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West Pharmaceutical Services, Inc. (WST)

Q4 2018 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Good day, ladies and gentlemen, and welcome to the Q4 2018 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 for all to participate will follow at that time. [Operator Instructions] As a reminder, this conference call is being recorded.

I would now like to introduce your host for today's conference, Mr. Quintin Lai, Vice President of Investor Relations. Sir, you may begin.

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

Thank you, Jimmy. Good morning, and welcome to West's fourth quarter and full year 2018 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; Bernard Birkett will review our results, provide an update on our business and provide a financial outlook for the full year 2019. There is a slide presentation that accompanies today's call and a copy of that presentation is available on the Investors section of our website.

On slide 2 is a Safe Harbor statement. Statements made by management on the call and in the presentation contain forward-looking statements within the meaning of U.S. federal securities law. 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 risk 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 risks 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 at constant currency, organic sales growth, adjusted operating profit, adjusted operating profit margin and adjusted diluted EPS. Reconciliations 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 now turn the call over to West's CEO and President, Eric Green.

Eric M. Green

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

Thank you, Quintin. Good morning, everyone and thank you for joining us today. We made good progress in 2018 to execute our market-led strategy, focusing on the containment and delivery of injectable medicines and the globalization of our operations and the results of these efforts are driving our 2019 outlook and beyond.

We see no change in the positive market trends that support our business. More and more prescription medicines are being developed as injectable drugs. Our customer base continues to grow around the world with faster growth in Asia-Pacific and South America.

The bar for quality and reliability continues to be raised by both our customers and global regulators. Our customers continue to request technical and regulatory services to support the packaging and delivery of their products. And companies are looking to couple their drugs with differentiated delivery devices to improve patient adoption and adherence. Each year we have seen growing interest and demand for our high value product offerings, device platforms and our contract manufacturing services. As we look to 2019, we are focusing the forecast organic growth in line with our long-term financial construct.

Before I review the specifics of our 2018 performance I want to address the voluntary recall of Vial2Bag, which was announced in January. The recall was prompted by reports of potential variable dosing with our 13 millimeter device. West's top priority is ensuring the quality of our products and the safety of the patients using them. It was this patient first mindset that drove us to recall the entire Vial2Bag portfolio so that we can thoroughly analyze these reports and ensure that our products can be safely used.

Our hospital customers tell us that our Vial2Bag devices have significantly advanced the standard of care for medicines delivered by way of infusion. We continue to believe strongly in Vial2Bag and are working closely with the FDA and other regulatory bodies with the aim of getting back to the market as soon as we can. Because we have built a diverse portfolio of high-value products and services we still anticipate 6% to 8% organic growth in 2019.

Let's take a look at each of the market units now. Slide 4 shows a detailed summary of sales performance in 2018. With the impact of the voluntary recall, Pharma was flat in the fourth quarter, however the underlying fundamentals of this market are intact and the rest of the Pharma business continues to perform in line with our expectations.

Generics finished the year on a solid note, we continue to have strong growing interest in our AccelTRA product line and our Generics market unit has seen heightened adoption of our self-injection devices.

Turning to Biologics, I am pleased to report that Biologics returned to growth in the fourth quarter, even up against a difficult comp from last year. With most of the headwinds that we experienced last year behind us, we are encouraged with a strong start to this year and can report Biologics is on track to grow as expected.

Contract Manufacturing ended of the year with a sales run rate similar to that of Q3 as we anticipated. This segment grew sales significantly in 2018. It is all the more impressive when we step back and consider we had a gap from the loss of consumer product sales last year and a challenge to scale up production from multiple customers in the diabetes space.

As we look to 2019, the focus will be on improving margins while we continue to grow the top line. We are working to address margin improvement with the addition of value-added services and ongoing operational excellence initiatives.

Let's turn now to operations and some of the progress we're seeing here on slide 5. In only its second full year, our global operations team has generated improved plant utilization while increasing our industry leading quality metrics and lowering our capital spending requirements. Our One West business operating system is delivering near-term efficiencies and best-in-class manufacturing practices to drive further growth and profitability.

Highlights from last year include record steady improvements in quality, safety and on-time delivery, 60 basis points of gross profit margin expansion led by 220 basis points from our Proprietary Products segment, the opening of our new state-of-the-art Waterford, Ireland site, and increased plant utilization across the network which reduced capital expenditure to $105 million, leading to higher free cash flow generation. We are early in our journey, the team is implementing more initiatives that will raise the bar on quality and lead times while we work to support new capacity for innovative products and reduce overall costs.

Coupled with the gross margin lift we're getting from greater high value product sales, we expect global operations to be a key lever for the company to achieve its long-term target of 100 basis points of operating profit margin improvement per year.

West's ability to drive this margin improvement comes from the scale and scope of our global operations. On slide 6, we're excited to highlight the development of our business in some of the fastest growing and dynamic regions of the world. Sales within Asia-Pacific and South American markets are currently about 10% of total sales and growing at double digits. With manufacturing locations in Singapore, China, India and Brazil and sales offices throughout many countries within these regions, West is well-positioned in these growing markets. The quality standards imposed by regulators and customers alike in these regions continue to increase and as a result, we are seeing strong high-value product demand.

In an effort to further strengthen our market position in the Asia-Pacific region, we are pleased to announce that we have entered into an agreement to acquire the business of our distributor in South Korea. The transaction, which is expected to close in April of this year and is not factored into our current guidance, includes customer relationships, related assets and employees. We're excited to build upon the strong foundation that our distributor has established with the global reach of our One West network so that we can deepen our presence in this fast growing and strategic market.

Slide 7 highlights the ongoing R&D strategy designed to fuel our future growth. This strategy is based on three core pillars and is generating new packaging components offerings, higher quality products and self-injection technologies to address the needs of the markets we serve. In 2018, we saw the launch of Westar Select, Daikyo

D Sigma components, and an extension of our AccelTRA product line. We also saw two commercial launches for our customers with our SelfDose patient-controlled injector.

In 2019, we anticipate additional new product launches and line extensions across these core areas. In fact, I want to take a moment to share some exciting developments in the area of the delivery devices. We continue to see strong customer interest in our SmartDose drug delivery platform. The SmartDose system was the first FDA-approved wearable pre-filled drug delivery combination product. Notably, we're seeing broad-based interest across our market units for this product. For example scPharmaceuticals, one of our generics customers announced that it is moving its key pipeline drug forward with our SmartDose platform.

This is just one example of a number of development agreements our teams are executing. As our R&D team works to further advance our self-injection technologies, these products will complement our high-valued product strategy to drive the company's future growth.

Now, I'll turn it over to our CFO, Bernard Birkett, who will provide more detail on our financial performance and our long-term outlook. Bernard?

Bernard J. Birkett

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

Thank you, Eric, and good morning, everybody. Let's review the numbers in a little more detail. Our financial results are summarized on slide 8 and the reconciliation of non-GAAP measures are described in slides 13 to 17.

We reported for the fourth quarter net sales of $422.5 million, representing organic growth 3.6% on a constant currency basis. Excluding Vial2Bag recall, organic constant currency growth would have been 6.3%. Gross profit of $133.2 million is $4.6 million or 3.6% above Q4 2017. Gross profit margin was 31.5%, a 60-basis-point expansion from the same period last year.

Adjusted operating profit of $67.1 million compared to Q4 2017 $60.4 million, shows an improvement of 90 basis points, and adjusted diluted EPS of $0.73 as compared to $0.64 last year representing EPS growth of approximately 14%.

Looking more closely at each segment of our business, Proprietary Products organic sales increased 3.7%. Our high value products represented 56% of the Q4 2018 sales, approximately the same level as achieved in Q4 2017. For the full year 2018, we had mid-single digit sales growth in high value products as expected. Contract Manufacturing net organic sales increased by 3.1%, slightly above our expectations. Continued growth in support of diagnostic and delivery systems for treatment of diabetes are driving much of the increase in sales.

On slide 9, we show the contributions to sales growth in the quarter. Volume and mix contributed $18.4 million or 4.4 percentage points of growth. Sales price increases contributed $2.5 million or 0.6 percentage points of growth. Changes in foreign currency exchange rates reduced sales by $7.9 million or a reduction of 1.9 percentage points and the loss of a consumer Contract Manufacturing customer was $6.1 million or 1.5 percentage points.

Moving on to margin performance, slide 10 shows our consolidated gross profit margin of 31.5% for Q4 2018 up from 30.9% in Q4 2017. Proprietary Products fourth quarter gross margin of 37% was 220 basis points above the margin achieved in the fourth quarter of 2017. This continued improvement in gross margin is primarily due to higher efficiencies and positive sales mix which more than offset the impact from the voluntary recall, unabsorbed overhead from Waterford and higher raw material costs. The Waterford facility generated its first sales of commercial product in Q3, and we expect continued improvement in operational efficiencies as our utilization of this facility increases throughout 2019.

Contract Manufacturing fourth quarter gross margin of 16.4% decreased by 370 basis points compared to the prior-year quarter. The year-over-year decrease in margins is due to unabsorbed overhead from plant consolidation activities, start-up costs associated with the launch of new programs and unfavorable sales mix. However, margins continue to improve with an increase over Contract Manufacturing gross margins in Q3 2018, which was in line with our expectations and comments on our Q3 call.

We have continued confidence that Contract Manufacturing margins will improve further into 2019 as we complete our restructuring activities, continue to improve our efficiency and utilization levels, and deliver on the new customer programs. Q4 2018 consolidated SG&A expense remained relatively flat versus the prior-year quarter. As a percentage of sales, fourth quarter 2018 SG&A expense was 14.1%, a decrease of 20 basis points as compared to the fourth quarter of 2017 and in line with our expectations.

Slide 11 shows our key cash flow metrics. Operating cash flow was $288.6 million for the full year 2018, an increase of $25.3 million compared to full year 2017. Part of this improvement is the non-recurrence of the $20 million voluntary pension contribution made in the prior year.

Our full year capital spending was $104.7 million, $26.1 million or approximately 20% lower than a year ago, as we have completed our major construction projects in Ireland and as we begin to see the early benefits from our global operations initiatives on capacity utilization and optimization.

Reviewing some balance sheet takeaways, our cash balance at December 31 of $337 million was $101.5 million more than our December 2017 balance, an improvement of approximately 43%. Debt at December 31, 2018 of $196 million is roughly the same level as at year-end 2017 and on a net debt to total invested capital ratio basis, we are completely de-levered.

Working capital of $610.7 million at December 31 was $146.7 million higher than at prior year-end. In addition to the increase in our cash balances, cash represents 69% of the increase. Most of the remaining increase is in receivables related to the growth in our business and an increase in our days sales outstanding metric. We have seen improvements in our inventory metrics as our days in inventory have reduced by approximately 2%.

As we consider Q4 results and look ahead to 2019, we have provided our sales and adjusted diluted EPS guidance for 2019 which is summarized on slide 12. We expect our full year sales to be in the range of $1.795 billion to $1.82 billion, representing an expected constant currency organic sales growth of 6% to 8% over 2018 reported net sales. This assumes a negative impact of approximately $30 million to full year 2019 sales based on current foreign currency exchange rates.

We expect full year 2019 adjusted diluted EPS of $2.77 to $2.89, which assumes operating profit margin expansion of approximately 100 basis points. And guidance excludes tax benefits from stock-based compensation. Excluding this, EPS growth is in the range of 6% to 10%. Growth excluding FX and the tax benefit from stock-based compensation is in the range of 8% to 13%. To be clear, this guidance format is returning to the format we used in 2017 where we also did not include tax benefits from stock-based comp in guidance.

To try to forecast these tax benefits would mean trying to forecast items we do not control such as stock option exercises by our former and current employees. Instead, we expect to recognize potential tax benefits as they occur. As a result, as we recognize them, we expect to see upside in our adjusted diluted 2019 EPS guidance. CapEx for 2019 is forecast to be in the range of $120 million to $130 million.

So to summarize the key takeaways for the quarter, we saw continued consolidated sales growth. Gross margin increases in our Proprietary Products segment and improving margins in our Contract Manufacturing segment, strong growth in adjusted diluted EPS over Q4 2017, together with strong operating cash flow growth. Our projections for 2019 are in line with our long-term construct of 6% to 8% revenue growth, operating margin improvement of 100 basis points and EPS expansion.

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

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

Thank you, Bernard. Our work in 2018 has positioned us well to grow organic sales and expand operating margins to increase free cash flow, all in line with our long-term financial construct. Our diverse portfolio of high-value products and services is on track for continued growth and will be fueled by new products and line extensions. We are making significant progress in our global operations to deliver improved efficiencies while deploying cutting-edge manufacturing strategies to advance our already-strong position in service and quality. We are confident in our strategy for continued growth across the geographies and markets we serve for both the short and long-term and look forward to the coming year.

Jimmy, we're ready to take questions. Thank you.

QUESTION AND ANSWER SECTION

Operator: Understood. [Operator Instructions] Our first question comes from Paul Knight with Janney Montgomery. Your line is now open.

Paul Richard Knight
Analyst, Janney Montgomery Scott LLC

Q

Hi, Bernard and everybody. Thanks for the time. A question on guidance, the 6% to 8% obviously maintain kind of what you've been talking about historically, yet the recall business is I guess out of numbers. What is causing you to have the confidence that you can maintain in effect, say, your business, core business seems to be a little bit better. Is that what you're saying and what's behind that effectively?

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

A

Yeah, Paul. Thanks for the question. This is Eric, okay? As we look at the business in 2019, our confidence of stronger growth than we experienced in 2018 in our core business, particularly in the Proprietary Products, is really driven by the growth that we're starting to see in the Biologics that we anticipated. So if we recall, in 2018, Biologics was relatively flat was due to some restocking and some replenishment of earlier launches. As we look into 2019, we believe in the Biologics business units can return to what we consider as typical growth for West, which is in the high-single digit range. And that unit really drives the high-valued products.

In addition to that, when we look at the Generics business, we did fairly well in 2018. However, we're starting to see additional growth with the launch of new products like AccelTRA and the new interest around self-injection devices in that area which has now been commercialized. So those are the key drivers that gives us the confidence in the growth that we're going to be returning to that higher growth in the proprietary area.

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

Paul, do you have any other questions?

Paul Richard Knight
Analyst, Janney Montgomery Scott LLC Q

I'm sorry. Is the operating margin expansion you're guiding to due to this, again, this growth you're guiding to in Biosimilars and high-value add products, Eric?

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

Yeah, Paul, the driver of operating margin expansion is coming out of a twofold. One is as we grow the high-value products high-single, low-double digits, that does give us some margin expansion naturally with this shift. And then, the balance of that really is coming from our global operations. We've demonstrated that we're gaining traction and particularly in the Proprietary area of margin expansion and we're confident that we are getting our hands around the Contract Manufacturing area as we scaled up last year with new installed equipment that we should be able to get further margin expansion in that area in 2019. So it's a combination of both, Paul, as we kind of move forward throughout 2019.

Paul Richard Knight
Analyst, Janney Montgomery Scott LLC Q

And then lastly on the product recall, is there any associated liability? Can you measure that? Any color there would be appreciated. Thank you.

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

Yeah. Thanks, Paul. I think just to be clear, when we look at the events that occurred in late 2018, we had a couple of reports from health care professionals, really the effect of a particular drug in the marketplace was oxytocin, which is variable and predictable when used with the Vial2Bag DC 13 millimeter device.

When you look at the Vial2Bag portfolio, this particular device is a small percentage of that entire portfolio. We took a very – while there's not been a causal relationship determined between these events and the device, we've taken the approach to ensure patient safety by pulling the entire portfolio off the market while we do the analysis and work with the regulatory bodies to bring the product back onto the market at the appropriate time, and we're doing everything we can to bring it back as soon as possible.

We still believe in the product. Our customers are very keen to get the product back into the hospital sector because it's very supportive of what they're trying to get accomplished. So that's where we are, Paul. At this point in time we're doing everything possible to ensure we've done the root cause analysis to make sure everything is analyzed and gives us confidence we can go back to the market safely.

Paul Richard Knight
Analyst, Janney Montgomery Scott LLC

Q

Okay. Thank you.

Operator: Thank you. Our next question comes from Larry Solow with CJS Securities. Your line is now open.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Great. Thanks, guys. Just a quick follow-up on the Vial2Bag. It sounds like you're erring on the side of patient safety, which obviously is what you should be doing. It seems like the $25 million had been growing pretty fast, I guess the $11 million a quarter, I don't think – there's probably some seasonality there. But do you expect this product back even sometime this year even though you don't really know for sure and it's not included in guidance?

Bernard J. Birkett
Senior Vice President, Chief Financial Officer & Treasurer, West Pharmaceutical Services, Inc.

A

Well, when we look at our guidance it – the range is pretty wide so it covers a number of different eventualities. So we've got to be careful on the timing. We just have to make sure we do our work and we work with the regulatory authorities to make sure that we get it back as fast as possible but our guidance reflects that.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Right. Just to be clear, is that – you're not including that number at all or are you actually incorporating that it does actually get back even to some number and something in your numbers there or is it sort of omitted completely from guidance?

Bernard J. Birkett
Senior Vice President, Chief Financial Officer & Treasurer, West Pharmaceutical Services, Inc.

A

The guidance covers a range of possibilities. I'll put it to you that way.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Okay.

Bernard J. Birkett
Senior Vice President, Chief Financial Officer & Treasurer, West Pharmaceutical Services, Inc.

A

But even with that, we're still guiding to 6% to 8%.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Okay.

Bernard J. Birkett
Senior Vice President, Chief Financial Officer & Treasurer, West Pharmaceutical Services, Inc.

A

And the other thing is just to be careful that – I think you mentioned there that it's about $11 million a quarter. That's that the annual revenue for 2018. The total revenue was $24 million for the year.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Right, right. Right, that's what I was saying. So it seems like that that $11 million number we shouldn't extrapolate. It sounds like there is some seasonality in that number, but I do believe that the $25 million annual number probably had – you had some pretty good growth this year. I know you had called it out, I think in Q2 and Q3 as doing well and perhaps that – maybe that benefited a little bit from shortages in the solutions and bag side on the IV industry and the infusion industry itself, but it does sound like there was some considerable growth in that product, but not the $11 million quarterly, I get that – right, that's a seasonal shift?

Bernard J. Birkett
Senior Vice President, Chief Financial Officer & Treasurer, West Pharmaceutical Services, Inc.

A

Yeah, that's correct. That's a seasonal number. So that's the level of returns we saw so there would have been inventory in the field and with our distributors.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Right. Okay. And just on the free cash flow, obviously, you guys – operating cash flow grew 10%, free cash flow grew close to 40%. You did a wonderful job bringing CapEx down. I think it was even lower than the previous guide down and material lower from the last two years. Is this $105 million plus or minus number? Is this a sustainable level?

Bernard J. Birkett
Senior Vice President, Chief Financial Officer & Treasurer, West Pharmaceutical Services, Inc.

A

We've guided $120 million to $130 million for 2019.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Okay.

Bernard J. Birkett
Senior Vice President, Chief Financial Officer & Treasurer, West Pharmaceutical Services, Inc.

A

But we just call that on our guidance.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Right. But – okay. Actually I missed that but I know last year I think you had originally guided towards a similar number in 2018 and you came down materially lower.

Bernard J. Birkett
Senior Vice President, Chief Financial Officer & Treasurer, West Pharmaceutical Services, Inc.

A

Yeah.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Can you maybe sort of bridge what drove the number down considerably from the guidance? And what would change that this year?

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

A

Yeah, Larry. This is Eric. That's a good question. I know that a year ago or so we guided around $150 million to $175 million. I think in prior years we were roughly around that area. And when you think about the team we put together and truly globalized the operations about 1.5 year, 2 years ago, one of the remits was to start thinking about how do we utilize our assets more effectively instead of running each site independently. And, therefore, what we have done is we have – able to identify where we put the next dollar of assets and to which location to really optimize the global network.

So, we guided this year at $120 million, $130 million. That's still includes, incorporates about $40 million, $45 million a year for maintenance which we need to do with all the presses and equipment we have around the world. We do have about $10 million to $15 million to $20 million depending on the year around our IT infrastructure to continuously enhance that and improve our operating systems. And then the balance of that is growth initiatives. I can assure you that the growth initiatives are still quite prevalent in our conversations. But how we allocate where that goes, we're starting to leverage existing assets instead of building new facilities. That's probably the biggest difference. So, guiding at $120 million to $130 million, we're very confident in that corridor and that's with several new growth initiatives that we have in the pipeline in 2019 and also in 2020.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Okay. Great. I appreciate that color. Just on the – you spoke to sort of Biologics returning sort of to this high-single-digit growth. If we exclude the Vial2Bag high-value product as a – in totality, it sounds like they should be sort of in line with that long-term high-single-digit growth as well in 2019?

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

A

That's correct, Larry. And just to reiterate the key driver of high-value products is really around the Biologics, heavier on the Generics with this whole new launch around AccelTRA product line. And also in the Pharma, but I would say mostly in the Biologics and Generics. And as we think about what 2018 and beyond back to the typical growth rates, it is a high-single-digit area. So that will be the key driver of the core thrust of high-value product growth for West.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Okay. And then just last question just on the ongoing restructuring, it sounds like it's progressing as planned and you guys have called out sort of about a $0.15 annualized benefit when complete. Do you expect to get some of this benefit even in the latter part of 2019 or is that really a 2020 and going further type thing?

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

A

Yeah. Larry, we are – we have officially as of last month, one of the sites that we were consolidating to another location has been officially completed. So now the ongoing benefit – and that's really in our Contract Manufacturing business, that will be a slight benefit going forward in 2019. We are very close to finalize a larger consolidation between two plants. They're literally seven miles, eight miles apart from each other in Florida. And that will be completed roughly mid to end of the second – end of – I'm sorry Q3, which gives us a little bit of benefit, but most of the benefit is in 2020. So, we'll have – we'll see some of that benefit that you're referring to in 2019, but majority of it starts in the latter half. So the majority starts in 2020.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Great. Thanks, Eric. Appreciate it.

Operator: Thank you. [Operator Instructions] Our next question comes from Dana Flanders with Goldman Sachs. Your line is now open.

Dana Flanders
Analyst, Goldman Sachs & Co. LLC

Q

Hi. Thank you for the questions. My first one is just on Biologics. I know you talked about kind of the return to growth this year and some encouraging signs so far. It's also been relatively volatile. Have you just changed how you are approaching forecasting demand in that segment. And are there any big launches this year that could drive volatility?

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

A

Well, Dana, thanks for the question and good morning. What we're seeing with Biologics, to answer your first question about visibility, I would say the team's done a really good job over the last two quarters to re-look at on how to understand the drug uptake in the marketplace because that is what's creating the largest volatility and working with our customers. So we've – a lot of work has been done. There's still more work that needs to be done, but there's a higher degree of confidence in the Biologics business as we started thinking about the demand. One of the areas we look at also while the numbers have changed because our global operations cycle times have changed drastically really is our backlog and the orders that come in for Biologics and we have really good visibility in the near-term, i.e. two to three quarters and that gives us really good confidence that our predictions through our analysis is coming through at this point in time.

So I would say though that the headwinds we had last year that we spoke of are behind us. There will always be some volatility between quarter to quarter, but it's not – we don't believe the drastic swings that we've seen in the past and if we are going to see that, we'll be very transparent. But on an annual basis, we do see this business back to what we expected as a high-single driver in the marketplace.

Dana Flanders
Analyst, Goldman Sachs & Co. LLC

Q

Yeah. Okay. Thanks. And I guess my follow-up. Just on the South Korean distributor that that you're buying, just I want to clarify, did you say it's not included in guidance until it closed and then how much top-line do you expect it to contribute when it does close?

Bernard J. Birkett
Senior Vice President, Chief Financial Officer & Treasurer, West Pharmaceutical Services, Inc.
A

Yeah, it's not built into the guidance. We'll wait until it's obviously closed and completed before we would do that, but we believe for 2019, it'll be relatively immaterial. And then as we develop that business out through 2019, it will have more of an impact in 2020.

Dana Flanders
Analyst, Goldman Sachs & Co. LLC
Q

Okay. Thank you.

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

Thank you, Dana.

Operator: Thank you. And our next question comes from Derik de Bruin from Bank of America. Your line is now open.

Derik de Bruin
Analyst, Bank of America Merrill Lynch
Q

Hey. Good morning, and thanks for taking the questions. And apologies if I'm asking something you said earlier. I'm juggling four calls this morning. So on the Vial2Bag, I mean, have you included a – what's your expectations for that coming back in 2019, and basically what are you doing in terms of remediating that to – what do you have to do to fix it?

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

Yeah, Dana, what we're looking at is – I'm sorry. Derik. What we're looking at is we need to understand with the few cases that were presented in regards to a particular drug molecule being used with the Vial2Bag DC 13 millimeter. Again, that's a small piece of all of Vial2Bag and we took the approach to ensure – pulled the entire portfolio off the line as a caution for patient safety.

And so right now what we are undertaking is root cause analysis and collecting and analyzing data to determine the root cause of this variability on this particular molecule. And once we have that appreciation, then we are able to assess if there is any implication on any other molecule and/or the 20 millimeter which is majority of the volume that we produce and been selling into the marketplace.

So we're well into this. We've put our best and brightest people on this in our labs, our regulatory group, our quality group, engineering group and we're working this on a daily basis with the regulatories, the FDA and other foreign regulatory bodies. So we haven't articulated exactly when this will come back because we need to understand the data first and then we'll be in a better position to make that comment.

Derik de Bruin
Analyst, Bank of America Merrill Lynch
Q

Great. Great. So just on the – what was the stock option contribution to fourth quarter and I see you're not including any benefits from stock option gains in your current guidance. But that seems a little bit unlikely. I guess what sort of is a – what sort of is a base level. Isn't like $0.01 to $0.02 a quarter a base level just to sort of think about?

Bernard J. Birkett
Senior Vice President, Chief Financial Officer & Treasurer, West Pharmaceutical Services, Inc.

A

Yeah, it could be. We're not obviously – we said we're not going to guide it because it's out of our control. I think what we've seen in the last number of years is it was higher given the level of retirements that had taken place and options that were exercised. We would expect that to normalize. So for the – just to keep everything clean and transparent, it's easier for us to guide without that because we don't have control over the number. And for the fourth quarter, it was about $1 million.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Great. And there's been some headlines with some of the – with Pfizer and some of their issues in terms of their injectable drug manufacturing. I guess could you sort of talk about just where we are in terms of the industry has sort of been plagued over the years by sort of recalls and quality issues and certainly in India and these other ones.

Can you sort of talk about sort of like sort of the status of where we are in the market right now in terms of some of the – where you have visibility, like are some of the issues that you've had – you saw in the past in the market have those sort of fallen by the wayside, are we more normalized? It basically is just a comment – it's just a question sort of like your confidence and your visibility on the end market.

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

A

Yeah, Derik, that's a very good question because we do take that in consideration as we start looking at the forecasts, particularly around the Generics business. That tends to be the area where there has been more 483s, particularly in India in the past three, four years. But from our vantage point as you know, we work with majority if not all the companies in the space. Our vantage is that there isn't – it's not on the rise as much as it was a couple years ago. So we do have visibility.

One of the benefits that we do have is if there is an issue at one particular firm – it doesn't happen immediately but over a period of time, i.e. a few quarters later, we're working with another firm to help get the molecule on the market and into the hands of patients.

But I think, Derik, what you raise though, is a very important comment is that there is a heightened awareness and a need for quality and global availability and that's why I believe that's why we are getting a lot of these phone calls to help solve some of these problems and it actually underscores why the team has come out with the AccelTRA portfolio because it addresses these needs exactly to the T. So, that's what we see right now. We don't think it's on a rise, but we do see when it happens at one location we usually work with another firm to get it back on line.

Derik de Bruin
Analyst, Bank of America Merrill Lynch

Q

Great. Thanks so much.

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

A

Thank you.

Operator: Thank you and I'm showing no further questions in the queue at this time. I'd like to turn the call back over to Quintin Lai for any closing remarks.

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

Thanks, Jimmy, and thank you everyone for joining us on today's conference call. An online archive of the broadcast will be available on our website at westpharma.com in the Investors section. Additionally, you can get a replay through Thursday, February 21 by dialing the numbers and conference ID provided at the end of today's earnings release.

So that concludes today's call. Have a great day.

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