West Pharmaceutical Services – Former Senior Executive, Corporate Development at West Pharmaceutical Services Inc

Former Employee | 2 December 2024

Specialist Background

- Over 10 years' experience in the pharmaceutical industry, focusing on corporate development and M&A
- Well-placed to discuss West Pharmaceutical's revenue margins, market penetration, injectable drugs and healthcare products, customer contract structure and SelfDose, its proprietary auto-injector
- Strong familiarity with West Pharmaceutical's work culture, management team, elastomer business, growth constraints, key purchasing criteria and market share

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Transcription begins

Analyst:
West pitches that 25% of their units are HVP [high-value products]. That represents 75% of revenue. What would you say is the penetration of high-value products by type of molecule? We assume a vast majority of that is biologics. How much is HVP in terms of units in biologics and small molecules in generics?

Specialist:
West has about 70% of the elastomers, the pharmaceutical elastomers market, and West produces about 50 billion elastomer units per year. As you mentioned, about 25 — maybe a little over 25% of the unit volume are high-value solutions, but with the price volume dynamic, it's an even larger segment of West's revenue. You could extrapolate from there, from 15 billion units owning 70% of the elastomers market globally, what the overall each's number looks like for injectable solutions that require either a plunger or a stopper, right? West is on essentially every biologic drug that's commercialised.

Just about every biologic drug that's commercialised has a West elastomer component if it's a liquid injectable. If it goes in a vial, a characterised cartridge or a prefilled syringe, and it's a biologic drug, it most likely has a West component. For the large volume, large viscous biologic drugs, which are a growing segment of the overall biologic drugs market, it has a high-value component, because of the benefits of the high-value product, whether it's the coating, the reduction in extraction and leachables and denaturing and what have you. I'll pause there. That would be sort of a perspective around sheer numbers that are going up from West and then you can extrapolate from there.

Analyst:
What is the HVP adoption by the type of molecule? Are biologics growing high single digits, double digits? Are biologics fully penetrated already with HVP?

Specialist:
Well, I think you're getting to a point where HVP is the standard for containment for biologic drugs. The unit economics of a biologic drug are such that the primary packaging is a de minimis line item in the biologic drug P&L. The cost benefit of using a component that assures reduced complications, reduced problems that you have with the drug just make it a pretty easy decision. From that standpoint, yes, you could argue that penetration is pretty high for high-value solutions into the biologic drug space, but you could also see that if you look at the clinical phase drug pipeline, the amount of or the segment of biologic drugs is growing as an overall percentage of the total clinical pipeline YoY. Again, I'll go back to West offering their growth construct , right? They're a pretty good barometer of the marketplace, because of their activity and coverage in the biologics space.

Analyst:
When we think about that 20% of units, the vast majority of it is biologics and then maybe followed by

generics and then small molecules. Is that right?

Specialist:
Yes. I mean the generics and small molecules are generally going to use some of the not the NovaPure line, at least from West, right? They're going to be a bit more cost conscious when you think about the drug P&L. You might still see some high-value solutions, but the mix is going to shift towards standard product, and even in the GLP-1 space, these are drugs that don't necessarily have the same denaturing risks that a biologic drug has. Even in that class of drugs, you may see the mix shift away from high-value solutions more so than in the biologics space.

Analyst:
What is West's contract structure with their customers? What are the terms of these contracts? What is the duration, pricing and how have these contracts evolved?

Specialist:
West has two different businesses. They have their proprietary business, which is primarily the elastomer components. Then they have the contract manufacturing business, which is also pretty sizeable. It's about 16% of the overall business, about USD 500m which makes them one of the larger drug contract manufacturers. The contracts would be a bit different between those two businesses, but I'm assuming that you're asking about the proprietary business, the elastomer components. Those are generally volume-based contracts with minimums and they typically have take-or-pay provisions. In many cases, the line would be dedicated if the volumes are high enough, because the product is relatively, it's a platform elastomer component that can be interchangeable between primary packaging, whether it's vials, cartridges or prefilled syringes, the lines don't have to be dedicated to a certain customer. In the event there is a line dedicated and co-investment of capital to put that line down and qualify it. That typically gets accounted for in the pricing where capital investment is spread across the volumes that are being produced and delivered.

Generally, you can work the price down to an each's level in these contracts, but they're typically, because of the sheer volume being manufactured, they're typically minimums are established at by the millions. When we talk about take-or-pay, this is usually a point of negotiation, but generally, for good long-standing customers, if minimums aren't hit, you'll typically see some sort of flexibility in the take-or-pay provision, right? Just for instance, if someone is contracted for five million eache's and they only hit four-and-a-half million, a typical straight take-or-pay would say, "Well, you're going to pay for the other half million, whether you took them or not or you're going to take them and warehouse them." In many cases, there'll be some sort of a provision where there's a flat fee paid to West, and so it's not set up to be punitive. It's just more set up to be volumes that can be relied upon by West, who is running the shift and resourcing the line and that sort of thing. Then the duration, they can be anywhere from one year to three years. Some of them are auto renewal. The pricing provisions, you see sometimes a CPI or 3-4%, whichever is lower, whichever is higher. That's typically how the pricing construct would work on renewal.

Analyst:
You mentioned different types of formulations out there. There are vials, which can be multi-dose or single-dose, PFS [progression-free survival], auto-injectors, which include PFS and also cartridges, samples, all that kind of stuff. To my understanding, there is a different elastomeric intensity depending on the formulation, which means some of them have elastomer components and others have one. Then there's also a frequency dynamic. Some of them are multi-dose, single dose. What are your thoughts on all of these?

Specialist:

I think, when a pharma company is trying to size the market, they look at the number of patients and then the frequency of dosage, and that's how they measure the size of the patient cohort. Then they have a price per unit, and that's how they come up with their market sizing, maybe oversimplifying, but that's essentially what they do. For a company like West or a primary packager, they have to think about whether this is a single dose like a prefilled syringe, for instance, that requires plunger or whether it's a multi-dose vial that might contain three or four doses, but only stopper, right, and so that's where in the past, you've heard discussion around a drug company shifting from a multi-dose vial to a single-dose prefilled syringe.

Well, obviously, that's a growth in market opportunity for a company like West, because now they're selling four components as opposed to one for the same treatment plan, and so to the extent that more of the packaging shifts towards prefilled syringes, which is what you're seeing in a lot of cases for biologic drugs and certainly for like GLP-1s, that benefits a company like West, because they're selling more components and typically selling a higher value component as many of the plungers that go into a prefilled syringe are of the higher value variety, because there's typically, the shift to a prefilled syringe is happening more for biologic drugs than it would for vaccines or small molecule drugs.

Analyst:
For GLP [glucagon-like peptide]-1s, I believe there is a prefilled syringe and also pens. In terms of volume, how much is PFS vs pens?

Specialist:
Yes, it's primarily pens right now. Yes, almost entirely, I believe. I think a good proxy is the diabetes insulin space where you still have 70% or so of the market on pens. For GLP-1s, it's going to be even higher than that.

Analyst:
Pens are multi-dose, right?

Specialist:
They can be, right? If they have a replaceable cartridge, then the drug would be delivered in a cartridge format and then the pen would be used to inject the drug. In those cases, it could be reusable multi-use pens. You also do see single-use disposable pens as well.

Analyst:
With pens, it happens the same as with auto-injector. An auto-injector will have a PFS or a cartridge inside it, right?

Specialist:
Correct, and in most cases, in pens, they're assembled from the manufacturer where the cartridge is already in the pen. In those cases, they're typically single-use disposable, whereas the auto-injector is generally more of a multi-dose device that uses replaceable cartridges. There are some pens that have come to market more recently from SHL and Ypsomed that also use either a replaceable cartridge or in some cases, a prefilled syringe. There are a lot of different platform varieties, but as a general rule, pens are single-dose disposable, auto-injectors are multi-dose reusable.

Analyst:
How does a multi-dose cartridge work? Is it that you have four doses and then you replace the cartridge?

Specialist:

Correct.

Analyst:
Are pens and auto-injectors more like a delivery device?

Specialist:
Exactly.

Analyst:
What are your thoughts on SelfDose, West's subcutaneous delivery system?

Specialist:
Starting with SelfDose, that's West's proprietary auto-injector. West owns the IP. That is not a market-leading device, and it's not a large revenue platform for West. Just order of magnitude, less than USD 100m in sales revenue, significantly less. The SmartDose product really trails in technology and acceptance. It trails Mali, which is SHL's product. It trails YpsoMate, which is Ypsomed's product and even BD's auto-injector as well. From a pen and auto-injector standpoint, West does much more non-IP contract manufacturing of pens and auto-injectors than they sell their own proprietary pen. Then SmartDose is an on-body wearable, and that is their subcutaneous delivery device. SmartDose was really the first on-body wearable to actually get commercial contracts.

In fact, I think there are four commercial contracts for SmartDose. More recently, other wearables have hit the market and have caught up and are now commercialised. BD has one SHL, Ypsomed, Gerresheimer. Most of the drug delivery and containment players in the space now have their own on-body wearable. West really struggled with commercialising at scale the SmartDose device. From a revenue standpoint, again, it's not a significant revenue generator for West, probably less than USD 50m in revenue. The four pharma companies that chose SmartDose as their subcu platform want more volume, but it's been a challenge for West to deliver on that. That was my experience anyway while there. I think, it's going to continue to be a space that grows as more drugs move from IV to subcu. I'm not sure that West SmartDose will end up being the leading platform now that some of the others have caught up.

Analyst:
There's no clear winner at the moment. The market structure of this type of device is fragmented, right?

Specialist:
It is. I mean, this is for the non-diabetes delivery platforms. It's a challenging business to make work fundamentally, because the manufacturing of a complex device like an on-body wearable is difficult to scale, and it's difficult to keep the unit costs down. Then the unit economics become challenging, because the price that the market will bear for that platform against the cost of actually manufacturing the device creates a margin profile that's not as attractive as a pen or an auto-injector, which is a bit of a simpler device to manufacture.

Analyst:
It's more convenient for patients, right?

Specialist:
Absolutely. From a patient standpoint, it makes a ton of sense, and that's why there's this continued push to try to bring that product on the market, and from an overall healthcare cost standpoint, it's much easier for a patient to treat themselves in the home with an on-body wearable than it is to go to an oncology centre or a special renal centre to have their drug delivered through an IV, right? There are a lot

of winners in the on-body wearable movement like the patient and the provider and even the healthcare payer or insurance company. The manufacturer is not yet getting as much of the value from that proposition as some of the other stakeholders. There's a bit of an imbalance right now in that market, which is what's kept it from really taking off the way you would think it should or could.

Analyst:
From a cost point of view for the healthcare system, an auto-injector is preferred over an on-body.

Specialist:
Yes, absolutely. It's just some drugs have volumes that won't work in an auto-injector or a pen, right? Once you get past, I don't know, 20ml or a certain viscosity of a drug, it becomes a little more challenging than to find a pen or an auto-injector format or if a drug needs to be delivered in a metered fashion, a pen or an auto-injector can't do that, an on-body wearable can, right, deliver drug over time, be a bit more prescriptive in sort of a volumetric delivery of the drug than a pen or an auto-injector. There are some boundary conditions that the on-body wearable solves for. If a drug doesn't require that type of delivery, then the pen or the auto-injector would certainly be preferred from a cost standpoint, from an ease-of-use standpoint.

Analyst:
Which molecules are using the SmartDose?

Specialist:
Yes. These are, again, sort of your larger volume, higher viscosity drugs. I mean, there are four of them. I know them. If you give me a second, I can recall them. Yes, there are four drugs that have a specialised delivery requirement, and that's why they moved from IV platform to the subcu platform. Repatha by Amgen is one of the drugs. Yes, Furoscix from Scpharmaceuticals, that was the most recent drug to choose the SmartDose platform that treats heart failure patients. Ultomiris is another one by Alexion, much smaller specialised patient cohort that uses that drug. Yes, so those are three. The fourth will come to me shortly. I think generally, what you'll see for on-body wearables is more and more oncology drugs or immunology drugs where the formulations may be switched to instead of once weekly or more frequent, less frequent, but delivered in larger volumes over time, maybe once a month, right? I think that's the goal for the on-body wearable is less frequent dosage, but more of a larger volume metered dosing for patients in the home.

Analyst:
It really depends on the molecule, right, on the viscosity? Not all drugs could shift to on-body.

Specialist:
Right. Again, you reach limits as far as volume and viscosity that can be handled by a pen or an auto-injector. Then I guess, one other factor for drug companies is patent life. I think that's one other thing to consider with the use of an on-body wearable is when a drug moves to a combination device like a wearable, they tend to have the opportunity to extend patent life, so for some of the drugs approaching a patent cliff, trying to extend exclusivity, that's also a motivation to move towards a wearable device.

Analyst:
Would you say there is a clear trend in terms of formulations? Is there a trend out of vials to PFS?

Specialist:
Yes. You're starting to see that more where the packaging format is shifting from vials to prefilled syringes. Again, this is as a result of a move towards more self-administration or ease of use for patients, extracting drug from a vial creates a larger margin for error, both in how the drug is ultimately

delivered to the patient, but also with more sensitive drugs, biologic drugs being somewhat more sensitive, and more of those coming to market, the less a clinician or a patient has to manipulate a drug, the more likely a drug will be delivered as intended to the patient. A prefilled syringe is a way to assure this, because it's packaged finally in a sterile fill-finish process. Then the next time the drug moves from the packaging, it's into the patient, and there's no need to do any sort of a transition from a vial to a delivery system.

Analyst:
From the total volume of vials out there, how much of those are multi-dose vs single-dose vial?

Specialist:
I think, there's a shift towards single-dose vials as more of the drugs become biologic in nature. You can almost follow the mix of biologic drugs to small molecule and vaccines as where the market would ultimately end up. Again, you don't necessarily want a complex large molecule drug in a multi-dose vial format, because that means you're going in more than once into the vial to pull the dose, and it just introduces more risk in denaturing of the drug. If you go to the current clinical drug pipeline and you look at how much of that pipeline is biologic drugs. You could essentially get a sense for where the multi-dose to single dose split would end up.

Analyst:
The formulation follows the molecule.

Specialist:
It does. That's very well said.

Analyst:
What are your thoughts on Annex 1? What are the consequences of not following it because I believe those are guidelines and not necessarily laws.

Specialist:
Sure. Annex 1 follows, was preceded by EU MDR, and so notified bodies in Europe have been pretty busy. I think, most US manufacturers are trying to align practices with Annex 1, whether the FDA would adopt those same guidelines or regulations is to be determined, especially now with the new administration in office. Many manufacturers are multinational, multisite networks with sites in key geographies in Europe as well as in the US. I think, what you'll start to see is Annex 1 practices being adopted and implemented even in US sites. I think, most are treating Annex 1 as imminent, right, whether it's a guideline or a requirement. Most are taking the necessary steps, certainly with new invested capital, but even in retrograding existing sites and processes to account for the new guidelines. It obviously comes at a cost. It comes at timing, adjusting the regulatory path. The idea of outsourcing certain activity that was once done in-house also is a discussion, right, to what extent does the pharma company want to take on the responsibility of the activity vs leveraging an outsourcing partner scale who's also implementing these types of practices and processes. It is creating a bit of a shift in the manufacturing processes for drug companies as well as for the CDMOs and outsourcing partners that serve the drug companies.

Analyst:
This applies for all the injectables, no matter if it's biologic or small molecule, right?

Specialist:
Correct.

Analyst:

There could be more HVP adoption as a second derivative to that in a small molecule, correct?

Specialist:
Yes, I think so. The value-added services that essentially create high-value products coming from pharma services companies like West, the washing, the sterilisation, the packaging to the extent that a company like West or a CDMO like Catalent or whoever it is, has to implement the Annex 1 guidelines at scale, more pharma companies will buy value-added products as opposed to buying standard product and doing those value-added services themselves.

Analyst:
How is West's culture? What are your thoughts on its management?

Specialist:
The drug delivery device space requires an approach across the value chain that's very specific, right, from the innovation of the device to being able to manage all of the regulatory and quality complexities to the actual manufacturing at scale, and then the downstream sort of marketing and commercialisation of those devices. West historically was a rubber manufacturing company, right, elastomer manufacturer producing 50 billion pieces of rubber at scale. They're great at manufacturing a rubber. They have a very advantageous relationship with Daikyo Seiko to ensure that they have a proprietary rubber formulation and coating formulation, and so all of that sets them up well to manufacture quality elastomer at very large volumes. What it does not translate into is the drug delivery device value chain that I just mentioned, right?

For contract manufacturing of devices where someone else owns the IP, owns the design file, the regulatory oversight and governance and all West is doing is specking in the manufacturing of the product. They've shown they can execute on that. As far as developing IP, commercial — manufacturing and commercialising their own proprietary devices, I think West has had a more challenging go at that. You're seeing companies like Ypsomed and SHL really grow mid-teens, high teens over the last several quarters, because they're getting the benefit of all of this shift towards these types of devices for biologic drugs, for GLP-1s and West has not necessarily been able to capitalise on that macro factor because they've not necessarily been able to execute well on the device side of the business. For West, there's no better ROI than laying down another high-value elastomer manufacturing line, and that's both a gift and a curse because it makes it much harder to think about allocating capital towards other projects that may seem dilutive to growth or dilutive to margin.

Analyst:
Still, they're exposed to the growth through their elastomer business, right? Maybe they are not (inaudible) with the actual device, but there's still a plunger inside that, right?

Specialist:
Absolutely. The West will continue to grow their each's output with the amount of shots in arms, right, but what West is really trying to do is shift that volume towards the higher-value product lines. In some cases, specifically the GLP-1 growth is driving growth for a lot of the pen and auto-injector manufacturers, because that's the preferred platform. For West, while they're seeing the volume grow with like the GLP-1, the need for a high-value component has not been there. Instead of selling a NovaPure high-value component for the use with GLP-1, they're selling something more standard, because there's less of a need for the coated rubber or the high-value solution, right, and so that's been a little bit of a difference for West as opposed to someone selling pharma glass or someone selling a pen or an auto-injector.

Analyst:

I believe they claim to be selling into the GLP-1s. It's a little bit lower tier, if you will, but still HVP (audio distorts).

Specialist:
Yes. It's not Altra. It's not the bottom of the barrel, right, product, but it's not the highest margin, highest priced product that they do sell into the biologic drug space.

Analyst:
I believe they are not seeing that outsized growth because they're experiencing destocking from the pandemic over ordering and the supply chain disruption that maybe eastern side of the world. Is that right?

Specialist:
Yes. I mean West was a clear winner in the COVID. A couple of years of COVID to the tune of incremental revenue that was strictly for vaccines. As the vaccines wound down, West saw most of that revenue go away. A lot of that was offset with uptake for biologic drugs, and that's secular and ongoing and will continue. I think, a lot of people think of GLP-1s as similar to COVID, where there's going to be some real winners and probably more sustainable for the foreseeable future. Again, where an Ypsomed gets to sell more of their high-value pens, the elastomer that West is selling to go with that pen is not their highest value product.

Analyst:
In terms of the drug delivery device, what is the key purchasing criteria? How could market shares evolve? It's relevant to think about the key purchase criteria of the drug delivery device, because to me, it seems that there is not a huge difference between players, but maybe there is.

Specialist:
It comes down to early involvement and expertise. If a drug is in the later clinical phases, and they're moving from a simple vial, which had been used up to that point for stability testing and small batch runs into choosing the ultimate format for drug delivery, which could be a prefilled syringe, could be a pen, could be an auto-injector. What they have to start taking into account is formulation, right? How viscous does the drug need to be, what's the volume of the dose, and that's where the expertise of an Ypsomed or an SHL comes into play, because they've already demonstrated with that existing pharma company that they can, they either have a platform that will already work within the tolerance levels required for that drug or they can make one that will work quite easily with some slight modifications to an existing platform. There's only a handful of players that have that kind of history, legacy capability in the space, and so they get the first call, right?

Ypsomed, SHL, SMC is another one who's emerging a bit and have some of those capabilities. What differentiates is not necessarily the product itself. I mean, that's certainly a consideration. It's the design, development and regulatory guidance that comes early on in the process as the drug company is formulating the drug and choosing which containment or delivery device they would plan to use because that gets spec-ed into the regulatory filing and becomes very difficult to switch once you've commercialised the drug. They're looking for certainty. They're looking for really the most risk-proof solution in the marketplace.

Transcription ends