West Pharmaceutical Services – Drug Manufacturing Analysis – 12 September 2018

Disclaimer

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1. Updated perspective on West Pharmaceutical Services' global increase in biologics and quality standards
2. The two main segments of West Pharmaceutical's business – proprietary products and contract-manufactured products
3. West Pharmaceutical's successful launch in the injectable-drug packaging and containment market, with focus on its high-valued products
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West Pharmaceutical Services – Drug Manufacturing Analysis

Transcription begins at 00:12:45 of the recorded material

SI: Hello, and welcome to Third Bridge's conference call on West Pharmaceutical Services. I'm Stephen Inglis and I'm facilitating today's call. We are very pleased to have with us Bob Hargesheimer, a former VP of Global Strategic Operations at West Pharmaceutical Services.

Bob, before we start today's conference call, can you please state, "I agree," or, "I disagree," to the following statement: You understand the definition of material non-public information and agree not to disclose any such information, or any other information which is confidential, during this conference call.

BH: I agree.

SI: Excellent, thank you, Bob. To our clients, should you have any questions, I will facilitate a Q&A at the end of the call. Alternatively, you can submit questions anonymously by e-mail to questions@thirdbridge.com and we'll do our best to pass them along at an appropriate time. Clients, as previously advised this call is being audio-recorded. Should you have any concerns with this, again, please e-mail questions@thirdbridge.com.

I'll now turn over to our specialist. Bob, if you would, before we begin the questions, I would love a brief introduction to your background, please.

BH: The background that you're interested in is a 20-plus-year career with West in various capacities, everything from finance operations, general management, sales. It spans really all the functional areas with West, so it's a pretty broad background and familiarity with West that goes back a long time. My last role, as Stephen mentioned, was as VP of Strategic Operations, and there my role was to reconfigure the global manufacturing footprint and build capacity in China and India, where West did not have a presence. In a nutshell, that's it.

[00:14:54]

Q: Could we get your updated perspective looking at West Pharmaceutical Services from the outside, including the key themes or trends that you find particularly interesting or noteworthy as of late?

BH: From a trend perspective, I don't think there's anything really new. It's really just a continuation of a couple of themes that have been relevant to the parenteral packaging business for probably 10-plus years. In my mind, those particular themes are really the advent of biologics and the continued growth of biologics in the pharma sector. The large-molecule drugs themselves have some peculiarities which lend themselves to some of the higher-value products that West developed. I think the other trend is really the increase in regulatory and quality throughout the industry and primarily in what I would refer to as the highly-regularly markets, which would be North America, Western Europe and certainly parts of Asia, most notably Japan. The level of quality that has been required by the regulatory agencies and the customers has just continued to grow and grow and again has allowed some of the higher-value products and services that West has provided for to continue to see volume and pricing increases.

[00:17:06]

Q: How has that regulatory piece impacted the competitive landscape? How does West navigate that, and how has it changed the dynamic for new entrants to the space?

BH: One of the key pieces has been the acceleration in detection capabilities of lab equipment, testing equipment. When I first started in the business in the early 90s, you were testing things parts per 1,000. It certainly then evolved to parts per million, and now we're down to being able to detect things parts per trillion. That advancement has led people to go back in and look at some of their own products, and things such as particle detection. The technology has improved over the last 30 years remarkably, and people are able to detect things that they couldn't 30 years ago. There's an old an adage in the pharma business, once you find something you've got to do something about it. I've had experience in cases where drugs have been very successful in the marketplace, no adverse effects, but somewhere along the way, maybe halfway through its 30-year lifecycle, somebody detects a particle load. You go and you find out that it's been there the whole time, but now they detect it and you've got to do something about it. That provides an opportunity for the packaging suppliers to provide cleaner product and some more advanced washing to it and allows them to charge more for it. The customers have been able to detect more things. The regulatory bodies have been able to detect more things and keep asking for a higher and higher level of quality. I do not see that dissipating, because the technology and the labs business keeps getting better and better, so I see continued growth in that.

[00:20:19]

Q: How does that improved detection impact the product cycle? I'm assuming that's really speeding up.

BH: What happens here, everybody knows and I'll use the example of a basic rubber stopper that sits on top of a vial. That's made out of a rubber formulation and the rubber formulation may have been designated 15 years ago to be chosen for that package. The piece about this when you're primary packaging in the pharma segment is that that particular stopper was filed with the new drug application and the customer can't change it without significant testing. At a minimum, it's usually about a three-year process, and then they have to resubmit the application. Customers are very, very reluctant to reopen their initial drug application, because then that opens it up to all sorts of other questions. In the example we talked about, 15 years after the drug was launched, everything's fine but the customer may be doing some of its routine testing and find a particle load that perhaps might have been traced back to that stopper. West, in this case, is not doing anything different that they haven't for 15 years, but the customer requests a reduced particle load. That opens up, then, West to approach the customer with what they call their Westar process, which is a more advanced washing process, and charge more for it. Although you're still selling this same stopper, you're now selling it at a premium, in some cases significant, for that extra service and meeting whatever particular particle specification that that customer is requesting. That provides an opportunity for West for pricing over and above any particular volume increases.

[00:23:09]

Q: You mentioned how you've seen that quality piece as well as the price piece really increasing. How much leverage does West have to increase pricing, and where do you see that pricing piece maybe tapering off a little bit? Or do you just see it consistently correlated with those quality increases?

BH: In the short term, West has a remarkable degree of pricing power. Again, because all these drugs are filed with the regulatory agencies with their product on it. In the short term, they've got an iron fist when it comes to pricing. They could literally double prices overnight, and the customer base, absent longer-term contracts, really couldn't do anything about it. They would have to continue using West for a significant period of time, 3-4 years. The danger in that is on the long-term prospects. Customers can, in fact, change over a product. Although they're reluctant to, that doesn't mean they won't if the value proposition isn't there, and getting on new drugs, the pipeline for West would dry up overnight. It's really been a balancing act to try and maintain long-term relationships with these pharma customers, which West has been very successful with, and pick pricing that makes sense to keep that long-term relationship. They do have significant pricing power.

[00:25:48]

Q: Historically, what have you seen in pricing increases, and what's your thought process moving forward? Would you expect significant year-over-year increases?

BH: I wouldn't anticipate significant price increases year-over-year unless there's a disruption in the materials market. West's two primary substrates are butyl rubbers, for which the source is oil, certainly, and aluminium for the seals, as well as some polyethylene in the plastics for the flip cap. Two out of those three are oil-based. Even back during the last oil shocks, West was able to get cost recovery from the customers, but beyond that, not much. Customers experience many of the same pressures, so they understand that, but I don't see a significant pricing increase over and above what I would consider a COLA, cost of living adjustment, type of thing. A fair amount of West's business is done on a contract basis, where they put together anywhere from a 2-5-year supply agreement with the customer. Pricing is usually dictated within that, and that could be a CPI basis, it could be a material-adjustment basis, but there are usually sliders in there that would dictate the pricing for that particular year within the 2-5-year timespan. The last time West went out in the mid-90s with a significant price increase, it quite frankly reverberated throughout the industry for about 10 years. Very well-received.

[00:28:34]

Q: You talked about the contract, and once you're locked in they have significant pricing power, but how much are these customers shopping around to their competitors? Can you give us a feel for that competitive landscape? Are these competitors putting pricing pressure on them, or could you see that happening in the long term?

BH: There's been, certainly, pricing pressure. The two key competitors that West faces in the highly-regulated markets are now the Datwyler Group and the Aptar Group. Both have a smaller share. Datwyler and Aptar have about a 50% share in Europe, just from a historical basis, because that's where they started. In the US, West certainly has the lion's share of the market share. Market share estimates range from 80-90% market shares.

SI: What would you say that that's attributed to?

BH: Really just historical basis and long-term relationships. West started out as a US company. We're going back. The growth of the parenteral packaging business, remember, started really post-war, with the advent of injectable penicillins. I should say that the heavy marketing of injectable drugs really started to accelerate post-war. They had suppliers on each continent back in the late 40s, 50s, etc. You weren't shipping product across the Atlantic like you are today, so they grew up. West acquired its European presence, started acquiring it, back in the 80s, I believe, with the phased-in acquisition of a company called Pharma-Gummi. Really, it's a historical perspective. The shares, the relative market shares are what they are, and as I said, these are long-term relationships with the customers, and that explains the market share differentiation.

SI: Could we dive into that pricing pressure?

BH: Historically, Datwyler and Aptar have sold at a 15-30% discount to West, so they have acted as a throttle on pricing. West has been able to command the premium over my 20-year relationship with them. It can be a value-add proposition, but, yes, there has been certainly a competitive threat. The good news for all these parties from a pricing perspective is that when you look at a pharma company's P&L or cost structure, that these components are very low down on the radar relative to their total cost structure. Although there's always a sometimes spirited discussion about pricing, the reality of it is the pharma companies don't need that to make their quarterly estimate. It really is a very small portion of their total cost structure, but it can have a very high impact, again, because it's a drug contact surface.

[00:33:27]

Q: I want to get us more clear on the 15-30% discount that their competitors are putting out there. In terms of quality, is West seen as a superior product? How are they able to justify their price differential?

BH: It has changed over the years, but right now, I think it's a couple of things. Certainly one is supply chain reliability. West has a great deal more flexibility in its manufacturing footprint than all the other players with regards to the locations of their facilities and the scale of their facilities. They're bigger facilities, they put out more parts. This in particular was demonstrated to the industry in 2003, when West had an unfortunate industrial accident at the Kinston, North Carolina plant, where we had an explosion and it took the plant out of production in its entirety. West was able to get the tooling out of the plant and distribute it throughout the globe. There was product that was transferred to Singapore, there was product transferred within the US, there was product transferred to Europe. With the loss of a facility, West was still able to fulfil every order that they needed to. I won't say that we weren't late on orders. We certainly were, but fundamentally we were able to recover from that and produce the same product for a customer in another one of our facilities. That kind of supply-chain reliability if you're a pharma company is a significant factor.

SI: Are there any other differentiating factors we should be taking into consideration besides the price and supply chain?

BH: I think the other piece of the puzzle, although they've got competing products in the space, is the washing and coating technologies that West has brought to bear. Again, that goes to the technical expertise. West's partnership with Daikyo has brought in the FluroTec coating, which is very effective on the biologic drugs, and I believe at last count they liked to say that they're on 19 of the top 20 biologics globally. Also, as we talked about the increase in quality, West invested in advanced washing systems back in the late 90s. What they call the Westar process has seen significant growth over the last 15 years, to the point I believe their public statements say something like 40% of the product that they make goes through that advanced washing process. As a customer, you're getting a very good technical support team. You're getting very good technology. You've got supply chain reliability and certainly I think West has differentiated itself on the service side with their technical customer service group that continues to support customers as they produce the product as things come up, as well as their laboratories, which can assist customers in diagnosing problems on their production lines. It's a suite of enhancements to the base product as the support for that product going forward, and that has justified the price differential over time.

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Q: Any sort of disruption in the space that we should be aware of? It doesn't seem like there are too many new entrants, but is there anything that you've seen or could see as a potential threat to disrupt this market dynamic?

BH: I don't see anything in certainly the 5-10-year horizon. The pharma industry moves pretty slowly, so even a "breakthrough" right now, and I use that term in quotes, would take a significant amount of time to ripple through the system. Again, because of all the regulatory space issues. Certainly there has been entrance into the US markets by competitors either from China or India, and because of their lack of regulatory history, they really haven't made, I don't believe, much in the way of headway, from all the information I have. Again, the risk of a pharma company trying to utilise an unproven supplier is just too high relative to the cost and the risk it involves with their product. With regard to technological innovations, I think injections are going to be around for a long time. People aren't going to change the mode of administration and the route of administration, because some drugs just don't lend themselves to it. Certainly, the biologics, because they're a large-molecule protein, they can't be introduced to the body orally, because the stomach acids tend to chew up the proteins. The other routes of administration, nasal, etc, are just not as effective as injections, so I don't see anything, certainly in the 5-10-year horizon, that would have any disruption in the space.

[00:41:21]

Q: Anything else we should be thinking of in terms of customer trends, that is important to understand with regards to the space in general or West specifically?

BH: No, I think from the customer perspective, really, it's the two pieces. It's the quality and the reliability. Those are the two key pieces that I think customers will continue to be aware of and desire.

[00:42:06]

Q: We've talked about the stoppers side. Could you walk us through the product portfolio, and with that the real drivers of each of those business segments?

BH: West divides itself into two segments, what they call proprietary and contract manufacturing. I'll speak to the contract manufacturing first. That's really just as it says. It's contract manufacturing, but it's primarily the acquisition of The Tech Group which occurred back in 2005. That acquisition was to expand West's plastics business. West has been in the plastics business since 1960. Ironically it had a pretty good consumer product focus and customer base, but they were having trouble making headway into the medical device marketplace. The tech acquisition brought really a medical device focus in the West plastic portfolio. Those products are, as it says, all contracted, contract manufactured for various customers. They could be pharma, they could be diagnostic, they could be medical device, and they still maintain some consumer business, so everything from toothpaste caps to the spouts on top of the orange juice cartons. Again, (a) it's a plastics business, and (b) I think it should it be around USD 350m in total revenue according to what I'm able to reconstruct. That's the smaller part of their portfolio. The rest that they refer to as proprietary, certainly the biggest portion of that is the rubber business. Those are the stoppers. They are the speciality components. It could be IV junctures. It could run the gamut. Syringe plungers. They also include some what I call medical devices in it. Pre-fillable syringe systems. Most of their new products, the self-injection platforms, the auto-injectors, attached pumps, are in that category, as well as the reconstitution systems. That portfolio spans across not only packaging components but medical devices as well.

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Q: Focusing on the proprietary side, the self-injection pieces and some more of those medical devices. How should we think about the growth drivers there, and maybe their market position within those sub-segments?

BH: What West refers to as their self-injection platforms are really two pieces to the puzzle on products. There are the injection pumps. Those are positioned for the biologics primarily. As customers are formulating their products, in order for the product to be effective they may need larger volumes, they may need a dosing regimen that is something other than a single shot to avoid that bolus effect that you get when you get a shot. They require an administration routine that is something other than just your one shot and done, and because it can be administered over time those patch pumps are very effective. It would be very difficult for a patient to give themselves a 0.1ml dose every hour on their own, whereas with a patch pump, they could put this on, leave it on for 24 hours, and then just peel it off when they're done. So that's targeted primarily for the biologics. The auto-injectors, again, that's positioned for products, could be biologics, might even be a small molecule, that the patient would need to give outside a clinical setting, or the pharma company would like to market being able to give that outside a clinical setting. I think the one most everybody sees on TV, if you've seen the new Neulasta ads, that's how they wanted to market that. The auto-injectors could be everything from a critical care such as an epinephrine for allergic reactions to an at-home delivery where the patient would not have to come into a clinical setting to receive a dose, so they can administer it at home easily.

[00:49:30]

Q: How do you think about the growth in the smart-dose delivery system? Can you see the adoption really picking up?

BH: It's really going to depend on the formulation strategy and development of the actual drug products that may or may not require it. I don't expect it to take over the world, but I expect it to be a nice niche. Again, because of its convenience, because of taking it out of a clinical setting or even a patient self-administration setting. All the patients in these cases have to do is apply the pump and start it, and it takes care of the dosing regimen on its own, so it really helps with compliance and adherence because it simplifies it for the patient. Not every drug is going to require it, but it's going to be very effective for the ones that do it. The big question that still remains is how many products will require it? As the biologic sector gets more and more sophisticated, I do see larger adoption of it than today, but how big that market is going to be is yet to be seen.

[00:51:25]

Q: How do you think about the positioning and growth of the injectable drug packaging piece?

BH: If you take their base business, their core business, which is the rubber stoppers and seals and all that kind of stuff, I think they're well positioned. They've got the quality high ground, they've got the reliability high ground, and injectable drugs are not going away. Even with the conversion to generics, the one piece of the puzzle for generics is generally the generic companies, in order to speed their approval process, request the same packaging components as the innovator. The volume will just shift. As drugs come off patent, West is well positioned to sell the same product, to whether it be the innovator or the generics. They're using the same formula rubber, and West can sell it at the same pricing.

SI: There's never any lock up for exclusivity for one specific branded drug?

BH: No. Not on the rubber side. When you talk about patch pumps or the auto-injectors, many times a customer will seek a lock-up for a therapeutic category, but not for the primary packaging. West wouldn't allow it, because West has positioned itself to serve the industry.

[00:53:55]

Q: Can you give us a feel for the benefits of having this broad portfolio and the rationale behind it? Is there quite a large ability to cross-sell, or do you have the ability to offer a full suite of services that customers are really looking for?

BH: There are certainly opportunities. Let's stay within rubber first. There are all sorts of speciality components there, but West's business grew out of making elastomer products for drug-contact surfaces, irrespective of the shape of how they were used in the business, so that explains a pretty broad category. Diverse products within the rubber business. Once you start getting beyond that, then West, because they were making syringe stoppers, wanted to get into the syringe business, albeit in a niche category with their CZ platforms. The ability to go to a customer and give them a complete solution was very attractive, and therefore the development of the pre-fillable syringe portfolio for West. West in the mid-2000s recognised where we grow, and that came into administration for parenterals. Therefore you saw the acquisition of The Tech Group to assist with that. You saw of the acquisition of the technology for the auto-injectors and the patch pumps and the reconstitution business. Those were all things that can be cross-sold to the customer and give the sales people a bigger bag to carry. Also, listened to the customers about what their problems were and their challenges in formula development. West has very good relationships with the R&D companies, or the R&D

departments of most of the major pharma companies. Listening to them and their challenges reinforced the acquisition of the medical devices that they've acquired up through 2013.

[00:57:21]

Q: It sounds very positive. Is there anything alternative to contracting with West or those other two players? Given the backdrop of the FDA [Food and Drug Administration] trying to move that approval process timeline up and get drugs to market quicker, with more generic drugs hitting the markets in the past couple of years, is this a manufacturing capacity constraint? Where would the bottlenecks start to hit?

BH: I think West saw some of the bottlenecks hit over the course of the last 18 months, but that was not in the raw manufacturing capacity of making the actual parts, it was in the finishing of them. West has since ameliorated that with the addition of capacity throughout their system, primarily in the enhanced washing systems. That's why their backlog was so large after that. They were fighting a pretty good backlog, I want to say about 24 months ago, but I really don't see it as a restraint on their growth. Really, I think they're well positioned. I know they're well positioned, because I was party to that positioning. It's a nice business. It's a niche business, but it's very nice, and the business will continue to grow. The question is at what level. I think you have to look at West over the long term. There's a cyclicality to the business that I can't quite explain, and even while I was there I could never get in to prove it, but it runs in a sine wave. It can be an 18-24 month sine wave, but at the end of the day, it's still going to grow mid to high single digits on a long-term basis.

[00:59:56]

Q: A very positive story overall. Can you give us some hypothetical headwinds that we should just keep an eye on, just to get a feel for that cyclicality piece?

BH: I had a lot of conversations with a lot of different people last year on concerns about West's growth slowing down. To me that was just a natural occurrence of, again, the cycle. They were just coming out of a cycle where, again, their backlog grew very large. People were over-ordering and they were pumping product out a fast as they could, but just couldn't keep up with the demand. What happens is a customer may order well in advance for a product launch, another customer calls in for a similar product, instead of a 6-8-week lead time, they may get a 10-week lead time, so then they order some more. That can domino throughout the system, and it has on West on multiple occasions. Eventually everybody gets through that cycle, West starts catching up, and customers find they've got a lot of inventory lying around so they decrease their orders. That was the cycle West was in. I don't think the management handled it well because they were inexperienced in that, so they didn't have a good handle on what was really happening in the market, and didn't talk publicly about it ahead of the curve. Overall, there really aren't. I think the challenge for West is going to be the new products going forward and the adoption of them. That remains to be seen, because from my perspective that's priced in. I think that's still an open question on their ability to sell the new products, especially on the device side.

SI: What do you think that comes down to? Is this in their control, or is more market-driven? You talked about the inexperience of the management team. Is this something that can be driven?

BH: I think the management team is marketing them well, but I think they probably need two pieces to the puzzle. They need some luck, as always, as anybody in this line of business does. That is, the customers that they're working with, their drug gets approved in the market. That's happened on more than one occasion, where you're working with a customer on a product and it could be with even just a single rubber stopper, and for whatever reason that drug just does not go to market. It either fails in clinical trials or it fails in the marketplace. They need a little bit of luck there. Then, really, just the continued marketing of it and utilising their contacts with it. Is their technology in those new products sufficient enough? There is more competition, certainly in the patch pump and the auto-injector sectors. Can they put out a superior product? Whether it be

SHL or Ypsomed, everybody has an auto-injector. Aptar, BD, etc. The playing field there is much broader. Are they going to be successful? I think they'll get some products, certainly, to market, but what will it be as far as a long-term driver? I think that remains to be seen.

[01:05:08]

Q: It seems like there are two completely different market dynamics there in terms of the competitive landscape, especially. Could you see some sort of spin-out of that division, keeping the devices separate from the manufacturing side?

BH: I don't at this point, certainly. I think if they were contemplating spinning it off, and this is personal opinion, they would have concluded that those businesses do not have long enough runway for them. I certainly don't believe they're ready to make that call yet, by a long shot. These are long-lead-time programmes, and it takes a long time to get these in the marketplace.

[01:06:24]

Q: In terms of further stimulating growth, could you see further M&A to shore up some sort of capability or bring out more capacity?

BH: M&A in the highly-regulated markets is extraordinarily difficult, (1) because of the concentration of players and (2) because of the market share that West holds. However, in the less regulated markets, India, China, etc, there could be some potential M&A candidates. Before West built capacity in India and China we looked very hard at it and the price value that we found in those markets just wasn't there, so the decision was made to build capacity there. I think in growth they have an opportunity both in the China and India markets to provide product for those markets to be sold in those markets, and I think they have an opportunity there from a geographic expansion perspective. Their shares in China and India are pretty small relative to the market available. Because these devices are such long runway and long adoption cycles, I'd like to see them go out and acquire another medical device technology for the market. What that is could range across a lot of applications, but I think they need to do that now in order to be ready 7-10 years from now.

[01:09:41]

Q: I know we covered a lot in the call today and as we're approaching the hour mark here, I would love to just get any sort of final comments on your end. Anything that maybe we haven't discussed that is important to understand the nature of the space, or any sort of outlook?

BH: I think West is very well positioned. They're taking advantage of their strengths. I think their strengths certainly outweigh any of their potential weakness vis-à-vis their competition, but I think the key for them will be the growth in the new products and primarily in the device sector. The contract manufacturing business, although it can be lumpy with its up and downs as products come in and out, they've done a good job with that and the growth there has been nice to watch over the last couple of years. The group contract manufacturing segment is very well positioned from a quality perspective in the segments they need to compete in. As I say, again, for West in general, I think the key is acquisition of new technologies, again, to be ready 7-10 years from now, because that's how long the cycle is.

[01:11:12]

SI: Got it. Let me just close by saying thank you for all your insights here. It's been extremely helpful on our end. To our clients, if you'd like to speak in a private call or meeting, please let your relationship manager know, and thank you all for joining Third Bridge Forum's conference call today. This now concludes our meeting. Thank you, everyone. Have a great rest of your week. Thank you again.

BH: Take care.

SI: You as well.

Transcription ends at 01:11:45 of the recorded material