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West Pharmaceutical Services, Inc. (WST)

CL King Best Ideas Conference

OTHER PARTICIPANTS

Ross Taylor
C.L. King & Associates, Inc.

MANAGEMENT DISCUSSION SECTION

Unverified Participant

[Abrupt Start] Great. Thanks, Ross. Yeah it's going to be a bit of a hybrid. So I'm going to zip through the slides quickly. It looks like everybody's got a copy of the presentation [ph] from Mike (00:08). Anyway if you don't, just raise your hand, we'll get you a copy.

You might want to take a quick look at the Safe Harbor statement just in relation to management's forward-looking statement.

What I'd like to do today is just cover a couple of topics, talk a little bit about the growth franchise of the company and our core injectables packaging business, our competitive advantages and growth drivers, and then talk a little bit about our evolving delivery business in terms of devices, very exciting field developing quickly, especially with some of the newer generation biologics coming out.

Yeah, West is an old world manufacturing company. We're founded in Philadelphia back in 1923. We have grown since that time through a series of acquisitions, partnerships, and organic growth in the marketplace to be the world's leading supplier of packaging and delivery systems for injectable drugs.

The current management team took over in 2002. Since that time, we've gone through a number of restructuring and asset dispositions that really get us focus back on our core business. During that time, we've grown from little over $400 million at the end of 2002 to just shy of $1.4 billion at the close of 2013; so good growth story.

One of the nice things about our company is that we enjoyed very long standing relationship with virtually all of the world's major pharmaceutical companies, and that ranges from the generic drugs to the biotech folks to the research oriented vertically integrated companies, the multinationals, very strong position in medical devices as well. BD has historically been our biggest customer. They're about 7% of revenues, but we've been suppliers to folks like Covidien, Abbott, Baxter for the better part of 40 and 50 years, so very long-standing customer relationships, very strong customer relationships and market shares in Europe and United States that approach 70% in standard injectable drugs and 100% on the biologics side, which I'll talk about in just a second.

From a management standpoint, we report earnings for two divisions, the first of which is called Pharmaceutical Packaging. That was just shy of $1 billion last year. The second one is Delivery Systems. That was about $375 million last year. The difference between the two is that the Packaging Systems group principally books its sales on the sale of individual components. So think about that as the bulk of the core business; it's stoppers, it's seals, all the things that go into injectable drugs, as well as disposable medical devices. The Delivery Systems side is not only our contract manufacturing group. It's also our assembled device group, so the major difference being that delivery, assembled systems, packaging, individual components.

So packaging is a very interesting business on the pharmaceutical side. We enjoy a very, very stable, very longstanding market share of about 70% in this world. So about seven out of every 10 dosage forms that come to the market that are for injection, they contain components made by West, whether it's a plunger for a prefilled syringe, or a stopper for a vial. But the key here is our intellectual property base which is comprised of something called the drug master file.

So the way the system works is that when one of our customers, whether it's Merck, Pfizer, Amgen, Novartis, Roche puts a new drug application, or a BLA into the regulatory bodies, they have to prove that the packaging materials were stable when in contact with the drug for the shelf life of the drug. That's typically a period of two years. The agency then writes a letter to West asking for a permission to review that file. They review it in the context of the entire drug application, and when approved, unless they've done stability onto packaging system, the West system is the only one that they can use, and essentially year on for the lifetime of the drug. So to illustrate the stickiness of our business, we still make components designed by Herman West back in the late-1930s for drugs that are on the market. So believe it or not, these were designed in the late-1930s, but because of the regulatory system, we still make the components to package them.

On the Delivery Systems side, really our strength is in our engineering, our high-speed assembly expertise when it comes to machinery, and a broad range of proprietary products that are patent protected. That's a snapshot of both of those. On the injectable drug front, as I said, this is really the bread and butter of our business. It is a very, very good stable category. There are many therapies that are very high priced. We are on all of those as we'll see in just a second.

These are the categories that tend to drive our business including oncology, insulin for diabetics, the so-called lifestyle drugs like Humira for autoimmune disease, and generic injectables and biosimilars as well. But all of those disease categories are ones that we benefit from in terms of the ageing population and demographics. They're all working in our favor.

In terms of the global markets, biologics, believe it or not, control about 70% of these key therapy areas. So think of large molecules like insulin for example, Herceptin, Enbrel, Remicade, all of these proteins, these monoclonal antibodies, they're all delivered by injection. And in this category field, the pipeline coming through from our customer base is as strong as it's ever been. Recently, you saw that Amgen has submitted its application for its new cholesterol lowering drug PCSK9, is the route.

Also, Merck just got approval for a new molecule in cancer called PD-1, a PD-1 inhibitor. There are a broad range coming through in each of these categories, but the pipeline for us and for our business is as good as it's ever been. And it's a market that we control a 100% of because of some unique technology we have, so it's one of the fundamental drivers of our business.

The top 35 injectables, they all rely on West through our Japanese partner Daikyo. There's not a better category in terms of our business potential. Packaging systems; our strategy is very simple. There's only three components to it, broadening the sales of our high-value products, expanding in the selective markets geographically like China and India and then optimizing our global footprint.

So in terms of the Packaging business, this is the most important curve in the deck today. The three colored circles basically represent three independent parts of the market that make up our Packaging business. As you can see, disposable medical device components, these are things like IV components, disposal syringe kits, packaging components for diagnostics. Very slow grower, moderate margins, and the kind of mid-teens. That business is

little bit less than $100 million for us. Standard Pharmaceutical Packaging, these are components that go on antibiotics for veterinary applications, human application, bulk vaccine, some diagnostic components as well.

Slightly faster growth in the low-singles, but again, margins that are moderate in the 20%, 25% range. The most important bubble is the green one. That represents the components that are in the high value product category, sold to the biologics producers. That business is about $400 million to $425 million currently, but as you can see over the last five years, it's grown at a compounded rate of roughly about 12% a year and it generates margins in between 50% and 60%. So the growth driver for the business is based on those components that we sell into the biologics space.

The logical question is how much run room is there left for that bubble? Well, two things are happening to drive that. One, sales within the blue circle for standard components are shifting into the higher value components because of regulatory factors, the FDA, the EMEA, the Japanese Ministry of Health, all driving our customers into cleaner and cleaner packaging systems and we're also picking up unit volume growth from growth into biologic sector and that's something we expect to continue for the next three years to five years certainly, so very strong, stable, good fundamental growth drivers in our Packaging business.

On the Delivery Systems side, the strategy is built on three pillars again, the first of which is the new material we've launched into the marketplace called Crystal Zenith. This is the unique polymer that can be used for primary containers and we think in high-value application as the opportunity to replace glass as the primary containment material. We're doing a lot of work in administration and safety and on the self-dosing side. We combined those under what we call our proprietary products initiative.

So much like the chart that I showed you for packaging, the key to this business is shifting from the light blue circle, moderate growth in contract manufacturing and gross margins that are in 18% to 20% range to the proprietary bubble on the upper right. That contains all of the systems that have West intellectual property as part of them, and as you can see the growth rates tend to approach 20% to 25%, gross margins of somewhere between 30% and 40%, and we think we can continue to drive margin growth there as the circle shift.

Publicly we've talked about our goal of moving roughly about 80% – or I'm sorry, moving to 50% of our sales being proprietary from about 23% now over a five-year period. The whole driver here is the phenomenon in our industry where the primary container and device are coming together, and indeed you what it called combination product. So whereas our core business focuses just on components, our future business will focus on the integrated delivery system.

One of the parts of that system is going to be containment using a polymer developed by Japanese partners that we have called CZ. It has a number of distinct advantages over glass. It is sold in Japan currently for use with biologics in contrast media. We think that has a very strong value proposition, especially for the biologics space, and expect us to help drive our sales in the post-2016 timeframe. The stability point that I raised with regard to our rubber components also applies to the primary container. So customers that want to use this material, have to go through the two-year stability period I talked about. And at the end of that period, if it's an existing drug they file a supplemental with the agency. If it's a new drug, it becomes part of your new drug application or their BLA.

The advantage is it eliminates silicon, which can contaminate the drug substance. You reduce breakage which improves your manufacturing yields, gets rid of some manufacturing losses. You've got a great deal of design flexibility. You can hold tolerances tighter. You get rid of contaminants like glue for the needle, and also tungsten which can get into the system from the manufacturing process. So there's a wide range of drugs that are currently being tested with this, and as I said, very successful in the Japanese marketplace; we think it's got a niche inside the proprietary space in biologics in America and Europe as well.

Just as an example in vials, in our second quarter conference call we've talked about a commercial application we expect an approval for in the early part of next year. It turns out that certain liquids that drugs are formulated with will actually delaminate the inside of the vial. You can see small glass flecks coming off the surface to become part of the drug solution, and as you can imagine the regulatory agencies aren't too keen on this. With the CZ vial, you get none of that delamination. So the first market for this we think will come to pass in early 2015 for an existing drug. The vial was custom designed for use with a diluent. So we think there's a broad range of applications there, too.

Product approvals in Japan; many uses in terms of contrast media on the protein side, calcitonin, hyaluronic acid. In Europe, many similar applications also approved for use with bone cement. In the United States, there's two. One is hyaluronic acid and this is also used for an oncology drug called Zometa, a bisphosphonate. So broad range of applications. We know it works. Uptake and in the pharmaceutical industry sometimes can be slow, but we do know the combination of the regulatory agencies pushing for cleaner products, cleaner packaging and our customers' desire to improve their manufacturing yields and get rid of many of these variables are very strong drivers for this product.

The product that best illustrates our strategy is one that we are working on with a number of customers called SmartDose. It goes by a number of names, automated mini-doser, mini-infuser, patch pump. Very simply, it's much like a type 1 diabetes insulin pump that is put on to your skin as a Band-Aid and can deliver a dose anywhere between 2.5 mLs and 5 mLs over a long period of time subcutaneously.

And the reason this is important is that many of these drug solutions are actually quite viscous. Anybody that's had an injection of drugs that are based on oil, know how thick they are. They actually can be quite painful. So there's many applications for a pump that can be put on the skin, and deliver the drug very slowly into the subcu layer. It also uses CZ as a primary containment system. So we own the intellectual property around the pump, we own the intellectual property around the container, we have the rubber in the container but the drugs that will utilize this system utilize not only a containment system from West, but also will have a license to use the pump technology. So it brings everything together.

In terms of the financials, we would sell 1,000 stoppers for anywhere from $50 to $300 for 1,000. We will sell a single one of these units anywhere between $50 and $60 for clinical trial, and $30 million to $35 million at commercial volume, a typical drug volume of $2 million to $4 million. If you had 50% of that $35 million in sales, you can see how it's going to drive the revenue curve and the earnings curve quite substantially in the future. The timeline for that commercially right now it's in development in Phase III trials with several customers. We expect applications and commercialization to take place probably in the mid-2016 to early-2017 timeframe by the time the agency finished their reviews.

The takeaway message for us is very simple. A very solid stable franchise in core packaging for injectable drugs, nicely growing market driven by demographics in the disease space that I talked about, like oncology, diabetes, arthritis. We've got a great competitive position globally. We're the only true multinational, multiplatform producer in this area. Our two competitors are Datwyler in Switzerland and Stelmi which is now part of Aptar Group. They do not have anywhere near the geographic spread that we do, nor their customer coverage.

And financially, we've managed very conservatively. Our net debt to total capital ratio right now is under 20%. We have very strong operating cash flows which we tended to invest back in the business. We think the growth factors that are in injectables are going to continue to drive our business for the foreseeable future. So we like our story. It's a great market to be in.

And with that, I'd be glad to answer any questions you might have. And that was a quick nickel tour. I apologize for that.

QUESTION AND ANSWER SECTION

Ross Taylor
C.L. King & Associates, Inc.

Q

I had a couple of questions and if anybody else in the audience [inaudible] (16:02-16:09). One thing I heard I don't think I heard before is I think you said that there were several companies [inaudible] (16:18)?

A

But that can take different form, okay? So some of those are actually human factor trials -getting used to the device, looking at geometries, looking at patient use, getting ready for user set instruction.

Ross Taylor
C.L. King & Associates, Inc.

Q

And I'm not sure I think [inaudible] (16:37-17:02)

A

Probably about the same time. I mean the auto injectors on the market currently use the 1 mL type syringe. We know that a number of customers have the 1 mL syringe with the FluroTec plunger on stability. We think the first of those are going to finish stability, probably sometime mid to late next year, then you've got the filing period depending on whether it's an approved drug or it's going to be a new drug. So that would take it into a timeframe. That's probably going to be pretty close to the SmartDose getting approved.

Ross Taylor
C.L. King & Associates, Inc.

Q

And also obviously the [inaudible] (17:36-17:41). You mentioned two factors [inaudible] (17:43-17:50) two factors that balanced out [inaudible] (17:54)?

A

It's tough to say. It really is going to depend on who adopts first. That's true in the case of CZ. In the near-term, the existing products that see either indication expansion or volume growth in our current sector is going to be the most important, but the pipeline is absolutely fantastic. So two things are going to happen, I think they're equally important. One is conversion out of the standard products into the high value, and the other one is that as these new products come to market, they all use the high value products. So we actually have two curves going on, we've got the adoption curve from the blue bubble going into the green bubble which we see room to run on, and then we've got the new products coming in which actually use the next generation will have very well penetration and we think we'll increase rapidly.

So one at the top which is the NovaPure high value product category, because of the way that that product is made in the paper trial for the FDA, it eliminates a lot of cost for our customers. And I would say that probably has been the most rapid adoption that we've seen in that category. We're at the point now where we almost can't build press capacity and mold capacity fast enough for those items, both are going to be driver.

Ross Taylor
C.L. King & Associates, Inc.

Q

[Question Inaudible] (19:13-19:23)

A

No, it should be a little bit higher. On the device side, if we don't get north of [ph] 40 (19:27), I'd be disappointed. In some applications, it ought to approach [indiscernible] (19:30).

Ross Taylor
C.L. King & Associates, Inc.

Q

[Question Inaudible] (19:34-19:45)

A

No, we see a lot of interest. I think a lot of people are still feeling their way around in terms potential applications for molecules that they have on the shelf. Some are looking at it in terms of life extension on products that they currently have, so doors will open when we get, I think, first approval. It's going to be very much like CZ, but there's an awful lot of interest in it.

Ross Taylor
C.L. King & Associates, Inc.

Q

[Question Inaudible] (20:09-20:31)

A

Yeah, Medimop, we see a lot of potential for. I mean, Ross is referring to a simple device that helps reconstitute freeze-dried drugs. Initially it's a pair of collars. Drug vial connects on one end, diluent vial connects on the other and you mix it up. You don't expose yourself to a needle stick. That business we've grown from about $12 million in 2005, 2006 to a little shy of $15 million last year. Great business with very nice margins and the engineers there have done a very job of variance on that theme where the vial can be connected to an IV bag, for example, where the vial can be connected to a prefilled syringe and a withdrawal made and the injection made. So there are a lot of things in the space there where it can be adapted to different delivery methods.

Safety, we love but it's an increasingly frustrating space. We've got an absolutely wonderful series of products there. We've had good success on Lovenox there, but not I think we would have given the fact that in many locations in acute care environment, safety is stipulated as mandatory on syringe system. So it's got great potential. We just need to figure out how to sell it better. We think we've got a lot of iterations technically off of SmartDose that can be done. Added features, you can work electronic components into it, for example. The question is you capture that data, how do you monetize that data? But you can get an awful lot off of information of patient behaviors, use trends and things like that. So we've been working on follow-ons to the current device

that can do electronic data capture as well. We continually discover the marketplace, lot of very interesting things out there to pick and choose from, but we've got plenty to work on to grow organically right now.

Ross Taylor
C.L. King & Associates, Inc.

Q

Another question I have is on the [inaudible] (22:20-22:36)

A

Yeah. So publicly I think we've talked about a number between a [ph] $125 million and $135 million (22:41) on a go forward basis. About [ph] $65 million to $70 million (22:45) of that will be maintenance capital, about [ph] $50 million to $60 million (22:50) would be new products and then the remainder gets invested in keeping the IT systems up and working. That number is probably going to be, on average, pretty good for the next five years. I would guess that you'll see a creep up potentially. We've been considering a novel type of facilities for finishing that helps us build in high-value products category. We've been working on the feasibility concept there.

If that happens, it will avoid some capital but we will put some into accelerate it, and we may creep up as high as [ph] $140 million to $145 million (23:23) for a couple of years, but that starts to pay itself back very quickly as does the capital going into the new products on the device side. So we've talked about the CZ cells before. The single cell is $2.5 million to $3 million. It generates revenue of anywhere from $2 million to $2.5 million, out of one of those sales that pay themselves back quickly, and the free cash flow off of those in the out years becomes very, very strong, but we tend to think of our operating cash flow going into investment in the business first, we've got great opportunities. We obviously pay a dividend. We selectively paid down debt where our CapEx has been lower than expected in certain years. And then, we've on occasion done share buybacks. But we prefer to investment in the business simply because we believe in the growth potential.

Ross Taylor
C.L. King & Associates, Inc.

Q

[Question Inaudible] (24:13-24:20)

A

It would depend on how fast, obviously, the segment grows. So right now the way we've designed our network and this is – another competitive advantage for us is that we have high-value finishing facilities in Germany, France, Singapore, Japan, one in the United States and the second one in the United States being built now. And the idea is to have redundancy in the event that we either have surge, or we have an accident, those plants are effectively equivalent in the regulatory body's eyes.

The plant that Ross was talking to and that I just mentioned won't be molding rubber, it will simply be finishing, but as that NovaPure category takes off and as the regulatory requirement gets stricter, my guess is this factory will fill up relatively quickly, and by 2019-2020, we may be looking at a similar type of facility, most likely somewhere in Asia given the fact that our growth in India and China for the last three years to four years has been 20% to 25% in each of those markets on average. The great problem to have, the only down side is that the capital goes in two years to three years ahead of the revenue curve.

Ross Taylor
C.L. King & Associates, Inc.

Q

[Question Inaudible] (25:31-25:59)

A

Yeah. So to explain the whole story, you have to go back a couple of years. As you know, we had this very high investment curve in 2008, 2009, 2010, even after the financial issue hit. That capacity started to fill in in the second half in 2011, and we had those phenomenal years in 2012 and 2013. Growth was in the high singles there, high-value product growth was in the doubles, and that capacity sold out very quickly. When we got to the second half of 2013, our customers started to see our lead times leak out. So we are a made-to-order business. We don't order raw materials or schedule production unless we have a firm PO from our customer. Our lead time stretched out to anywhere between 22 weeks and 24 weeks with some of those key products, and that was driven by several of our key biologic customers actually doubling up on orders.

So the good news is the regulatory boundaries protect your business a great deal. The bad news is when you have a change, you have to tell the world about it, and they have to test and make sure that change doesn't affect your drug product. All of that growth when we got to the end of last year beginning of this year, not only resulted in the lead times expanding, but the detergent change that I just talked about resulted in customers double ordering, and they began to work through their inventories at the end of 2013 when the slowdown started, we knew that would continue into the first quarter. We told everybody about it.

We thought it would work its way through by the end of this year and we think that's still pretty much on track. We're starting to see orders return from those customers, but it was fundamentally driven by one of those regulatory timing things with our customers where they ordered more than they needed in one year, it goes into the next year and slows you down a little bit.

Our backlog looks good. Our order patterns are strong. I think the outlook for the reminder of the year is still pretty much in line with what we talked about at the end of the quarter. And there was no business loss in that timeframe either. That's the most important thing. Every once in a while we get inventory adjustments that change our backlog and order pattern that happens you work your way through them.

Ross Taylor
C.L. King & Associates, Inc.

Q

Other questions. The first one, when you [indiscernible] (28:05) the economic relationship with [inaudible] (28:07-28:40)

A

Sure. Let me answer the second one first. The ones you always worry about are the ones you don't control. As you may recall, in a way we got whacked by the CMS suddenly changing its reimbursement rules on the erythropoietin drugs, and within the blink of an eye it took away $18 million in revenue and $9 million in LP. So we spent a lot of time worrying about what can happen from a regulatory standpoint, that's really going to change the dynamics of the business. Doesn't happen often, but when it does, it has a pretty bad effect on us. So we worry about that, number one.

I worry about the availability of raw materials. It's getting tougher and tougher in the United States and in Europe to prime suppliers that are willing to produce materials that go not into products like we make, but into medical devices and especially implantables in general. So we've spent a lot of time securing our supply chain, making sure they understand why they can't change the raw materials, and making sure that we've got a very, very long-term source of supply in some term, as much as 10 years and 20 years, a little bit unchanged. I worry about the approval timelines for our customers' products. We don't control those timelines but we have to be concerned about them, and how fast that happens.

So those who probably have the things that would concern me the most with regard to Daikyo, it's a very longstanding relationship. We're 25% equity holder. We've been partners with them since 1973. There is an interlocking distribution agreement that has us wrapping and servicing Daikyo products in Europe and in the U.S., and Daikyo doing the same for West in Asia-Pacific and Japan. No monetary relationship there. It's just the business agreement. There are a series of technology exchange agreements that govern our use of Daikyo's technology and Daikyo's use of our technology. There's typically a nominal fee for that. In some cases, there is a royalty of a couple of the percent but not that much. We do agree to do all of our raw material purchases that are Japanese, sourced through Daikyo so that we get advantage of their vendor network, and then we make a distribution margin on their products and they do on ours as well. So it's relatively simple and straightforward.

Ross Taylor
C.L. King & Associates, Inc.

Q

[Question Inaudible] (30:54-31:13)

A

Sure, yeah. CZ needed to be thought it was a platform. So it in and of itself is a raw material. It's a polymer that's made by a Japanese company that the Daikyo chemist reformulated specifically for pharmaceutical applications. The approval we expect to happen in next year was driven by this delamination phenomenon, it's actually a vial. So that product is a supplemental filing for an existing drug and an existing diluent. They simply had to prove stability in the vial. The good news is it proves out one of the thesis that we put forward which is the regulatory bodies have looking at this problem, and that's going to help push CZ into other areas were we know there's delamination issues.

With SmartDose and with the syringe, different geometries, obviously but they are the primary container for the drug now, not just the diluent. With what we know about stability in the 1 mL syringe and this can be used independently or in an auto-injector, as Ross had questioned. We think that the first of those come of stability, sometime middle to end of next year. You'll then have the filing which will take you through the middle end of 2016, and commercial production to start end of 2016, beginning of 2017, maybe even before and if they want to build volume for the market launch.

In SmartDose, it's actually a cartridge and that cartridge geometry is very, very unique. It's a stubby fat little thing that gets inserted into the device when the patient's about to use it. That's been developed in tandem with the device and the drug. So the drugs that are currently being looked at are all new indications. They're new drugs for new indications. That's probably going to push it out a little bit further. Our guess would be maybe mid-2016, early-2017, again, one of the downsides to our business is as we don't control the timing of the filings, we don't control the timing of the FDA's review, but for CZ as a platform, you have a cartridge, you have a syringe, and you have the vial application, we think that's all very positive.

Ross Taylor
C.L. King & Associates, Inc.

Q

But the one thing that you said [inaudible] (33:18-33:23)

A

Correct. Yeah. That's right.

Ross Taylor
C.L. King & Associates, Inc.

Q

[Question Inaudible] (33:33-33:42)

A

Two in a quarter to five, I think is really the range that we're getting questions about.

Ross Taylor
C.L. King & Associates, Inc.

Q

[Question Inaudible] (33:50)?

A

It can probably go bigger. I'm not sure you want to be walking around with a pack on your on your chest, it's about this big if you want it to go to 50 mL, but certainly going up 10 mL, is the possibility.

Ross Taylor
C.L. King & Associates, Inc.

Thank you very much for coming.

Unverified Participant

Great. Thank you, very much. Appreciate your time.