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West Pharmaceutical Services, Inc. (WST)

Q2 2017 Earnings Call

CORPORATE PARTICIPANTS

Quintin John Lai
Vice President-Corporate Development, Strategy & Investor Relations, West Pharmaceutical Services, Inc.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

OTHER PARTICIPANTS

Sara Silverman
Analyst, Wells Fargo Securities LLC

William March
Analyst, Janney Montgomery Scott LLC

Lawrence Solow
Analyst, CJS Securities, Inc.

Jared Meggison
Analyst, Jefferies LLC

Derik de Bruin
Analyst, Bank of America Merrill Lynch

MANAGEMENT DISCUSSION SECTION

Operator: Good day, ladies and gentlemen, and welcome to the Q2 2017 West Pharmaceutical Services Earnings Conference Call. At this time, all participants are in a listen-only mode. Later, we will conduct a question-and-answer session, and instructions will be given at that time. [Operator Instructions] As a reminder, this conference call is being recorded.

I would now like to turn the conference over to Quintin Lai, Vice President of Investor Relations. You may begin.

Quintin John Lai
Vice President-Corporate Development, Strategy & Investor Relations, West Pharmaceutical Services, Inc.

Thank you, LeAnn. Good morning, and welcome to West's Second Quarter 2017 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 results, give you an update on our business, and provide an updated financial outlook for the full year 2017. There's 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 2 is the Safe Harbor statement. Statements made by management on this call and in the presentation contain forward-looking statements within the meaning of U.S. Federal Securities Laws. These statements are based on management's beliefs and assumptions, current expectations, estimates, and forecasts. There are many factors that can influence the company's future results that are beyond the ability of the company to control or predict.

Because of these known or unknown risks or uncertainties, 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, which could cause actual results to differ from our expectations, please refer to today's press release as well as any further disclosures the company makes regarding the risk to which it is subject 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 in constant currency, organic sales, adjusted operating profit, adjusted operating profit margin, and adjusted diluted EPS. Reconciliation and limitations of the non-GAAP financial measures to the most comparable financial results prepared in conformity to GAAP are provided in this morning's earnings release.

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

Eric Mark Green

President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

Great. Thank you, Quintin, and good morning, everyone. Following a strong start to the year, our second quarter performance fell short of expectations. While we delivered 4% organic sales growth with strong performance in Contract Manufacturing and Pharma, unexpected softness in Generics and Biologics caused an unfavorable sales mix, which resulted in a drop in the gross margin for the quarter.

While we have taken several actions, including increased customer interactions to better forecast their demand patterns and have put in place increased costs controls over our processes, we remain confident that the fundamentals of our markets, our products, and our strategy are solid. Our long-term outlook remains unchanged, and we believe that our growth profile will improve in Q4 of this year. I will focus my comments on the details of our sales performance in the quarter.

First, at a high level, two areas of our business, Contract Manufacturing and the Pharma market unit, which account for approximately 55% of our total sales, performed well and were at or above our expectations. On the other hand, the Generics and Biologics market units, approximately 45% of our total sales and accounting for 70% of total high-value product sales, were softer than expected due to a variety of customer issues, including continued customer inventory management, drug launch delays, and customer-related regulatory issues. I will go into more detail in a moment.

Turning to slide 4, we have laid out our organic sales performance over the last five quarters and show our updated full year guidance for each market unit and the Contract Manufacturing segment. I want to take some time to go through each of the businesses in detail regarding the second quarter and talk about the outlook for the balance of 2017.

As we expected, Pharma grew mid single-digits after strong double-digit growth in Q1. For the first half of the year, we are very pleased with Pharma's growth coming in at high single-digits, thanks to the realignment of our customer commercial organization, which is helping our team better focus on value creation. We are finding more of our large Pharma customers seeking higher quality containment and delivery systems and are converting to high value products.

In fact, I had the opportunity to meet with the senior leaders of a major customer at our Jersey Shore, Pennsylvania facility a few weeks ago. And they reaffirmed their commitment to move from standard products to high-value products commencing later this year.

They believe that doing so will aid in their initiative to drive toward zero particulates and defects, which ultimately has a positive impact on patient care. This is a trend we are seeing throughout our customer base, and we're well positioned to address the market needs. We expect continued growth in both standard and high-value products sales in this market unit, resulting in healthy high single-digit organic sales growth for the full year.

Turning our attention to the Generics market unit, we experienced a continued trend of customer inventory management that began in late Q4 of last year. We've talked about this issue on past calls. In 2016, when our capacities were constrained, our lead times became extended, and as a result, our customers built up inventories to make sure they had sufficient safety stock to cover manufacturing requirements. Our global operations team is successfully reducing lead times for key high-value products, and our customers are responding, as we would have expected them to do, by reducing their safety stock.

More importantly, the increased confidence by our customers and our ability to supply on time is opening up discussions for converting even more of the drug portfolio to West's high-value product offerings. This includes our new AccelTRA Program developed specifically for Generics customers. We are experiencing a positive response from this program. And with a number of customers currently testing their drugs for stability with AccelTRA Component, we expect to commence commercial production by early 2018.

Additionally, as the quarter progressed, we gained visibility to order pattern changes from some customers who have been impacted by FDA regulatory actions unrelated to our products. These customers, who purchased both standard and high-value products, have experienced impact to their operations. As a result, these actions depressed their growth over the quarter. Our revised guidance assumes a similar trend in Q3, and to a lesser extent in Q4. Our visibility around the corrective actions these customers are taking is limited. While it is difficult at this time to predict when order volume will return to normal levels, we do have new orders with our largest Generic customers, who for the last three quarters have been running down their safety stock. Therefore, we believe that by Q4 we should see more normal order volumes return.

In Biologics, we also experienced some customer inventory management issues in the quarter, but to a lesser extent than in Generics. This did, however, push growth in the market unit down to the mid single-digits. The inventory management activities are related to product launch bills in prior quarters, some customer product launch delays, and adjustments associated with conversions to high-value products.

I want to reiterate, we are the clear market leader in the growing Biologics market. In fact, our products are on 100% of the newly approved biologic drugs in the U.S. so far in 2017. This, combined with our improving visibility to demand with committed orders, gives us the confidence to believe our Biologics units will finish out the year strong.

As far as our Crystal Zenith and SmartDose platform sales, we had strong double-digit growth in the quarter. Our customers are adopting CZ for applications where traditional glass falls short of meeting their needs. CZ is well characterized and the recent FDA approvals using CZ containers have brought more customers to West to begin stability studies for future products.

Also, the commercial success of our SmartDose technology has resulted in new customer interest and opportunities to West. To that point, in Q2, we signed development agreements with two large global customers for the use of SmartDose with their drug candidates.

Our Contract Manufacturing business had its third consecutive quarter of double-digit organic sales growth. All the hard work in 2016 is paying off in 2017. And we're proud to be critical partners to our customers that are bringing new drug deliveries and diagnostic devices to the market. Our Dublin facility is currently ramping up and we're on track to hit our expectations for the full year.

I want to spend a minute on the progress of our newly created global operations and supply chain organization. The team is focused on driving safety, quality, service, and costs. And on all accounts, the team is making good progress. As an example of this progress, I am pleased to share that our customer, Bristol-Myers Squibb, recently named West as the 2017 Supplier of the Year in quality.

I also have an update for you on a major investment we're making to ensure our ability to meet customer demand in the years to come. The Waterford, Ireland investment is tracking under budget and on time. We are currently partnering with customers to validate the critical insulin sheeting in production line, and we expect to start commercial production in first half of 2018. In Phase 2 of Waterford, we plan to have high-value product finishing capabilities up and running in late 2018.

On slide 5, we have revised our sales outlook to reflect the Q2 results and our second half outlook. We are reducing our sales guidance. We now expect full year 2017 to be at the lower end of our long-term 6% to 8% organic sales growth targets. Our 2017 adjusted diluted EPS guidance takes into account the margin impact from lowered high-volume product sales growth related to Generics and Biologics, and is offset by cost controls and favorable tax benefits from stock-based compensation expense.

I'll now turn it over to our CFO, Bill Federici, who will take you through our detailed financial results for the quarter. Bill?

William J. Federici

Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

Thank you, Eric, and good morning, everyone. We issued our second quarter results this morning, reporting net income of $38.8 million or $0.51 per diluted share. Our reported results this quarter include a $0.15 per share charge for the deconsolidation of our operations in Venezuela. Excluding this charge, our Q2 2017 adjusted diluted EPS was $0.66 as compared to adjusted diluted earnings of $0.59 in Q2 of 2016.

As a reminder, 2017 reported earnings include tax benefits on option exercises due to an accounting change that took effect in 2017. Our Q2 2017 reported earnings includes a $0.13 per diluted share tax benefit related to stock option exercise. A reconciliation of non-GAAP measures is included at slides 12 through 15 in the presentation that accompanies this call.

Turning to sales, slide 7 shows the components of our consolidated sales increase. Our consolidated second quarter sales of $397.6 million increased by 2.5% versus our second quarter 2016 sales. Excluding the $5.6 million adverse currency effect, our Q2 2017 sales increased 3.9%. Proprietary net sales increased 2.2% versus the same quarter 2016, excluding exchange.

Sales price increases were marginal. Higher sales of CZ and SmartDose, as well as gains in tooling and development revenues contributed the majority of this sales increase. Sales of our high-value products rose just 2.2% versus the prior year second quarter.

Current quarter HVP sales as a percentage of total Proprietary Products sales were unchanged versus a year ago. Both Q2 2016 and first half of 2016 saw a significant growth in HVPs, up 16.6% and 19.6%, respectively.

The combined Q2 revenues from CZ and SmartDose of approximately $10 million were $6 million more than the combined 2016 Q2 sales, reflecting strong customer demand. Contract-Manufactured net sales increased by 10.5% versus the prior year quarter, driven by the ramp up of diabetes customer activities in our newly completed Dublin facility as well as our Arizona facilities.

As provided on slide 8, our consolidated gross profit margin for Q2 2017 was 31.4% versus the 34.4% margin we achieved in the second quarter of 2016. Proprietary second quarter gross margin of 35.4% was 3.1 margin points lower than the 38.5% achieved in the second quarter of 2016. The decrease in gross margin is primarily due to the unfavorable mix of sales, volume decreases, higher raw material costs, and normal inflationary increases in labor and overhead costs.

We sold a higher percentage of Contract-Manufactured Products, standard components, CZ and SmartDose devices, and tooling and development revenues, all of which carried lower margins than our high-value product components. HVP sales lagged as customers specifically in the Generics market segment delayed orders as a result of regulatory actions, which impacted their operations, as well as certain Biologics and Generic customers working off high levels of inventory acquired as part of product launches and/or other inventory management initiatives.

To dimension the high-value product sales impact on margins, in Q2 2016, high-value product sales increased by 16.6%. This favorable sales mix added 1.4 margin points to our Proprietary gross margin, as contracted to the current quarter's 2.2% growth in HVPs, which yielded an unfavorable mix impact of 1 margin point to Proprietary gross profit margin.

Contract-Manufactured second quarter gross margin decreased by 0.8 of a margin point to 16.8%, a favorable mix of product sold was more than offset by higher labor and increased overhead costs associated with new capabilities supporting Contract Manufacturing customer programs, especially in our new Dublin facility.

As reflected on slide 9, Q2 2017 consolidated SG&A expense decreased by $1.9 million versus the prior year quarter. Meriden head count increases in compensation costs were offset by lower incentive comp costs. As a percentage of sales, second quarter 2017 SG&A expense was 15.2% versus 16.1% in the second quarter of 2016.

Slide 10 shows our key cash flow and balance sheet metrics. Our year-to-date operating cash flow is $26.8 million above what we generated in the first six months of 2016 due primarily to our higher operating earnings and the impact of the accounting change for tax benefits associated with stock option exercises net of higher current year pension plan funding.

Our capital spending was $67 million for the first six months of 2017, approximately $7 million less than at this time in 2016. We expect to spend up to $150 million in capital in 2017. Approximately, 60% of our planned capital spending is dedicated to new products and expansion initiatives, including approximately $20 million for the construction of our new Waterford facility.

Our balance sheet continues to be strong and we're confident that our business will provide necessary future liquidity. Our cash balance currently of $226 million was $23 million more than our December 2016 balance, due primarily to the higher operating cash flows. Approximately $69 million of our cash balances are held by U.S. subsidiaries.

Debt at June 30 of $229.5 million was $1 million more than at year-end. Our net debt to total invested capital ratio at quarter end was 0.2%. Working capital of approximately $429 million at June 30 was $28 million higher than at year end. The majority of the increase is due to increases in our cash balances, accounts receivable, and inventory balances, partially offset by higher accounts payable and the reclassification to current liabilities of our headquarter building note that matures in January of 2018.

Looking ahead, our committed Proprietary Product orders were $382 million at June 2017, 7% lower than at June 2016, excluding exchange. As expected, due to operational gains resulting in lower lead times in our plants, customers do not need to place orders as far in advance, which has the effect of lowering committed orders on hand.

We've revised our full year 2017 guidance as reflected on slide 11 based on our year-to-date 2017 results and our analysis of the orders on hand. We believe our remaining 2017 quarterly results will follow historical seasonality, wherein Q3 results are traditionally lower than the results achieved in the first and second quarters due to customers and our plant summer shutdowns for preventive maintenance.

We expect Q3 2017 EPS to be flat to the prior year. However, we expect a strong Q4 with a return to more normal customer order patterns. We now expect full year adjusted diluted EPS to be in the range of $2.66 to $2.73, which includes the $0.34 of tax benefits from stock option exercises. We have based our guidance on an exchange rate of $1.14 per euro versus $1.05 per euro rate used in our prior guidance.

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

Eric Mark Green

President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

Thank you, Bill. In closing, we remain confident that the fundamentals of our markets, our products and our strategy are solid. We are maintaining our leadership position with customers. We are expanding our customer portfolio with emerging biotech and small pharmas, as the number of new therapies based on injectable drugs continues to grow.

The regulatory hurdles for quality and reliability continue to rise and our global customer base is increasingly looking to West for worldwide availability, scientific expertise, innovative new components and injection devices, and deep technical service, which we continue to deliver.

I want to be clear we see no change in the fundamental growth drivers and no change in long-term sales growth expectations of 6% to 8% per annum, with approximately 100 basis points of operating profit margin expansion per year. LeAnn, we're ready to take questions. Thank you.

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] And your first question comes from Tim Evans with Wells Fargo. Your line is now open.

Sara Silverman
Analyst, Wells Fargo Securities LLC

Q

Hey, guys. This is Sara on for Tim.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Hi, Sara.

Sara Silverman
Analyst, Wells Fargo Securities LLC

Q

I have a question on costs. So I was wondering what levers can you guys pull to manage costs during the delays. I think you mentioned earlier on the call you're implementing some cost controls. And then, kind of as a related question, how should we be thinking about operating margin expansion this year, given the headwinds?

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Yes. Thank you for the question and good morning. So when we look at our opportunity, what levers we have available to our business on a short-term is more around typical cost measures around how we are deploying our resources in our plants. It's also looking at ways to reduce our SG&A or maintain our SG&A as a percentage of sales around that 15% to 15.5%, which we're currently at. This is more around the discretionary spend that we have here at West.

Fundamentally, when you look at our infrastructure and you look at where we have our operations and our plants and the capacity that we have available, there is a demand – we expect the demand to continue to pick up latter part of this year and we're ready to take that on. So the lever we're looking at is more around the discretionary.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

And just to answer your question directly on the operating profit margin expansion, we do expect about 100 basis points increase based on our current forecast versus prior year.

Sara Silverman
Analyst, Wells Fargo Securities LLC

Q

Thanks. And then in terms of visibility, what are you guys doing to gain better visibility with your clients? I don't know how much you can share with us, but are you able to provide kind of any narrative of what changed between now and last quarter and what you're kind of doing to address that?

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Yes. So what we're doing with our global operations team and our commercial organization is that we have a pretty robust supply chain group that is actually being tied to our customers and start looking at demand patterns, not just historic but also forward looking. And so these are the initiatives that we have put in place. But it is really around the overall demand planning, not insular but actually working side-by-side with our customers.

Just to reiterate, I mentioned earlier that I had a meeting – several of us had a meeting with the key leaders of a major pharma company up in Jersey Shore and that was one of the key deliverables from that discussion, is integrating our group with their group to actually build forecast to demand short-term and more long-term.

Sara Silverman
Analyst, Wells Fargo Securities LLC

Q

Great. Thank you, guys.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Thanks, Sara.

Operator: Your next question is from William March with Janney. Your line is open.

William March
Analyst, Janney Montgomery Scott LLC

Q

Hey, guys. How are you?

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Hi, Bill.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Good morning.

William March
Analyst, Janney Montgomery Scott LLC

Q

Hey. So first question, Bill, just if you could provide a little more color around the second half financials, just in terms of 3Q is typically a lighter quarter as factories are retooling, so maybe just a little bit on the revenue cadence? And then, you also highlighted 100 basis points of margin expansion. Is that mainly going to be coming in 4Q, considering the flat EPS? So just a little more color on the model.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

So, yeah, I think what we've said in the release and what we're confirming here is that Q3 will be flat on the EPS line to prior year. We will continue to see the effects of the Generics and the Bio being soft. As we look towards the fourth quarter, we will be expecting to see more – return to a more normal order pattern from our customers in both of those regards. So, less robust in Q3 as we expect normally in sales, but higher growth rates in the fourth quarter.

William March
Analyst, Janney Montgomery Scott LLC

Q

Got it. And then, Eric, maybe just you highlighted the double-digit growth in CZ and SmartDose and called out a couple of new customer wins. Could you just give us a sense of the growth you're seeing? Is that coming more from the products that have recently been approved commercially, or are you seeing stronger growth from clinical trial and stability trial work? Thanks, guys.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Yes. So around CZ and SmartDose, what you're seeing the increase, as we anticipated this year, is really due to commercial launches. And our comment about additional DAs in the areas around SmartDose is obviously filling the pipeline for future opportunities. But the growth you're seeing today is really around the commercial launches.

William March
Analyst, Janney Montgomery Scott LLC

Q

Thanks.

Operator: Your next question is from Larry Solow with CJS Securities. Your line is open.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Good morning.

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

Good morning. Thanks, guys. Good morning. Just if you can give a little more color – your Proprietary orders down 7%. I realize obviously this is a function of several positive variables, including reduced lead times and your improved throughput and capacity expansion. But is there any way to sort of – is this – year-over-year decline of 7%, is that also being impacted, I assume, by some slowdown in the – outside of the inventory management, but some of the slowdowns you guys have cited?

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Yes, let me – no, Larry, that's a very good question and thank you for bringing that up. I think when you take a look at our high-value products and our backlog today, I'm really pleased with the progress of our operations team have delivered on over the last 12 to 18 months. Just to remind you, if we look at our high-value product portfolio, it's roughly around 17%. Last year, it was about 17% of the number of units we produced at West. And when you break it down, one of the early entrants of high-value products for us historically has been around Westar. And that process is roughly a third of the high-value product portfolio.

Just to remind you is that about two years ago, with customers, we were averaging a little over 30 weeks for lead times, and that's not acceptable. The work that has been in place, today, we're less than a third of that to our customers from a lead time perspective. And that work over the last year, year and a half is a direct correlation or a direct impact on the increased confidence from our customers and reducing the large [indiscernible] 28:17) orders that were coming in historically due to the lead times.

And also just to build off of that, to give you line of sight and confidence, while the Westar was down double-digits in the last quarter, the other parts of the high-value product portfolio that we're pushing into new commercial drugs and opportunities is growing very strongly. Such as, we talked about self-injection CZ already with your initial question. But the NovaPure and the Envision line, all very much strong double-digits, yes, from a smaller base. But this supports the strategy of continuously expanding the pipeline of new products, higher quality to meet the needs of our customers.

So it really is that the backlog right now is a direct correlation to the reduction of lead times, specifically around the Westar processing in the Generics space.

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

Okay. No, that's good to know. Okay. And then, just if we can just shift back a little bit on – you discussed, obviously, the slowdown in the quarter on both Biologics and Generics. And just sort of to press on the Biologics side, is the inventory management – it sounds like that sort of also ties into some of the delayed ramps that these customers are. Is that change in their plans on their own side or is that more of a regulatory delayed approvals and whatnot that's causing some of this?

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Yes, Larry, mostly in the Biologics space a lot of that's driven from our customers in new commercial launches.

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

Right.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

There was some due to a similar situation with Generics, but that's a much lesser extent.

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

Right.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

It's really around delayed drug products into the marketplace that we have visibility of. And I won't go into details of any one particular customer, but we believe, based on the conversations that latter part of this year, we'll see those becoming real. As far as commercial revenue for less to our customers.

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

Got it. So it sounds like it's more customer decisions, timing related, not as if there's been – that they were too aggressive on their approval forecast, or as a whole, forecasts were too aggressive or anything.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

No. Larry, as you know, many of our customers when they are about to launch new molecules, they buy ahead...

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

Right.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

... to prepare for the launch. And if there's a delay in a launch, it does create a little bit of an issue on the flow of new orders. I just want to reiterate, when you look at Biologics, we have no visibility of any lost sales. And the question that I look at every day is when you look at new molecules coming through the pipeline, are we participating on those molecules, and we can constantly say yes. Specifically in the Biologics space, it's very positive.

And I'll just give you an example. There was a major customer there with a major biosimilar has just been recommended for approval in a vial presentation. And what I'm excited about is our NovaPure line is on that. So, again, it's another win for West, but, frankly speaking, it's win for our customers and for the ultimate patient.

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

No. Okay, fair enough. That's great. And then just on the Generics side, that sounds like that's a little bit more – at least recently, a little bit more regulatory issue that sort of crimped production and you guys did – fairly enough sounds like you don't have great visibility on that, at least for the next couple of quarters. So you go down in Q3. And I guess you have some visibility on the timing of other orders so that that'll improve – that'll offset some of the weakness. Any way to sort of gauge, maybe very high level, what some of these regulatory issues are or would that potentially crimp – has there been a change in standards or anything? Or is it anything like that or is it more just coincidental timing – a bunch of regulatory issues sort of bunched together that caused a more significant slowdown that was noticeable for you guys?

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Yes. So, Larry, it's a good question. Let me try to dimension this for you. When you look at the business of Generics today, there's – that's question, there's been a decline. So we said mid single-digit decline in Q3. Last quarter, we were sitting here saying that we felt more comfortable of the large generic players, which are about four of them, frankly, make up 40% of the Generics business. We have visibility, line of sight, orders on hand and how it's going to play out for the rest of the year.

What we didn't anticipate, frankly, is about half of the decline of that mid single-digit decline in Generics came from mostly in India. What was seen there is that it's not just one or two, there's several of our customers that have gone through audits and they have 43s that were supply and there's delays right now on material going into those customers to produce. Now, we're very sensitive of the fact that if they're not able to correct their – have corrective actions that actually get approved, we know that these drugs will have to be picked up from somewhere else. And we're staying tune to that.

Our best estimate based on talking to the customers and also looking at some available data in the market place, such as IMS, suggests between three to six plus months before a transition would occur. Now, that's what we're focused on right now. So, about half of the decline in Generics came from specifically, not 100% but mostly, out of our customers in India.

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

Got it. And that's where the regulatory issues have obviously appeared then.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Correct.

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

Got it. Got it. Okay, great. And then, just last question just on the euro. I guess using an average of $1.14 versus a prior $1.05, I think that's a $0.09. Is that about the historical $0.01 to $0.01 rates still apply?

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Yes. Larry, it's a little bit less than that because you've got some other currencies running against you in Asia and Europe – Asia and South America.

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

Got it.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

The way we're looking at it is about $0.03 in the back half of the year will be the benefit, if it stays at $1.14 for the rest of the year.

Lawrence Solow
Analyst, CJS Securities, Inc.

Q

Got it. So the $0.45 it's about – so you get a little offset on the Asian currency, so it's about $0.03. Great, excellent. Thank you. I appreciate that.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Thanks Larry.

Operator: You're next question is from Dave Windley with Jefferies. Your line is open.

Jared Meggison
Analyst, Jefferies LLC

Q

Hi guys. This is Jared Meggison on for Dave this morning. I have one quick question regarding high value products. So we've had a little bit slower growth in 1Q and 2Q now. And I'm just wondering how are you guys doing to switch up the value chain for high-value products. Is there still demand from customers to move from Westar and FluroTec all the way up to NovaPure? Or given the kind of slower environment here, is there maybe a slowdown in that shift up the chain?

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Yeah, that's a very good question, and thank you. When you look at the high-value product portfolio and you look at the whole spectrum that we've laid out on the bottom left hand side of that portfolio, it's really the Westar, the entry point of high-value products. And that's where we're seeing the decline, specifically around the customers that I mentioned around the Generics space.

When you look around the NovaPure and Envision, they're all – again, it's a relative small base. So look at Westar, it is larger than the accumulation of self-injections CZ administration systems, NovaPure and Envision, but those product portfolios are growing well in the double-digits, significantly. So we're seeing a continue of migration towards the highest, call it, by design, of NovaPure. We're also seeing an increase in Envision inspection requirements, specifically in the Biologics and now coming into the Generics space.

So we're comfortable that we're continuously moving up the value chain when you look at the quality of these new products. I just want to reiterate, though, the high-value products right now – last year was about 17% of the number of units we produced and we believe that will continuously increase 100 to 150 basis points every year.

Jared Meggison
Analyst, Jefferies LLC

Q

Great. Thanks, guys.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Thank you.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Thank you.

Operator: Your next question is from Derik de Bruin with Bank of America Merrill Lynch. Your line is open.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Hey. Good morning.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Good morning, Derik.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Good morning, Derik.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Hey. I'm pleasantly surprised to hear that you're still talking about 100 basis points of margin expansion this year. That's certainly better than we had on our first pass at the model. Could you just sort of talk about how much of that is sort of like currency versus operational, just like that? Could you just sort of walk in what's the underlying margin for guide?

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Yes. So, currency is not going to affect the margin percentage very much. It does affect, it's $0.03 on the EPS, but the margin is generally not terribly affected by it. We do have – as Eric mentioned, we have operational work that we're working on with our group in the operations that should bring down the operating cost a little bit, and we're looking at continued cost controls around SG&A that will help.

And then, we believe that there's the ramp-up in HVPs in the back half of the year that, as I mentioned in my prepared remarks, that the HVP growth has a very large impact on that mix shift. It has a very large impact on our margins. So we believe that that's the big story there. So return to hopefully normal order patterns in Q4, good cost controls, as well as operational efficiencies, and we believe we will get to approximately 100 basis points.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Got you. So this sort of then begs the question I'm getting this from a couple of people this morning. It's like – I mean you've seen – this isn't the first time we've sort of seen these sort of – this isn't the first time we've seen some of the slippage in terms of the HVPs and like that. I think you go back to 2011, 2014, there were some other historical numbers. But could you sort of talk about comparing to what you've sort of seen in the past, and how long it took you to sort of reset and the – how this sort of compares with some of the other delays and sort of the other things you've seen in the past?

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Sure. Thanks, Derik. And yes, absolutely, we have seen this before in the first quarter of 2014 and also in 2011, and quite frankly, before that in 2008 and 2009 as well. Yes, the underlying fundamentals of the business are that if the products don't go away, if they're not pulled from the marketplace, or if there's no leakage to other – of market share that we will continue to see those units come back. And a lot of what we're seeing today is driven by both our operational excellence where we've reduced lead times and also customer inventory management issues. So, some of this is expected to happen. It does happen periodically and we do believe that we will continue to grow.

The marketplace demand for our higher-value products, driven by the needs for higher quality product, more purity, and more cleaner product with what our customers call zero defect mentality is going to continue to drive the need. And as we continue to believe, we've got very high market share in the Biologics space. We're not losing any business. There's been no fundamental change. So we believe that these order patterns will return more to normal.

And then lastly, I think there's also, you've got to remember, we grew very, very high percentages of high-value products, I mentioned both in the first half and the first two quarters of 2016 in high-value products. The growth rates were high teens.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Yeah.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

So those are above the norm of where we would say high-value product should grow, which is high singles to low doubles. So there is a return, reversion to more of the mean and that's what we're seeing today. No lost business, no change in the fundamentals. We believe that the products are still there. The demand is there. It's just got to – it'll come back in future quarters.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Great. And that was sort of the in question on basically nothing to sort of shake your view on the long-term outlook.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Absolutely nothing.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

No, Derik, no change there.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Yes. So, I guess on the Generic issue and sort of like the 43 and the quality issues there. You had some issues with the Generic customers in Q4 and in Q1. Were these sort of like the ones that sort of manifested this quarter, were these the same ones or were these new ones? I'm just sort of thinking about your visibility in terms of what is it? Is it just like something that's lingered or is it like whack-a-mole where new ones are popping up?

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Yes, Derik. It's been – from our perspective work with our customers is newer issues that are being faced with our customers, specifically in India. There are some issues that are outside of India. They've been going on for some time now. This is specifically more than a handful, I would say, in India.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Got it. Okay. And just, when we talk about FX being a tailwind for that, what's the overall top line tailwind – what's just overall top line for the full year for the FX contribution?

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Well, I'd just tell you, in the back half of the year, it'll be approximately $20 million.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Got you. Spread over the three quarters. Great. Okay. Great. I think that does it -can we talk a little bit about the tax rate as well?

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Sure.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Just as a sense as you've got the stock option changes. I realize that makes things a little bit lumpy. But how do we see – any guidance in terms of how to think about it given it's single digits the last two quarters.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Yes. And that's driven by the tax benefits from those option exercises. If you pull that out, the business is still strong, from a geographic mix perspective, in the U.S. and in places like Germany, which have high tax rates. So if you strip that out, our tax rate, if you're thinking about tax rate without it, should be about 30.5%.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Okay. Yes. Okay. It just makes the next couple of quarters – it just makes quarters much more complicated to model.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

It does. And we apologize for the accounting change, but there's not much we can do about it.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Yes. No, you're not the only ones are doing this. It's always a surprise now whenever we read the earnings releases, which is great. All right. Thanks. I'll get back in the queue.

William J. Federici
Chief Financial Officer & Senior Vice President, West Pharmaceutical Services, Inc.

A

Thanks, Derik.

Eric Mark Green
President, Chief Executive Officer & Director, West Pharmaceutical Services, Inc.

A

Thank you, Derik.

Operator: And I'm showing no further questions. I would like to turn the call back over to Quintin Lai for any further remarks.

Quintin John Lai
Vice President-Corporate Development, Strategy & Investor Relations, West Pharmaceutical Services, Inc.

Thanks, LeAnn. Thank you for joining us on today's conference call. An online archive of broadcast will be available on our website at www.westpharma.com in the Investors section. Additionally, you can get a telephone replay through Thursday, August 3 by dialing the numbers and conference ID provided at the end of today's earnings release.

That concludes this call. Have a nice day.

Operator: Ladies and gentlemen, thank you for participating in today's conference. This concludes the program and you may all disconnect. Everyone, have a great day.