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West Pharmaceutical Services, Inc. (WST)

JP Morgan Health Care Conference

CORPORATE PARTICIPANTS

Donald E. Morel
Chairman, President & Chief Executive Officer

MANAGEMENT DISCUSSION SECTION

Unverified Participant

Hello, everyone. I'm [ph] Tim Hawkins (00:04) with J.P. Morgan. Thank you for coming. I'd like to introduce Don Morel, Chairman and CEO of West Pharmaceutical Services. Immediately following the presentation there will be a breakout session with question-and-answers across the hall in the Georgian Room. Thank you.

Donald E. Morel
Chairman, President & Chief Executive Officer

All right. Thanks very much, [ph] Tim (00:25), and good morning, everyone. I'd like to thank the folks at J.P. Morgan for an invitation to speak at this year's healthcare conference.

First order of business is always is call your attention to our Safe Harbor statement in relation to forward-looking statements that management may make as part of the presentation. It's also posted on our website at www.westpharma.com.

What I'd like to do today, it's our first time here at J.P. Morgan, is walk you through a little bit of the company's business, it's history, our strategies for growth and how we see the future unfolding. For those of you that aren't familiar with the company, we've been in business for a little more than 90 years. We have a very specialized niche in the packaging and delivery of injectable drugs. So the major theme you'll hear going through today's talk is looking at the materials and the manufacturing science and the regulatory barriers to our business that govern very specialized rules with how our customers utilize these components and how they're integrated into the drug solution itself.

For the last 10 years, we've been transforming the company in some respects. We had embarked on a number of acquisitions in the 1990s where we really became a services firm focusing on formulation, focusing on contract manufacturing. We owned a Phase I hospital with 80 beds and also Rx-to-OTC switch work. We divested all of those business when the new management team came in and began to focus back on our core business. So over the last 10 years, we've embarked on a very nice growth trajectory. We built an absolutely fabulous sustainable business on the Packaging side. And as you'll see, we've got some terrific opportunities in the future, as we see some changes in the way the drugs are packaged and delivered, especially on the biologics side.

We've got a tremendous customer base. When you look at the diversity of our revenue streams and where we serve the healthcare field, we serve every major vertically integrated multinational pharma company. We package almost every biologic drug that is on the market today from the major biologic producers. We do a lot of work for the major medical device guys, either with proprietary devices or with things that we manufacture for them. And a very unique part of our business is the way we participate in generics, when the molecules come off-patent and the

generics jump in. We actually have an advantage because we're spec'ed into the product with the innovator and the generic folks like to know what they're using and they often come to West for their Packaging solutions. So we keep not only the innovator business, but we also grow as the generics grow.

We don't have a whole lot of revenue concentration, BD historically is our biggest customer, they're about 7% of revenue somewhere in the $85 million, $90 million range. The one therapeutic category where we do have some concentration is diabetes, with Lilly, Sanofi and Novo, all of the 3 milliliter cartridge insulin that is sold into the diabetes market is packaged utilizing West components. So we make the rubber and the seals that go on to that package, we do not make the glass, that's made by somebody else.

In 2013, we finished the year just shy of $1.4 billion in revenue. Our business is organized into two divisions. One focuses on components, this is the Packaging that goes mainly into small volume parenterals. So the 13 milliliter vials and 20 milliliter vials, 28 millimeters for IV infusion solutions, disposable medical devices that go into syringes for example into IV sets and things like that.

Within that group, we make roughly about 36 billion pieces of something that get consumed in the healthcare markets on an annual basis. About four years or five years ago, as we were reorganizing the business, we formed a new division to focus on Delivery Devices. And then this business is actually a hybrid between contract manufacturing and engineering services that we provide to our customers as well as the development and marketing of proprietary devices that are under the West name. So roughly about $1 billion on the Packaging side, about $400 million on the Delivery Device side.

Within Packaging, our growth has been very nice organic over the last couple of years, a little under 7% on a compounded basis. There's a category in here that goes into biologics, so that is growing roughly about 4 percentage points to 5 percentage points faster than that. It's becoming an increasing part of our revenue base and that is a series of products that go specifically into the packaging of biologics.

Proteins have unique characteristics that make the storage and stability of those products within the vial of the prefilled syringe a little bit tougher. And as a result some of the things we've been add into the products have resulted in the sales increase. It's not necessarily more units, but we're able to gain an up charge and a margin uptick in terms of the attributes of those products making it easier for our customers to file.

On the Delivery Systems side, revenue growth has been a little bit slower about 5%. We expect that to pick up over our five-year plan and I'll give some targets for that when I get to the end of the talk. But we expect that to ramp up rapidly, and really driven by two things. One, some of the challenges with glass as it involves packaging of proteins. And the second thing is really a change in the way that they're delivered. You're seeing a lot of movement in our space to devices where the patient can self administer. So whereas five years to 10 years ago most of this was done by syringe or infusion by the physician or the PA or the nurse in a hospital or the clinical setting. In the future, what you're going to see is much more home administration through patch pumps and auto injectors and we think we're very well-positioned to take advantage of that.

Won't spend a lot of time on our contract manufacturing capabilities. It's a little over $250 million of our revenue base. We have very sophisticated capabilities in the large scale assembly and manufacturing of very complex devices. So, we do an awful lot of pens for the auto injector market, lot of insulin pens for example, a lot in the cardiology market for our customers, and in things like continuous glucose monitoring.

One of the unique features of West is that we enjoy a very nice niche in biologics. So when you think about the top 50 biologics in the market today every one of those utilizes either a West or Daikyo component, as part of the packaging, a part of the delivery system. And it comes back to these rubber components that we make whereas

you'll see in a moment from a regulatory standpoint, they're actually a key part of the product, when the customers file, they're required to actually show stability of their drug formulation with the components of choice for the package that becomes part of the CMC section in the filing and it becomes part of the product for its lifetime. So we have a very, very nice niche and a very strongly growing market with great characteristics for the future.

It's that regulatory part that gives us an enormous competitive advantage within that small volume space. So West enjoys about a 70% market share in the Packaging side of the business in Western and in the United States. On the biologics side, as I said before, that is greater than 99%. And it comes back to the way the regulatory system works. Our data is kept at the FDA in what's called the Drug Master File, that Drug Master File 1546 is the single most reference document in the FDA's archives. And what we've done in terms of broadening that competitive moat is do another series of Drug Master Files that govern our manufacturing processes all of which are confidential and kept by the FDA, but all have to be referenced and reviewed in conjunction with our customers seeking marketing authorization and approval to sell the drugs.

On the Delivery Systems side, it's really built over a proprietary set of devices and designs and also materials where we basically have negotiated exclusivity with the material provider for the healthcare markets. So very nice, very strong defensible competitive position.

Last speaker spoke about some of the major drivers in the market. We would echo and emphasize those. If you take a look at injectables over the last couple of years as a percentage of drugs that were approved, there were 41 new molecules in 2014, 19 of those were injectable. And if you follow the FDA's website, you can see that many of the new therapies that are coming to market are biologic-based and injectable. And given where West is in that space, we expect that for the next five years to 10 years to continue to be a very strong driver for our business.

On the globalization front, we operate all across the globe. We've been in China and India for 25 years. We see great opportunities there both domestically and for their export business. And regulatory changes in the marketplace actually help us, so the FDA is getting stricter and stricter with folks on the manufacturing front and they're starting to drive cleanliness is a major issue for the future. The way that we manufacture, the way that our partners Daikyo manufacture gives us we think even more of a competitive advantage serving these customers.

When you look at injectables, as I talked about a moment ago, this is an area where we see substantial growth continuing. We participate in all of the major formats. So what ordinarily happens is a customer will launch in a vial, where you use a traditional syringe to extract the medication and deliver it, more and more in the biologics space these are converting initially to a prefilled syringe, but again you have the primary contact with the drug solutions, same regulatory boundaries. And in many delivery formats, especially with some of the biologics coming to market you have larger volumes that are required. So you're starting to see cartridges integrated into a device as the primary container, but again, same sort of characteristics.

The nice part about what we do is that the formulations and the designs used in the vial can actually be translated to the prefilled syringe plunger or to the plunger tip that goes into the cartridge as well. So we participate in each one of the delivery formats as it goes through its maturity cycle.

We see biologics as one of the major drivers of our growth for the future. As I talked about, this is a category in terms of revenues for our customers, it's growing in the high double digits. For us, it's going to continue to grow in the double digits as well. This segment of that $1 billion that I spoke about within the Pharmaceutical Packaging segment is roughly about 45% to 50% of our business. We think it's got some nice runway to go over the next five years to 10 years as I spoke about.

With the biologics, though, have come a number of challenges for delivery. We see a trend towards some of these molecules being formulated in long-acting or depot injection, some of the new molecules coming out are going into smaller patient populations. The customer base is looking for a new way to deliver these medicines. And we think that West, over the last four years or five years has developed a very, very nice pipeline for how we're going to service that market, and I'll get into that in just a second.

This is probably one of the more important charts that I'll show for the Pharmaceutical Packaging business. This is the $1 billion part of what we do. There are three categories in it. The light bubble to the lower left is what we call disposable device, not real high margin, not real high growth more of a historical business for us. The light purple bubble is one that we call standard product. This does not have all the attributes that go into the high value ones, which is the light blue bubble. What's happening for us is that the bubble in the upper right quadrant, which is the higher margin rapid growing one, that's the one we're trying to expand is growing both organically from new products and sales of existing products, but also from the conversion of products out of that lavender bubble into the blue bubble. So as a result, we think that our compounded growth rate in this segment is going to be in the high singles over the next three years to five years, sometimes it will be in the low doubles, sometimes it maybe a little bit lower depending on market factors. But on average, we've been very good at predicting what happens over five year timeframes. So we're going to continue to see terrific growth out of this franchise.

A similar chart for the device side of the business, but one that contains only two bubbles. The light blue is the contract manufacturing services. As I said, that's roughly about 75% of our revenues in this segment now, proprietary is about 25%. Over the next five years, our business is aimed at driving that bubble in the upper right quadrant to grow in the double digit range. And only two things have to happen for that growth to occur, both of which are in the late stage of development and we expect to bring to the market in the next couple of years.

Growth has been a little bit slower than in the Packaging side of the business. The gross margins are a little bit lower because we don't have as much IP participation in these products as we would like to have. As we drive to the upper right, our IP percentage increases, we have similar locks on the customer that we do in the Packaging side of the business. And again, that's what's going to drive the growth in that segment.

So for the next five years looking to the future, there's only a couple things we have to do in each business to keep the momentum going. On the Packaging side, it's what we call the high-value products. It's going to be driven by organic growth in the biologics, expanding indications and new products coming to market where we are seeking to expand geographically, principally China and India. We see good growth opportunities there, both serving the indigenous domestic markets as well as the export markets that are growing.

And then optimizing our global efficiency. We have put a tremendous amount of capital into our manufacturing footprint and that also gives us a competitive advantage. Managing that is a very complex task. We have 37 plants globally historically because of the way the regulatory bodies have worked. It's very difficult to switch plants to manufacturing in some cases because that actually is stipulated in the customer's drug filing. So we see some opportunities for margin expansion simply in the way that we operate our facilities.

On the Delivery Systems side, it's very simple. It's conversion of the market in biologics out of glass into a proprietary plastic system that we're developing called CZ and it's growth of our device portfolio, and really driven by one device in particular something we call SmartDose, which is a patch pump that the patient can use to self-administer. And I'll talk a little bit more about that in a minute. So the strategy is very simple. It's more of the same. It's focusing on markets where we've got a tremendous footprint and competitive advantage and building on that advantage.

The one major change that's going to happen over the next couple years is that the primary container is going to become integrated into the delivery device. So you may see a product launch in a vial format, you may see it launch in the syringe format, but our customers are very interested in product differentiation, where you have multiple participants in any therapeutic category, whatever they can do to gain an advantage for their product they're going to do. So we're starting to see the customers going towards these integrated systems more and more quickly as their products are in the marketplace. That sets us up very well.

So we've been executing on our strategies. We've seen very, very nice growth in the categories that I talked about. The SmartDose is we're spending a little bit more time on, however, this is a device that uses a cartridge, goes on to the patient's abdomen like a band-aid and delivers anywhere from a couple of milliliters to 5 milliliters, potentially up to 10 milliliters of the therapeutic subcutaneously.

And the reason the higher volumes are important is as you compound some of these biologics to keep them stable. When they're in high concentrations, they actually have the consistency of honey and it can be quite painful to inject a large volume subcu. What the patch injector does is give a lot of formulating flexibility through the molecules developers. And the interest in this system has been absolutely tremendous since we launched it a couple of years ago. It's in Phase III trials now. We have been conducting a series of human use trials, very, very favorable response. And we now have a series of four contracted development agreements with customers. So we think that this part of the market is going to grow very rapidly for the future and we think we've got a terrific position.

I talked about this resonance proprietary to West and our Daikyo partners. This is one where we believe that in the high value part of the market there is going to be a substitution for plastic into glass. Now glass has been used by the pharma companies for a 100 years. It's a wonderful material in most respects, but with some of the more advanced formulations, with some of the oncologics that can be quite potent, there is a phenomenon where you see the interior of the vial actually delaminating and you can see flakes of glass within the drug solution. So it's big concern to the industry. CZ this doesn't happen with, we think that it does a number of things that give a big advantage to the customer, eliminates the glass particulate. It's much more break resistance in glass. There have been instances of re-calls where the glass syringes are broken inside auto injectors prompting a recall.

More importantly for the formulations with glass, you have to use silicone oil to make the system work. And when you manufacture glass you have to use tungsten to form the tip of the syringe. At the atomic level that tungsten and that silicone actually interact with the proteins in the drug solution and cause these to agglomerate and come out and obviously you lose the potency of the drug. So the customer has to overfill. Eliminating those problems with the packaging is going to be a huge issue for the biologic space going forward. We think we're uniquely positioned here, not only with the proprietary resin, but with a series of technologies around how we coat the rubber piston and allow that system to work collectively without the use of silicone oil.

We've got over six customers now doing formal stability on these systems with their drugs. Formal stability requires them to test for two years and then use that data as part of their submission for a new molecule or as part of a supplemental when they're going to change their packaging components for an approved existing drug. More than 100 molecules have been tested in conjunction with this material. We currently sell about $55 million in Japan with our Japanese partners used on everything from contrast media for radio imaging all the way up through molecules like calcitonin and parathyroid hormone and growth hormones. So it's not going to happen overnight, but as the groundswell builds to move towards plastic as the primary packaging means. We're very well-positioned to take advantage of that in the market.

I talked about our capital investments being rather substantial. We've been on an expansion program for the last three years to five years. It's the biggest in the company's history. We finished a facility in India mid-year last year

principally for metal over seals that's now up and operating, finished our second plant in China earlier that year producing rubber components for our device customers as well as the domestic Chinese market.

We are expanding our North Carolina plant to give us high value pharmaceutical capability, our second plant in the United States. And then in the fourth quarter of last year announced the company's largest investment ever in another plant in Ireland focused on high-value components and to give a second sourcing for the sheeting we make for our insulin customers. We will start in 2018 with the manufacture of that sheeting. Eventually that plant will also take on being a finishing plant for our high-value pharmaceutical customers. If you follow where our customers are investing in terms of their production capability, Ireland is really becoming quite a concentrated center of biologics excellence in terms of manufacturing and filling of finished dosage form. So I think we're very well positioned there.

One aspect of our business is the downside is that we usually have to invest two years to three years in advance of the sales curve so that we can validate our systems, our customers can test the products before we actually see commercial sales. So we expect that facility operating for insulin in 2018, and then in the 2020 timeframe for the biologic packaging components.

Outlook for 2015 and beyond, we think our sales growth ex-currency for the year is probably going to be in the range of 5% to 8%. Like all large multinational med companies, the currency situation is going to work against us given where the dollar and euro are right now. We do have some exposure there. As a reminder for those that follow us, everything in, in terms of positives and negatives on the currency with regard to yen, krone, Sing dollar et cetera, for the full-year a $0.01 change in the euro-dollar rate is roughly a $0.01 hit to our earnings. So that rule of thumb still applies.

We don't see any changes in our underlying fundamental growth drivers, aging of the population, increasing use of biologics, cancer being treated as a chronic disease. Our position in oncology and diabetes in autoimmune disease and in vaccines, all of those categories are going to be very nice growers for our customers and for ourselves for the future. And we expect it to continue to drive our revenues.

We have a major initiative underway led by the factory in Ireland to get ourselves to zero defects, so that we're leading the charge within the FDA and within our customer base to address these concerns with particulate contamination in manufacturing. Our goals for 2019 looking out about five years, revenue should be in the range of $2.1 billion to $2.3 billion depending on the timing of approvals for some products in line with the expectations that we set forth on our Investor Day early in 2014. We think our operating profit margin on a consolidated basis is going to grow from the low double digits to the high double digits during that period.

So we think, we're very well set. You ask yourself, what can go wrong. West is in a very enviable position, once we're on the products. But the one thing, we don't control is the timing of our customers' submissions to the FDA nor do we have anything to do with the FDA's time in reviewing them. So there is a little bit of latitude in there to allow for those submissions and to allow for the FDA to opine on those submissions.

But overall, when you take a look at where we are, we think, we are tremendously well-positioned. Great customer base, great diversification of revenues within that customer base, great diversification, in terms of those revenues and geography. The business tends to be extraordinarily sticky, because of the regulatory body. We make products developed by our founder Herman West in 1930s still. They go on products that we may make every third year for a customer, but there are still some drug formulations that's used and sold to utilize the original packaging components developed over 70 years ago. Tremendous competitive position because of our manufacturing footprint. Our intellectual property base was in the Drug Master File system. Our patent portfolio and as I said before, all those market drivers, we think are really strongly support our continued growth for the future.

Financially, we're in a very, very good position. We generate very strong operating cash flows. Our strong preference over the past few years has been to reinvest those cash flows into our manufacturing infrastructure, into our technological capability, do pay a small dividend out of that. Our net debt-to-total capital, at the end of the third quarter was right around 10%, we've got a nice cash position, like most of folks some of that trapped overseas, we're working on ways to get it back and put it to work in the business.

The last item for me is that in October the company did announced that I would be stepping down as CEO. There's no real update on the search, it is underway. Our board has formed a search committee, and once we have more information, we'll keep you fully apprised of where we're going. But right now, it's business as usual. We liked our order book for the first quarter. I think we've got a great story to tell and obviously a wonderful position in the industry.

With that, thanks very much for your time and I think our breakout is in the Georgian Room. Thanks very much.