West Pharmaceutical Services – Injectable Drug Device Market Entry & Professional Company Outlook

20 July 2023

Key Insights

- West Pharmaceutical Services “has a depth of knowledge and experience that the other organisations just don't have.” Datwyler and Aptar lack strong US presence, necessary pharmacy and regulatory proficiency and analytical knowledge
- West’s decision to enter the injectable and technology market “makes a lot of sense” from a strategic standpoint. West possesses the lead with the first successful FDA-approved product
- West has been able to move pharma companies up the value chain across various product lines by adding on levels of processing and increasing the incremental value, especially in washing and sterilisation
- “[O]ne of the biggest challenges has been capacity” specifically for customers requiring samples for valuation or clinical trials on a short-term basis
- “[W]hole move towards selling of a system […] is, I think, ultimately, the future”, but complexities such as integration, lack of scientific understanding from customers and safety issues still exist

Specialist Fran DeGrazio (FD), Former Chief Scientific Officer at West Pharmaceutical Services Inc

Moderator Raemen Sahney (RS), Third Bridge Sector Analyst

Agenda

- Significant trends and developments in the injectable drugs industry as it pertains to West Pharmaceutical Services (NYSE: WST) with the shift towards longer-acting drugs
- Product portfolio overview, discussing strengths, weaknesses and innovation strategy – Daikyo, SmartDose and FluroTec Cartridge – touching on manufacturing capacity, reliability, technology service and customer support
- Generic competition threat assessment for West Pharma, outlining key differentiating factors and ranking major global players within the space, including Datwyler (SWX: DAE) and Aptar
- West Pharma’s partnership blueprint, touching on past and future possibilities, considering synergies from the company’s January 2022-announced Corning partnership
- Customer base expansion opportunities, plus material headwinds and tailwinds impacting the near-term growth outlook of West Pharma

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Q: At the end of Q1 2023, West Pharma experienced net sales of USD 716m, which decreased by 0.5%, but at the same time, the company increased its guidance rates for 2023. Why do you think company experienced this small downturn and what are your performance expectations and commercial outlook across generic and pharma market units? 7

Q: You mentioned West has been able to move pharma companies up the value chain. Can you provide further insight elaborating on how the company has done? What exactly did you mean by that? 7

Q: High-value products, including components and devices, represented more than 70% of segment sales for West Pharma, with about 23% of volumes being high-value products. Specialists expect high-value products to be greater than 30% in five years. What are your projections around the global capacity expansion for high-value products for West Pharma? Would 30% be a reasonable percentage or is that too ambitious? 8

Q: I'd like to understand West Pharma's general technology. The company has decided to enter into the injectable devices and technology market, which is a relatively newer focus, and there's perhaps a risk of deviating too far from its core strengths. What do you think it's hoping to achieve from a technical perspective? How might the economics of this push look like? What are the positives and negatives? 8

Q: Given West Pharma is choosing to make the shift from its core strengths of packaging towards more of an injectable market, what might be the barriers to entry while the company makes this transition and how would you assess its capabilities to make this move? 9

Q: West Pharma recently released a SmartDose self-injection product in this department. What makes this product so differentiated? It is considered a high-margin product with the ability to capture larger 10ml volume, which nobody seems to be addressing at the moment, so what is your general consensus on this product and expectations going forwards? 9

Q: Understanding that West Pharma has been able to adjust to market need with the SmartDose, some people have mentioned that customer adoption remains a very high barrier to entry due to that complexity. Do you think that will be a significant risk to customer adoption going forwards for this product? 10

Q: West Pharma is proactively working to accelerate CAPEX on high-value product capacity, and some of those products include Daikyo, FluroTec and NovaPure components. What are your commercial expectations for these products, breaking down the strengths, drawbacks and technical specifications that make them unique? 10

Q: Could you expand on the technical specifications of NovaPure and FluroTec? Why do you consider NovaPure to be the premium product in the marketplace currently? 11

Q: We've spoken about why West Pharma is unique and how the company is adjusting to challenges, so let's discuss other companies in the market. Datwyler and Aptar are two of the major global players. You addressed what separates West Pharma and mentioned a couple of product differentiation factors including capacity, reliability, tech service and customer support. How would you position the company on these vs other players in the market? How would you rank them and why? 12

Q: What cross-selling opportunities do you think West Pharma's collaboration with Corning presents, especially in relation to the glass vial system and glass container system departments? The company also recently released the West Ready Pack, so given that it's targeting the exact same customer base, what unique value proposition has this presented? 12

Q: Could you share your outlook for West Pharma? The company has committed to spending about USD 350m in CAPEX in 2023 for product development purposes. If you were in a position of leadership, where would you be allocating resources over the next 12-18 months? What are some gaps or improvements that are worth highlighting? 13

Q: What is your general outlook for West Pharma? Are you positive or negative here? 13

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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 Drug Device Market Entry & Professional Company Outlook. I am Raemen Sahney and I'll be facilitating today's Interview with Mr Fran DeGrazio, former Chief Scientific Officer at West Pharmaceutical Services.

Fran, 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.

FD: I agree.

RS: Could you please begin with a brief introduction of your background?

FD: My background is, I retired from West at the end of March 2022 as Chief Scientific Officer. Prior to that I had worked at West for close to 39 years, in various, mostly technical roles, some commercial roles. Almost all the roles that I had were customer and market-facing so have experience in leading the organisation in quality, regulatory, technical services, the analytical laboratories and R&D, along with six years leading the marketing organisation.

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Q: What 2-3 pharmaceutical packing industry trends and growth drivers do you think should investors be aware of as it relates to West Pharmaceutical Services? Will the development of longer-acting drugs have a significant long-term risk or impact on the company?

FD: I think as we just look at the market broadly, certainly there is the development of longer acting medication and specifically injectables but at the same point in time, what you'll see the growth of biologics, which most, of course, at this point in time, are injectable products. You'll also see another trend, which is the movement from IV to subcutaneous, from a medication standpoint, also. What I mean by that is that instead of a typical infusion type of delivery, many companies are evaluating the move to subcutaneous. What that does is not only make it easier for the patient but lower costs because the move may be, for instance, a product that would take four hours to go in through an infusion can now take several minutes or even less than that from a subcutaneous standpoint. I think there are various trends from that perspective that counterbalance each other. One of the other things that you'll see, movement, generally speaking, across the market is from the use of vials into prefilled syringe systems.

RS: I lost you there briefly, would you mind repeating the last part?

FD: Movement from vials to prefilled syringe systems. Also, in some cases, there may be people using a multi-dose vial, where they're taking several doses out of a vial. Now, the move is to put one dose into a syringe system. What that does, in essence, is you're going from the use of one stopper, one seal, for instance, that could go for several doses to the patient, now to one dose per prefilled syringe, so what that does is also then increase the potential for just more production from a componentry standpoint. There are, I think, these mutual trends that are going on, some that will reduce the use of injectable packaging components and some that will increase the use of injectable packaging components. Generally speaking, at this time, if you look at it from a market trend standpoint, biologics continue to grow, which means injectables will continue to grow so along with that also comes the trend towards self-administration, more home administration. I think that really facilitates the movement towards prefilled syringes and also the use of prefilled syringes with auto injectors.

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Q: What is your understanding of the evolution of West Pharma's customer base? Might the company benefit from targeting an additional audience? Do you suspect they are having trouble while trying to penetrate certain end markets?

FD: Who are they targeting? Optimally, you want to be able to work within the same customer space that you have been and just have a broader portfolio because you're already in with many of those customers and that's where certainly many of the products that they're already making and that I'm sure they'll have in the future will be targeting their same customers. When we talk about who they are, certainly it's big, large pharma and it's not a discrete this is a biologic company and this is a pharma company nowadays, these large companies do all of these things so they will be doing small molecule pharmaceutical products and large molecule biologic products. Where it becomes more unique is when you talk about the smaller entrants because again, within these larger pharmaceutical companies now, they don't have a strong R&D. Usually, what they're doing is doing some kind of an acquisition of an emerging biotech company and then taking their pipeline in and what the large pharma's actually doing is doing the development and commercialisation then. The issue then becomes targeting those emerging biotech or smaller companies. West certainly has had a strategy for years now of targeting those smaller emerging companies and has been very successful at that, as you can see.

I know one of the things that they often talk about in general investor presentations that are made, is the fact that they're on so many of the biologics that are already commercialised in the market. The reason for that is because of the strategy to target emerging biotechs years ago and because it takes so long for these products to actually come to market, having that strategy has worked very successfully for them. When you're talking about other areas of challenge, generic companies, they continue to grow but very cost conscious so that can be a challenge at times, especially as some of those generics now, many of them, are being made overseas. I think the real growth for West from that perspective comes in both the India and the China markets and how do they continue to grow and get into those spaces more completely?

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Q: Could you break down West Pharma's diversification of products across various distribution channels, the main ones being hospitals, retail and pharmacy stores? Hospitals can be a little bit tricky to work with, so what pushback has the company witnessed on this front?

FD: West really works, on the most part, directly with pharmaceutical companies. They're not working directly with hospitals, at this point, they do have a product line, the administration product line, which

is the former, used to be called Medimop, so things such as Vial2Bag and things of that nature. Actually, West has a partner, Progressive Medical, and Progressive Medical goes into the hospitals and actually sells those products. That's their current avenue for reaching hospitals directly but certainly, the vast majority of what West currently sells, and I don't know if they're going to change that dynamic at all, at this point, but it is directly to the pharmaceutical companies. They're not selling to pharmacies directly, hospital pharmacies and things of that nature. There may be some special pharmacies that they sell to, for instance, for ophthalmic application, because there are some uniquenesses necessary there, if you're injecting in someone's eye. I know that's an avenue of potential growth but I would say those are areas that are relatively limited in comparison to just the main model, which is selling to the pharmaceutical companies directly.

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Q: How would you describe the regulatory landscape surrounding West Pharma and the larger packaging industry? Could you outline some key challenges that have manifested as a result of these guidelines? Do you have a positive or negative view on the overall regulatory outlook?

FD: Yes, let's break this down into two pieces. The most significant portion of West's business is the packaging components and the packaging components are governed under CFR 210 and 211, which are the drug regulations, so when a drug gets approved by a customer, the package then is approved specifically with that drug as part of that drug application. The other portion of the business is devices and devices are under, from a US standpoint, code of federal regulation CFR 820 regs. Those would be the products such as the administration system products that I mentioned earlier and also the SmartDose on-body delivery device, so anything that is technically a device falls under the 820 regs so, from an FDA standpoint, those would get approved by CDRH and such. When a device is combined with a drug product, say the on-body delivery device, the SmartDose, when a customer wants that to be used and then filled with a drug product, it becomes technically, from a regulatory standpoint, what is called a combination product, meaning that you basically have to meet the regulations for both a drug and a device. However, that is really owned by, again, the pharmaceutical company because they own that combination product application so they have to make sure that their suppliers, of which West, in that case, would be a critical supplier, are meeting all the requirements necessary from both a FDA standpoint, an EMA standpoint if they're going into Europe with the product, and really ISO because now ISO is trying to harmonise more from a global perspective, things such as doing the development work from a risk-based standpoint and incorporating risk management techniques, having documentation such as design history files in place from a regulatory standpoint. Those products, any of these devices, for instance, are much more challenging from a regulatory standpoint to upkeep and resource-wise because again, it's just the nature of the regulatory beast there.

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Q: West, of course, has its positioning in the market but given the regulatory challenges, what are some of the key barriers to entry that a newer or smaller company might have to face? What might disrupt their potential to catch up to West, or even vice-versa, could the regulatory challenges be more conducive to these players and enable them to catch up? How difficult it is to get into the market?

FD: Regulatory is a key benefit once you are in so if you're the first on a drug product or even just in the market, in the industry, West was really, from a packaging component standpoint, a first-in, that gives a substantial benefit vs the competition and the main reason for that is what I mentioned earlier, for instance, the drug is approved with those packaging components so if a customer, a pharmaceutical company, wanted to go in and change their packaging component, they would have to open that drug

application up. What that means is that instead of them being judged by 1980's standards, when that drug was approved, they, now, are going to be re-evaluated under 2023 standards and that could lead to a series of issues for that pharmaceutical company. Unless there's a problem, the pharmaceutical companies are very reticent to open their drug applications for any substantial change of packaging components, and the same would go, quite frankly, for a delivery device or that's part of combination product because again, unless you're having a problem or there's a big driver as to why would you want to change or go with another supplier, they'd really want to keep things as stable as possible. You also need to remember that, quite often, these pharmaceutical companies are not only approving in one country or one region, they're doing these things across the globe so the management of changing all that regulatory documentation and getting approvals, for the pharmaceutical company, it's quite resource intensive, both manpower and money-wise.

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Q: At the end of Q1 2023, West Pharma experienced net sales of USD 716m, which decreased by 0.5%, but at the same time, the company increased its guidance rates for 2023. Why do you think company experienced this small downturn and what are your performance expectations and commercial outlook across generic and pharma market units?

FD: My guess, of course, not knowing any real facts associated with this, is certainly there was a downturn in the COVID flu vaccine business, which had substantial growth opportunity over 2020-21 and into 2022, has now backed off pretty substantially. What is offset a lot of that is the natural growth of all those other injectable products and a lot of those being biologics, that I had mentioned earlier, so I certainly believe that that growth, from just a normal biologic drug standpoint, will continue to be there. I think there's also, of course, one of the characteristics of West has been to be able to move pharmaceutical companies up the value chain, going from what we would term a bulk product, which is a component, for instance, that is not washed, not prepared, just plain rubber, which is what they did many, many years ago, up the value chain to Westar washed, processed or ready-to-use, Westar ready-to-use product or ultimately, even NovaPure product, which is certainly their premier product line.

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Q: You mentioned West has been able to move pharma companies up the value chain. Can you provide further insight elaborating on how the company has done? What exactly did you mean by that?

FD: If you go back, I'm going to, say, probably back to the late '80s, early '90s, certainly the majority of products, in the '90s, being sold were bulked, which means they weren't really prepared in any special way for customer use so a pharmaceutical company would get these products in, packaging components, they would wash them themselves, they would sterilise them and then they would use them. The issue with that is that the pharmaceutical companies, of course, were not necessarily always equipped with knowing how to do these things because it's rubber and what the pharmaceutical companies are equipped to do is develop and make drug product, two totally different things. With the introduction, initially, of Westar RS, which is Westar Ready-to-Sterilise, and that was, I believe in that '90s-ish time period, that was really the first where West started taking responsibility for what was the customer's process and that's the pharmaceutical washing of these components. The next step after that was then to take on the sterilisation process, which is what the West ready-to-use product is. Also, at the same time, you have product improvements being made so, for instance, the introduction of West's FluroTec product line, which FluroTec being a fluroelastomer film that goes on the surface of the rubber and what that does is minimise potential interactions that can occur between the drug and the rubber component.

There was also the introduction of Envision, which is a vision inspection process. One of the trends, if you go back and you talk about regulatory trends and quality trends, was that there were a lot of challenges in the market with particle formation, when especially visible particles would be formed, the regulatory bodies were telling customers that they were not able to keep product out in the marketplace. There was a time period where if they had even one particle that was visible in a batch, they would have to recall or not ship that batch of product. One of West's answers to that, in addition to the washing processes, which were much more consistent, was to introduce what they called, from a brand standpoint, Envision and that's where each individual component actually goes through equipment and is inspected for many different kinds of defects, including some particles. Each of those variations of product type and adding on the levels of processing increases the value of the component, not only to West, of course, but to the customer because the customer doesn't have to take this responsibility on so they don't have that piece of the regulatory struggle to deal with, nor do they have to deal with just the associated challenges in working with products that they're not as familiar with. That's really how that whole idea and concept of value chain started and, in many cases, West was able to do that across various product lines that they produced, especially the washing and the sterilisation.

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Q: High-value products, including components and devices, represented more than 70% of segment sales for West Pharma, with about 23% of volumes being high-value products. Specialists expect high-value products to be greater than 30% in five years. What are your projections around the global capacity expansion for high-value products for West Pharma? Would 30% be a reasonable percentage or is that too ambitious?

FD: My guess is that that is a reasonable percentage and that I know that they've been actively working on increasing capacity globally and I think that also is key. One of the unique strategies, if you want to call it that, from a regulatory standpoint, that occurred probably, I'm going to say, maybe eight years ago now, was to make sure that the DMF, which is the drug master file, for the Westar wash process was global, meaning that it was equivalent in any site that was producing that Westar product, so in Singapore, for instance, in Europe, in France and whatever other sites they have Westar and then, certainly in the US and Jersey Shore and in Kingston. What that does is that's key in allowing the customer then to have more flexibility with capacity so it's not only the component and how that gets made that you need to think about capacity flexibility but it's also post-process, those high value post-processes that we talk about. The fact that they are seen, from a regulatory standpoint, as equivalent in all those locations and the data, of course, has been generated to show that, that then forms a basis to build in more flexibility into that supply chain. Aside from that, as I said, I just know that they've been invested fairly heavily in capacity, especially when COVID hit, they accelerated a lot of that spend.

RS: To conclude, given all these tailwinds, you would expect it to reach that 30% mark over the next five years?

FD: Yes, if that's what they're projecting, I would believe that.

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Q: I'd like to understand West Pharma's general technology. The company has decided to enter into the injectable devices and technology market, which is a relatively newer focus, and there's perhaps a risk of deviating too far from its core strengths. What do you think it's hoping to achieve from a technical perspective? How might the economics of this push look like? What are the positives and negatives?

FD: From a potential strategic standpoint, it makes a lot of sense and the reason why it makes a lot of sense is that, I talked a little bit about combination products, there are very few device manufacturers that also do packaging and what you need to understand is that the packaging is very critical to how well the device will function. The three pieces that are really key are the drug, the package and the device so if the three of those are not working together, you don't have a sound combination product. It was, I think, the very good move to go towards the device area, it is very different than producing packaging components and that's a little more, I think, where the challenge historically may be but logically, it makes a lot of sense. I mentioned earlier the market move towards self-administration and that, again, is really where the industry is going so having the ability to produce devices, whether it be West proprietary devices, like the SmartDose, or devices for customers and through the contract manufacturing arm, they're able to produce contract devices such as auto injectors for pharmaceutical companies. That's really a growing space, for sure. There is a lot of competition in the on-body injector space because I think, again, a lot of companies saw that as an opportunity but West was first with a successful product approved by the FDA in the market so, again, that gives them a lead in that space. Now, they have, I think, at least four or five companies that are out in the market with the a SmartDose.

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Q: Given West Pharma is choosing to make the shift from its core strengths of packaging towards more of an injectable market, what might be the barriers to entry while the company makes this transition and how would you assess its capabilities to make this move?

FD: I want to make sure that it's clear, the investment in packaging is extremely important and keeping leadership in the packaging business is going to be important, even as they continue to grow in the device or the delivery side. I think there's value to both, as I mentioned, but the investment in delivery systems is certainly different from the capital standpoint, the challenges from a regulatory standpoint are different and I think have been more challenging. The fact that they've gotten experienced with a lot of this now is certainly a benefit for the organisation. It is, from a quality and regulatory standpoint, more challenging with the devices being produced than, like I'm saying, on the packaging side of the business. I think it's just been around longer so you just have the history and the knowledge there that you just don't necessarily have all of that on the device side of the business yet.

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Q: West Pharma recently released a SmartDose self-injection product in this department. What makes this product so differentiated? It is considered a high-margin product with the ability to capture larger 10ml volume, which nobody seems to be addressing at the moment, so what is your general consensus on this product and expectations going forwards?

FD: I think it's hitting a need in the market and the best thing that you can do is understand what the market needs and they want higher volumes, they want to be able to inject higher volumes of these biologics so the (? 38.00) does that. Also, the fact that the drug would already be set in the device, again, is something that I think was a need that was heard from the market. The thing that's unique about these kinds of combination products is that, from a regulatory standpoint, each unique application of the drug and the therapy and the patient target group, the pharmaceutical company has to build out what it is that they're trying to achieve and then work backwards into what product gets us there. That's, again, in essence, what the regulatory bodies are looking for, is that if, now, I'm using a system where it's pre-loaded, is the patient happy with that? Is that more suitable for the patient? Things like what's called human factors are heavily involved when you talk about devices and combination products. That's another more unique area of investment when you're in devices that you don't have with the packaging

as much, or really minimal, and that's human factors work, which is actually out working with patients and clinicians and things of that nature to build the understanding of the device and is it truly meeting the need for that target group, what changes need to be made and then ultimately validating that as part of the development process.

When you talk about the development process itself for a combination product, you talk about what's called verification and validation. Verification is, in essence, saying, "The way I built this delivery device is meeting what we had defined as specifications, as objective specifications, like, for instance, it'll deliver this drug in 10 minutes, it'll deliver the correct amount of drug, etc, etc." That's what verification is. What validation is, which it also needs to meet, is this the right device for this group of patients? That's a whole different ballgame, that's where you need to do the testing with that patient group or the clinicians that are working with them.

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Q: Understanding that West Pharma has been able to adjust to market need with the SmartDose, some people have mentioned that customer adoption remains a very high barrier to entry due to that complexity. Do you think that will be a significant risk to customer adoption going forwards for this product?

FD: I think the issue is the complexity for West's product is the same as the complexity for any other alternatives, also. From that standpoint, it's just an on-body injector, an on-body combination product is going to have more complexity than a syringe. The issue is, typically, what these companies will do is they will evaluate the pharmaceuticals, is this something that I can deliver by a syringe in an auto injector? If it is, they will most likely got that route but there's still a problem exists when they need to deliver higher volumes. Right now, there's technology out in the market, a standard auto injector delivers around one mil of a drug product subcutaneously so you have that auto injector held up against your skin for maybe 10 seconds, 15 seconds tops. If they want to deliver two mils, so double that, there have been syringes and auto injectors that are built to do that, however can patients meet that because now, they're going to have to hold those auto injectors up against their skin for maybe 30 seconds. Not only that, is it going to be able to actually be absorbed into subcutaneous tissue in that area of the body or does that lead to pain? There are question marks around all of that and it's probably going to be very drug specific. If you go above those volumes, to five mil, (inaudible 43.52), even up to twenty mil, you need to have an on-body injector to do that.

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Q: West Pharma is proactively working to accelerate CAPEX on high-value product capacity, and some of those products include Daikyo, FluroTec and NovaPure components. What are your commercial expectations for these products, breaking down the strengths, drawbacks and technical specifications that make them unique?

FD: Daikyo, FluroTec, or Daikyo products are actually produced over in Japan by West's partner, Daikyo, so they, I think, are the ones that would be making probably most of that investment, although West holds certainly a percentage of that business with Daikyo. The NovaPure certainly is what I would consider to be the premier product for the marketplace currently. I was very involved in that, both from a strategic and marketing standpoint and an R&D standpoint so I know what went into the development of the product line and have certainly, through the years, engaged with many companies around the product line. They can get it in both stoppers and plungers. I think one of the biggest challenges has been capacity, which is why they're making the investments in that. What's key is when a customer needs

samples for valuation or they need samples for clinical trials, they need to be able to get their hands on it quickly so that's why the investment in capacity is so important, over and above commercial quantities because typically, they'll build to commercial quantities, you'll have time to have those discussions with customers about what are their quantities needed going to be from a commercial standpoint? The challenge is, every day, there can be a call that you're not aware of asking for samples to put up for stability studies or for clinical trials and you need to have product prepared for that, also.

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Q: Could you expand on the technical specifications of NovaPure and FluroTec? Why do you consider NovaPure to be the premium product in the marketplace currently?

FD: NovaPure, really, the concept came out of there were three at the time, there are more now but there were three guidances that were put out by ICH, which is the International Committee for Harmonisation, for drug products and they were ICH Q8, Q9, Q10, and what they cover is development, qualities systems and then, really, tech transfer and commercialisation of drug products. They're setting the stage for the drug industry as to how they should be developing their drug products. What I mean by that is historically, it was done more like black magic, we have these formulation scientists and they go in the back room and they do their thing and they come out and, "Let's see if this works." To a certain extent, formulating rubber was the same way. When I saw that these guidances were being introduced to the drug industry, the thought was if they're being guided, from a regulatory standpoint, to start developing their drugs this way, then why wouldn't we develop our components the same way, because again, go back to the way these are approved, they're approved drug and package together. That was one thing, secondly, the learning the terminology around what that's called, that style of development is called quality by design, so they would go by QBD, and being able to talk in the same language as the customer was using for the drug product is also helpful so that thought process of truly understanding the product and the process that produces it to a much greater degree than historic.

One of the challenges nowadays is that you'll hear especially some of the other packaging component manufacturers throw around QBD like they know what it is, when, really, it's a whole process of development that the products went through and then have to be maintained in, part of that being also what's called a control strategy. A couple of things, the product is targeted to tighter specifications for critical areas. For instance, NovaPure was the first and only product that was out in the marketplace that had not only a visible particle specification but a sub-visible particle specification and the reason for that is because again, understanding the industry, we knew that there was concern about visible particles, especially sub-visible particles, especially in conjunction with biologics because the potential for immunogenicity issues. Knowing that, it was one of the reasons why we put that sub-visible particle spec on. That was certainly one aspect of the product that was unique. Again, it's a whole story of how it was developed, what it means when it's developed that way, what better understanding of the product and the process that you have and that West has and able to support customers too because no matter what, customers may call up with challenges or problems or issues and to be able to understand a product to a much greater degree, so there's a lot more technical documentation to support the product.

For instance, the NovaPure plunger has a drug history file associated with it. What that means is... not a drug history file, sorry, design history file associated with it and the DHF is the same kind of concept that is used for a device and the reason why it was done for the plunger was, again, anticipated where things were heading with combination products. With a plunger, it's used as part of a syringe system, that when the drug is put into it, it becomes a combination product so that was an anticipation of the regulatory support that would be needed for a product that was utilising that plunger. Those are the things that are unique, that, I think, again, other competition is trying to catch up on.

[00:52:51]

Q: We've spoken about why West Pharma is unique and how the company is adjusting to challenges, so let's discuss other companies in the market. Datwyler and Aptar are two of the major global players. You addressed what separates West Pharma and mentioned a couple of product differentiation factors including capacity, reliability, tech service and customer support. How would you position the company on these vs other players in the market? How would you rank them and why?

FD: Certainly, I think West has a depth of knowledge and experience that the other organisations just don't have. At West, the business is totally focused on pharmaceutical and biologics so even if you talk about Datwyler, and I know they have two arms, the reality is their executives are really not necessarily experts at pharmaceutical things so, sometimes, historically, I would say, some of the decisions that were made around investments and things of that nature may not have been optimal. I do think that they're learning, they certainly have hired some people from West in various roles, like sales and things of that nature, so they are coming along. I think they've made some major investments in the US and that is probably the biggest thing that Datwyler needed, was to have the investments made in the US. They're still lacking, in my perspective, in areas such as analytical knowledge of products, even the concepts, like what really is quality by design and the development of those types of things. They have more of their power in Europe, since they're a European-based company, where in the US, certainly, one of the advantages that West has is the fact that they have a very strong analytical laboratory. The real development of that analytical lab was more strategic, I would say, than anything else because it really allowed one to build and understand products and customer challenges more effectively and have resources to address, certainly, various issues.

These products are technical products, they're not commodities, and I think that's one of the historic remnants from years ago, that you still sometimes may find purchasing people that think that way but they're not, these aren't commodities. These are products that you need a technical and a scientific understanding of. Aptar, same thing, I think they were slow in getting into the US and having a site in the US. I don't know that either Datwyler or Aptar is very strong from a regulatory standpoint and it's not only being strong in just supporting your products but in understanding the regulatory landscape and where things are heading is very important. I don't know that either of them have that at this juncture.

[00:57:13]

Q: What cross-selling opportunities do you think West Pharma's collaboration with Corning presents, especially in relation to the glass vial system and glass container system departments? The company also recently released the West Ready Pack, so given that it's targeting the exact same customer base, what unique value proposition has this presented?

FD: This whole move towards selling of a system, from a West perspective, is, I think, ultimately, the future and to develop the components, the elastomer components, whether they be stoppers or plungers, you really have to have an understanding of systems and if you think about the value now, from a very basic standpoint, you're taking vial, a stopper rather, and a seal and now you're adding a vial to it so you're double, if not triple what just selling the vial or the stopper and seal would be, just looking at it from a very basic standpoint. The issue is being able to have that scientific understand that we're talking about, of really understanding what's important for a system and what do customers need to be able to use these types of products more easily. Again, having things like Ready Pack, which, actually, the original Ready Pack was developed under my tenure in marketing, was to get that reach into the start-ups and into the R&D laboratories because they didn't have to then do a lot of thinking about is this and this and this going to work together, is this vial and seal and stopper? I can tell you, again, you're not

necessarily familiar with details around these things but it's much more complex than people understand, so you can easily choose a vial and a stopper and although, visibly, they look like they fit together, they have integrity issues because when you talk about sterile products, it means you have to have integrity from microbiological issues.

Not only that, in some cases, you need to make sure it's gas tight, if you have an inert gas, for instance, that's placed on top of a drug because it's oxygen sensitive or something like that. There's a lot of details behind how these things fit together, even for a vial system. The same thing goes, of course, for a syringe system or a cartridge system.

[01:00:28]

Q: Could you share your outlook for West Pharma? The company has committed to spending about USD 350m in CAPEX in 2023 for product development purposes. If you were in a position of leadership, where would you be allocating resources over the next 12-18 months? What are some gaps or improvements that are worth highlighting?

FD: I believe in both the packaging and the delivery device side of the business. I think they probably need technical and regulatory resources on both sides of the business, not only on R&D though. I think it's, I mentioned before, about just technical support and having strong support staff that can interact with customers that are calling to enquire about what they should be using for a product or where they need certain information to support their filings or things of that nature. I think the more technical people that have a broad understanding of the market and regulation, those are things that I would invest in.

[01:01:54]

Q: What is your general outlook for West Pharma? Are you positive or negative here?

FD: Positive, I think the future is bright, the market's bright, they're in a great position, as, really, the market-leader and they just, I think, have to continue with that leadership role, you have to continue getting it out there and showing that you are leader at what they do.

[01:02:30]

RS: Thank you so much, Fran, I think this has been super helpful and very insightful, so I thank you so much for taking the time.

FD: Okay, good talking to you.

RS: You too, I hope you have a great rest of your day. Take care.

Transcription ends at 01:02:42 of the recorded material

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