greater than eight years.

From a cash standpoint, we have agreed to escrow $150 million within 30 days of signing the master settlement agreement. From a conservative timing standpoint, you can model the entire $240 million associated with the master settlement agreement to be paid by the end of 2017.

The actual amount will be impacted by, among other things, the amount of opt-outs and when those are ultimately resolved. We do expect to incur additional cost to resolve the revision claims that are excluded from the master settlement agreement, and we expect that there will be future revision claims. We are unable to estimate all those costs at this time. However, we do not anticipate incurring material near-term cash costs related to those items. We also continue to pursue additional insurance proceeds from the remaining three carriers.

We still anticipate turning consistently cash flow positive in the first half of 2017; and that, combined with our cash on hand, we believe will be sufficient to fund the settlement, pay the potential $45 million of AUGMENT revenue milestone payment, and grow our business. We also continue to evaluate our options for a line of credit to provide additional operational flexibility.

I will now discuss our updated 2016 full-year guidance. Consistent with Wright's past practice, please note that our guidance ranges and assumptions for 2016 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 will 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.

As stated in today's press release, we are maintaining the existing midpoint of our net sales guidance for 2016, but narrowing the range to $677 million to $683 million. This guidance assumes dis-synergies of approximately $15 million for full-year 2016. This dis-synergy expectation is in line with the underlying assumptions we used when we raised our revenue guidance in Q2.

From a currency standpoint, rates have deteriorated fairly meaningfully in recent weeks, and this guidance assumes Q4 rates generally in line with current rates.

This full-year net sales guidance range is almost $20 million higher than our original guidance range for the year, adjusted for the impact of moving large joints to discontinued operations. This projected over-performance to our original guidance is driven by both lower-than-anticipated revenue dis-synergies in fiscal 2016, and by over-performance in the underlying business.

One quick reminder as it relates to the Q4 growth rate implied by this guidance. In Q4 of 2015, the Wright legacy business had four fewer days as a result of conforming to legacy Tornier's 4-4-5 calendar. Also in Q4 of 2015, the legacy Wright business benefited as a result of conforming the two companies' revenue recognition policies. On an apples-to-apples basis, our guidance implies a small deceleration in the Q4 top-line growth rate as compared to Q3, as we hit peak dis-synergies and we annualize the launch of AUGMENT.

For full-year adjusted EBITDA, today we are increasing our outlook to be in the range of $43 million to $48 million. This increase to adjusted EBITDA is driven by the year-to-date performance and our ability to capture synergies earlier and at a greater level than anticipated.

This full-year adjusted EBITDA guidance assumes cost synergies approaching $25 million for the full-year 2016. This adjusted EBITDA guidance is approximately $25 million higher than our original guidance for the year, adjusted for the impact of moving large joints to discontinued operations; and, at the midpoint, applies approximately 800 basis points of adjusted EBITDA margin expansion as compared to full-year 2015.

The Company estimates approximately 103 million diluted weighted average ordinary shares outstanding for fiscal year 2016.

Entering the year, we faced a wide range of potential outcomes for our financial performance, including the impact of salesforce integrations, ability to execute on cost synergies, and our ability to execute and drive growth in the underlying business, while dealing with a very large volume of work and potential distraction of merging to similar-sized companies.

Through the strong integration of our integration plan and the hard work and dedication of our people, we have been able to significantly mitigate those risks, resulting in the strong financial over-performance we've seen year-to-date.

One year post- the merger, our integration work is not complete, and we still have considerable opportunities that can be realized. However, we believe the integration has been dramatically de-risked from where we were a year ago.

The last item I would like to cover is some directional comments on 2017. As is our normal mode of operation, we will provide formal 2017 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 2017 models.

First, we continue to expect strong sales growth in the underlying business. We expect the extremities and biologics markets to continue to be high-growth. We have differentiated products and focused salesforce in all three areas of our business, and we have additional important new products that we expect to come to market in 2017. We believe this will allow us to continue to grow the underlying business at rates that are above market.

From a dis-synergy standpoint, as I stated earlier, we expect the full annualized impact in 2017 to be approximately $25 million, which is an incremental headwind of roughly $10 million in 2017 as compared to the $15 million that will impact 2016. From a growth rate standpoint, the dis-synergies will have a much greater impact on the first half of 2017.

In addition, as part of the agreement to divest the US Salto ankle business, the buyer has the option to purchase the international Salto ankle business in the second quarter of 2017. We expect that the buyer will exercise that option, which will create an additional revenue headwind of approximately $3 million to $4 million in 2017.

From an adjusted EBITDA perspective, we expect to continue to drive significant leverage and additional cost synergies. We still expect to realize $40 million to $45 million of cost synergies by year three, post-close. The $25 million of cost synergies in 2016 is more than we anticipated, and over halfway to our year-three goal.

Also, we don't expect to get all the way to our $40 million to $45 million goal in 2017. Therefore, the year-over-year benefit from cost synergies in 2017 will be less than the $25 million benefit we expect in 2016. As a result, we still anticipate great adjusted EBITDA margin expansion in 2017, but certainly less than we are seeing in 2016.

In closing, we are pleased with our third-quarter results and believe we have a great plan to drive sales, improve profitability, and improve the underlying operations of the business as we exit the year and move into 2017.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). Travis Steed, Bank of America.

Travis Steed - *BofA Merrill Lynch - Analyst*

Just wondered if you could elaborate a little more on your 2017 comments. Help us understand how we should think about the path to your 20% EBITDA margin. Should we think about it as fairly linear? So would somewhere around $100 million EBITDA next year be a reasonable assumption?

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

Travis, we're not getting that specific on 2017. We gave you some directional comments on the path to the 20%. There were some specific comments about the year-over-year benefit from cost synergies will be less in 2017 than they were in 2016, and that will result in less adjusted EBITDA margin expansion in 2017 than 2016. You can do the math on that off-line, but I think that would not get you to $100 million of EBITDA in 2017. But that's about all the detail that we're going to provide today.

Travis Steed - *BofA Merrill Lynch - Analyst*

Okay. And then the remaining 15% of cases that weren't included in today's settlement, how should we think about that? Will they play out over time, or will there be another settlement down the road?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

You're talking about the 15% of the revision cases that were not included?

Travis Steed - *BofA Merrill Lynch - Analyst*

Yes.

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Those will play out over time. The opt-in rate is at 95%, so there's part of that there. And also we -- there are some cases pending in state courts that are not included in the MDL. So I think that -- we will see those play out over time. But the settlement gets us really far down the road in terms of the revision cases. It covers 85% of the revision cases, so it's a long way to get everything done.

Travis Steed - *BofA Merrill Lynch - Analyst*

Okay. Thank you.

Operator

Joanne Wuensch, BMO capital.

Joanne Wuensch - *BMO Capital Markets - Analyst*

I just want to confirm, or I should get my head around -- are we now calling this largely done, the litigation moment? Or should we expect additional updates on future calls?

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

Joanne -- and we highlighted the things that weren't included in the litigation. Those revision cases will have to be dealt with over time. We do expect there will be future revisions, to some degree, that will result in future claims. And then we'll have to deal with those as well.

So yes; I think you should expect -- I don't know if we'll address it on the call specifically. But certainly in our quarterly results and in our 10-Q, there will be further updates as we move through the rest of these things that have to be addressed.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Okay. Thank you for that clarification. As my second question, could you give us a little bit of granularity on how AUGMENT sales are doing? Thank you.

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Yes. AUGMENT is doing well, as witnessed by our 45% year-over-year growth rate in our biologics business. We also anniversaried -- I was just reminded of this -- one month of AUGMENT in Q3. So it is doing well from a sales perspective.

Clinically, it's doing spectacularly well. There was a slowdown, I think, in July and August when we -- VAC committee meetings were not held, but they picked up pretty rapidly in September. So the key leading indicators here remain to be VAC committee approvals, as well as training of surgeons. All of that is on schedule. I think AUGMENT is a home run, and will continue to drive our biologics business to very rapid growth.

Joanne Wuensch - *BMO Capital Markets - Analyst*

Thank you, and very nice quarter.

Operator

Larry Biegelsen, Wells Fargo.

Larry Biegelsen - *Wells Fargo Securities, LLC - Analyst*

Lance, maybe could you help us understand the Q4 guidance a little bit? Our math suggests it's 5% to 9% reported, but there's a few different things going on here.

So FX, Lance, how much -- what's the impact in Q4? The additional selling days that you have this year versus -- you talked about an offsetting benefit last year. I wasn't clear on what the net impact is this year.

And then assumptions for dis-synergies, it sounds like you are expecting it to be a little bit softer quarter, Q4, because of additional dis-synergies. But just help us -- all those pieces -- the 5% to 9% we're seeing as the reported number, what is that when you adjust for all these moving parts?

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

Yes. There are a lot of moving parts, Larry, in the days and the revenue recognition. Those are things that we went into some detail on in Q4 of last year. So there is information out there on how that impact is, if you want to spend time on that later off-line.

Really when you add all those things together, what we're saying is our guidance, on an apples-to-apples basis, is for a slight deceleration from what we saw in Q3.

And that's really driven by two things; dis-synergies we expect to hit their peak levels in Q4, so it's a little bit of an increase versus the drag on the growth rate we saw in Q3. And then we will fully anniversary the AUGMENT launch in Q4, which we expect that the growth rate will come down off the great 45% we've been seeing, but it will still be very strong, but will be a deceleration as you annualize that really important launch.

Larry Biegelsen - *Wells Fargo Securities, LLC - Analyst*

Thank you. Bob, there's been just a little bit of concern here in Q3 about a slowdown in some of the med tech end markets and procedure volume. Can you talk a little bit about what you are seeing in the upper and lower extremities markets, from just an end-market demand standpoint?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Yes, I think the markets remain strong, Larry. I'd also point out that as we get to our -- the midpoint of our annual guidance that we've put out there, is that will be, excluding synergies, about 14% growth for the year. So that's pretty good, and represents good markets.

The dis-synergies that we always anticipated and talked about each call -- and I talked about it at your conference, and at other conferences -- were clear to us that they were going to happen mostly in Q3 and in Q4. And that's rolling out pretty much as planned; but in total, less than we had anticipated at the beginning of the year.

So, our end markets in the upper and lower extremities are perhaps better than they are in some of the orthopedic companies. Because I think our markets are intrinsically better in terms of growth than other areas of orthopedic -- other orthopedics are.

So, all in all, this is a pretty good story. And I think that as we get out of this year into next year, we will continue to see a really solid growth rate for our products. And the end markets, I think, still will remain very solid in 2017.

Larry Biegelsen - *Wells Fargo Securities, LLC - Analyst*

Thanks for taking the questions, guys. Very helpful.

Operator

Andrew Hanover, JPMorgan.

Andrew Hanover - *JPMorgan - Analyst*

Bob or Lance, I just wanted to ask in regard to the dis-synergies in the cadence, right? So I thought that -- or we were thinking that third-quarter would be the peak, and then it would come off a little bit in the fourth quarter. Do you mind just going into a little bit more clarity as to what you are seeing on the dis-synergy front?

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

Yes, Andrew. And maybe that was you not understanding exactly how we were thinking about it. But I'd say it's working out exactly how we thought it would. Really we thought by the time we got to this call, we would have clear visibility to where they were going to land. Not necessarily that it would all be in the numbers, but we'd have really good line of sight to where it's going to be. And that's really how it has shaken out. We saw some dis-synergies in Q2; certainly more in Q3; and then we expect a little bit more in Q4.

And then as far as moderating, the dis-synergies really don't -- they don't really moderate until you start annualizing them. They are a drag on the growth rate until you start annualizing them. So, really as we get into the second half of 2017, we'll start to see that stop being a meaningful impact on our growth rate. And we'll be through that, on our as-reported number.

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

I'd add to that, Andrew, is that at the beginning of the year, we had guided towards a dis-synergy number of $25 million to $30 million for the year. So now we're saying it's $15 million, so that's a lot better than we had anticipated. And we also had anticipated that most of them will hit in the second half of the year. There was a little bit -- I remember saying at the end of the Q2 call that we did start to see it. But they mostly are in the third and fourth quarter.

Next year will be different. Next year, the dis-synergies that we have in front of us will be in the first half of the year. And by the second half of the year, it all should be out of the way.

Andrew Hanover - *JPMorgan - Analyst*

Right. And I think the reason why I was asking the question is more to the fact that we were assuming quite a bit of dis-synergies in the third quarter, and it came in a lot better -- probably $4.5 million.

So, going back to Larry's question, maybe see if we can get some more granularity just on the cadence within the quarter, on a month-to-month-basis. July, August was slower, and then there was an uptick in September. That's sort of how it looks like the AUGMENT sales played out, at least the ones that we can see. Why would the volume slow down from that uptick that we saw in September?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

The volume of sales, or the volume of dis-synergies? I'm confusing the two.

Andrew Hanover - *JPMorgan - Analyst*

More of the strength in just markets. So, just the cadence within the quarter -- was it a slow quarter at the beginning of the quarter, and then it picked up towards the end?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Well, yes. July and August are typically slow. And don't forget we're on a 4-4-5 schedule. So September is always going to be larger because of the extra week of sales. But I do think that our business picked up pretty significantly in general in September as opposed to July and August.

Andrew Hanover - *JPMorgan - Analyst*

Thank you.

Operator

Chris Pasquale, Guggenheim.

Chris Pasquale - *Guggenheim Securities LLC - Analyst*

Lance, about $3 million to $4 million you called out for next year for the potential loss of the o-US Salto business -- is that the annualized impact or the actual impact if you were to lose half of your sales next year?

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

That's the actual impact that we would expect to occur, assuming that the option gets exercised at the point it can.

Chris Pasquale - *Guggenheim Securities LLC - Analyst*

Okay.

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

So the annual number is a little bit bigger than that.

Chris Pasquale - *Guggenheim Securities LLC - Analyst*

Okay. And then you are ahead of schedule on the cost synergy realization; and really have been, since the beginning, tracking ahead of your plan. But you are sticking with the $40 million to $45 million in year three. Why shouldn't that target at least get pulled forward, if not increased, given the progress we've seen so far?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Well, I think that the total amount is still going to be that. We're seeing more of it, quicker, but we won't be all the way through it in 2017. There will be still some to be gained in 2018. But we are ahead of schedule, and certainly would rather be ahead of schedule than behind schedule. So I think that it's playing out pretty well and that it is faster than we had thought, but there will be still some -- we will not be completely done in 2017.

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

To be specific, Chris, basically we are still executing the same plan that we expect to get the same benefits. We've been able to do some of it sooner to get the benefits sooner. But we still expect the full plan to be completed pretty much in line, on the same schedules as we said before. So it's going to take us the same amount of time to get the full $40 million to $45 million benefit.

But we're getting a lot more this year than we thought we would, and so that's great. And I think there's a good chance we are going to be in 2017 ahead of where we originally thought a year ago we'd be in 2017. But I do think it will take us all the way to 2018 to get to the full $40 million to $45 million.

Chris Pasquale - *Guggenheim Securities LLC - Analyst*

Thanks. That's helpful.

Operator

Jeff Johnson, Robert Baird.

Jeff Johnson - *Robert W. Baird & Company - Analyst*

Bob, maybe you answered the question already with your 4-4-5 comment. But when I look at the AUGMENT revenue in September it looks like it was up 35%, 40% sequentially from August, and more than double what we were seeing early part of the year.

So, is there anything in September? Was there a backlog of demand, because some of those fewer meetings maybe over July or August? Or is it (multiple speakers) that September number, and think about that annualized or growing off that, even?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

No, I just think that July and August are slow. They were slow in terms of the total number of surgeries done. Doctors take vacations, et cetera. Then when we get into September, things really pick up. VAC committees started meeting again, trainings take place, cases start to get done; and I think we capitalized on that pretty well at the end of the quarter.

Jeff Johnson - *Robert W. Baird & Company - Analyst*

Okay. So that September number you feel like is a good base to build off then for future quarters?

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

(multiple speakers) You got to take into account the five weeks (multiple speakers).

Jeff Johnson - *Robert W. Baird & Company - Analyst*

Okay, fair enough. And then Lance, or either of you I guess, really, just clarifying maybe some of the numbers around the settlement. So, I want to make sure I understand. The 1,292 patients -- of those, that represents 85% of the revision cases? And you have to have 95% of those 1,292 opt-in for this to be something that you move forward with? Is that how to think about it?

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

Yes, that's basically correct. Yes, the 1,292 in the settlement, 95% have to opt in; or we can, at our discretion, either stop the payment or waive the requirement. That's up to us. And that settlement covers 85% of the known revision cases that don't have questions regarding statute of limitations.

Jeff Johnson - *Robert W. Baird & Company - Analyst*

Okay. So another way to say that is there could be 300 to 400 -- and I know you have some other numbers in that press release -- but several hundred other of those cases that have not opted in. And those are the ones we have to look at, or monitor, as far as the onsie-twosies coming out over the next couple of years, potentially, in individual litigation?

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

Yes. So the ones that aren't subject to the settlement, we will have to address those over time. Those were not in the settlement because we view them very differently than the claims that are in the settlement. And we will have to deal with those. Additionally, there will be some future revisions, as well, that could result in future claims.

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

A large number of the ones that aren't part of the settlement are non-revision cases. So, without getting into a lot of detail about that, those are ones that probably have little or -- we don't know how to value those, because the ones that have always been settled by us -- had been cases that have been revised. So, there's a large number of those that are non-revision cases that we will continue to monitor. They are still cases, but should be very manageable, we think.

Jeff Johnson - *Robert W. Baird & Company - Analyst*

Okay. And I'm sorry, last clarifying question on that, then: out of those cases that are not in the settlement, it sounds like you were saying that was your choice that they are not in the settlement. But are some of these cases of people who think, no, I've got a better case; I'm not going to join the settlement at an average of $185,000 or whatever it is? I'm going to go after these guys for more.

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

No, I think the 95% opt-in rate is a really high opt-in rate. So that -- we were happy to get that. And the ones that do opt out, those are valid cases that may or may not have higher value to them; it depends on the particulars of those cases. But 95% opt-in rate we felt was pretty good.

Jeff Johnson - *Robert W. Baird & Company - Analyst*

All right. Thank you, guys.

Operator

Matt Miksic, UBS.

Matt Miksic - *UBS - Analyst*

So, maybe shifting gears to the end markets, and some of the products that you have launched and are launching there. Can you talk a little bit about where in the product launches you are seeing some of the greatest traction? And then I have one follow-up.

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

I think the SIMPLICITI shoulder system is a real home run, Matt. We're leaders. We've launched this product well -- years probably in ahead of competition. And so that still is a high-growth market. It cannibalizes some of our other shoulder business, quite frankly, but it's at a 60% higher ASP. So it's a good story. Obviously AUGMENT Total Ankle, INFINITY, are all meaningful products that we have launched either this year or within the last two years.

We have a great pipeline of new products, both in lower and upper, that we will be launching as early as the first half of 2017. That will give us additional distance between us and our competitors, both in the lower extremity and in the upper extremity. So it's a robust pipeline of products.

Matt Miksic - *UBS - Analyst*

And then the follow-up on total ankle -- and Bob, I've been jumping back and forth here between calls and I'm on the road, so I apologize if someone has asked this already. But can you talk a little bit about -- you had talked before about how much runway that that product and that category has in front of it. Education has been an issue. Confidence in doing the procedure for some surgeons, new surgeons, have been an issue. Can you talk a little bit about where you are on those, and maybe how Augment is playing into that, if at all (multiple speakers)? What are some of the factors there?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

I think that in the -- we are converting fusion cases to total ankle cases all the time. That's a big, important part of our process. We had year-over-year revenue growth in total ankle of 19%. It's actually closer to 20%, when you look at the same day sales average. But we were up against a real tough comp last year, third quarter. I think we grew 54%. So I think that the -- and I've always said that I think that this business will be in a 20% growth area for a pretty good period of time, and still anticipate that.

So, medical education is a big piece of that. The more total ankles that are done -- both by us and our competitors, quite frankly -- are better -- are good for the whole market in that doctors have confidence in these products are pretty good. I think we have leading products.

And the big differentiator between us and anybody else that has a total ankle implant is our enabling technology, PROPHECY. Now, about 70% of our cases involve PROPHECY. What PROPHECY does is provide individual cutting guides so that doctors can more easily do these cases and pre-plan these cases.

The benefits are quicker times to surgery. That benefits the hospital; it benefits the patient; and it benefits the doctors to spend less time in surgery. It also benefits us in that we can better pre-plan the surgery and hopefully take in less inventory, which is always a good thing.

So I think that we're really ahead of the curve. There's a very dynamic, growing part of the extremities business. We have -- we've talked in the past about our revision product, INVISION, that we expect to launch next year in the third quarter. That, we think, will also make doctors more comfortable

in taking on this procedure, given that there's a bona fide bail-out option for them if something goes wrong, or the patient needs revision for any reason.

So I think this is a great story, and it's one of the real underpinnings of our business.

Matt Miksic - *UBS - Analyst*

That's great. Thank you for the color.

Operator

Matthew O'Brien, Piper Jaffray.

Matthew O'Brien - *Piper Jaffray & Company - Analyst*

Just a quick question on AUGMENT. Can you just comment a little bit on the reorder rates you saw in Q3 here, compared to Q2 and Q1, from existing accounts? And then is the way to think about your pull-through opportunity there most likely somewhere into 2017 as you stem what going on with your salesforce in lower extremities? So we should see the benefits of some pull-through revenues to these new accounts more next year and beyond. Thank you.

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Matt, I have to apologize. I have recently heard what the reorder rate was, but I don't -- I forget it, quite frankly. I do know that the reorder rates are very high. We'll have to get to that separately, what the exact numbers. But I did have a presentation on this perhaps three or four weeks ago, and I just forgot. I don't remember the number.

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

And Matt, I think the other part of your question was ability to further penetrate new AUGMENT accounts with our foot and ankle hardware, and when do we think we would see that? We have continued to open new accounts, and we are making some progress. But I think, yes, that's probably going to be on to 2017 before we can get any kind of meaningful benefit from that. But that is definitely an opportunity that AUGMENT brings, as well.

Operator

(Operator Instructions). Kaila Krum, William Blair.

Kaila Krum - *William Blair & Company - Analyst*

So, without getting into too much detail around 2017 revenues, but you reiterated your expectation to be a mid-teens grower. And then I imagine there would be an incremental $10 million in revenue dis-synergies. So just -- is the right way to think about 2017 is that you all would have been delivering 15% growth next year, and those dis-synergies will reduce that growth rate down to something around 13.5%?

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

Yes, Kaila, I think we weren't being that -- trying to be that precise with our comments. I think at a high level, what you can think about is the incremental dis-synergy impact in 2017, plus the headwind from the likely loss of the international Salto business. Is that headwind is going to be very similar to the headwind that we had this year for dis-synergies, and so that's a similar kind of thing year-over-year. And you know the kind of growth that we're posting this year, so that's really probably as detailed as we're going to get, at this point in time.

Kaila Krum - *William Blair & Company - Analyst*

Okay. And then just on the upper extremity side of the business, can you just talk a little bit more about the integration process and what additional steps we still have to take from here?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

The upper extremity salesforce in the US was totally integrated -- completed in Q3. We had originally thought that would go into Q4, but that was completed. Basically, it was not as complex an integration as the lower extremity business; in that there were hand, wrist, and elbow products that were simply handed over to the upper extremity salesforce. And we didn't have those conflicts -- in general, there were a few -- that we did in the lower extremity, where reps were competing against one another. And one stayed, and one went and took their customer with us. So we haven't seen that to any great extent. So I think that the upper extremity integration is behind us. There is some dis-synergies attached to us, but nowhere near the amount nor the complexity that we saw in the lower business.

Kaila Krum - *William Blair & Company - Analyst*

Got it. Okay, that's helpful. Thanks, guys.

Operator

Rich Newitter, Leerink.

Unidentified Participant

It's actually Robbie here. Just a quick one on profitability drivers. I was hoping you could remind us, just again, what are your levers next year as we think about 2017 EBITDA for profitability growth? Just if you could remind us, number one, what your cost synergy assumptions are for the full-year 2017, and what kind of underlying leverage growth in the organic business that you are seeing; and any sort of contribution from AUGMENT, and how that all builds together to drive the margin expansion story that we're seeing. Thanks.

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

Sure. So, we haven't laid out point-blank 2017 expectations for those numbers. But a couple of things: we expect cost synergies in 2016 approaching $25 million, and we've said we still expect $40 million to $45 million by year three. And we don't expect to get all the way there next year.

So that pretty much means we're going to have less year-over-year benefit from cost synergies in 2017 than we did 2016. We still expect to have good growth. And we still expect to have a great opportunity to drive leverage in SG&A. And may also have some gross margin expansion opportunities, although I'd say at 78% to 78.5%, it is getting pretty high up there at this point.

So, those are the ingredients. We still expect to have really strong EBITDA margin expansion in 2017, although I think the amount of expansion will be less than what we're going to see in 2016.

Unidentified Participant

Great. Thanks, Lance.

Operator

Mike Matson, Needham & Company.

Mike Matson - *Needham & Company - Analyst*

I think at time that you guys did the Tornier deal, you had set a longer-term EBITDA margin target of around 20%. I think it was within three years, but that may not be right. But just given the trajectory of your margins here, I'm wondering if that -- if that still stands, or you think you can do better than that?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Well, what we set out -- we have three financial metrics that we said that were a rationale for the merger. One was that we felt we could be a mid-teens growth company. I think when you -- we are there now (technical difficulty) without dis-synergies. Secondly, we'd be a high-70% margin company, and we're there. And then we would be a 20% EBITDA company in 3 to 4 years, post-merger.

So, this year was a better year for EBITDA than we had anticipated. And generally, of course, we got our cost synergies a little bit faster than we had originally planned. And next year, there should be less cost synergies to get.

But we still have a tremendous amount of leverage that we think we get a great deal of sales drop-through for incremental sales, and that our expense base doesn't need to grow dollar-for-dollar. So we can get a lot of leverage. So I think that we will keep on looking at this, but we're not saying anything different than what we originally said on those three metrics. They are still intact: 20% in 3 to 4 years. We're a little bit ahead of that now. And hopefully we can maintain that, but we're not calling for anything different as of now.

Mike Matson - *Needham & Company - Analyst*

Okay, thanks. And then you commented on the plans to try to get the injectable version of AUGMENT approved. So, I understand you probably can't comment on what that pathway is going to look like right now, or the timing. But just wondering, from a market perspective, what does having an injectable version really do for you? Is that something that's really going to help drive more adoption of the product?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Yes, we're certainly not going to get into that nightmare of conversation about when AUGMENT is going to get it approved again. So I'm not going to comment on that. But the injectable form of AUGMENT, which we have launched in Australia and Canada, was a big driver of growth. We expect that will be the same way here.

It can be used in more cases. It's easier and faster to use. So we expect that not only will our existing customers use more; new customers are going to be more apt to use it because it's much easier to use.

Mike Matson - *Needham & Company - Analyst*

All right. Thanks a lot.

Operator

Matt Taylor, Barclays.

Matt Taylor - *Barclays Capital - Analyst*

In thinking about your growth now, that you've gone through this period where you've had the dis-synergies largely behind you or figured out, can you talk about your plans for expanding distribution? And I'm really thinking here around how much of your sales growth is going to come from increased productivity versus salesforce additions. Can you help us understand that?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Well, I think there's a combination of both. I think that in both the lower and upper extremities businesses, we have opportunities in both areas. We are -- I mentioned in my prepared remarks that we are moving the upper extremities products into the distribution system that we have for lower -- the hub system. When we did that in the lower extremities business, not only did we get better control over our inventory, but it had a dramatic effect on salesforce productivity.

Salesforce productivity in the upper business is about $600,000 per rep. In the lower business, it's about $1.2 million. Now, as our business expands, we do not want to get more than $1.2 million in the lower business. So as our business grows -- is that we will, by necessity, be having to add more reps.

In the upper business, however, I think that there's a lot of room. There might be some opportunity that what we would need more reps. But there's a great opportunity by getting the reps out of the business of inventory management, which they spend a lot of time in, and getting them more in the business of selling and servicing customers, that we could see a similar type of productivity in the upper extremity business as we see in the lower extremity business.

So I think both things are opportunities for us.

Matt Taylor - *Barclays Capital - Analyst*

So just as a follow-up, I guess if I understand your comments correctly, then if you are at or near your target for lower rep productivity, does that mean essentially the mid-teens growth that you are projecting via the mid-teens rate of hiring or additions in that channel?

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

I don't have the -- I can tell you we have a project underway to study that. We haven't finalized what that is. I don't think it's necessarily a 1 by 1 combination. But I do think that the lower business is at its maximum capacity right now, in terms of productivity; and that as the business grows, we will need to add more reps.

Lance Berry - *Wright Medical Group N.V. - SVP and CFO*

The other thing, Matt, I'd say in the lower business at the sales per rep level -- the productivity levels we have now, it's a lot easier to add reps and still get really good leverage, as long as those reps are productive and drive growth. So, that's another part of that is -- it's easier to look at that now with the productivity levels where they are, as opposed to where they were a couple years ago.

Matt Taylor - *Barclays Capital - Analyst*

Great. Thanks for the time.

Operator

Thank you. This concludes today's Q&A session.

I would now like to turn the call back over to Bob Palmisano for any closing comments.

Bob Palmisano - *Wright Medical Group N.V. - President and CEO*

Thanks, operator, and thank all of you for joining us today. We have multiple opportunities through our robust new product pipeline to further accelerate our growth, continue to expand our markets, and gain market share. One year post-close of the merger with Tornier, we have successfully executed our plans to maximize focus and alignment while minimizing disruption. I believe we are well positioned to continue to accelerate our business momentum and drive market-leading growth and profitability.

I want to express my appreciation to our team for their efforts during the quarter, and for their successful execution of our one-year integration activities. I look forward to updating you on our next 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 concludes the program, and you may now disconnect. Everyone have a great day.
