13-May-2015

# West Pharmaceutical Services, Inc. (WST)

Bank of America Merrill Lynch Global Health Care Conference

# CORPORATE PARTICIPANTS

Donald E. Morel, Jr.
*Chairman*

Eric Mark Green
*Chief Executive Officer*

# OTHER PARTICIPANTS

Rafael Tejada
*Bank of America Merrill Lynch*

# MANAGEMENT DISCUSSION SECTION

## Rafael Tejada
*Bank of America Merrill Lynch*

Hi. Good afternoon, everyone. My name is Rafael Tejada. I'm analyst with the life sciences team here at Bank of America Merrill Lynch. Up next, we have West Pharma. And presenting for the company, we have Chairman of the company, Don Morel. And we have Eric Green. He's the new CEO. And I should mention that Don was the former CEO of the company.

So we're going to do a bit of a fireside chat. But I'm going to ask that, Don, that you just provide a quick overview of the company for those that are new to West Pharma in terms of the segments and then we'll do Q&A and certainly anyone in the audience, I encourage you to just jump in and ask some questions if you have them.

So Don, let me turn it over to you.

## Donald E. Morel, Jr.
*Chairman*

Great. Thanks, Rafael. For those that may not be familiar with the company, West is a specialized manufacturer of packaging and delivery systems principally for injectable drugs. We have been in operation since 1923. We're located just outside Philadelphia, operate 37 manufacturing facilities around the globe. We operate two business segments, principally one we call Pharmaceutical Packaging that's a little north of $1 billion at the end of 2014, and one we call Pharmaceutical Delivery Systems, which is a little over $400 million.

When you look at our product portfolio, if you're familiar with injections, we do syringe plunger tips, we do the packaging that goes into vial-based medicines. We do an awful lot on the medical device side. But the product portfolio basically serves all of the major vertically integrated multinationals, all of the specialized biotech companies, all of the generic companies and all the med device companies globally.

We don't historically have a large revenue concentration with any customer. Becton, Dickinson is our biggest customer. They're a little bit north of 7% of our revenues. Then you run into a band of customers after all the consolidation that's happened in the industry where we have anywhere between $40 million, $50 million in sales and about $80 million in sales. Very nice business. There are very strong regulatory and manufacturing moats around what we do. Our business is very sticky, especially on the packaging side. It's covered by the EMA guidelines and FDA guidelines whereby when the customers qualify our products on their drug products, we basically are with them for the life of the product. As an example, we make some things once every couple of years. They were qualified back in the 1930s and 1940s, and they're still indeed in use today. So very nice recurring revenue stream.

The major thing I think to take away is that when you look at the top 35 selling biologics in the world today, we or our Daikyo partners in Japan package all 35 of those. It's the fastest-growing segment we have. If you look at the pipelines within the major research and development-focused companies, last couple of years, if you look at the injectables, we were on 14 out of 14 new products that were approved. We enjoy market shares in the range of 70% to 80% in certain segments in the West. In the biologics space, it's over 90%. Again, because of the regulatory system, we are locked into those products.

Five-year plan that we've published for the industry. We typically work in five-year segments. We guide the years, not the quarters. We are looking at taking the business from about $1.4 billion today to north of $2 billion in five years. Overall, operating margins should be in the 18% to 19% from the low-double digits today. So it's a very, very nice business. We love it. We have competitive advantages that we've been fortunate to build over the last couple of years and should be able to generate nice sustainable growth for the foreseeable future.

### Rafael Tejada
*Bank of America Merrill Lynch*

It's a good overview. It sounds like you've done that before.

### Donald E. Morel, Jr.
*Chairman*

Once or twice.

### Rafael Tejada
*Bank of America Merrill Lynch*

I also just wanted to add that Bill Federici, CFO of the company, is in the audience; and Mike Anderson with IR and Treasurer is also on the audience.

# QUESTION AND ANSWER SECTION

**Rafael Tejada**
*Bank of America Merrill Lynch*

Q

So Eric let me turn it over to you first time. I think this is one of your first appearances after the initial quarter out in the public domain. So I think it will be great if you kind of provide basically what drew you to West? Why you were interested in the CEO position here? And as you look at your skill set, your past work experience, what do you think is going to allow you to really do well and continue the strategy that's been laid out for the company?

**Eric Mark Green**
*Chief Executive Officer*

A

You know first of all, Rafael, thank you for the invitation to be here today with you and several others. I've had a good fortunate of pleasure to work with Don and the team for the last couple of weeks joining West as the new CEO and it's a fantastic organization. If you take a look at the foundation of the company, it's a 90-year history that has evolved with a strong global presence, servicing all top 50 pharma and biotech firms around the world.

It has a very in-depth supply chain manufacturing capability in over 35 locations again around the world which is very unique for a firm at this size and the growth rates that we're seeing at West. I think also what was very attractive of West is around the innovation strategy and the R&D efforts, not just internally but externally. The partnerships they have with Daikyo and a few other organizations has really enabled them to position well today but also the future to solve some very complex problems for our customers in the pharma environment.

Couple of areas that I have experience in the scientific environment for the last 22 years is really around – one is around the R&D and innovation side. I think that's another platform that West has started and will continue to invest in. Secondly is around the emerging markets. I've spent a lot of time, particularly in China, India, Korea and the whole Asia-Pacific region and also Latin America, and I see that as the growth opportunity for West. Today, it's less than 10% of its revenue. But as everyone knows, large multinationals are making significant investments in those regions, but also the national and the biosimilar organizations are also evolving in those particular markets. And I think that's an area that we can leverage and continue to grow forward.

I think also the other part is around the operational footprint, as the investments that we're making anywhere between $120 million to $150 million a year at West to add capacity and new product portfolios is starting to push more of those capacities, again, on a global scale versus concentrated in Europe and the United States. So Rafael, I'd say, those are the particular areas that, A, attracted me to West; and, B, the opportunities we can continue to grow within this organization.

**Rafael Tejada**
*Bank of America Merrill Lynch*

Q

And basically since your appointment, I've been – one of the top questions that I've been getting from investors is just around whether we should – just with the timing of Don's departure and [ph] not (07:20) certainly your appointment, just whether there's going to be a shift in the strategy, right. So I guess I want to pose that to you because I've given my opinion, so just want to ask you the question. Are you looking to make anything – change anything drastically? Is there anything that as you evaluate the strategy that's been laid out, is there something that you think doesn't quite make sense and needs to be just changed a bit?

**Eric Mark Green**
*Chief Executive Officer*

A

Rafael, I believe the strategy that's been set by the team at West is quite solid. The growth rate that we're experiencing today is mid-to-high-single digits, the profitability continues to expand, and we are continuously capturing new customers and working on new drug launches into the near future. I would say a couple of areas that we'll look into further. As I mentioned just a few minutes ago, one really is around the whole – the global emerging market approach. I know that we've had focus at West, but we'll continue to ramp that up and accelerate that focus.

I think also there's been a tremendous amount of energy towards people from the culture at West. And if you look at West, where they stand today is a very healthy organization. And we have a very strong management team. But as the business continues to grow, we need to make sure that we have the bench step and the organization ready to take on a bigger, more complex organization.

I think, third is also continue the effort around the bolt-on strategy, continuously get new technologies, whether it's IP or new product portfolios to supplement our current capabilities, but also new geographies to look at. So I would say, these are areas we'll particular take a focus on, but the core fundamental strategy of the company is solid and we'll continue to deliver the results that we've articulated.

**Rafael Tejada**
*Bank of America Merrill Lynch*

Q

Great. And so let's just drill down on business a little bit. On the packaging side, I think what I've been pleasantly surprised with is just ongoing strength for the high-value products. So with that backdrop, I think, can you just talk about the drivers that are really pushing the growth there? And how should we think about the future growth for those high-value products and the implications for the margins within that specific business segment?

**Donald E. Morel, Jr.**
*Chairman*

A

Yeah. So if you take a look at our first quarter and then maybe go back a couple of years, we've always talked about the increase in the biologics space. And that really is driving the high-value product market. And you're seeing a number of things. One, you're seeing renewed pipelines that are getting through the approval process. You have some innovative new therapies that are coming to market. We have talked about the PD-1s for cancer in immuno-oncology. We have talked about some of the new GLP-1s and drugs that are being used to treat diabetes. Vaccines are seeing a resurgence in a number of areas, and then autoimmune disease as well, plus potentially the new PCSK9s coming out for cholesterol treatment.

West enjoys a very, very nice position in the biologics space. If you look at approvals over the last couple of years, then we or our Daikyo partners are on every one of those drugs. And more importantly, with things like the PD-1s, you're going to see a rolling series of approaches to new indications that are going to help bolster that category as well. So we're going to see organic growth out of existing categories and existing drugs that are approved. We're going to see better sales out of new indications as they get broadened; and as we look forward over the next couple of years, the pipeline in large molecules is tremendous. And as you know, large molecules, once they get into Phase III, have a very, very high chance of approval. They don't have the risk that small molecules do. We think all of those factors bode very well for continued growth in the HVPs of anywhere from 8% to 12% per year. And we think that that is sustainable for the foreseeable future.

**Rafael Tejada**
*Bank of America Merrill Lynch*

Q

And just quickly comment on just the margin. How do we think of the standard packaging products gross margins and [indiscernible] (11:36)?

**Donald E. Morel, Jr.**
*Chairman*

A

Sure. So in our business, we typically look at three different categories. We've got the high-value products that go under the biologics and the more expensive oncologic drugs. We have what Rafael refers to as standard products, which go onto the bulk antibiotics. Drugs that are in very large volume tend to be small molecule, very standard vaccines. And then we have what we call the med device category which is only about 10% of the $1 billion, which tends to be lower margin, very high volume, more to the historic med device customers.

I think right now, you've got in the low to mid-40%s in terms of penetration overall for the HVPs. So out of the $1 billion of sales in this group, roughly about $440 million, give or take any given years in the HVPs. We're seeing that incrementally increase every year. And I think over the longer run, we can probably approach about 60% of that overall category getting to the HVPs. You won't see 100% conversion because there are some products that simply don't require them. And that will be a combination of organic growth in current categories that are served by the HVPs. And then also, conversion out of standard products for ones that are on the edge that'll generate additional volume.

**Rafael Tejada**
*Bank of America Merrill Lynch*

Q

And just within this – sticking to this category, is there anything that we should be concerned about in terms of the competitive landscape? I know that there is high barriers to entry. But are there any sort of copycats out there trying to enter this very attractive market?

**Donald E. Morel, Jr.**
*Chairman*

A

Yeah. Absolutely. We have two principal competitors in the packaging side. One is based in Switzerland, Datwyler Corp, which offers a product called Omniflex. It's a different technology than ours in terms of the way the manufacturing is done. It's been around for years and hasn't really gained much traction. FluroTec has always been looked at as the standard.

More recently, the Aptar Company acquired Stelmi Group out of France. They recently, at a trade show, announced what they call PremiumCoat. They are looking at a fluoropolymer-coated closure as well. It's only a serum closure. It's something where obviously our history in the space gives us a very, very distinct advantage. But we think they're also performing some vantages in the way that we manufacture. So yes, there will be competitors nipping at our heels. We expect that it's a category that's very attractive to everyone in the space. Between our supply chain, our method of manufacture and our proven history, I think we've got a very nice-to-sensible market position, and we will continue to grow it.

**Rafael Tejada**
*Bank of America Merrill Lynch*

Q

So let's switch gears a little bit just to the delivery side of the business. This is a business that is anticipated to really be a source of engine of growth for the company and certainly margin expansion opportunities for the company. And one of the platform technologies here is Crystal Zenith. So for CZ, can you talk about your

relationship with Daikyo, just exclusivity around it and just what's so special about CZ and how it differentiates from traditional offerings such as glass?

Donald E. Morel, Jr.
*Chairman*

A

Sure. Our partner, Daikyo, back in the mid-1990s, saw that for contrast media and certain oncologic drugs, glass represented a risk in the treatment environment. There were breakage issues. You would drop a syringe with radioisotope, obviously not a good thing or some of the toxic oncologic drugs, and they worked with one of their suppliers to develop a resin that they call Crystal Zenith. This is what's called the cyclic olefin polymer. And they did a number of things to the formulation to make it unique for pharma, and they indeed, through the supplier, have a single source relationship. So West and Daikyo are the only ones with access to this polymer.

It turned out to be only one part of the equation because it turned out as biologics started to get put into prefilled syringes. There were problems with contamination of the drug from tungsten, from glass manufacture, from the glue that was used to position the needle and most visibly, from free silicone oil that helps the syringe function that aids the barrel sliding back and forth. And it turned out that the silicone particles would actually bind with the proteins and effectively weaken the strength of the drug by pulling these proteins out of solution and agglomerating them.

We began to work on a solution three years or four years ago to actually form the syringe in a way that needed no silicone oil, needed no glue to stake the needle, and would not utilize tungsten in the manufacturing process; and through the combination of the FluroTec technology and the CZ, we now have an offering that is completely silicone-free into the space. Now glass has been used for pharma for 100 years. The change won't come overnight, but we've seen tremendous interest over the last couple of years since these problems emerged in applying CZ to packaging biologics and very-high pH drugs.

We expect over the next three years to five years that the CZ will make very nice in-roads into very high-value drugs that are currently packaged in glass as well as we will see other packaging geometries, vials that are special design, cartridges that go into on-body injectors and into auto-injectors. It will be a slow and methodical process, but there's no doubt it's going to happen. There's going to pressure from the FDA to get rid of particulate. There's going to be breakage inside manufacturing, breakage losses that can be recovered through utilizing the plastic.

I've said it many times, every time I've spoken to investing audiences, I don't know when it's going to go commercial at large scale in the Western markets for biologics. I just know that it will. And our Daikyo partners sell about $50 million to $60 million in Japan now, not only for biologic molecules but for contrast media.

We announced recently that two of our customers have gotten first U.S. approval. One is for a diluent on an existing drug that actually delaminates the glass. So we see the delamination thesis that we've talked coming to the fore. And another one is a smaller custom vial that was recommended for approval by the FDA advisory panel for a cancer drug that we think will get approval in a couple of months. So vials are the first geometry, so it was a little unexpected. With what we know about, what's instability within the syringe category, we think that those approvals are going to come sometime latter part of 2016, early 2017. What we caution everybody about is that once it's out of our hands with stability, it's in the customers' hands to do the filings and then it's in the FDA's hands for review and approval. We just don't control the timing.

Rafael Tejada
*Bank of America Merrill Lynch*

Q

Right. I mean you've been fairly transparent about that. The timelines are sort of away from you. But one of the things that, I guess, sort of excited me was when I was looking at opportunity, which was basically Amgen's decision to evaluate the CZ platform. And I know that there are a number of other customers that are evaluating. So I think it would be – you mentioned some of the clinical trial activity, but I think it would be helpful just to kind of think about the number of trial activity that are out there just to get a flavor for what the volume potential could be for the CZ in terms of – let's look at 1 mL syringe or just [indiscernible] (18:53)?

**Donald E. Morel, Jr.**
*Chairman*

A

Sure. I can try and frame it simply. There's a lot of numbers in there. But right now, the prefilled market in the 1 mL area is about 2.5 billion units, give or take. A lot of those are bulks syringes that are used for things like heparin. Within the high-value category, we think that number is about 600 million that potentially CZ and other offerings that our competitive offerings could potentially access. We are assuming in our model only two to three approvals over the next five years within the syringe at relatively small volumes inside each one of those lines.

The thing with CZ and the syringes is that the customers need to be able to fill on their existing lines and use that data as part of their application to the FDA or the EMA, and that's been one of the delays for us. As the demand for their products has been so high, they've had trouble breaking into their manufacturing to do the stability run. Stability numbers that Rafael referred to, we know that more than 100 products have been tested by our customers in combination with CZ and we know that out of those 100 products right now, somewhere between 9 products and 12 products are on formal stability or nearing the end of formal stability and that number is roughly about two times where we were at the end of 2013.

So we're starting to see a lot of momentum. The data we're getting back from our customers in terms of compatibility and what they measure as they look at stability has all been very good. So the news continues to be encouraging. We just have to keep pressing forward.

**Rafael Tejada**
*Bank of America Merrill Lynch*

Q

Any questions from the audience? So the other aspect I wanted to ask was just on – I get this very often. It's just pricing, right. So how does a drug sponsor look at the different packaging solutions that are out there, specifically for CZ, so how does that fit in into the overall equation of a delivery system?

**Donald E. Morel, Jr.**
*Chairman*

A

When they look at packaging per se for the higher value drugs, the reason we enjoy such a very nice position in the biologics is that they want safety and stability first. I mean obviously, there's not an unlimited level that they're going to go to, but they're willing to pay for value and reliability and security of supply, and that's what drives the margins in our high-value product categories north of the 50% to 55% range.

On the device side, it's totally different because it starts to become a question of differentiation, repeatable delivery and a whole bunch of other things that enter into the equation. Pricing for us is value to the customer and what we think we bring to the party, we want to capture fair value. It's difficult to talk about the pricing environment now simply because roughly about half our business in packaging is covered by long-term contracts that are just on the annual anniversary with a CPI or a basket of goods that we use as the pricing indicator.

Couple of years ago, we enjoyed pricing overall in kind of the 2%, 2.5%, 3% range. This year, it's going to be 1% or a little bit north. We take price where we can on the remaining 50% that goes into the smaller customers. We

always have to balance. The question we get all the time is that if it's in the regulatory filings and they have no other choice but to use you, why don't you just raise price regularly? And the answer is quite simple. We don't want to forego future opportunities. It's a very fine balancing act between capturing value for what you provide today without sacrificing the potential for future programs.

Rafael Tejada
*Bank of America Merrill Lynch*

Q

So another key emerging product for West is SmartDose. What are the unique aspects of SmartDose? What's the early feedback so far on that product and how should we think about the potential – addressable market for that device?

Donald E. Morel, Jr.
*Chairman*

A

So a very interesting product that accidentally came about looking at another market segment. We actually were looking at a disposable pump solution for type 1 diabetics and it turned out that one of our customers mentioned, we would like to be able to deliver more than [ph] a mL (23:01) subcutaneously over a long period of time of fairly large molecular weight compound. And our engineers took this little pump, it's about half the size of a pack of cigarettes that has a cartridge reservoir in it and a motor that drives the piston. When the patient puts it on their body, they push a button, and then the mechanics and the electronics take over, and it delivers repeatedly this dose subQ. And it opened up a whole world of the formulators being able to now get away from somewhat concentrated solutions and into larger volumes that could be delivered very predictably over time.

We think very attractive in the autoimmune space, very attractive in certain other spaces. Customers, we have eight active development programs ongoing right now, I think, one of which is in a clinic al trial. The feedback has been very, very positive. It's opening new avenues for the guys as they take a look at drugs that they might have had on the shelf because of formulation issues. We're excited enough about it that we're augmenting our production capacity in Israel with greater backup capacity, which will become the predominant line in Scottsdale, which will be validated this summer. But anything that gives you the opportunity to take the caregiver out of the cost equation and yet make it safe, reliable, repeatable and easy for the patient to use is going to be a winner in this space and we think SmartDose falls into that category.

Rafael Tejada
*Bank of America Merrill Lynch*

Q

So let me ask you about the competitive landscape with regards to CZ and SmartDose. What's out there? Who do you see as your biggest competitor? Any threats out there? This is such an important part of the growth engine for the company?

Donald E. Morel, Jr.
*Chairman*

A

Yeah. The competitive landscape actually divides into internal and external capabilities. So we do know the number of firms who have internal device capabilities that are working on their own concepts. There are companies like BD that has been working on a prototype, not very actively recently. You've got Unilife, relatively small startup with a patch injector as well. You've got folks like Insulet looking at adopting technology originally developed for insulin and bringing that out of the diabetes category and into other categories. I'm sure there'll be other entrants as well, as we start to see success with the category. But right now, that's the primary competitive landscape.

Rafael Tejada
*Bank of America Merrill Lynch*

Q

And in terms of alternatives to CZ and the other resins that are out there that [indiscernible] (25:22)?

Donald E. Morel, Jr.
*Chairman*

A

There's a whole slew of them. And the plastic syringe category actually is a very complicated one in terms of the number of [ph] value layers (25:28) that you have to work through. There are some what are called COC versus COP polymers that are made at large scale now that are just good enough for the compounds they deliver that they're being sold in fairly significant volumes.

As you get into the COP category, there are other competitors that have come out of Japan principally that are close to the CZ, not quite as good in the number of technical attributes, but what gives West the secret sauce in the category is that Daikyo and ourselves have exclusive rights to the FluroTec technology. And it's the combination of FluroTec with the CZ that eliminates the need for silicone. The glass guys trying to compete with an offering for bio have to bake on silicone or plasma coat or use some other technology. It still results in a free silicone that can extract and cause the protein binding I talked about. So we love where we're at. The position is very, very good in terms of sole source supply, exclusivity for us in these materials, as well as our manufacturing technology.

Rafael Tejada
*Bank of America Merrill Lynch*

Q

And the business still has a lot of CapEx associated with it especially as you noted that there's additional volume requirement or new facilities that are opening up. So can you remind us of the bigger projects that are still left? And longer term, how should we think about potential free cash flow generation for the company?

Donald E. Morel, Jr.
*Chairman*

A

So I'd kind of split the capital discussion into two categories. If you look at the Pharma Packaging side, the major projects are in Waterford, Ireland and Kinston, North Carolina. Currently, in the U.S., we have a single plant in North Central Pennsylvania that is the leading producer of our high-value components in a place called Jersey Shore. Our customers are very keen on risk mitigation. And although we have a very broad project globally to make sure we're redundant between France, Germany, the U.S., and Singapore, we continue to work on making sure that all our processes are harmonized in the eyes of the regulatory bodies.

We will build a facility in Waterford. It'll be a combination facility to give us insulin sheeting capacity. It's another material unique to West. Diabetes is a category for us that's north of $100 million between pens and packaging and for cartridge-based insulin for the three major manufacturers. We provide all of the packaging except for the glass cartridge. So very substantial category. Ireland will be backup capacity there for future growth as well as a fill/finish facility where a lot of the value add will be done for the pharmaceutical products in the future. So Kinston and Waterford on the Pharmaceutical Packaging side, plus some small R&D expansion in Asia and in Europe as well to bolster R&D capability.

On the device side of the business, it is the expansion of Scottsdale in Arizona and also Dublin in Ireland where we have a couple of new large programs coming on board that we think will start to launch in the one-year to two-year timeframe.

One of the things that's important to understand about CapEx in our packaging business is that we typically build two years to three years ahead of commercial sales. No matter where we build or what we do, if it goes on to a pharma product, all of the processes and equipment have to be validated. Once it's validated, the customer has to be sampled, the customer has to test, and then we get the okay for production. So you'll often see in our investment cycles that we'll take a small dip on our returns and then it'll pick right back up again as the commercial sales start. We understand it. We don't mind it. It helps us build that moat around the business.

**Rafael Tejada**
*Bank of America Merrill Lynch*

Q

And as a final question, just how should we think about M&A for the company? What sort of targets are you sort of looking at, any capabilities, anything like that?

**Eric Mark Green**
*Chief Executive Officer*

A

Yeah. So we'll continue to look at M&A opportunities [indiscernible] (29:19) bolt-on strategies, identifying areas that we can continue to accelerate the high-value products, whether it's IP or again product expansion and also look at some geographic opportunities and start making sure that we're co-located with our customers as they migrate in different geographies around the world. So we'll continue to look down and look at opportunities as they present themselves.

**Rafael Tejada**
*Bank of America Merrill Lynch*

Great. Well, thank you so much for the time. And Eric, best of luck as you take over the company.

**Eric Mark Green**
*Chief Executive Officer*

Thank you.

**Donald E. Morel, Jr.**
*Chairman*

Thanks, Rafael.