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West Pharmaceutical Services, Inc. (WST)

Q4 2015 Earnings Call

CORPORATE PARTICIPANTS

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Vice President-Corporate Development & Strategy

Eric M. Green
Chief Executive Officer & Director

William J. Federici
Chief Financial Officer & Senior Vice President

OTHER PARTICIPANTS

Derik De Bruin
Bank of America Merrill Lynch

David Howard Windley
Jefferies LLC

Larry S. Solow
CJS Securities, Inc.

Paul Richard Knight
Janney Montgomery Scott LLC

MANAGEMENT DISCUSSION SECTION

Operator: Good day, ladies and gentlemen and welcome to the West Pharmaceutical Services Fourth Quarter 2015 Earnings Conference Call. At this time, all participant lines are in a listen-only mode to reduce background noise, but later, we will be conducting a question-and-answer session. Instructions will follow at that time. [Operator Instructions] As a reminder, today's conference call is being recorded.

I would now like to introduce your first speaker for today, Quintin Lai, Head of Investor Relations. You have the floor sir.

Quintin John Lai
Vice President-Corporate Development & Strategy

Thank you, Andrew. Good morning and welcome to West's fourth quarter 2015 conference call.

We issued our financial results this morning, and the release has been posted in the Investors Section on the company's website located at www.westpharma.com. This morning, CEO, Eric Green and CFO, Bill Federici will review our fourth quarter and full year 2015 results, will provide an update on our business and recent organizational realignment and will provide a financial outlook and expectations for the full year 2016. There is a slide presentation that accompanies today's conference call and a copy of that presentation is also available on the Investors section of our website.

On slide two is the Safe Harbor statement. Statements made by management on this call and in the presentation will contain forward-looking statements within the meaning of the U.S. Federal Securities Law and that are based on management's beliefs and assumptions, current expectations, estimates and forecasts. Many of the factors that will determine the company's future results are beyond the ability of the company to control or predict. These statements are subject to known or unknown risks or uncertainties, and therefore actual results could differ materially from past results and those expressed or implied in any forward-looking statement.

For a non-exclusive list of factors that could cause actual results to differ from expectations, please refer to today's press release as well as any further disclosures the company makes on related subjects in the Company's 10-K, 10-Q and 8-K reports.

In addition, during today's call, management will make reference to non-GAAP financial measures including sales at constant currency, adjusted operating profit and adjusted diluted EPS. Reconciliations and limitations of the non-GAAP financial measures to the most comparable financial results were prepared in conformity to GAAP are provided in this morning's earnings release.

I now turn over the call to West's CEO and President Eric Green.

Eric M. Green
Chief Executive Officer & Director

Great, thank you Quintin and good morning everyone.

As you saw in this morning's press release, we delivered another solid quarter with overall growth in net sales at constant currency of 9.7%. This reflects strength across the entire company both business units and all geographic regions contributed. In our Packaging Systems business, sales grew nearly 10% constant currency; our high value product portfolio delivered another quarter of double-digit growth. As anticipated, we continued to experience strong demand from our customers for the higher performance FluroTec products ready-to-sterilize and ready-to-use Westar products. We also experienced strong demand with Envision, in our industry leading NovaPure offerings that ensure the highest standards of quality.

In Delivery Systems, sales grew above 9% at constant currency versus the prior quarter and delivering sequential growth as we expected over third quarter of 2015. The growth was driven by demand for diabetes care products including components for insulin pen and glucose monitoring devices. Growth in high-value products and volume driven efficiencies produced 190 basis points of gross margin expansion in the quarter. The related increase in gross profits more than offset $8 million of currency headwinds. This led to Q4 adjusted diluted EPS of $0.47, which was in line with our expectation despite a $0.05 currency headwind. Excluding currency impact, earnings per share would have grown by 16% year-over-year.

The solid fourth quarter capped a successful full-year 2015 as highlighted on slide four, resulting in net sales of $1.4 billion in constant currency sales growth of 7.2%. For the year, we generated adjusted diluted EPS of $1.83, which was in the upper end of the most recent guidance range. This was despite a $0.29 headwind for currency. Excluding that impact, we would have grown adjusted diluted EPS by 19% over 2014.

On slide five, building off a history of success and the strong foundation, in the fourth quarter, we reformulated our long-term strategy to become the world leader in the integrated containment and delivery of injectable medicines.

In order to achieve that, I believe that we need to be more market-focused. And at the start of this year, we realigned our company with that in mind. We formed three functional groups: commercial, global operations, and innovation and technologies. And each one will focus on customer experience, operational excellence and product service differentiation. We have historically managed through two segments each having regional business units. As shown on slide six, the commercial customer facing organization is transitioning to focus on three major market segments globally: pharma, biologics, and generics.

While all three segments are involved in the injectable therapy space, they each have different challenges and needs. We believe we can more effectively deliver a broad proprietary product portfolio by focusing on this particular need in each market from standard to high-value products, delivery devices and our industry-leading contract manufacturing. West is in a unique position to address these market needs with tailored products and service offerings.

Turning to slide seven, the chart provides our relative net sales by category in 2015. Going forward, we are combining our packaging component sales with proprietary devices including reconstitution into the safety system CZ and self-injection devices like SmartDose to form the proprietary product business segment. The proprietary products represent just under 80% of our sales in 2015. Sales and marketing responsibility resides with the new commercial organization. And our industry-leading contract manufacturing segment which represents just under 20% of overall sales will become a new standalone reportable business segment, also under the leadership of the commercial organization.

Critical to our long term strategy is the improved coordination in our global operations and supply chain as noted on slide eight. To that end, we are combining management of our global capacity in the newly formed global operations organization. With favorable macro trends for injectable therapy, the demand for our products and services, we have expanded and will continue to add to our capacity and capability.

In 2016, we expect to invest between 10% to 12% of sales in capital expenditures. Projects range from the ongoing construction of our new center of excellence in Waterford, Ireland to further expansion of high value component capacity in Kinston, North Carolina and in Singapore. We are convinced that increasing our focus on operational efficiency and excellence will improve productivity, operating leverage and profitability at our sites around the world.

In conjunction with the overall organizational changes, we are optimizing our existing capacity and leveraging our talented workforce. This past week, our Board of Directors approved a restructuring program that will result in a modest reduction in force as we streamline our operations and investments in commercial activities and technologies that will drive growth for the future. Bill will provide more details on the program in a few minutes.

Turning to slide nine, we are continuing to invest in the development of new products and services. Building on the success of our R&D efforts, the newly formed innovation and technology organization will focus on product design and development to push leading edge applications to contain, administer and deliver injectable therapies. These include quality enhancements such as the NovaPure 1 mL and 3 mL syringe plungers, delivery platforms including follow-on generations of the SmartDose wearable injector, and new applications of Daikyo Crystal Zenith technology. We continue to see a high level of interest in our technology platforms as highlighted in last week's announcement that a major biotech customer is using Daikyo CZ vials and West's FluroTec stoppers for its new oncology drug.

Before I hand it over to Bill, I want to conclude by saying that West's outlook is very bright. The fundamental long-term trends remain favorable. We can grow profitably by continuing to meet the unique needs of our customers and managing our quality and costs. We have a talented workforce that is over 7,000 strong that is focused on quality, safety and the needs of our customers.

As we look at 2016, on slide 10, we are reaffirming constant currency sales growth guidance of 6% to 8%. We expect that high value products will lead the way with high single to low double digit growth. Today we provided further 2016 guidance, adding that we expect adjusted EPS of between $2.10 to $2.25 representing 15% to 23% growth over 2015. We will continue to benefit from an improving sales mix and operating efficiencies.

Now, I turn over to Bill Federici, our CFO. Bill?

William J. Federici
Chief Financial Officer & Senior Vice President

Thank you, Eric, and good morning, everyone.

We issued our fourth quarter results this morning. Excluding the effects of special items from both periods, fourth quarter 2015 earnings were $0.47 per diluted share versus the $0.45 we earned in Q4 2014. A reconciliation of these non-GAAP measures is provided on slides 17, 18 and 19.

Turning to sales, slide 12 shows the components of our consolidated sales increase. All references to sales amounts are to constant currency. Consolidated fourth quarter sales were $359.7 million, an increase of 9.7% over fourth quarter 2014 sales.

Packaging Systems sales increased by $24.3 million or 9.8% over the same quarter 2014. A favorable sales mix and volume growth accounted for 7.8 percentage points of the increase. Modestly higher selling prices in Packaging Systems contributed the remainder of the increase. High value product sales increased 13.5% versus the prior-year quarter. For the full year 2015, high value product sales increased 14.8% versus 2014.

Delivery Systems sales increased $9.5 million or 9.2% over sales in the prior-year quarter. The sales increase was driven by our contact manufacturing business. Fourth quarter sales of proprietary products decreased by $1.6 million and were 23.7% of the segment's revenues in the quarter. CZ sales and development activity were approximately $3.7 million, and SmartDose sample sales were $1.9 million in Q4. On a full-year basis, total 2015 proprietary product sales declined by $2.5 million versus 2014 and represent 24.7% of Delivery Systems segment sales.

As provided on slide 13, our Q4 2015 consolidated gross profit margin was 33.3% versus the 31.4% margin we achieved in the fourth quarter of 2014. Packaging Systems fourth quarter gross margin of 38.5% is 2.3 margin points higher than the 36.2% achieved in the fourth quarter of 2014. The favorable mix and volume of products sold, modest sales price increases, and continued lean savings and plant efficiencies more than offset the impact of higher general inflationary costs. Delivery Systems fourth quarter gross margin of 21.1% was 1.5 margin points higher than the prior-year quarter. The higher margin was mainly due to a favorable sales mix and greater capacity utilization in contract manufacturing versus the prior-year quarter.

As reflected on slide 14, Q4 2014 (sic) [2015] (14:21) consolidated SG&A expense increased by $3.6 million compared to the prior-year quarter. The increase is due primarily to higher estimated achievement levels on incentive comp programs and annual merit increases. As a percentage of sales, Q4 2015 SG&A expense was six tenths of a percentage point more than the prior-year period.

Slide 15 shows our key cash flow metrics. Operating cash flow was $202 million for the full year of 2015, $30 million more than 2014 due primarily to our strong operating results and lower working capital requirements. Capital additions of roughly $131 million were made in 2015. Roughly half of the capital spend was on new products and expansion efforts including approximately $27 million in Waterford.

We expect capital additions of between $150 million and $175 million in 2016, including approximately $60 million of costs associated with the New Ireland facility.

Slide 15 also provides the summary balance sheet information. Our balance sheet continues to be strong and we are confident that our business will provide necessary future liquidity. Our cash balance at year-end was $275 million, $20 million higher than our December 2014 balance. Roughly half of the cash is invested overseas and is generally not available for repatriation without tax consequences. However, we repatriated $120 million of overseas cash during the second half of 2015.

Debt at year-end was $298 million, $37 million less than at the prior-year end. Our net debt-to-total-invested capital ratio at year-end was 2.3%, a significant improvement from the prior-year end ratio of 7.7%. Working capital totaled $359 million at year-end, $47 million less than the prior-year end. Our higher cash balances were partially offset by the reclassification to short-term of our $70 million euro note B debt maturing later this month.

Our backlog of committed PPS orders remained strong at $413 million as of December 2015, which is approximately 29% higher than our December 2014 balances, excluding exchange. Demand-driven extended lead-times for certain high-value products continue to result in advanced customer orders, which inflate our backlog. We expect actions taken to increase capacity and throughput will reduce those lead-times and relieve the backlog in the third quarter of 2016. We have issued our full year 2016 guidance in this morning's release. The guidance is summarized on slide 16.

Our guidance is based on an exchange rate of $1.12 per euro. Our actual 2015 results are translated at $1.11 per euro rate. While exchange rates will continue to be a headwind throughout 2016, we expect the euro headwind will be less than the 15% devaluation experienced during 2015. However, currency volatility is high and Asian and emerging markets' currencies are creating added headwinds to the business in 2016.

We expect our 2016 effective tax rate to be approximately 28.5% versus the 27% ETR we experienced in 2015. Our tax rate is highly dependent on a geographic mix of earnings, which is driven by sales of high value products as we're migrating towards higher tax jurisdictions like the U.S., which has an adverse effect on our tax rate. Our guidance includes a $0.02 EPS benefit, resulting from our previously announced 700,000 share repurchase plan, which is intended to maintain a neutral share count.

We expect a strong start to 2016 with Q1 EPS growth of between 8% and 15% versus the prior year quarter. We expect to deliver on our full-year earnings guidance of $2.10 to $2.25 per diluted share, which on a constant currency basis, represents an increase of between 15% and 23% in diluted EPS over 2015. That guidance excludes the 2016 restructuring plan charge we announced this morning, which will result in a reduction of force of approximately 1% to 2% of global employees to meet our new market focused commercial organization.

The restructuring charge is expected to range from $23 million to $28 million and will be recognized over the next 12 months to 24 months. We expect 2016's savings of $4 million to $6 million, which is included in our 2016 guidance. Annual savings of $8 million to $10 million are expected as a result of the restructuring. Furthermore, beginning in 2016, we will realign our external reporting to reflect our new organization.

Our two external reporting segments will be proprietary products and contract manufacturing products. We will also provide sales data on our three key market groups: Biologics, Generics and Pharma. We expect that in advance of our Q1 earnings call, we will provide a historical results bridge from our previous reporting segment to our new reporting segment. At that same time, we expect to provide a guidance bridge between old and new reporting segments.

I'd now like to turn the call back over to Eric Green. Eric?

Eric M. Green
Chief Executive Officer & Director

Great. Thank you, Bill.

In summary, we delivered a solid quarter, which capped off a strong year. We are moving into 2016 with momentum and making progress, executing our growth strategy to become the leader in integrated containment and delivery of injectable medicine. I want to invite you to join the leadership team at our Investor Day on March 10 in New York City.

Operator, we are ready to take the questions. Thank you.

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] Our first question comes from the line of Derik De Bruin from Bank of America. Your line is open.

Derik De Bruin
Bank of America Merrill Lynch

Q

Hi, good morning.

William J. Federici
Chief Financial Officer & Senior Vice President

A

Hi Derik.

Eric M. Green
Chief Executive Officer & Director

A

Good morning, Derik.

Derik De Bruin
Bank of America Merrill Lynch

Q

Hey, sort of going through your press release, getting some questions on your actions around the Venezuelan currencies and so could you talk a little bit about that and the size of that business and sort of what your expectations are for Venezuela and I guess the decision why you're treating it like it is, why you're doing the treatment this way?

William J. Federici
Chief Financial Officer & Senior Vice President

A

Okay. So let me answer your questions in order.

So sales are roughly $10 million annually, Derik, not a big number, and our operating profit off of those sales is a little over $1 million annually. In terms of the where we are, where we are, we have been using the official exchange rate of 6.3 for medical device and pharmaceutical companies, which is the one mandated by law and we have been transacting at that rate through 2015. Obviously, they announced a devaluation to an official rate of 10 going forward. That will impact us to a certain extent, but we will continue to not recognize the full impact of a devaluation to the unofficial rates that you see that are being used to transact since we'll be at that – required to transact at that rate.

We do have exposure in terms of our monetary assets of about $2 million. So when we look at our ability to get dollars out of the country, if we continue to experience delays in receiving dollars out of the country despite the fact that they've told us that we can transact at an official exchange rate of 10, we will most likely end up writing off those monetary assets. Again, rough number is about $2 million. If we were to take out the entire operations over there which is what we've disclosed in the release, that number would be somewhere in the range of $7 million to $8 million.

Derik De Bruin
Bank of America Merrill Lynch

Q

Got it, thanks. That's helpful. So could you talk a little bit about some of the expectations in terms of capacity builds, I mean I know you're adding things and you're doing that. I guess is there an issue that you may not have enough capacity to sort of meet demand in 2016? I'm just sort of – just want to know what sort of the pluses and minuses are to your organic revenue growth guidance around timing.

Eric M. Green
Chief Executive Officer & Director

A

Yes. I'm going to first start with this Derik and then turn over to Bill on some of the guidance.

When you look at the capacity and actually I just came back from Jersey Shore and Kinston to see the plants firsthand. Jersey Shore capacity has been running pretty much almost all out because of the demand has increased quite nicely with our high-value product portfolio. I can assure you that the lean efforts that are going on at Jersey Shore is increasing productivity on a per-hour basis, so that's very positive.

When we look at capacity expansion that we've completed in Kinston, North Carolina, that has been validated and so we're working with other customers that continue to divert orders from Jersey Shore to Kinston, North Carolina to start offsetting some of that pressure. But the demand that you've seen in the backlog is the combination absolutely of increased demand from our customers but also still the fact that we have to get it through the system.

William J. Federici
Chief Financial Officer & Senior Vice President

A

So, I think just to add, agree with Eric said, we have enough capacity to be able to meet our customer demands today. We do have certain bottlenecks in the operations especially for our high-value products. We've done some work, some lean activities in those affected plants to be able to increase the capacity going through those plants, and we've seen the benefits of that at the very end of 2015 and certainly are seeing it in 2016 to begin with.

Eric mentioned the Kinston facility and additional capacity there to help process some of those high-value product orders. So we believe we're okay, it is very tight, Derik, and will continue to be tight but we believe that the actions that we've taken are actually helping with that tightness and we believe that we'll actually start to see the backlog come down probably in and around the third quarter timeframe of 2016.

Derik De Bruin
Bank of America Merrill Lynch

Q

Great. I'll get back in the queue.

William J. Federici
Chief Financial Officer & Senior Vice President

A

Thank you, Derik.

Eric M. Green
Chief Executive Officer & Director

A

Thanks Derik.

Operator: Thank you. Our next question comes from the line of Dave Windley from Jefferies. Your line is open.

David Howard Windley
Jefferies LLC

Q

Hi, good morning. A follow-up on Derik's question; so, in identifying these bottlenecks, Bill, that you just referred to, is it the increased demand and the stress on the system that has brought these bottlenecks to light or is this a result of some of the capacity reorganization, creation of centers of excellence and maybe moving things around that has caused the bottlenecks to occur?

Eric M. Green
Chief Executive Officer & Director

A

Yes, Dave, this is Eric.

There's two elements that we are seeing. One is there is a true increase in demand that we are seeing both from the biologics customers but also we are seeing an increase with our generics customers and they tend to come in at larger volumes and shorter terms. So therefore that's one of the issues that we face in the latter half of 2015 that created some of the bottlenecks that we are experiencing today. So it is a little bit of uneven of the demand coming in, but it is also due to the demand that we're seeing with the biologics customers.

I would not contribute this to any network optimization that we are working on. In fact, I believe the approach that we're taking is really with new sites, new capacity, it's with new orders coming onboard. So it's not creating a bottleneck for us.

David Howard Windley
Jefferies LLC

Q

Okay. And I wanted to – my next question is around your segments and groups. So as I read the press release, I was a little confused by the identification of the groups, but those are not – and those sound like your sales organization, your kind of – your direct cost line, your manufacturing production capacity and your R&D organization is what it sounds like those groups are to me and so I was a little confused about how you would have revenue to report in global ops and innovation and technology, but the answer is you're not going to report segment along those lines, rather your reporting segments will be proprietary products and contract manufacturing. So first of all, is that correct? Is my understanding correct there?

Eric M. Green
Chief Executive Officer & Director

A

Absolutely correct.

David Howard Windley
Jefferies LLC

Q

Okay. And then secondly, you did mention I think reporting or maybe you're only discussing some KPIs around the three groups. What will those be? What will you be telling us about the three groups going forward?

Eric M. Green
Chief Executive Officer & Director

A

Yes, so that's a great question. So when we look at the commercial organization, we are really breaking up into four areas. Three of them are around our customer segments of biologics, pharma, and generics. So you will have – we will give visibility of the size and the growth we are experiencing within those three customer segments. The fourth one we are keeping contract manufacturing contained and we will continue to report that as a standalone entity going forward.

David Howard Windley
Jefferies LLC

Q

Okay. So you will report that in commercial, and then will there be anything to tell us about the other two groups or not necessarily?

Eric M. Green
Chief Executive Officer & Director

A

We'll give you updates and then give you visibility on our cost of our operating manufacturing; really that's going to drive our gross margin expansion and outflow and R&D is clear line of R&D investment, and we'll give you visibility of new products being launched as we introduce them into the marketplace.

David Howard Windley
Jefferies LLC

Q

Okay. I'll ask one more and drop back in, if I could. So I think in the past you have talked to us about contractual arrangements for supply of the inputs to your rubber components, and I'm wondering what the precipitous drop in the price of oil does to your supply costs. How much of that comes up for renewal in a given year, for example, how much of that can you affect?

William J. Federici
Chief Financial Officer & Senior Vice President

A

Yes. Dave, the way to think about it is that there has been a drop in the underlying commodity, but if you remember the way our supply contracts work, we have a delay into when that commodity price fits our orders, i.e. our inventory and then when that goes to our P&L, it's generally a four- to six-month delay.

On the sales side, we have contracts with customers that are multiyear contracts with customers and they allow us to, based on a basket of goods, either CPI or PPI, allow us to increase prices based on the last 12 months of activity in those underlying commodities and labor et cetera. So there is a muting effect or a hedging effect on the input cost and on the – our ability to catch that in raising prices or declining prices as it may be.

So the effect is muted. It's not as strong as the reduction that you see in the underlying commodity. We have baked into our budget that we will – that the commodities are roughly in a standard state about $45 per barrel into our budget. So we've already taken that into our guidance. So if it remains at that $30 versus $45, it's not a

$35 versus $45 based on this morning. It's Brent not West Texas by the way, that's the underlying reference commodity. That would not be a significant difference from where we have guidance today.

David Howard Windley
Jefferies LLC
Q

Okay. And would you be able to quantify what margin impact that slight change within 2016 has on guidance? Can you do that or is that too-?

Eric M. Green
Chief Executive Officer & Director
A

It's pretty small, Dave, order of magnitude of couple of cents.

David Howard Windley
Jefferies LLC
Q

Okay, all right. Thank you.

Eric M. Green
Chief Executive Officer & Director
A

You are welcome, Dave.

Operator: Thank you. Our next question from the line of Larry Solow from CJS Securities. Your line is open.

Larry S. Solow
CJS Securities, Inc.
Q

Hi, good morning guys.

Eric M. Green
Chief Executive Officer & Director
A

Good morning, Larry.

William J. Federici
Chief Financial Officer & Senior Vice President
A

Hi, Larry.

Larry S. Solow
CJS Securities, Inc.
Q

Just a couple of questions on just gross margin in the quarter and more importantly on the outlook; in Packaging Systems, obviously you had a very solid year and I think margin was up close to 200 bps on a gross level. Clearly that's being driven by the high-value products. But what prevents – the high-value packaging components, what prevents this number from rising similar or maybe modestly below last year's rate but above what your guidance implies?

William J. Federici
Chief Financial Officer & Senior Vice President
A

Yes, I mean, as you know, the growth that we've seen in the high-value products has been a little bit more than what we would look at in terms of our long-term growth trajectory for this business. We believe that our high-value products will continue to grow in the high-singles to low-doubles. We've seen it obviously this quarter with 13.5% and for the full year, it was 14%, almost 15%. So that's above the average. And we see this from time to time, Larry, as customers do make inventory adjustments either based on demand or in this case, some of it was in reaction to our extended lead-times and for some of those high-value products.

Larry S. Solow
CJS Securities, Inc.
Q

Right.

William J. Federici
Chief Financial Officer & Senior Vice President
A

So we always come back to looking at this as what is the real underlying growth of the business. We don't think anything has changed in those long-term growth drivers. Eric mentioned that in his comments that would cause us to believe that if anything different than that long-term 5% to 7%, 6% to 8% growth that we expect for the business of which high-value products being in the high-singles to low-doubles.

On the margin line, there is a corollary effect. So we saw a very high percentage increase in the gross margins for PPS, driven as you said by that really strong high-value product growth in the quarter. But when you look at that, again try to normalize it, we have things, we know that that growth will come down, so the margin expansion will come down also. We know we'll have inflationary increases in underlying overheads and labor, and we know that there are additional costs we are adding to the pool. For instance, the work we are doing in Ireland and elsewhere to increase our capacity in the future, we are adding support around that, so regulatory, quality support, underlying support for those new businesses that we're trying to expand globally around the world.

So we look at a normalized growth, Larry, no different than we had in the past. There's somewhere 50 basis points and 70 basis points on the margin line is over a period of time. Some years, it will be higher as we've seen, other years will be less, but that's where we feel very comfortable with the business in those kinds of ways.

Larry S. Solow
CJS Securities, Inc.
Q

Great. Switching gears a little bit, can you just update us, I know you had an initiative for some of your lower volume products, sort of limit production runs with customers, how has that been – is that still something that's an ongoing process or-?

William J. Federici
Chief Financial Officer & Senior Vice President
A

Yes, it is Larry. It's a long-term process. Though, as you can imagine, you have to work with the customer to get them obviously on the same page you are. But you're right, we have made some progress there, especially some of the customers on the medical device side certainly and we look to continue to make more progress there. The obvious intention is to be able to spend our productive capacity in meeting the needs of the biologics and the generics and pharma customers for high-value products.

Larry S. Solow
CJS Securities, Inc.
Q

Okay. And then just on the Delivery Systems side, I assume the margin – the gross margin outlook is primarily driven by the expected nearly 30% increase on CZ and SmartDose; are there – is that basically the primary or are there other efficiencies and I know you had some inefficiencies and build out in some other capacity areas that has been hurting that group. So any color on that would be great.

Eric M. Green
Chief Executive Officer & Director

A

Yes, Larry, it's a combination of both. So we're seeing expansion of our CZ and SmartDose franchise as we continue to build off of that, and utilize our facilities more effectively. I think also on our contract manufacturing business, we'll continue to see – have seen expansion with our lean processing that team is actually quite very good at. So we are pleased to see the contract manufacturing making good progress.

Larry S. Solow
CJS Securities, Inc.

Q

Okay. Could you – I know, you guys generally provide some kind of quantitative update, I don't know, maybe you'll do that at the Analyst Day. In terms of CZ, I think it was in 14 programs and SmartDose was in eight last – we heard last quarter. Any change to that or do you want to defer until next couple of weeks to answer that question?

Eric M. Green
Chief Executive Officer & Director

A

Larry, I will give you a quick response to that, because that's a good question. I think when you look at SmartDose franchise, we have – today, we have about – we have seven in development and they continue to do quite well. The reason why they came down from eight is because we do have one that is scheduled from our commercial, depending on the PDUFA date that's with Amgen that's scheduled for July of 2016.

In regards to CZ, we're continuing to make progress as indicated with our recent announcement, we have 10 in formal stability studies and then we have about one to four really specifically around the generic zoledronic acid area. So again, we're making progress, customers are liking the technology that they're seeing. And as we indicated in my earlier comments, we're not standing still. We're also looking at what's next for SmartDose for West to support our customers. So we're constantly moving forward and we'll give you a greater update on March 10.

Larry S. Solow
CJS Securities, Inc.

Q

Got it. And then just lastly on the cost savings related to the 1% to 2% head count reduction -

William J. Federici
Chief Financial Officer & Senior Vice President

A

Yes.

Larry S. Solow
CJS Securities, Inc.

Q

-so that's $4 million to $6 million and then that gets realized this year, $8 million to $10 million next year, assuming sort of you do half this year or average it out to half, is that – how is that going to – roughly in the P&L, would that be both, I guess is partially manufacturing, partially SG&A, is that a good way to look at it or -?

William J. Federici
Chief Financial Officer & Senior Vice President

A

Correct. That's correct, Larry. As Eric said, most of it was in the reductions [indiscernible] (38:29) operations, but there is some SG&A as you can imagine. There is some write-off of assets and there is some people costs.

Larry S. Solow
CJS Securities, Inc.

Q

Got it. And then obviously it's a flu situation, but I think maybe going out as you look further, there may be other sort of broader sweep cost cuts like this one or is it more just obviously you'll have the lean this year, so it will always be ongoing, tweaks and stuff, but do you see other bigger needle movers that you can actually call out?

Eric M. Green
Chief Executive Officer & Director

A

Yes, Larry, I think what drove this decision and this change and as you know, we're a growing organization. We continue – we are expanding capacity, we are expanding our relationships with our customers, the business is fundamentally very strong. The driver of this really was taking an operation that had three regions and two divisions and bring it together. And well, when you move through that type of organizational change, you do create some opportunities.

We're exhausting all avenues to identify how we can redeploy our colleagues to the best we can, but the fact is, by going to more of a global approach with some of these areas, we are seeing some synergies, which we're taking advantage of at this time. Again, as we add capacity in our new facilities, we'll be adding appropriate resources as we expand and we'll continue to invest in our commercial, and also in our innovation engine groups.

Larry S. Solow
CJS Securities, Inc.

Q

Got it. And last question and I'll stop. CapEx, $150 million to $175 million, I think that's pretty well [ph] high telegraph (40:04) as you expand especially in Ireland. Do you see that number sort of sitting in that range for the next couple of years and then maybe beginning to tail off in the back-end of the outlook?

Eric M. Green
Chief Executive Officer & Director

A

Yes. Larry, let me – I'll talk briefly and I'll get Bill to give you the exact numbers, but the concept is right now, we're about 10% to 12% of sales. As you can see, the big part is from Waterford, Ireland and some other capacity expansions. Our intent is to bring that down as a percentage of sales as we go forward. This year and next year, you are absolutely correct, Waterford is a larger number, but our intent is to drive that number down as we go forward.

William J. Federici
Chief Financial Officer & Senior Vice President

A

I have nothing to add. That's perfect.

Larry S. Solow
CJS Securities, Inc.

Q

Okay, great. Thanks guys, appreciate it.

William J. Federici
Chief Financial Officer & Senior Vice President

A

Thanks, Larry.

Operator: Thank you. Our next question comes from the line of Paul Knight from Janney Montgomery. Your line is open.

Paul Richard Knight
Janney Montgomery Scott LLC

Q

Hi, Eric. Congratulations on the quarter and congratulations on that CZ win last week. Can you talk a little bit about how many trials you are involved in on the proprietary product side and what does the numbe r look like to you in terms of the CZ, SmartDose and the proprietary products kind of trial and trial backlog so to speak?

Eric M. Green
Chief Executive Officer & Director

A

Yes. Paul, thanks for your comments. As we look at where we are right now, as we mentioned in regards to CZ, we are in 10 formal stability studies and as I said, one to four generic zoledronic acid. There are various stages and as we indicated, we've had launch of two vial, CZ vial products just recently. So we're starting to see th e momentum of getting to the point where we actually can start commercializing these endeavors. So I think around SmartDose, again under proprietary, we have seven developments, again at various stages, but the interest continues to be strong.

I would also argue that you know with the SmartDose as it stands today we are looking at the next generation which is also stimulating a lot of good conversation with customers in identifying how we can improve on where we are. And then we're also obviously anticipating the commercial launch later this year of partnering with Amgen with Repatha. So those are where we are with our formats, and again we are starting to see momentum in the right direction.

Paul Richard Knight
Janney Montgomery Scott LLC

Q

And Bill, you guided 150 bps increase in the tax rate this year. What happens after Ireland capacity gets built, should that tax rate move back down? And then lastly, does the tax rate multi -year get even lower with other moves you can do?

William J. Federici
Chief Financial Officer & Senior Vice President

A

Absolutely, thanks Paul. Good question. We absolutely agree with your comment.

So, the idea is we are the beneficiary of having a very, very strong high value product portfolio. Right now, most of that is manufactured in our highest cost jurisdictions from a tax perspective both United States and Germany, little bit in France and also those are the three big ones. So when you think about it as you continue to increase the amount of high-value product sales and profits, they happen to be in those high cost jurisdictions. So it's a very high quality problem to have but one of the reasons that you know from an operating perspective we think that these centers of excellence are excellent ideas from an operating perspective. So making sure that we are providing our customers with the best absolute highest quality product we can that will be uniform in terms of where it's manufactured from.

So we'll do the core manufacturing in our existing facilities like the U.S. and Germany and France, but we will transfer those for finishing, where there a lot of the high-value product capacity will be will be in Ireland and in Singapore. When we get those things online, obviously the tax rate differential between some place like Ireland that is 12.5% or Singapore that's even lower than that and say the United States which is 35% will reduce our overall effective tax rate. How low can that go is you know we certainly believe that it certainly would come back to that 27% and quite frankly over a longer period of time and longer means it's going to take a long time to get these productive facilities up to speed and validated by our customers. That we could see in the mid-20%s.

Paul Richard Knight
Janney Montgomery Scott LLC
Q

And then last Eric, why such good traction with Amgen?

Eric M. Green
Chief Executive Officer & Director
A

Paul, I'd love to be able to announce all the customers we have really good – I have to tell you we have a really good connectivity with a lot of customers around the world. Amgen has just been one of those great partnerships that started when they started up and I believe [ph] we are (45:10) on every injectable drug that's in the marketplace today. I think reality is, is that and then we're to get even closer to our customers that we are identifying and working with them to solve their problems and their needs and that's what West is good at. We'll enhance that as we forward, so thank you for the question.

Paul Richard Knight
Janney Montgomery Scott LLC
Q

Thanks.

William J. Federici
Chief Financial Officer & Senior Vice President
A

Thank you, Paul.

Operator: Our next question comes from the line of [ph] Arnie Ursaner (45:36) from – he is a private investor. Your line is open.

William J. Federici
Chief Financial Officer & Senior Vice President
A

Good morning.

Eric M. Green
Chief Executive Officer & Director
A

Good morning, [ph] Arnie (45:42).

Q

Couple of quick questions for you: in your revenue guidance, what's the mix between mix and volume, please?

William J. Federici
Chief Financial Officer & Senior Vice President

A

The mix between mix and volume, it's higher obviously on the mix change than the volume. We expect some order of magnitude about 2% to 3% on volume, a little bit of price – just under 1%, and the rest would be mix, [ph] Arnie (46:07).

Q

And then your backlog jump of 29%, what is the mix between high-value products and kind of the core or base business, and how much of that backlog do you expect to ship – the percent you expect to ship this year versus stuff that may move even further out?

William J. Federici
Chief Financial Officer & Senior Vice President

A

Yes, that's a great question. So I won't give you the actual percentages that are high-value product, but the high-value product percentage of the total backlog is increasing, and that is one of the reasons why we have such great faith in the future, but also the fact that it has caused the number of orders and the duration of those orders to expand. So normally, we would see in our backlog a very high percentage of that backlog be actually produced and shipped in the following quarter.

With our increased lead times and our customers' additional orders both on the biologics and the generic side, we're seeing that get pushed out not only to the next quarter being produced and shipped, but being in the next quarter, but in the subsequent quarters after that. So we are seeing a much more even distribution than a big bell-shaped curve for the high-value products and also for the overall backlog. So if we're looking at percentages rough numbers each of the quarters has increased the amount that we are going to be – expect to manufacture and ship, but the ones in the – first quarter obviously is very high, but then the second, third quarters are higher than we've seen in the past as a percentage of the total.

Q

So what's evolving to your longest lead time at this point?

William J. Federici
Chief Financial Officer & Senior Vice President

A

I am sorry, [ph] Arnie (47:59), I didn't catch the question.

Q

The longest lead time products, how far out are going on those?

William J. Federici
Chief Financial Officer & Senior Vice President

A

Well, we're in the mid-20s right which has come down from where we were with certain of the capacities and it's not the entire plan, [ph] Arnie (48:11). It's just, for instance, we had a bottleneck in the washing area where we perform our Westar process. We've done some changes to the manufacturing footprint, we've actually decoupled the washing from the tack off and that has allowed us to increase the utilization of the wash loads there and has been a big benefit to us. So lead times are coming down, but as I mentioned in my commentary, we don't expect to get through all of this and see the actual backlog return to more normal levels until about the third quarter of this year.

Q

Okay. Can you give us a quick update on the Arizona facility transition to SmartDose manufacturing?

Eric M. Green
Chief Executive Officer & Director

A

Yes, [ph] Arnie (48:58), it's going quite well. We are ready to go with the ramp-up of commercial volumes when they become available. So at this point, we are – the Arizona investments are in place and have been validated.

Q

Okay, two final questions for me: can you expand a little on the SmartDose sales decline? You obviously have quite a few products in development. We are hearing a lot of new news on large molecule products that would clearly benefit from SmartDose. I guess I'd like a better understanding what caused the slowdown in your view for the upcoming year and then I have a follow-up on that.

William J. Federici
Chief Financial Officer & Senior Vice President

A

Thanks, [ph] Arnie (49:37) and first of all, let's put it into context. The slowdown was $2 million on our $1.5 billion business, so not a huge number, but it is reflective of the lumpiness of sampling activities in those proprietary products. As you know, last year, during the fourth quarter of 2014, we had a lot of actual trial activity going on for SmartDose and that has subsequently ceased obviously for that one product. So you don't have that same level of orders coming through.

Again, when we look at CZ and SmartDose, the sales level, we expect a significant increase in that sales level from the – rough number is $30 million that it is today to maybe even a 50% increase over that for 2016. But it's still small in terms of the overall context of our business. And high value products in the components proprietary part of this business is going to continue to drive the business in the short term, but important progress is being made on those technologies and we continue to see that and expect it to be very impactful at the back half for our plan.

Q

Final question for me; you mentioned in your prepared remarks $45 million in 2016 from proprietary products and you also provided in the past your 2021 outlook or view. Can you walk us – maybe give us a sense of the 2021 goal for proprietary product revenue in the past from the $45 million in 2016 to the past in 2021?

William J. Federici
Chief Financial Officer & Senior Vice President

A

In 2016, $45 million I think you're referring to, [ph] Arnie (51:23), is just CZ and SmartDose combined.

Q

Correct.

William J. Federici
Chief Financial Officer & Senior Vice President

A

Remember, there are other proprietary devices like our Medimop which is about $50 million and our safety product which is about $20 million. So overall our proprietary sales today are rough numbers, $100 million. And we expect that certainly to grow very significant teens, high teens to low-20%s kind of rates, not over the time period and we expect when we look at the makeup of using the old segment nomenclature of Delivery Systems business, that's the combination of the proprietary Delivery Systems and the contract manufacturing, which right now is about 75-25, to be closer to 50-50 by the end of 2020.

Q

Thank you very much.

William J. Federici
Chief Financial Officer & Senior Vice President

A

You're welcome, [ph] Arnie (52:15).

Eric M. Green
Chief Executive Officer & Director

A

Great.

Operator: [Operator Instructions] Our next question comes from the line Dave Windley from Jefferies. Your line is open.

David Howard Windley
Jefferies LLC

Q

Hi, thanks for taking the follow-up. On Ireland, slightly different twist on the question that was asked; I believe you're starting in Ireland with the rubber sheeting for your diabetes clients, at what point, if not already, at what point does that activity begin and what impact should we expect that to have, I guess, I am thinking primarily tax rate, but if that also has a margin impact, I'd be interested in that as well.

Eric M. Green
Chief Executive Officer & Director

A

Yes, Dave, we are looking at completion of Phase 1 of the Waterford expansion at the end of 2017 with commercial revenue working with our customers in early 2018. So that's the timeframe of going live with manufacturing. Now, the volume and the impact is actually quite small on the start-ups. So it's very narrow on this particular portfolio. The bigger opportunity as we get into Phase 2 of Waterford of putting the capabilities of high-value packaging components in that facility, which will be more 2018-2019 time period.

David Howard Windley
Jefferies LLC
Q

Okay. So that was going to be my question is, so we are talking about two – probably close to three years, two and half years to three years to get Phase 1 in place; does it take that long to get Phase 2 in place. It sounds like, maybe not quite.

Eric M. Green
Chief Executive Officer & Director
A

No. Phase 1, just to remind you, it also has all the backbones of any additional expansion that will require on this campus, so it's really more of a campus-like manufacturing process. So it won't require the same amount of time to implement.

David Howard Windley
Jefferies LLC
Q

Okay. And then my last question on R&D and innovation, last quarter you called out in remarks that the development activities had shifted toward customer-funded projects, which then was the reason why R&D was a little lower year-over-year. This quarter R&D in each segment jumped up a little bit year-over-year, and I hear you talking about second generation SmartDose. If you could just maybe zoom out on that and help us to understand what their trajectory is, the activities within R&D, are they more say, company-funded and proprietary or are they more customer development projects where customers stepping into fund and how does that trajectory look over the next couple of years?

Eric M. Green
Chief Executive Officer & Director
A

Yes. No, actually, there is two major drivers to that going forward, actually the changing that occurred in Q4 and going forward is, one is looking at the next generation of SmartDose and that is launched and we are working on that at this point. And also, if you look at our high-value product portfolio in the NovaPure, specifically around the one and the three amount plungers that gives us an opportunity to invest in R&D and launch into commercial – meaningful commercial revenues down the road. So those are the type of investments.

I do want to just comment that as we – one of the changes that we made with our organization is having multiple pockets of R&D and innovation in different parts of the organization, we're bringing that together, so we can start looking at the interconnectivity between containment and delivery devices. So while it gives some efficiencies on leverage on our innovation group, we will still continue to invest and these are two particular areas that we have invested in Q4.

David Howard Windley
Jefferies LLC
Q

Okay. Thank you.

William J. Federici
Chief Financial Officer & Senior Vice President
A

Thanks Dave.

Operator: I am not seeing any other questioners in the queue at this time. So I would like to turn the call back over to management for closing remarks.

Eric M. Green

Chief Executive Officer & Director

Thanks, Andrew. An online archive of the broadcast will be available at the site three hours after this call. You can also dial-in for replay and that will be available through February 25, and those instructions are on the press release.

Thank you again for attending on this call, and we look forward to talking to you again on our March 10 Analyst Day.

Operator: Ladies and gentlemen, thank you again for your participation in today's conference. This now concludes the program, and you may all disconnect your telephone lines at this time. Everyone have a great day.