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West Pharmaceutical Services, Inc. (WST)

Q1 2019 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Good day, ladies and gentlemen, and welcome to the Q1 2019 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.

Good morning, and thank you, Jimmy. Good morning and welcome to West's first quarter 2019 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 an update on the 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 this 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 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, 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 for our Q1 call. I'm very pleased to report that we're off to a good start to the year and delivered a strong first quarter. Our team executed well on multiple fronts with solid performance that demonstrates the success of our market led strategy. The markets we serve remain robust and we're delivering differentiated products and services for our customers, which is driving above market growth in all segments and market units.

We continue to see good uptake of our new product pipeline, including an increasing number of development agreements for our delivery device platforms and continued growth momentum of our high value product portfolio. And our global operations team is successfully delivering on its strategic initiatives, which has resulted in improvements to our quality and service metrics along with higher gross profit margins.

As we look to the rest of 2019, we are reaffirming overall net sales guidance despite the headwinds we are assuming based on current FX rates. We're also raising our EPS guidance to include the incremental tax benefits from stock-based comp we saw in Q1. We expect that strong high value product mix shift and operations initiatives will offset some of the expected FX headwinds in the back half of the year. Let's take a closer look at the performance of the business.

Slide 4 shows a summary of our first quarter 2019 sales performance. Before I get into the specific market units, I want to highlight the increasing demand for our high-value products. We saw strong double-digit growth in Q1. Based on market dynamics as we see them today, we expect this trend will continue for the balance of 2019. Now, let's turn to the details.

In Biologics, we had a strong quarter with double-digit organic sales growth. This was led by high value product sales including NovaPure, Westar RU, and Daikyo products. Many of the issues that affected 2018 organic sales growth are behind us and we expect full-year sales growth in this market unit to be in the double digits.

In Generics, we grew high-single digits in the quarter. Leading the way was the increase in self-injection device development agreements for SmartDose and demand for SelfDose. We have a solid book of committed orders for HVP in standard components, and we expect full-year organic sales growth to be in the high-single digits.

Our Pharma unit grew low-single digits. We saw a good uptake of our high-value products including Daikyo and Envision components, which offset the impact of the Vial2Bag voluntary recall we initiated earlier this year. Excluding this impact, Pharma would have grown in line with our expectations at 3% to 4%.

I want to provide a quick update on Vial2Bag. We're still working through the various actions associated with the recall and the work we need to do to bring this product back to market. Therefore, we don't have a specific timeline to share with you yet. Our customers have made us aware of the positive impact that this product has had on patient care. And we have communicated to them that we remain committed to returning to the market as soon as we can. As we look to the rest of the year, we expect Pharma to have organic sales growth in the low single-digits and to be conservative, we are assuming that Vial2Bag does not return in 2009 (sic) [2019] with meaningful revenues.

Turning to Contract Manufacturing. We had strong double-digit sales growth led once again by healthcare-related injection and diagnostic devices. As we look at the pacing for the next three quarters, we expect growth to moderate given the more difficult year-over-year comparables. Full-year organic sales growth is expected to be in the mid-single digits.

Slide 5, provides a brief snapshot of our market-led strategy that continues to build on our leadership position, secures growth across the market units and provides increasing value to our customers. I'd like to cover a few highlights from the quarter that we believe will support our customer base even more broadly and effectively.

First, to drive our digital transformation, we opened a new Digital Technology Center in India, which will serve as the Global Center of Excellence. The team there will play an important role in our ongoing efforts to enhance customer engagement through digital marketing, digital manufacturing and automation to accelerate internal and external business processes.

From a geographic expansion perspective, the Asia-Pacific market continues to be an important driver for our growth. We have worked to strengthen our presence in the key markets there, including China, India, and now South Korea. In Q1, we finalized the acquisition of our South Korean distributor. We are excited to engage with our customers more directly in the strategic and growing market especially for Biologics as it is the home of leading global biosimilar companies.

A significant pillar to our growth strategy is the globalization of our operations. And I'm encouraged by the progress we're making. In Q1, we saw continued improvements in our quality and safety metrics and strong results from our focus on service to our customers. In an effort to maximize investment across our global footprint, we made progress on our previously-announced restructuring plans. With our former site in Indiana consolidated into our Williamsport, Pennsylvania facility earlier this year, we are currently finalizing the consolidation of two more sites in the U.S. by the end of 2019.

Our One West global operations business system is generating the margin improvement we anticipated with these and other strategic initiatives. In Q1, we reported an 80 basis point expansion of gross profit margin, led by 180 points from our Proprietary Product segment. However, we still have more work to do in our Contract Manufacturing segment to improve our profitability. Bernard will review these actions or the actions we're taking later in this call.

I truly believe a key differentiator for West is our ability to provide our customers with a scientific and technical support they need to bring their products to market in an increasingly complex regulatory environment. We saw continued momentum in this area of our business in the quarter. For example, in march, West and the PDA hosted more than 150 customers at our headquarters to discuss the latest advancements in the containment and delivery of combination drug products. This is just one instance of how our team of dedicated scientists and technical experts have put themselves at the forefront of industry efforts to ensure that customers can meet today's challenging drug development hurdles.

Now, I'll turn it over to our CFO, Bernard Birkett, who will provide more detail on our financial performance and the 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. We'll first look at Q1 revenues and profits where we saw continued solid growth while absorbing the impact of the Vial2Bag recall. I will take you through the margin growth we saw in the quarter and how we see it continuing to improve in 2019, in addition to some quarter end balance sheet takeaways. And finally, we review the guidance for 2019.

First off, Q1, our financial results are summarized on slide 6 and the reconciliation of non-U.S. GAAP measure are described in slides 11 to 14. We recorded net sales of $443.5 million representing strong organic sales growth of 11%. We also saw growth across each of our market units as Eric noted earlier.

We are pleased to see continued improvements in gross profit. We recorded $146.8 million in gross profit, $12.4 million or 9% above Q1 of last year. And our gross profit margin of 33.1% was an 80 basis point expansion from the same period last year. We also saw improvement in adjusted operating profits with $71.3 million recorded this year compared to $56.7 million last year, a 25.7% increase. Finally, adjusted diluted EPS grew 19%.

So what's driving this growth in both revenue and profit? On slide 7, we show the contributions to sales growth in the quarter.

Volume and mix contributed $44.5 million or 10.7 percentage points of growth. Sales price increases contributed $2.9 million or 0.7 percentage points of growth. And changes in foreign currency exchange rates reduced sales by $19.6 million or a reduction of 4.7 percentage points.

Taking a look at margin performance, slide 8 shows our consolidated gross profit margin of 33.1% for Q1 2019, up from 32.3% in Q1 2018. Proprietary Product's first quarter gross margin of 38.9% was 180 basis points above the margin achieved in the first quarter of 2018.

The key drivers for the continued improvement in gross margin are, favorable mix of products sold focusing on high-value products, sales price increases together with improved utilization and efficiency in operation. In fact, our high-value products represented 60% of Q1 Proprietary Product sales. We had double-digit growth for this area of the business in line with our overall strategy to grow HVP revenues and margin expansion.

Contract Manufacturing first quarter gross margin of 14% decreased by 80 basis points compared to the prior quarter. The year-over-year decrease in margins is primarily due to an unfavorable mix of sales with higher than anticipated engineering and tooling sales and some one-time costs. However, margins on product sales expanded in the quarter compared to Q1 2018. As we continue to improve our efficiency and utilization levels, delivering on the new customer programs and improvements in margins on product sales, we have continued confidence that Contract Manufacturing margins will improve further into 2019. Operating margin grew by 250 basis points over Q1 2018 as we continue to expand gross margins and closely manage our operating expenses as we execute on leveraging our income statement.

Now, let's look at our balance sheet and review how we've done in terms of generating more cash for the business. On slide 9, we have listed some key cash flow metrics. Operating cash flow was $47.6 million for the first quarter of 2019, an increase of $2.6 million compared to the first quarter 2018. Our first quarter capital spending was $28.8 million, $0.8 million higher than a year ago.

Working capital of $562.9 million at March 31, 2019 was $47.8 million lower than at December 31, 2018, primarily due to the decrease in our cash balance. Our cash balance at March 31 of $266 million was over $70 million less than our December 2018 balance, primarily as we purchased 800,000 shares of our common stock under our calendar year 2019 share repurchase program at a cost of $83.1 million during Q1 2019.

Now, let's turn to guidance. Slide 10 provides a high level summary. First, despite increasing FX headwinds and taking a more conservative view on Vial2Bag revenues for 2019, we continue to expect our full-year sales to be in the range of $1.795 billion to $1.82 billion, which represents expected organic sales growth of 6% to 8% over 2018 reported net sales and assumes a negative impact of $34 million to $37 million to full-year 2019 sales based on current foreign currency exchange rate. Second, we are raising our full-year 2019 adjusted diluted EPS to a new range between $2.80 to $2.90 compared to prior guidance of $2.77 to $2.89.

There are some key elements I want to bring your attention to as you review our guidance. At this point, guidance does not include any material revenues for Vial2Bag in 2019 and forecasted cost of remediation are included in our EPS guidance. FX headwind has an impact of approximately $0.07 to $0.08 compared to full-year 2018 adjusted diluted EPS based on current FX rate. The estimated impact on prior guidance was $0.06.

So, to summarize the key takeaways for the quarter. Strong top line growth in Proprietary and Contract Manufacturing, gross margin improvement, growth in operating margin, growth in adjusted diluted EPS over Q1 2018. Our projections for 2019 and performance to date are in line with our long-term construct of 6% to 8% organic sales growth, operating margin improvement of 100 basis points, and EPS expansion.

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

Eric M. Green

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

Great. Thank you, Bernard. Our Q1 results underscore the value that our teams are providing for customers. At a recent customer advisory board meeting, we got feedback from key decision makers from various pharmaceutical and med device companies. They talked about the need for more systems and solutions that can support and improve patient care in the injectable space.

We are addressing these needs with new product development and initiatives such as our Integrated Solutions program. We're also expanding our capabilities to include drug handling and cold storage within Contract Manufacturing. All of which will allow us to partner more closely with our customers, as they work to introduce new products to the market.

Through the execution of our strategy, we're focused on delivering on our financial goals to grow our business, expanding operating margins, and generate more cash for our business to reinvest in our future. We're confident in our growth strategy across the markets we serve for both short and long-term and look forward carrying this momentum through the year.

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

QUESTION AND ANSWER SECTION

Operator: Thank you. [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, Eric. Can you talk to the operating margin initiatives that you have undertook or reflected in the quarter, and what you're doing in the months and years ahead?

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

A

Yeah. Good morning, Paul, and thanks for the question. No, the team has done a good job and focused on driving margin improvements as we discussed. That's been our focus, 100 basis points per year ongoing. And so, there is two really key drivers. One is, we're getting a good mix shift with our solid high-value product growth from a product point of view. And if you look at the outlook and the order book that we have on hand we're pretty confident we should see continued growth and adoption of the high-value product portfolio.

If we move down the income statement and start thinking about in SG&A while there were some costs to the remediation of the Vial2Bag, we've offset that with really leveraging existing asset base around the – of our SG&A to be more effective on a global basis. And what you're seeing is it has really fallen down through to the operating margin expansion. So, I would say, those are the two biggest levers. And one area that we need to focus and work on, the teams are very cognizant of that is expanding our margins in Contract Manufacturing. So we still have more work to do to continue that momentum there, Paul.

Paul Richard Knight
Analyst, Janney Montgomery Scott LLC

Q

And what's the latest on the Ireland facility, specifically capacity utilization in those facilities?

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

A

Yeah. Specifically in Dublin, we're still ramping up on a couple areas in our Contract Manufacturing in regards to – in the diabetes space and also in auto injectors. And so as we continue to – we're not at full capacity at this point in time. As you know as we install the capacity and we're seeing ramp-up throughout 2019. So we should see closer to capacity towards the mid to the end of the year.

When you think about Waterford, which is really the state-of-the-art facility for high-value product portfolio, we're seeing increase in demand in regards to our Westar Select offering that we recently launched. And while we're still – obviously there is headwinds on cost of that facility until we fill it, they're dissipating because we're getting more revenues through the plant as we speak. So to give you a number around that we'll probably about $5 million better this year than we were last year.

Paul Richard Knight
Analyst, Janney Montgomery Scott LLC

Q

Okay. And lastly on the Vial2Bag guidance, you are no longer assuming that that is a product in sales again this year, but is there any change in your process of getting that product or any change in customer feedback or is it conservatism? Thank you.

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

A

Paul, I would – thanks for the question. Paul, I would say at this point in time, the teams are working diligently to get working with the regulatory authorities to get the product back in the market. We are still getting significant response from the marketplace, particularly the hospitals saying that this product does create and helps them deliver better patient care. So we are working with them diligently.

We've gone through our research, human factors, device testing, all the necessary steps. And I'm confident the team will have a product back on the market that we can continue to stand behind and support the healthcare at the hospitals. We have, as you noted, we reduced our guidance – we didn't reduce the guidance, the guidance stayed the same, but we reduced the contribution of Vial2Bag to be conservative because it's uncertain at this time the exact point in time when it'll be back in the market.

Paul Richard Knight
Analyst, Janney Montgomery Scott LLC

Q

Thank you very much.

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

A

Thank you, Paul.

Operator: Thank you. Our next question comes from David Windley with Jefferies. Your line is now open.

David Howard Windley
Analyst, Jefferies LLC

Q

Hi. Good morning. Thanks for taking my questions. I'm wondering if you could first, on that last question, quantify the delta in guidance. Obviously, Eric, you said guidance unchanged, but what is the amount of change in Vial2Bag that you're absorbing in that guidance update?

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

A

We've probably taken about $12 million plus.

David Howard Windley
Analyst, Jefferies LLC

Q

Okay. All right. Very helpful. Thank you, Bernard. Eric, on the – to follow up on Paul's question on efficiency in margin. I hear you talking about mix shift in HVP, and that certainly helps. We all know the margin differential there. You're also taking some absolute cost out. You mentioned Indiana, a couple other facilities to consolidate over the balance of this year. How should we think about those activities influencing margin. Is it simply the $14 million that's listed in the press release that essentially comes out of the operating cost or is there – I mean are there more dynamics that we need to consider?

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

A

Dave, that's great question. I would tell you, it's almost about two years now ago, we pulled together the global operations. At that point of time, we had 28 sites, while each site had a discrete purpose, obviously, service our customers. By globalizing the operations, we have more opportunities to leverage across our operations globally.

So the case in point, we've created centers of excellence, our investments around capital are going to specific sites for specific product portfolios. This focus is allowing us to leverage not just on capital investments, but also on labor. So you think about burden reduction, and you think about asset utilization, these are key indicators that we're looking at. It's not a one-year journey, it's a multiple-year journey. I'd say, we're still in the early stages, but I'm actually quite excited because when you go to the plants, you're seeing it, you can see the improvements when you start – sitting down and looking at the labor burden rates. So you're absolutely correct. The gross margin expansion while major thesis and driver of that is around high-value product conversion, there is global operation opportunity. And the One West business system we put in place should enhance that on a – going forward on a continuous basis.

David Howard Windley
Analyst, Jefferies LLC

Q

And so on that, are we seeing that today or is that not really something that's materially impacting your financials yet?

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

A

I would characterize it as minimal at this point in time because some of these site consolidations require cost. And I know it's taken; we're looking at restructuring on that part of the activity. But these are really early initiatives that we have in place. While we're seeing some of the benefit, I would say the larger benefits are more forward-looking at this point, Dave.

David Howard Windley
Analyst, Jefferies LLC

Q

Okay, which is encouraging. When I look at the margin performance, the idea that that's still to come is certainly encouraging. So, my last question is on this margin performance, if not the added benefit from what we just discussed, how did – what are the factors that drove kind of a 45% to 50% sequential incremental margin in Proprietary Products so looking at it that way. Or if I look year-over-year, it was actually 100%. Talk about the various factors that are driving that kind of incremental margin improvement.

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

A

Yeah. One of the major drivers of the margin expansion that you've seen is really in the Biologics as the high-value product growth. Let me get little more granular. If you look at the NovaPure product portfolio that we've been talking about over the last couple of years, we seeded the market and it takes time to seed the market and get the expansion. I can tell you in the first quarter, the absolute dollar value of revenues is 2X in NovaPure. And you know where that fits in our portfolio of products, it's the highest ASP and the most profitable. And so, we're gaining traction on initiatives that we'd seeded a couple of – a few years ago that we're seeing come through and particularly in the Biologics area. So you're right to point out that that's one of the biggest drivers of the margin expansion that we have today.

David Howard Windley
Analyst, Jefferies LLC

Q

Okay.

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

A

On a consolidated basis, it's true though the Contract Manufacturing brought it back, and that's why we have the focus to make sure that we continue expand our CM business in addition to high-value product growth.

David Howard Windley
Analyst, Jefferies LLC

Q

Got it. Great. Thank you very much. Very interesting.

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

A

Thank you.

Operator: Thank you. And 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. Good morning. Great quarter. Just a couple of questions on the margin enhancement. On the Proprietary Products particularly is that – these margins it sounds like with sustainable high-value – growth in the high-value products and the ongoing efficiencies, are these margins you know plus or minus somewhat sustainable as we look out through the year?

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

A

I would say, if you think about we want to continue to have high – well, we are going to have continued high-value product growth and double digits for the balance of the year. It was very strong in Q1. We anticipate it continue throughout maybe not as – by a lower double digits in the second half because of stronger comps. So let me say that when you sort of think about the margin expansion, we do think it's sustainable. If you think about the thesis of – the high-value product portfolio while 60% of the revenues from a unit's perspective, it's still about approximately 20% of the units. When we think about the pipeline of – that we're feeding right now in the Biologics, and also the work we're doing with AccelTRA in Generics, and the opportunity for conversion over the next one or two years, that's why we have confidence of continued healthy margin expansion to give us that 100 basis points plus of operating margins over long periods of time.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

And it's really nice to see this NovaPure growing, I was just looking back couple of years ago, some write ups and it was just sort of in the beginning of sort of hockey stick growth, if you will, but on the front end of it. And you mentioned to double contributions this year. Is that still – I imagine on a volume basis, still lots of opportunity, I imagine still worth you know – I don't know [ph] you – go ahead (00:30:24).

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

A

Larry, to mention that, it was about less than 2% of revenues last year for NovaPure.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Right.

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

A

So – but if you can – we continue to focus on the pipeline, that's what drives this portfolio. It's what's in the pipeline that's coming through. We've been seeding it for a period of time and that's the exciting part. You think about the number of biologics that are in the pipeline, more than they have been in the past. And the other exciting part is that we're touching a lot of smaller biotech companies. If you look at our portfolio of customers and there's a statistic recently roughly around three-fourths of the drug molecules coming through are coming from the smaller firms. So it equates well for us if we start thinking about future growth potential.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

And just on the Contract Manufacturing piece, I realize I guess some of that's still sort of over high capacity absorption. Just any other more color there obviously is some of these global initiatives I assume will help Contract Manufacturing as well a little bit. Just such strong growth top line this year, I would figure maybe the gross profit margin would have moved a little bit higher. Any color on that?

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

A

Yeah. What we're seeing with that is that on just if we look at the products themselves, we are seeing margin expansion in line with our expectations. I think in the first quarter as we commented earlier, it's down to product mix. And we did have a lot of tooling cost, tooling sales and engineering sales, and they typically have a much lower margin profile. So that impacted the gross margin percentage within the quarter. But when we look out for the remainder of 2019 and beyond, we would expect to see incremental improvements in gross margin within Contract.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Okay. Great. And then, just lastly, Eric, you mentioned sort of it seems like somewhat of an acceleration in some strategic agreements across a lot of your platforms, maybe a little more color on that, maybe update on SmartDose and CZ?

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

A

Yeah. No, absolutely, Larry. It's exciting we're seeing – look, we have more work to do with our clients and our customers, but we have a number of – in the double digits of feasibility and development agreements with specific customers around SmartDose. And we obviously have discussions with several more, some of our customers are making that public, but we tend not to discuss the details in great detail.

So we're feeling more comfortable as we started thinking about the potential of SmartDose. But I would say like we experienced with [ph] repath, (00:33:16) it's a long journey to get it to over the goal line and get it as a combination device in the market. Now, what's encouraging on top of that is not just in the Biologics space, we're seeing the interest level increase in our Generics space. So that takes me over to the SelfDose. We have three discrete customers that are going into commercial launches with SelfDose. This is that unique product in the auto injectors space that is gaining traction for the dosing with multiple molecules.

The last thing I'll comment is on CZ. We obviously use CZ for the SmartDose component. But what's also encouraging we've been working for quite a while with a couple of customers on 1 mL insert needle and we're looking at commercialization later on in 2019, early 2020.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Okay.

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

A

So as you think about these development agreements, it takes – they take time to develop and work through, but it's very encouraging. And the quality of these agreements are strengthening also.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Okay. And then just lastly I might add, you had a really, really great start to the year. And obviously I realize some of the year-over-year increases were due to a little bit of a better easy comp compared to Q1 2018. But just with some of the initiatives going on – sort of your guidance sort of implies like a 50 bps-ish decline in operating margin from the Q1 level. Might there be a sense of conservatism in that or how should I sort of connect those dots?

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

A

Yeah. We've got a lot of initiatives going on and our focus – we have to be really focused and disciplined in our approach. And the key thing for us is to execute on the guidance that we put out there. And that's foremost in our minds, and that's why we want to make sure – it's the first quarter and it's been a really positive start.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Sure.

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

A

And we want to make sure that traction continues as we move through 2019.

Larry S. Solow
Analyst, CJS Securities, Inc.

Q

Fair enough. Great. Okay. I appreciate that. Thank you very much.

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

A

Thank you, Larry.

Operator: Thank you. And our next question comes from John Kreger with William Blair. Your line is now open.

John Kreger
Analyst, William Blair & Co. LLC

Q

Hi. Thanks very much. I wanted to ask another question on the margin outlook for Contract Manufacturing. Bernard, you said you expected to improve sequentially, do you expect for the whole year to have an improvement in gross margin or should we still assume it's down year-over-year for the full-year?

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

A

No. We would expect to have an improvement – an overall improvement year-over-year as we move through 2019. And we – there are a number of initiatives underway. There is a lot of focus within that area, because we realize that we want to capitalize on the revenue growth. And we know we have to improve the margins within that business. And we've seen this take place in the Proprietary business. So if you look over the last four quarters, we've seen margin improve in that area. Now, our focus is on improving within Contract Manufacturing to make sure that we capitalize on the total revenue growth that the business has seen.

John Kreger
Analyst, William Blair & Co. LLC

Q

Great. Thank you. A question about the geographic mix. What sort of growth differentials do you expect across regions based upon your pipeline at this point. And does that have a mix impact on margins?

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

A

I'll start with this, Bernard. When you look at the growth in the first part of the year, it's pretty even when you think about the Americas and Europe, it's close to the double digits. In Asia, as you know, it's a smaller piece of our overall business. Overall, we're looking at for the full-year about double digits as we have done the last couple years. And we're actually more excited now with South Korea onboard and able to generate more revenue growth in that particular market. But as we go forward, it's relatively a consistent growth across the three regions. What's interesting is when you think about Generics, it's a healthy growth in both the Americas and Europe. And obviously Biologics is more right now heavily in the U.S. markets as we speak. So, that's kind of the mix that you would see. But we're not seeing much of a difference at this point in time in the different geographies.

John Kreger
Analyst, William Blair & Co. LLC

Q

Great. Thank you. And then just one last one, are you able to tell us what impact the Vial2Bag recall and your remediation efforts for that had on Q1 EBIT margin?

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

A

Bernard?

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

Yeah. Cost wise, we probably picked up $2 million to $3 million in incremental cost within our SG&A line. We did look at and have some inventory obsolescence accrued for within COGS. And that range is at about just over $4 million. And that – and then we had some other one-timers we just in case people sort of backing that out of the COGS number and extrapolating it into margin, we had some one-time revenues that came in from agreements that we have in place around our SmartDose device. So that kind of offset the obsolescence charge.

John Kreger
Analyst, William Blair & Co. LLC
Q

Great. Thank you.

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

Thank you, John.

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

Juan E. Avendano
Analyst, Bank of America
Q

Hi. This is Juan on behalf of Derik. Congratulations on the quarter. My first question is on research and development. Total R&D spend as a percentage of sales has come down slightly. It's been down about by 10 basis points year-over-year over the last couple of years. Can you tell us about your outlook on R&D spend going forward, if you see R&D spend continuing to decline as a percentage of sales going forward? And how do you feel about this level of R&D spend and your ability to continue to innovate on high-value products and self-injection devices?

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

Yeah. Juan, it's a great question, and thank you for dialing in this morning. When we take a look at R&D, I would like to first isolate it against Proprietary as CM is growing much faster than the rest of the business. I think as a percentage of sales, you're right, it's somewhat flat maybe slightly down. What we are seeing though is that there is a significant amount of resources within our R&D team that are focused on these development agreements for our customers. And particularly it's not just in devices, but it's also in some of our Elastomer components that we're designing for – on behalf of specific customer.

So when you think about that and that's actually on the rise. And we capture that in our COGS or cost of goods sold, and – because we obviously got revenues to offset that. So if we look at that in totality, it's probably relatively neutral to slightly up as far as expense as a percentage of sales, come out of our R&D group. Now, it's a great question about the future and making sure that we are seeding the future portfolio. We continuously evaluate how we're going to use, leverage R&D and look at – is there opportunities to put more resources, [ph] particularly in the (00:40:59) core part of our business. And that's an ongoing review [ph] Juan (00:41:03) and we'll continue to feed it if there's opportunity for future growth in new products.

Juan E. Avendano
Analyst, Bank of America

Q

Okay. Good. On the Contract Manufacturing segment, has grown low-double digits in the last couple of years, and it has exceeded your guidance in both years started off being mid-single digit and then eventually high single-digits, but it did exceed your guidance. And so, I know that for this year you're continuing to guide mid-single digit growth for the whole year. How conservative is that and why can't the CMO segment continue to do low double digit growth going forward especially after you realigned this business to do more healthcare business as opposed to consumer products? What is the new long-term growth target for this segment going forward?

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

A

Yeah, Juan, it's a good question. I think when we look at installed capacity, we're just looking at how as we're building components for our customers, the installed capacity and the ramp up we have for this year and what we have on the order book gives us confidence to be solid in the mid-single. There's always upside, I'll tell you what the upside. The upside is the diabetes market continues to I guess I would argue exceed expectations. And the actually phenomenal impact of having on patient healthcare. And so, we – and we play part of that, we're part of that. Not just from a device point of view, but also from an auto injector. So I think a lot of it comes from our Contract Manufacturing, but we also benefit with some of the primary containment, Elastomer coming out of our Proprietary business.

So, Juan you're correct. That part of the diabetes market has been a little more aggressive than we anticipated, I would say, if you look back. We do have some pretty tough comps in the second half this year. And that's why we're seeing that it's lot more mid-single digits. And as we go forward, we have de-emphasized the consumer products is less than 10% of our revenue within Contract Manufacturing today, and we'll continue to invest in the healthcare space. So I would say why – we're in a good situation. But we need to continuously improve the margin and profitability of that unit. That's our primary focus outside of the – and make sure we deliver on time in full and high quality to our customers. But we've got to get profitability and we'll continue to expand as we see profitable business come into West.

Juan E. Avendano
Analyst, Bank of America

Q

Okay, got it. And one last one if I may. This is sort of a very different question, a lot of people don't focus on this. But when I look at your product sales by I mean your overall sales by product type, we barely talk about the standard packaging components. Everyone just focuses on the high-value product. But I was looking at historical slides for standard packaging components. When I compare the slides that you typically would have noted with the bubbles and the gross margin associated by product type and the five year CAGR associated with them, I've noticed that for standard packaging components, the size of the bubble has decreased significantly. The growth profile has gotten from mid-single digits to about low single digits and the margin – gross margin profile with standard packaging components has come down from high 20s to below the CMO segments, and so about mid-teens at best. And so given that this product category still accounts for over a 30% of sales on a product basis, can you just give us an update on the standard packaging components? Any loss to high-value products and your outlook in this product category in the future?

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

A

Yeah. Juan, it's a good question. When you look at standard products, obviously, it remains an important part of our portfolio because there are several molecules in the mark that rely on that that portfolio. I can tell you in our global operations initiative, one area they're looking at is continue to see driving cost out of the system so we can continue to deliver the product, high quality product to our customers.

Now when you think about the conversion of existing products to high-value products with our customers, so standard to high-value products that is still going on. So when you think about a high-value product growth and strong double digits, that's not just new product pipeline or just biologic. That spreads throughout all three of the market units. And so, there is an element of conversion and therefore there is I'll say in different ways a little bit of cannibalization of ourselves. But that's a good thing because we get better ASP and get better margin.

When you look at the margins itself, we don't believe that it's declining as much as I think you are articulating there. It's relatively consistent, I would say, you're right, we probably don't get a lot of price, additional price in that area. It's probably less – it's less than 1%, but still positive. But I would say it's – we're really focused on driving cost and lean out of the system at this point in time.

Juan E. Avendano Q
Analyst, Bank of America

Okay. Got it. And in that vein, I guess can you give us an update on the market penetration rates of high-value products by customers. And so Pharma, Biologics, and Generics and overall what percentage of volumes do they make up overall and across each customer category nowadays?

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

Yes. So in the Biologics space, over 90% of our transactions are what we classify as high-value products, and it's just the nature of the portfolio. If you think about the generic side – and by the way when we think about the pipeline, feeding the pipeline, if we were doing Westar RU and if we're doing coating, and then – the FluroTec coating and also maybe Envision, our focus from that point is move them up to NovaPure. So there's a conversion within high-value products, we're still focused on in Biologics.

In Generics, it's roughly around 50% of the portfolio is high-value products, and you can see that increase. The reason why is because the AccelTRA program, which has gained a lot of attention from our customers and interest to convert over the next couple of years. So you'll see that shift from 50% to much higher over the next couple of years. And when you think about Pharma, that's probably the slower transition. It's roughly around 30% to 40% – 35% to 40% of Pharma is in high-value products. But I won't say the shift towards HVP will be faster than Generics, I'd say it's probably slower just for the nature of the product.

Juan E. Avendano Q
Analyst, Bank of America

And overall?

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

Well, again, overall, it's 20% of the volume we produce out of our Elastomer portfolio and 60% of the revenue in Q1. That's to give you 60% of Proprietary sales and it's roughly around 20% of the units. And that's – I'm using Q1 as a proxy and slightly better than it was last year.

Juan E. Avendano Q
Analyst, Bank of America

All right. Thank you. I appreciate the update and I'll follow up online with additional questions.

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

A

Great. 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 to Quintin Lai for any closing remarks.

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

Thanks, Jimmy. Thank you for joining us on today's conference call. An online archive of the broadcast will be available on our website in the Investor section. Additionally, you may access the replay through Thursday, May 2 by dialing numbers and conference ID provided at the end of today's earnings release.

With that this concludes today's call. Have a nice 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.