West Pharmaceutical Services – Injectable Medicines Franchise Development & Present-day Corporate Positioning

24 February 2023

Key Insights

- Development of longer-acting drugs could have a “significant long-term risk” on West Pharmaceutical, which depends on unit volumes of injections. Specialist expects high-value products >30% in five years
- SmartDose is a high margin and “differentiated product” capturing the larger 10ml volume which “really nobody” is addressing. However, customer adoption remains a “very high barrier” due to its complexity
- West Pharma’s collaboration with Corning resulted in a unique product, adding “tremendous value”. It has carved out a niche, enabling customers to evaluate another level of drug product compatibility
- Specialist doesn’t think anyone can impact West Pharma in the next 3-5 years. It is setting the “high-water mark” and will offer more “interaction between the primary container and the drug product”
- West Pharma’s long-term contracts and yearly incremental price hikes makes it extremely hard for customers to switch vendors. Customers have been conditioned, but this remains a point of contention

Specialist Lawton Laurence (LL), Former Senior Director, Applied Research & Technology at West Pharmaceutical Services Inc

Moderator Raemen Sahney (RS), Third Bridge Sector Analyst

Agenda

- Q1 2023 West Pharmaceutical Services (NYSE: WST) company update – key trends and developments in the pharmaceutical packaging and delivery system and biologics market
- Expectations for West Pharma’s drug and product launches, including Daikyo CZ (Crystal Zenith) insert needle syringe system, the SmartDose device and more established revenue streams
- West Pharma’s competitive landscape, noting significant areas of differentiation and pertinent market share dynamics
- Collaboration and capacity expansion efforts, highlighting possible synergies via West Pharma’s recent collaboration with Corning
- 12-18-month outlook detailing potential capitalisation opportunities and future headwinds

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Transcription begins at 00:00:05 of the recorded material

RS: Welcome to Third Bridge Forum's Interview entitled West Pharmaceutical Services – Injectable Medicines Franchise Development & Present-day Corporate Positioning. I am Raemen Sahney and I'll be facilitating today's Interview with Mr Lawton Laurence, former Senior Director of Applied Research and Technology at West Pharmaceutical Services.

Lawton, before we start today's Interview, 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 Interview.

LL: I agree.

RS: Perfect. Thank you, Laurence. If you would, could you please begin with a brief 60-second introduction of your background?

LL: I've spent my career in medical device development and the last 10 years or so in combination product development, starting at a company called Unilife that was developing novel injection systems. Essentially, the innovation group that I was responsible for, the technology was acquired by Amgen. I went along with that acquisition, helped facilitate that technology transfer and ended up joining Teva for a little while as Director of Platform Technology Development. From there, I joined West and spent about four years there forming a group focused on upstream innovation, looking at disruptive technologies. They had a need for a development capacity in creating new business units in both adjacent spaces as well as potential offensive or defensive disruptive technologies that were maybe facing their own business, so endured a few different organisational changes there, but ultimately decided to join Apellis Pharmaceuticals, which is focused in rare disease and ophthalmology. I have a background of seeing both sides of the equation, both as a device developer working with pharmaceutical companies as well as being a customer side acquiring the units that West produces.

[00:02:35]

Q: How would you assess the industry growth for primary packaging of injectable medicines as it relates to West Pharmaceutical Services? You indicated that this is a slow-moving field, so how has broader transition from molecules from vial to pre-filled syringes facilitated industry growth?

LL: You generally assess it by the unit volume growth of the underlying markets, so whether you're looking at novel therapies, how many patients are being treated, how many injections are occurring and what the underlying volume there drives the pharmaceutical packaging growth. When I say it's slow-moving, there's certainly a long duration associated with drug development generally on the order of a decade, so when you see those new drugs come to market, it's quite a long time in development. Because

of that, when I say slow-moving it's, they've had to make decisions about pharmaceutical packaging much, much earlier in that process, so you're seeing a very lagging indicator of a selection process when you're actually looking at what West is producing on a quarterly or annual basis.

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Q: What ancillary drivers are worth highlighting regarding industry growth? What is the bigger picture assessment?

LL: The growth drivers are, primarily finding new ways to treat diseases, and there are both drivers and suppressors in that. Generally, when you're looking at injectable medicines, patients don't want to be stuck with a needle, it's as few times as possible, and you can see that manifesting in some of the drugs that have come to market. For example, Humira vs Skyrizi, Humira going from an every-other-week treatment to Skyrizi, I think, is once a quarter, so there's a significant amount of investment going on on the pharmaceutical development side to produce longer-acting drugs, drugs that can be injected less often, and that's certainly going to have a downstream impact to companies that are driving on the unit volume of the injections. That's an ongoing suppressor in biologics. The other side of that is the new treatments for new diseases that never had a treatment or a therapy available before. That's certainly increasing the volume, but on the other side, if they're investing in things like gene therapies that, again, go from an injection on a recurring basis to one injection or one time per year to reach a cure, that's a significant long-term risk.

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Q: What is the general time frame for recurring injections? How is the development of less frequent injections and longer-acting drugs impacting business for West Pharma?

LL: It varies widely from, on one end, continuous delivery in insulin and certain intrathecal delivery modalities to something like Skyrizi that's once a quarter and there's a wide range in between there. I think if you see therapies come to market initially, they're going to be more frequent dosing and then the companies behind them will invest in life-cycle management plays to decrease the frequency of dosing and extend the duration of the impact.

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Q: How would you assess West Pharma's non-pandemic related growth, especially given the company experienced a bolus of demand during coronavirus and, as expected, there has been a big pullback as we reach the tail end of the pandemic?

LL: Frankly, what they've produced in the last year is the biggest indicator of the strength of the underlying business, that they're barely close to maintaining, albeit a lower rate, but a very consistent, still an increase in overall revenue, which is a pretty a significant accomplishment and it really speaks to the underlying business that's able to overcome that hangover from COVID. The part that you can never really recapture is the operational efficiency you get from just producing a much smaller set of SKUs, so when you're producing the stoppers for the COVID vials, they're running lights out, they're not switching over, they're not doing a line clearance on the various other component demand, and that operational efficiency, that's unmatched. You're just pumping out that one SKU, where most of the regular recurring business is highly diversified across hundreds, if not thousands of SKUs.

RS: Is that operational efficiency continuing? Is that driving the post-pandemic growth?

LL: No. They're actually going to return to a more diversified SKU set because their growth in, as you mentioned, pre-filled syringes and other areas are just inherently more diversified. Those are still in the high-value product category, but it's hard to match that efficiency you get from producing such a small number of SKUs at such high volume.

[00:09:45]

Q: What is the underlying demand for biologics or C&GT [cell and gene therapy] products using West Pharma's systems? Is that growth going to be fast enough to overtake the decline of coronavirus volumes?

LL: I would say, based on what you're seeing this year, the bulk of the COVID volume, when they're producing that product and they're recognising the revenue against it, that's been shipped long ago, so that's already a lagging indicator. The strength of the business that you see today actually speaks to that they're able to manage the loss of quite a lot of COVID revenue. That being said, to hit on your question, biologics is the area of growth, but you ask an expert what biologics means vs what West defines as what biologics means, it's a really opaque definition. West can choose whatever they want to put into that biologics bucket and it isn't necessarily clear how to untangle that from the outside, so their market units of pharma, generics and biologics are not really representative of how their customers think about markets. They think about treating diseases and they might execute a number of different ways to treat those disease states that would include small molecules, peptides, biologics, etc. Each one of those organisations have their own sales forces, so when you're on the customer side and you're, "Today, I'm representing cardiovascular disease and I've got a number of molecules, some large, some small, that are going into that," how does that get pulled out in West's assessment of that market growth?

Ultimately, I think it becomes, what's important to them is biologics and they're like the A-Team in that business unit, and so the things that are important to them, like gene therapies or COVID, roll into biologics. That's really not a biologic by any traditional definition. A lot of people do this, they lump cell and gene therapy together, but for a company like West, it's really important to disintegrate those, because cell therapies, I don't know that West has any products in cell therapies and ever will. Those are provided in bags. Those are vein to vein, they're provided in blood bags, whereas the gene therapy side, there's certainly a tremendous amount of investment in gene therapy and a lot of optimism for how that's going to impact human health, but you're taking something that is, right now, being treated on a recurring basis and moving it down to a one-time injection and you're charging essentially the same amount of money for that, whatever that is, USD 2, USD 5 for a single set of pharmaceutical packaging. It's a tremendous threat to the business, and unless it adapts and finds a way to capture more value in that ecosystem, it's not a positive element to think about for the future.

RS: That's a very interesting point and that was going to be one of my follow-up questions regarding the pricing. How significant is that threat, just looking at it over the next couple of months or years? How do you expect that to evolve?

LL: It's nothing, it's immaterial. To have any material impact on the business, it's 10 or 20 years away.

RS: It's a long-term problem, not really a short-term one?

LL: Yes.

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Q: West Pharma's organic net sales grew 2.6% in Q4 2022. Which segments are undergoing the most amount of growth across biologics, generics, pharma and contract manufacturing? Generics and pharma saw double-digit and high single-digit growth respectively. Where's the revenue growth vs slowdown across segments?

LL: This is where, if you look at the market as a whole and understanding injectable drug delivery, it's very difficult to map that onto these somewhat arbitrary segments. I think last year, it was announced, just as an example here in generics, the SmartDose device was approved for scPharma for delivery of subcutaneous furosemide. Furosemide has been around for a while, so it's a generic, but that's a novel, high-value product that is looking at multiples like 10 -20x on what you would get for a traditional pharmaceutical closure system. I believe that maps into generics, so when you see, "It's a great result in generics," scPharma just announced this week that they're launching that product, so you would imagine there's a tremendous amount of stocking going on to facilitate that launch on that product category, so my visibility of what the market looks like vs how West is defining those market segments can be very, very different things. That being said, it is no doubt that the core biologics business, that is the large molecule pipeline, is rich. It is where the high-value products are, it is where customers like myself are unwilling to take any risk related to jeopardising the launch of the drug, and any opportunities to accelerate the development of it, all roads on that path lead to West and their high-value products.

RS: Where are you seeing the most amount of slowdown? Would that be on the contract manufacturing or pharma side? Given there are already so many established players in those segments, how is West performing there?

LL: It would be hard for me to talk about contract manufacturing as a business segment because it's just highly depend on West's individual pipeline as a company. There's tremendous growth in that market. The only issue is that it's fairly low-margin, so every dollar sold in contract manufacturing for a company like West is a hole to fill from the biologics in order to maintain the overall enterprise margin. There's, on a market basis, tremendous growth in contract manufacturing, but it's just not all that attractive for a company that has so much more accretive ways to go about their business. I've never been really that exposed to it, so I don't know anything to share on that other than that on the market as a whole, tremendous demand in contract manufacturing, but there's just, we'll stand that up as a customer. We pay for the capital. If we don't like the way you're operating that capital, we'll pull it out and we'll send it over to somebody else. We'll send it to Flex Medical [Flex China] in China, we'll put it over in Phillips-Medisize in Minnesota.

There is no tolerance for arbitrary pricing increases in that category, but I don't see a slowdown per se in any segments. The only issue from an enterprise level is that when you don't have the capacity to deliver to the market demand, then what do we do as pharmaceutical customers? We cannot not launch our drug, that's not going to happen, so how do we deal when the preferred component, whether it be a stopper or a plunger or anything else, is not available on the timeline that we need? We go somewhere else, reluctantly, but you have to, and when that happens, you basically are inviting in pricing pressure because now, I've got a qualified component from another manufacturer and I know what their prices are, it's running on my equipment, it's running on our fill-finish equipment, I have drug compatibility data on it and the next drug that comes in development, maybe I say, "Keep a Daetwyler plunger in the mix. Do all of the work on that one too so that we can have a little bit of leverage," whereas if capacity was not a constraint, then I'd rather invest my time and my company's money on something else.

RS: If that stopper isn't available or if the company can't provide capacity, is West subjected to a lot of these cancellations or supply chain issues that might lead to a significant delay?

LL: In my mind, I segregate supply chain issues from overall capacity. West, they're manufacturing everything from the native chemical constituents, so drying, mixing, they produce everything from those chemical constituents and move it up the value chains and sell it. The only constraint there is their own capacity to produce it, their own equipment, their own facilities, and that is absolutely. If you look at the lead time for these components, it's somewhere between six months and two years, and if I have to wait two years to get a component, I can't use it.

RS: What is the risk of a customer choosing another provider in that case?

LL: The risk is that it's proliferated throughout their portfolio. Not only does that customer on the innovative molecule use somebody else's elastomer or somebody else's closure system, but they're looking at it internally and saying, "If West has capacity constraints, then we need to diversify our supply chain and use these other components more broadly." They're not going to do that across a single molecule. Generally, I've seen it done very rarely, but you don't go to the FDA with two different elastomers in your product presentation. It would be, "We've got this one, that's the one and it will almost never change," so once you've captured it, it's there for good, and you have that also when the biosimilars or generics come out. The fastest, least risk, most direct way to go to market is to use that exact same elastomer, so by capturing that innovator molecule, you also get some large percentage of the downstream generic market when that manifests, and likewise, if you're not using a West elastomer, you're using somebody else, that proliferates on its own as well.

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Q: What are your high-level thoughts on West Pharma's SmartDose device? One of the highlights from the JPMorgan conference was customers receiving four drug approvals using that device. Are there any strengths or weaknesses to highlight? What's your outlook for the commercial uptake?

LL: The overall strategy on that is, as I alluded to earlier, as you see, these drugs go from weekly or biweekly dosing to monthly or quarterly dosing. To recapture that value, you move up and you add devices like the SmartDose that are 10-20x on price and revenue associated with it that not only refills that, but actually builds the business on that, but the other side of it is that very rarely are those drugs launched only in a device like SmartDose. Just to use Skyrizi there as an example, it's also available in pre-filled syringe, it's available in vials, it's available in an auto-injector. Repatha, I think it was approved in 2018, that was the first SmartDose molecule that was available in auto-injector and in the SmartDose. It's great for West to be in a position to have a component of the auto-injector and then also have the higher-value side with SmartDose. I think what we've seen is that in that volume range, SmartDose is really offered in two volumes, a 3ml and a 10ml. The 1-3ml space has really been more captured by either larger-volume auto-injectors or multiple 1ml auto-injectors. That's what has transpired there, which was a little bit unexpected, but luckily, West had invested in this larger volume, 10ml, where there's really nobody that's going to do 10 auto-injectors as a dose, so that is a differentiated product and that's meaningful. That being said, it's a primary container that is unique and has unique filling challenges associated with it. The way these pharmaceutical drug products are filled, generally, they're aseptically processed. That equipment that fills and stoppers in this very controlled, super-clean aseptic environment is very difficult to change from a syringe to a format like is used in the SmartDose, so there's a very high barrier to actually adopt that product, but when you look at recapturing some of that lost volume, the dollar value and the margin associated with it is very attractive.

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Q: How challenging is it for customers to adopt the SmartDose device? You mentioned it's a long runway. Is that a significant challenge or minimal?

LL: It's a huge challenge. It asks them to do something that they really don't want to do, and any pharmaceutical company, they're somewhat hesitant to adopt devices. They don't really want to do it. They want to sell vials. Vials are not devices. They want to sell that as much as possible and push it out. They're forced into having device solutions and they make a difference, but it's not really core to their business. The scale and the way that the filling lines work with vials is, you're pumping out millions of units. When you go to something bespoke like what's required for the primary container and SmartDose, instead of vials being squeezed into the high-volume automation lines, we've got individual tubs being processed of 30 units at a time. You just think about the allocation of manufacturing space at a pharmaceutical company and you see, the productivity of that space that's going to go into that type of product is minuscule in comparison and the headaches associated with it are tremendous. It's a burden that is hoisted upon the manufacturing science and automation teams at pharmaceutical companies, but it is one that ultimately serves patient need and supports the uptake of their drug, and lower dosing supports adoption and differentiation.

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Q: How long is the runway until most of West Pharma's volumes are high-value products? It seems like around 23% of volumes drive over 70% of sales volume. Where is the natural ceiling and what does the run rate look like?

LL: Again, this goes back to what I was alluding to with pharmaceutical companies and their portfolios, and what individual elastomers they're using today and how those are going to be adopted into the new drugs that they're trialling and ultimately commercialising. It varies widely by customer to customer and to have some real foresight on it, you would have to understand which customers and which ones are buying which elastomer, which I simply don't have, but I would think about it in terms of in five years, if they were up above 30% HVP, that would be a pretty good pace.

RS: That's a reasonable expectation, for 30%. Would you expect it to be a bit higher or is that a reasonable run rate?

LL: I think if you're shifting over 10% over 5-10 years, that's the fastest you can possibly go, that's maximum rate. That could change. The ideal is that you're using the same elastomer formulation for your vial as you would in your pre-filled syringe, and FluroTec has tremendous performance advantages in the pre-filled syringe, and so you want to use that as well as in vial. It processes much smoother, there's every reason to adopt it, but for the fact, once you're already running something else, that becomes the default choice.

RS: I appreciate that quantifiable number, because that gives us an idea. It's pure speculation, but it gives an idea of what's going on there.

[00:32:04]

Q: Can you give us a feel for the competitive landscape surrounding West Pharma's market positioning noting key players such as Daetwyler, Aptar and other international players? Does operating in quite a

niche environment provide a competitive edge vs other players in this space?

LL: I'll speak primarily about the largest portion of West's business, which is the elastomer manufacturing. If you get into certain areas like the Crystal Zenith, CZ, system, there are other players that would be more prominent, but in the core business, which is, as we say, squeeze and rubber, you've got Daetwyler, Aptar and to a lesser extent, Sumitomo in Japan. I would also add, even though they're half-owned by West, Daikyo. Every unit that's sold out of Daikyo is half the potential revenue hitting West as if it was coming directly from West, so it is something that should be quantified as well. In terms of the niche industry, as you've probably gotten the flavour of from me speaking about their product, in every case, we're going to try to get the West product first and foremost, and do they have the capacity to supply it? I'm in ophthalmology now and there are, I think, two other competitors that have pre-filled syringes in ophthalmology and they're both using West elastomers. I'm going to do everything I can to get that West elastomer. There is no reason for me to put the programme timing at risk, especially when everybody cares about moving faster. I don't even need to price another competitor, to be honest, that isn't even in the calculation. It is, can I get it? That's the significant concern for a company that I would say has been really leaned out to the point of not having the capacity to support the demand.

Then you look at Daetwyler, certainly not exactly the same type of chemistry, but it's very similar. Very wide offering, very well-regarded company, but I would look at somebody like Aptar who has a very beneficial relationship with Becton Dickinson, who's the largest manufacturer of syringes for pre-filled syringe applications. BD sells West elastomers too, no doubt about it, one of the largest customers for plungers, but they have gone out and forged a partnership with Aptar, and Aptar can manufacture product that is, call it, similar quality and chemistry as the West products. Head to head, you might not even be able to tell the difference between the two products, but all of the other trappings around West, we know them, we're already dealing with them on a business level, they have components that fill out a catalogue, not just a single component in this category that looks like a, I don't know what Aptar calls it, premium coat. They have one 1ml plunger, and if you look at the catalogue of West, it goes across vials. It goes to 0.5ml, it goes to 2.25ml, 10ml, and no matter what you're choosing, you're going to get essentially the same chemistry and same construction. All of that creates this really very difficult-to-challenge position if the customers can get the product.

RS: Apart from the legacy players you mentioned, Daetwyler as well as Aptar, are any newer or other players rising in the market and could potentially disrupt market share in 3-5 years?

LL: No. It is so slow-moving. Just imagine the scale of these facilities that are pumping out these components. I don't think anybody, even if they had infinite money, could produce a facility that would make enough product to have any material impact on West on that time frame.

[00:37:55]

Q: How might pricing dynamics change within the drug packaging and injectable medicine space? Another specialist [*see West Pharmaceutical Services Inc – CDMO, Proprietary Products & Rubber Business – 12 November 2020*] noted that there has always been a tension between West Pharma and its customers when it comes to pricing. Has pricing always been a topic of contention with customers potentially shopping around for other lower prices?

LL: It's a point of contention, because once I've submitted to the FDA and gotten approval on my drug product, that is a 10-year endeavour. It is possible, but it is highly, highly undesirable to try to switch to a different elastomer, so now, however long the duration of that drug product's life is going to be, we'll call it 10 years, I'm tied to my elastomer and primary container manufacturers for the duration of that. If they

choose to increase prices by something crazy, we'll call it 20% in a year, I would have no choice, I would pay and I would pay it for years and years, and they could do it 20% a year and we'd scream, but there would be almost nothing we could do about it for a period of time. The tension there is that if they did that, every single product that we were looking at in the pipeline would then go to somebody else and all of that downstream impact would come in, so that's the dynamic that West has to play. I don't actually care. When we're looking at speccing a new product, the price is immaterial, I'm completely price insensitive to the components of that, but when it gets into more operational elements and we're reporting on our COGS and we've got ongoing operations that those may have impact on, then you're creating a problem for the business as a partnership. West could charge whatever they want and we would have to pay it, but it would have long-term impact to the business.

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Q: How often does West Pharma increase its prices? How often does that happen during a down situation?

LL: They do it every year. They've conditioned their customers to expect price increases every year.

RS: Are those price increases significant or nominal?

LL: They're nominal. Even in inflationary periods like this, what are they talking, about 5%? The supply chain folks will scream for every penny on it, but it's really immaterial in the overall picture.

[00:41:10]

Q: To confirm, switching is very, very hard for customers. Is there a particular time frame for contracts or does it differ from company to company?

LL: It does differ, but the relationship is not always directly with the pharmaceutical companies either. If you look at the fill-finish CMOs, the big ones being Catalent and Vetter, Thermo Fisher, a lot of times, they're buying those components direct from West and they will have multiyear contracts with anticipating their business needs and that growth associated with it, and that aggregation of customers gives them more pricing power and also decreases West's reach into the pharma space.

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Q: What is your understanding of the expertise and regulatory requirements required for West Pharma and other competitors in this space? Is it particularly hard to gain a foothold on the regulatory side?

LL: When speaking about the core business, the elastomers, the regulatory expertise, anybody can develop it. If I started today in a garage and said, "I'm going to make a knock-off product," we'll have the expertise, for a few hundred thousand dollars, we'll have all the chemical extractables and leachables identified, we can submit a master file, we can do all of that, but nobody is going to buy it from me, nobody is going to trust this no-name shop and I wouldn't have the scale to meet the demands. Building out that scale is years, 2-3 years and you have to have that scale before you can sign any customer volume. That customer has a product in the pipeline that may or may not come out for five years, so you've got some good indications and that's, let's say, one in every 10 of those molecules actually come out, so I need 10 customers to get one to come out and I've got to have the scale to support all of them. It is tremendously challenging just from that scale and that trust and that relationship with the pharmaceutical customers. Everything else is really not that hard to do.

[00:44:05]

Q: I'm aware of numerous product recalls across the injectable drug delivery market. Is West Pharma heavily subjected to this problem, either due to voluntary action or regulatory oversight? Recalls can cause a significant loss in revenue and pull back growth, so has there been a significant impact on the company?

LL: Recalls from West's customers actually generate more revenue and volume. The only recall that I remember West being a part of where West was responsible for it was Vial2Bag. There might have been a couple other smaller device-related things, but those are really sideshows compared to the volume and scale of the core business. Does something like a Vial2Bag recall impact West's, we'll say, standing in the industry? A little bit maybe, but that's really a hospital market product, it's not a pharmaceutical customer product, for the most part, so it would be washed away quite easily. I'm actually not aware of any recall that I can ever remember for West's core business of elastomers or primary containers.

RS: I came across it during my research, so I wondered if it would be a big impact. I appreciate you giving that insight.

LL: It would be, but this is just a component of going into their overall system, and the rigour and analysis that goes in at multiple stages throughout the development and manufacturing of those elastomers make it exceedingly unlikely for there to be a recall related to their core product, and these other things on the devices, they're not material impact.

[00:46:24]

Q: What are your thoughts around upstream product development and R&D? What approach is West Pharma taking to drive innovation? Has the company invested sufficiently across the various business categories?

LL: This market, because it's slow-moving, and when we talked earlier about disruptive technologies and how they might manifest, there's nothing that can really come and have any real impact in the three- to five-year range. When innovation is coming up, what West is doing primarily is filling out the category, filling out their product offering that every product that they're making has the same sort of NovaPure types of specifications associated, continually moving up the bar of the specifications that they can deliver so that their customers get used to those specifications. As a customer of them, I care about these particulate levels and endotoxins and things that, when they set a spec, I can accept their certification that it meets that spec and it prevents me having to do work on that individual product. If other customers don't have that, then it really furthers the moat that they have for their products. That being said, if you look at entering new business units and new areas, it's really tough to find something that is as attractive as what West is already doing, and if you look at the running of the business and incentive structures that are built into it, there's nothing that will return on invested capital as well as putting in a new press for more plungers.

There's nothing else, there's no way that they can get that investment return, the challenge there being, we've got, like I was alluding to, capacity issues. They want to put in a press, they want it to be fully utilised on day one and that means that you're always going to be behind the demand, and when that's the case, then you've got going out to other customers or other potential suppliers of those components to meet the unfulfilled demand. If you look at what's going on at West on innovation vs those large competitors, I think you'll see West comes out with a new business strategy, for example, integrated services where they're able to offer more characterisation of the interaction between the primary

container and the drug product, they roll those things out and within a year, you'll see their competitors doing it. I think on the core business, they're setting the high-water mark for what the language and opportunity is around the industry.

[00:49:56]

Q: What's your assessment of West Pharma's Daikyo products and FluroTec cartridge plunger, which were presented in the Q4 2022 results? What are your commercial and scientific expectations for these two products as we enter 2023?

LL: We'll start with the cartridge plunger. That particular one, it's important to recognise the volume, the format that that is associated with, so looking at their latest quarterly presentation, that's the 5-10ml cartridge. I can't even think of a drug product that is in that format. I've never even seen one. I don't think I've ever even seen a 10ml cartridge. It's important because what I think they're doing is capturing large-volume drug delivery from other systems. We talked about the SmartDose being a 10ml product, they may be capturing that component that's going into other companies' large-volume delivery devices. It's still a nascent market. It's probably 10 years away from having material impact. I don't know, maybe they're able to charge an astronomical amount for it and it'll be impactful sooner, but that's what that is, and on the CZ, which is the Daikyo 2.25ml, the competitor there is a glass system and those have been out. You're not going to use, generally, a pre-filled syringe alone in that volume. You're going to put it into an auto-injector from SHL or Ypsomed, and those auto-injectors have to be qualified and designed to accept the unique aspects of the CZ system, and there are some very valuable pieces of that system for those large-volume auto-injectors. It's just important to realise you've got adoption of that system, the CZ system, the 2.25ml, you've got to be able to fill and stopper that, which has unique aspects associated with it that not any filling operation can do, and then you have to integrate that syringe into an auto-injector from another manufacturer that then goes to the pharmaceutical company. These sequential dependencies have very long durations to realise any substantial revenue.

[00:53:04]

Q: To what extent has West Pharma's initial collaboration with Corning facilitated growth for the elastomer glass system solutions and vials from a synergistic standpoint? West recently expanded its collaboration, providing exclusive distribution rights for the vials and the launch of its first product.

LL: Corning is offering a great little product there in the vial and there's a unique value proposition associated with it. We're a year from the announcement on that, something in that order. There's virtually no way a customer could have adopted it and put it into production because of the duration associated with the FDA filings. It's a 12-month review, so you're not changing it out on an existing commercial product, you're going into the pipeline. Any revenue or opportunity that they're talking about today would likely have been harvested by Corning before that partnership was established. I think zooming out a little bit on vials, vials are regulated significantly differently than a pre-filled syringe. A pre-filled syringe is a combination product. Those are device performance aspects that are a totally different level of FDA scrutiny. A vial is just a drug packaging. There's no performance associated with it from FDA's perspective, the device centre doesn't get involved in that review, and that trends toward the value, so with that lower expectation, there's lower dollar value and lower impetus to switch over to higher-performing materials, other than the niche thing that Corning has carved out there.

The issue is, again, that now, you've got a unique chemistry on your vial. Until they have a pre-filled syringe, you don't have a corollary for that, so you have to re-evaluate your drug product compatibility

with the Corning system and then look at it again. Maybe something changes on compatibility with traditional type 1 borosilicate glass, so until they have a pre-filled syringe, that's where all their investment dollars are going to go, and that system is going to be a tremendous value to customers because they can certify the performance of it. I think when they're talking about, "We're going to sell a system," a vial system doesn't really have all these performance aspects like a pre-filled syringe does and the number of test methods and ways that you have to evaluate a pre-filled syringe is imposing, but that creates the opportunity for this system-level sale that is really incremental value.

[00:56:30]

Q: How should we understand West Pharma's international positioning? Europe seems to be having a lot of sector growth and then the company is trying to expand in APAC. How would you characterise the growth in both regions? Are you positive or negative, especially on the Asia market given what a wildcard it is currently?

LL: Europe and US, those are the two areas that any pharmaceutical company is going to target and have clear plans to deliver commercial scale to, and that means that West, when you're looking at what they're going to capture, they're going to capture those two markets in any deal that they do. The China market is one that's a little more insular and there's a lot more in-country-for-country manufacturing and unique marketing aspects there. I really can't comment on what types of volumes or opportunity is in China because it is a bit opaque to me. India is a little bit more open-border, although it is generally much, much lower on the specifications, so they're less likely to adopt HVPs.

[00:57:58]

Q: Where do you see West Pharma positioned in the next 6-12 months, considering growth opportunities, market focus and hypothetical headwinds investors should be monitoring?

LL: The shorter-term elements, I think that you can use their last quarter as a good example of how it's going to be moving forward. They've taken the biggest hits in the last really 6-9 months from the downturn of demand for COVID, so I would think about their most recent quarter as probably the strongest indicator of what you're likely to see going forward. They're going to continue to get that quarterly, quarterly, YoY look hit from the previous year's COVID capability, but the ongoing underlying demand for biologics and HVP is going to buoy it.

[00:59:09]

Q: Is there anything else to highlight about the overall market or West Pharma?

LL: I don't think so. I think you hit most of it.

[00:59:30]

RS: Thank you so much and I appreciate you taking the time today. This has been a really insightful conversation and I look forward to keeping in touch.

LL: Alright. Thanks. Take care.

Transcription ends at 00:59:41 of the recorded material

If you'd like to speak to Lawton Laurence in a private call or meeting, please let your relationship manager know.