Global | Pharmaceutical Svcs.

Jef U: Injectable Packaging Insights w/ Former Chief Scientific Officer at WST

Our call guest, Fran DeGrazio, spent 39-yrs at WST, culminating in her role as Chief Scientific Officer. Highlights were: 1) WST products are differentiated, particularly higher-tier components (NovaPure); 2) destocking has played out like previous cycles, and suppliers should have greater clarity by year-end; 3) GLP-1 messaging is consistent w/ previous checks; 4) integrated systems must show regulatory, quality, and/or efficiency benefits to gain adoption.

WST Products are Differentiated; NovaPure "One of a Kind". Ms. DeGrazio explained that Westar stoppers and plungers are sterilized in an autoclave vs gamma radiation, which helps to 1) be more consistent w/ manufacturers' processes (most sterilize in autoclave already) and 2) extend life of the elastomer. NovaPure is one of a kind since it took a "quality by design" approach, i.e., was specifically designed to meet the regulatory and quality needs of customers (often driven by regulatory agency guidelines). However, our expert noted that suppliers differentiate less on the product itself, but instead by the service, documentation, and technical acumen that accompanies the product. Consistent with prior messaging, rubber is more differentiated (each competitor has own formulation), while glass is more interchangeable.

Learning from Previous Destocking Cycles. Similar to previous cycles, large customers drive the majority of the destocking (WST said 6-7 customers drove 75% of the headwind) and visibility is low past 8-12 weeks (typical lead time). Importantly, customers place orders based on quoted lead times. As lead times return to normal, customers feel comfortable lowering safety stocks and bleeding down inventory. Ms. DeGrazio explained that pharma companies do a year-end budget review, which should bring greater clarity to WST and peers on customer inventory levels. Some enduring challenges to visibility are 1) WST doesn't know if an order is tied to a specific fill/finish batch run, to increase safety stock, or when that order gets pulled-through to demand (i.e., doctor writes prescription); 2) the drug product for which a component is ordered is not always clear, particularly if the order is placed by a CDMO; and 3) component suppliers rely on pharma drug forecasts, which often turn out to be wrong.

GLP-1 Commentary Mostly Confirmatory. Our expert says it makes sense to spec in NovaPure for an important drug like GLP-1s due to dimensional tolerances (w/ both the machinery and the syringe or cartridge). Consistency in manufacture and risk mitigation are also important considerations that NovaPure addresses. However, from a chemical standpoint, GLP-1s don't require NovaPure. WST should be the primary supplier for plungers in GLP-1s, but Aptar likely dominates rigid needle shields (that go on syringes), consistent with prior messaging. Pharma packaging companies likely are not seeing the full benefit from GLP-1s due to supply constraints, highlighted by LLY's roll-out of tirzepatide vials. On that topic, LLY would likely use the same quality level on stoppers and plungers for regulatory ease.

More Points on Competitive Positioning and Innovation. Vertical integration generally doesn't provide a competitive edge (e.g., 1SXP's parent co. supplying glass tubing or WST's contract manufacturing biz). However, our expert said that STVN's Engineering segment is very well-regarded in the industry. End-to-end service providers struggle to add value unless several offerings are best of breed. Ms. DeGrazio believes that integrated systems (e.g., Valor glass + WST rubber) will gain traction over time, but needs to show a tangible benefit from a regulatory, quality, or efficiency standpoint.

EXPERT STUDIES

GUEST SPEAKER

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Fran DeGrazio

Fran DeGrazio is currently the President and Principal Consultant at Strategic Parenteral Solutions LLC (6/2022 – present), her own consulting firm. Before this, she held several roles over her 39-year career at West Pharmaceutical Services, including Chief Scientific Officer (2/2020 – 7/2022), VP Scientific Affairs & Technical Services (2/2016 – 2/2020), VP Global R&D, Global Strategic Program Management, and Global Tech Customer Support (6/2012 – 2/2016), and VP Marketing & Strategic Business Development (4/2006 – 9/2012). She's an expert in the technical and regulatory requirements of sterile packaging, delivery devices, and drug device combination products.

Edited Transcript

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David Windley: Great. Happy Monday, everybody, if there is such a thing. I appreciate your joining us. I'm Dave Windley with Jefferies Healthcare Equity Research in the US. I'm based in Nashville, Tennessee, cover CRO, CDMO-related stocks as well as managed care. Joining me is James Vane-Tempest, who's based in our London office. Also cover some of the drug supply chain and contract manufacturing. Together we cover this injectable drug packaging space that is West, Stevanato, Schott, Gerresheimer, Catalent is fill-finish, et cetera.

James and I are collaborating around this space and we're fortunate to find and be able to talk to Fran DeGrazio who is joining us today. Very much appreciate your time. Fran is the former chief scientific officer of West, with a 39-year career at West. She's recently retired from West in the last couple of years and started her own consulting firm. Serves as president and principal consultant for Strategic Parenteral Solutions since the middle of '22. Prior to that, she was, as I said, at West, 39-year career, including chief scientific officer from 2020 to 2022.

Prior to that, held a number of roles in scientific affairs and technical services, Global R&D, Global Strategic Program Management, and Global Tech Customer Support. She knows the ins and outs of West. Fran, thanks very much for giving us a little bit of your time and your insights.

Fran DeGrazio: Thanks Dave, and glad to be here.

David Windley: Great. Fran, let's start with product portfolio. You and I talked just before we came live about the progression that West has seen over several decades of bulk to pre-washed, pre-sterilized, vision-inspected, then coated FluroTec and NovaPure, and you're certainly familiar with all of those. I want to just jump to the punchline on NovaPure.

We have been the recipients of, in the investor community, strong messaging around NovaPure now being the gold standard, and that it's the product that biotechs in particular are looking to spec into. I wondered, from your experience, if you'd call that a fair characterization, and technically speaking, why that is?

Fran DeGrazio: Sure. Yes, I would agree with your position on that. What really was behind the development of NovaPure was where regulatory and quality was heading in this space and in the pharmaceutical and biotech space. From that perspective, it was developed with the intent to address a lot of the needs going forward in the biotech space. It certainly does that through the techniques that were used in development, and then, of course, with the product that's put out for commercialization.

David Windley: Sure. We know it on the outside to be a cradle-to-grave clean-room made, processed, developed, cleaned, et cetera, minimizing particulate, optimizing spec, and very low tolerances. Are those the right characteristics to know about NovaPure or is there some other secret sauce that we should actually be focused on more?

Fran DeGrazio: Well, I think those are certainly a lot of the keys, but what really underlies the whole development and the whole strategy behind it is the fact that it took what's called a quality by design approach in development and in manufacture. What's key about that is that quality by design was actually applicable to drug products. It's what the regulatory agencies have told our customers in pharma and biotech, "This is how we want you to develop your products," rather than the old-fashioned way of developing.

What we actually did was to take the guidances that are out there, that are applied to drug development and say, "If it can work for drugs, it can work for packaging components." What that did was really build a much better understanding of the product and the processes around it. What's key to understand is that, with any of these products now, you're not just selling a product, you're selling knowledge and documentation and service and all these things that come with the product.

That really is key to the development, is really understanding and mitigating significant risks, making sure that the product was not very variable so that it was consistent product. Yes, the specs are tighter. You mentioned dimensions, you mentioned particles, but it's all about how it was developed and how the manufacturing process was built so that the output was consistent and that there's such a much better understanding of the product and the process.

David Windley: Got it. Then our understanding is, as we've made some calls here-- Well, let me even set the question up a little bit more thoroughly. In this elastomer space for injectable drug packaging, there's only really three competitors. If it was easy to do, one would think that there'd be more new entrants, there'd be competition to a greater degree than that. We then also have interpreted from that that these products are hard to make and that West has this significant market share above the other two players, and so those products must be quite differentiated for the client to choose West over its competitors as significantly as it does.

I'd say we haven't talked to a lot of people with 39 years of experience, but when we've made other calls like this, we'll get the response from buyers, "They all kind of have the same products." That confuses me. I guess I'd ask you to describe, are they the same or are they not the same? I guess I've even heard maybe a middle ground of, well, the ready-to-use are the same, but nobody really has a competitor to NovaPure. In all of that, what's the truth in your mind?

Fran DeGrazio: Yes. Well, first off, the comment is when you talk to buyers, and that's a typical buyer position, because they're trying to turn whatever's out there into a commodity. The issue is, when there's a problem with the drug product and the packaging component, all of a sudden that commodity mentality goes away and it's, "Hey, this is the most important product in the world, this small piece of rubber." That's just, from my perspective, a technique of people that don't understand the intricacies of the products.

Certainly, there are commonalities amongst the products that have been developed by each of the competitors, but NovaPure is, in my mind, a standalone at the top of the realm. You also have to remember that first in on these innovations means a lot too. That's one of the things that I think, traditionally, in the packaging space, West specifically has lead versus their competition.

David Windley: Good. Got it. Maybe another way to come at this, before I move over to destocking, would be, I think Westar was originally brought to market maybe in the late '90s and that might have been RS and then RU and then Envision. I guess, say, it's 25-ish years and five or so gradations of quality improvement through the product portfolio. Call it, roughly, every five years, there's a new rung on the quality ladder, so to speak. NovaPure, I think, was originally launched in the market in 2015 or 2016, something like that, or seeded, at least, in the market. What should be next?

Fran DeGrazio: That's a question for West.

[laughter]

Fran DeGrazio: I think you need to ask them that one. One other point that I do want to make, because you mentioned that you've heard in the market that all the ready-to-use product is probably very similar, one big differentiator for West is that their typical Westar RU is autoclaved, both the stoppers and plungers. That's a difference because, typically, all the competition gamma irradiates for sterilization and there can be differences in the final product because there's different sterilization methods. Just something to keep in mind as even a differentiator in the RU space.

David Windley: To interpret that, is autoclave viewed as more consistent in its sterilization ability or?

Fran DeGrazio: Yes, there's less energy added to the rubber and it's the energy that can start to degrade rubber and things of that nature. If you think back to prior when people were purchasing their own bulk components, they would sterilize them. The pharma company would sterilize them in an autoclave, not by gamma radiation, typically. It's very consistent with-- Okay, if stoppers, for instance, are being autoclave sterilized by the industry, even when they did it in-house, now they can get both autoclaved stoppers and autoclaved plungers. A new standard was set by West in doing that because the standard prior to that for plungers was gamma radiation.

David Windley: Moving on to thinking about some of the market gyrations, we've covered the company since about 2010, our understanding was that the company, as early as, say, the mid-20 teens had a process of looking at IQVIA data, what would have been IMS data at the time. Looking at script trends, what's the pull-through on the backend? How much are we selling in on the frontend?

To some degree, as we've been told many times over, you don't exactly know-- A client might buy the same SKU for multiple products, and so you don't exactly know what's being pulled through, but you have a sense. Are there are some market intelligence processes to determine how much inventory the client is sitting on and are we over or undersupplied? Things like that. You're nodding your head, I gather that you agree with that. How was that market intelligence process augmented in the last, let's call it, seven, eight years? I've got a follow-up to that. Let me just stop there. What's the current standard on client insight and intelligence around supply?

Fran DeGrazio: Typically, I know you're asking this question because the connectivity to demand and all of that-- [crosstalk]

David Windley: Exactly.

Fran DeGrazio: There's several different layers that you need to look at. Again, I had the marketing organization for a period of time years ago. You're getting demands sent by the customer directly. There's a relationship there. Certainly, even with the larger customers. Direct relationships between planners and supply chain and, of course, sales people are involved in that. You have history that planning at West, for instance, would leverage. You then also have sales, which is going to be tied into unique or new opportunities that may exist. Then lastly, I think is the point that you're bringing up, which is more of the general market trends.

Now, to your point, can you go and understand exactly, for drug products, this is how much they purchased from us, and so this is what should be that pull-through on the backend? I could tell you we try to do that and it's not an exact science because so much gets caught up into the supply chain between when they purchase it from us and prescriptions that are written. Again, it's something that you look at, but it's just another one of those points that come in. Then there's also should be just general market analysis that's being conducted to understand where growth opportunities seem to be coming from. You have those five or six feeders into what eventually ends up being that demand forecast plan.

David Windley: Maybe to then bring it forward to the current situation, how do we find ourselves-- I think our audience understands lead times got long, clients reacted by overbuying, increase in safety stock, then you fixed lead times, then they correct the safety stock, but what we're hearing from the

company is that their volume, like management is saying volume sell-through is in the 2% range, and that's ex-COVID, I would guess that injectable drug volume ex-COVID is at least 2%. We're talking dating back to pre-pandemic and CAGR-ing that forward. How do you end up with that much excess stock in the channel? How does that happen?

Fran DeGrazio: The way that I see it, because, again, in the 39 years I was there, we did have several other similar situations. It wasn't COVID, maybe not to that degree, but I know we went through similar destocking situations for a period of time because especially larger customers, they're overordering because they want to get their hands on whatever product they can, and they come to realize it at the end of the year, "Hey, we have way too much."

Then there's been the adjustments made at West from a capacity standpoint, so their lead times dropped. You have to remember, typically, pharma companies are only placing their orders based on the lead times that they're given. West, under normal circumstances, may not know what's coming for maybe three, four months in advance when their normal lead times are 8 to 12 weeks. That would be a normal lead time for, say, Westar.

David Windley: Given that you've seen some of these cycles over your career, investors are listening for any little indication about orders improving, et cetera. When you were inside, what were the reliable indicators that the destocking that needed to be done, had been done and was complete and coming out the backside?

Fran DeGrazio: Again, what I've heard, which is, I'm sure, the same thing you guys have heard, a lot of this is being driven by a handful of customers. It really becomes the connectivity and relationships with those customers to understand where they're at in their queue. Now, we're coming towards the end of this year, I believe pharma companies will do that same review that they did at the end of last year, and they realized, "Hey, we have way too much stock." So, by the end of this year, West and the other competitors that are out there should have a much better understanding from the pharma companies.

You got to understand that, certainly, any other market data that West gets in, they are certainly making it, or they should be making adjustments up and down, but the one thing you can guarantee for sure is that the forecast is never going to be exactly correct. That's the reality, and it is a challenge because these pharma companies are not real great at their forecasting. I've seen where they've thought, "This is going to be the world's next biggest blockbuster," and it dies out, or just the opposite, something that they thought wasn't going to be a hit is blowing the numbers out, and then all of a sudden you need increased capacity.

David Windley: Yes. One of the descriptions that I've gotten around, on a sheet of paper, how this process is supposed to work is that the manufacturer who sees where their inventories are, managing that, thinks, "Okay, I need to schedule a fill-finish campaign for X product." You schedule that however much in advance with either your own manufacturing plant or a contract manufacturer, and that fill-finish appointment then triggers the buying of the components that need to be there for that. Management at West will emphasize that they are a made-to-order shop.

Fran DeGrazio: That's correct.

David Windley: Again, coming back to the question, I don't mean to sound unsatisfied by the answer you just gave, because I thought that was a good one, but coming at this a different way, if the order for the component is tied to a batch run at a fill-finish shop, is it that that appointment gets canceled, it just gets delayed and that's how you end up with more than you thought?

Fran DeGrazio: You're saying, if they're trying to run at a CMO and they don't go through with it, then West gets stuck with the stock, is that what you're saying?

David Windley: Well, I guess what I'm asking is, if an order of West stoppers is made specific to a fill-finish batch run that is scheduled, tied one-to-one, but if it's a one-to-one tie, then, again, how do you get over-ordered? Or said differently this, "We're a made-to-order shop, so we can't get that much in the channel because we make it to a specific need?" That's not the protective safety net that maybe we thought it was in terms of making sure there's not too much in the system.

Fran DeGrazio: Right. West is reacting based upon what orders are placed. Now, if the pharma company is over-ordering because they want to have-- Remember, part of what they're thinking about is risk mitigation. Everything right now from a pharma company standpoint is all about risk, whether it be in their supply chain or with certain products and components that they get in or whatever. They're looking, "How do we mitigate not being able to have a product shortage, for instance, because we didn't get components?" They will over order.

Now, West or the other suppliers may not know that one-to-one that you're talking about, it is not necessarily conveyed to West. There are just orders that are conveyed to West. Now, at CMOs, for instance, depending on the customer, a CMO may just place an order. Again, you don't know necessarily what customer at CMO that they're ordering for either. In some cases they may know, and in other cases they may not. They're definitely having a CMO involved, which is very common, though does bring more complexity to the situation.

David Windley: Switching gears, still within this demand cycle, there's a narrative in the market that during the pandemic, with the stretching of lead times, with the strain on suppliers of all types and sizes to supply, but particularly in this industry, where we needed to get as much vaccine as we could in the market, that some clients perhaps were having to be moved down in the pecking order because of the prioritization of vaccine, and that that might have created an opportunity for competitors. The client says, "Hey, we're not getting everything we need out of our primary supplier." Maybe that's West, "Let's look at dual sourcing. Let's look at another supplier. Situations that maybe crack the door open for the Aptar/Stelmi or Datwyler's of the world to get their toe in the door." How much truth do you think is behind that narrative?

Fran DeGrazio: I would believe that's a possibility, that that could have happened in a handful of circumstances, because certainly, the smaller opportunities are not going to get the attention like the big guys that needed the volume. I think it was probably that way at all the suppliers to a certain extent. These companies and smaller companies that may have been working on R&D projects, if they couldn't get their hands on certain product lines, for instance, and small volumes of product lines, because if you're doing R&D work in the lab, you don't want to buy a commercial quantity. You don't want 100,000 pieces of something.

Typically, what they would do is order smaller volumes. For instance at West, they have what's called the West-ready pack, which was specifically designed for small volumes, like 500 pieces to a bag, so it could be easily used by a laboratory or in clinical trials. If they can't get their hands on that kind of thing, yes, they may then go to Datwyler. Now Datwyler came out with their following version similar to what West has on ready-pack of their smaller volumes. Certainly, that opportunity exists, that in a handful of places they may have caught on to an opportunity.

As I mentioned, it's all about risk mitigation. In their supply chain, they're looking at, "Do we need a second source of supply as a backup in case there's some kind of a problem that would occur?" Now, West has a significant amount of manufacturing sites, so they are able to deliver from multiple sites, and that may satisfy a certain pharma company's risk mitigation plan, especially if they've qualified those multiple sites. They're looking at all those things certainly as potential risk mitigation options.

David Windley: To triage this, you see it as a possibility, you call it maybe in a handful of situations, and the bias would be towards smaller of those situations where the client may not have gotten high priority at the mothership, and so looked for other alternative sources for their supply

Fran DeGrazio: That's what I was thinking, and so it would be connected to new opportunities, not currently large-scale commercial.

David Windley: Last question for me for now before I hand it over to James is you would have been at West through what we'll call the small molecule loss of exclusivity cycle that probably started in the late aughts and stretched into the early 20-teens. As those products kind of precipitously decline as their generic competitor comes in, does that create a more complicated visibility and an order pattern issue that we should be aware of as we head into another one of those cycles in the next handful of years?

Fran DeGrazio: Great point. Certainly, there's some loss of visibility for sure because you have the originator's product and that may end up being split up now among three, four, or five different generic companies, and some of those, if not most of those companies now are overseas. That's really where Asia-Pacific comes into play.

David Windley: Sorry, James, to follow up on this, does the fact that those generics, be it now it's going to be biosimilars, does the geography difference actually create an advantage for West because West has invested in such a global supply network or not necessarily?

Fran DeGrazio: Well, what actually gives West, I think, an advantage, number one is certainly the global aspect, but is the fact that the quality and regulatory standards aren't different, whether it's a product that's being produced in Asia for the US market, for instance, or for Europe versus somewhere else. From that standpoint, with West being the leader from a quality and regulatory support standpoint, that really helps to enable those opportunities in addition to just having a good quality product.

David Windley: I just want to make sure that I heard it right. The regulatory and quality standards are not different. Is that what you said?

Fran DeGrazio: Right. Say it's something that's getting produced over in India, for instance, and being shipped to the US market, those regulatory and quality standards are the same as if it was being produced here.

David Windley: Got it. James?

James Vane-Tempest: Thanks, Dave. Thanks, Fran, for your time. Maybe just to start, just picking on one of your earlier comments, I think you mentioned obviously that West has led by first introducing innovations, but then we also hear sometimes that pharma companies resist innovation as they want what's proven. You've already talked about a risk mitigation mindset. If everyone has something and you don't, then that's a disadvantage but then if you're the only one that got something, then there's risk in terms of having something new. My question is really, how do you work with that mindset to increase the adoption rate of new innovations?

Fran DeGrazio: Actually, that's a great question, because believe me, I've been with customers and have, in essence, said that, "You're always asking for new innovation but the minute we give it to you, then everything slows down." The qualification of that innovation. I think the real issue is that you need to understand the market and the customer's pain points and address those in the innovation that is developed. If it's just innovation for innovation's sake, it's not going to go anywhere.

If you go back to, let's take NovaPure as an example. We were addressing various issues that we heard out in the marketplace from a quality, regulatory, and technical standpoint, that we had heard about, say, the current standard, which was, at that point in time, a West FluroTec Plunger. We took those pieces and built those into the NovaPure product and also had forethought into seeing where's the industry going in areas like particulate.

NovaPure, for instance, was the first product in the market with not only a visible particle specification but a sub-visible particle specification. Again, that was done because we could see where the industry was heading and the sensitivity around particulate.

James Vane-Tempest: The way we should think about future innovation then across the whole supply chain is what are those regulations that are coming from? Let's look at the product portfolios, which are basically going to help address those kinds of needs. That's really the only thing that's going to drive it, not just because you've got something that you think is pretty interesting, but there's risk management. That's really helpful. Thank you.

My lens from the European side is mainly on Schott and Gerresheimer. Schott and Gerresheimer both said de-stocking should improve as we move towards year-end. Stevanato, I know it's based in Europe, but covered by Dave in the US. They're still growing its glass business in the second half but West and Datwyler are both flat to down in the second half. Why has de-stocking been less severe, and appears to be moving faster on the glass side? I'm just wondering whether the glass supplier has perhaps more visibility, for example, or is there anything in terms of glass holders being put forward ahead or something like that?

Fran DeGrazio: Yes, my guess on that would just be that there was-- It's typically been easier for customers to utilize multiple suppliers on the glass side than the elastomers. Let's just say 100 as a whole is what the demand is, you've got that split between maybe three different suppliers when things were critical with COVID. Naturally, then they're going to bounce back quicker than if they all had the demand, maybe just for West or for Datwyler, or even the two of them and they had requested so much more product from each of those individual suppliers. That would be my guess as to some of that. They're just able to be more flexible with the supply chain on the glass side.

James Vane-Tempest: Even though the units are bigger per se, that doesn't really have much of an issue. It's just more the flexibility in the supply chain, just so I understand.

Fran DeGrazio: That's what I would guess. It's much tougher to be able to replace one rubber with another rubber because the formulations themselves are very different. With glass, though, although certainly there are some differences, it's a more standardized product.

James Vane-Tempest: Understood. When we think about the differentiation of some of these companies, Schott Pharma, their parent company supplies the glass tubing. Stevanato has its engineering segment and sells assembly and vision inspection equipment. West obviously has a sizable contract manufacturing business. These relationships help to vertically integrate, but do they actually create any competitive advantage across the supply chain?

Fran DeGrazio: Yes, I think now certainly Schott supplies the wealth of the tubing. I don't know necessarily what competitive advantage that may bring them. I think more where there's a competitive advantage, to be honest with you, is with Stevanato and the equipment and their engineering skills. I think again, from an industry standpoint, they have a very good name in the market from an engineering standpoint and technical standpoint. I think from what I've heard, that is bringing them some advantage in the marketplace.

James Vane-Tempest: In terms of being able to differentiate as a packaging company-- I guess my opening question, you want standardization to be relevant, but what can you do in terms of being able to be most relevant to your customers?

Fran DeGrazio: Well, I think I mentioned earlier when we first started talking about the fact that products are one thing and you can differentiate around a product, but when push comes to shove, it's the service and the documentation and knowledge and things of that nature that really differentiate companies. Historically, certainly, through the years that I was at West, knowledge and

technical acumen were an extremely important differentiator. That's certainly, I think, a key piece to differentiation and is a little more challenging than just product differentiation, to be honest with you.

James Vane-Tempest: Understood. The last one for me before I hand back to Dave then, thinking about these industry collaborations. West obviously got the collaboration with Corning on the Valor Glass. I guess I'd love to know your thoughts at least around that in terms of the scope, in terms of where that could potentially go, just from your perspective there, but maybe a broader question and that's when you think about the pharma companies themselves, do you think that we're going to be moving more towards integrated systems over time to buy components? Could that actually become a differentiator over time?

Fran DeGrazio: My belief, absolutely that integrated systems are the way that the industry will move. Reasons for that, from a regulatory and a compliance standpoint, how things are moving. Also, just even from an efficiency standpoint, whether it be running full finish equipment and making sure that everything comes together and it's compatible and consistent and minimizing variability.

With the new compendial standards like the United States Pharmacopeia, there was an upgrade to what was called the USP 381 for elastomers, and that had chemical testing. Then they actually came out with what's 382, which is systems testing. In essence, saying just basic compendial testing now needs to be done on the systems as they're put together because ultimately, that's what the patient is going to end up seeing, and you need to make sure that it all works together the way it's supposed to and that it functions properly. From my perspective, integrated systems are absolutely the way the industry is moving.

James Vane-Tempest: Maybe just one quick follow-up on that, I can understand from your perspective, but is that actually what pharma clients want? Maybe it's a bad example, but I'm going to give it anyway because when you think about bioproduction and a lot of the big bioprocessing companies offer end-to-end, but then when I speak to the pharma companies, they don't want end-to-end because they want to go with the best bioreactor, they want the best bags, they want the best filtration system.

Is it the same here? They want the best stopper, you want the best glass, you want the best syringe, so you might offer it, but is that actually something that the market will actually want?

Fran DeGrazio: Well, I think the issue is going to be is it the best? Is it good? Is that integrated system differentiated? If you're going to put out a third-rate integrated system, you're not going to get anywhere. You've got to know what you're doing, and it's got to be a top-of-the-line integrated system, but ultimately, over time, there's the potential there to adopt.

Now where I see the pharma companies pushing back a little bit is this day and age, they don't like to buy everything, and they feel like they don't have leverage from a pricing standpoint as much. That's the question mark that comes in, but ultimately, you're selling these products to technical people because they've got to work.

James Vane-Tempest: Understood.

Fran DeGrazio: If the technical people see the advantage, and that means advantage from a technical standpoint, a compliance standpoint, a regulatory, quality, and it works, then that gives you an edge.

James Vane-Tempest: Understood. Dave, back to you. Thank you.

David Windley: Great. Fran, we could go on for two hours, I think. I wanted to come back to this loss of exclusivity cycle question. It's a two-parter. When you have a brand that is moving to generic or biosimilar and you go from one to many, how should we think about the market share of the

suppliers when you just have to win one, but now you have to win five or seven or whatever the number is. How should we think about that evolving?

Fran DeGrazio: Well, that's true. It's certainly more challenging because now you do have to address multiple customers in the market and you may not get all five. The reality is you may only get three out of five. Now the issue though is that quite often once it goes generic, you're getting higher volumes because now the drug product is more accessible to larger quantities of people, so that may offset some of the loss.

The other thing is the FDA is really discouraging too many generic players for the same drug product. Because they're like, "Why invest in having necessarily five? We're not going to just approve the fifth one of the same thing." You've got that, which is I think a little different twist that you have now versus historically. I think there are different ways of needing to understand what's that volume going to grow to, and that gives you more opportunity in some ways.

David Windley: Dating back to my earlier years of covering the company, the argument on the transition from brand to generic was always that the generic would likely copy whatever the brand was doing, like eliminate risk, minimize differences, use the same packaging components, same quality level, et cetera, rather than I think the inclination at the time was, well, would they look to save money and go cheaper? Let's flip that coin the other way. Is there an argument for the generic or biosimilar to buy up, to go up the quality spectrum?

Fran DeGrazio: I think that possibility exists certainly with some companies that again, they may try to-- really, the generic companies and biosimilar companies should be looking at how do they more uniformly have less variation in what they need to manufacture. One of the biggest challenges for a generic company or a CMO is that they have such variety that they need to keep or that they need to order on hand from an inventory standpoint.

One of the ways to drive efficiency is for them to say, "You know what, we're just going to put this better product on everything and our manufacturing is going to be so much more efficient now." That is certainly something that I'm sure several of them are looking to do rather than have all this inventory of different things that they need to manage.

David Windley: Got it. I'm going to get to GLP-1s, but I want to lead into that with a question about the order of magnitude. West is serving a 70% market share across a very wide swath of injectable drug patent holders and biosimilar and generic companies. The message externally has usually been, "We're not dependent on any one product, don't really have a lot of concentration." I guess flipping that on its head a little bit, how big does a product have to be to move the needle?

Fran DeGrazio: Exact quantities, to be quite honest with you, I would just be guessing at that, but certainly, when you talk about products like the GLP-1s, those volumes, the vaccine volumes-- when you're talking just from a volume standpoint, those are the things that right now are probably the kinds of things that could sway things pretty significantly.

David Windley: Coming back and invoking the quality and the product quality level within West's portfolio, we hear some different debates about GLP-1s or peptides, they're not small molecule, but they're not fully large molecule either, are they the type of products that should be spec'd into NovaPure?

Fran DeGrazio: Again ultimately, the customer needs to make that final call, but again, there are other reasons to be spec'd into NovoPure when you're running a key product like that and at the volumes that you need to. Let's just talk about, for instance, dimensional tolerances. Your dimensional tolerances have got to be extremely consistent with these products in both your machinery; so your equipment that the pharma companies are using to do their fill/finish, and then also with that plunger that's in either the cartridge or the pen system or in the syringe system that's in the auto-

injector. When you're talking about consistency of product, you want to risk mitigate by getting the best quality product that you can. Now, is there necessarily a chemical compatibility reason to go with a higher-end product? Maybe not, because it's not a full-blown protein, but, like I'm saying, there are other reasons that it would make sense.

David Windley: Okay. In thinking about, I guess, the tailwind of this, maybe you can help us understand cadence. GLP-1s have been in the market for a long time. I'll call them the more modern versions of these, the Ozempic, Wegovy, Mounjaro, and Zepbound versions, still in the market for a couple of years. Is that enough time, given the lags of supply to manufacturing to prescription as you talked about earlier, should the suppliers into these GLP-1 manufacturers be feeling the full benefit of that activity today, or I guess, is there enough of a lag that we're still actually climbing the curve pretty steeply?

Fran DeGrazio: The challenges from a supply standpoint of these products have gotten better, but it's still not necessarily meeting the demand, which is why I think Eli Lilly has introduced vials, right? The reason for that is because they're trying to make sure that you don't have compounding pharmacies or some other Joe Blow that's developing or trying to develop their own versions of these GLPs to get them out into the market and just to patients directly, and there's not enough guardrails around it.

In order to really protect that space and ultimately the patients, I think, Eli Lilly is a good example of going now direct to patients, but in vials. Ultimately, longer term, again, especially when you're talking about self-administration, it's going to be into the traditional systems that they already have, like auto-injectors or pens. That's the easiest to continue to grow that portfolio. My feeling is, at this point, it's still not quite where they want to be in the long term. I think there's still more optimization to be done.

Also when you talk about putting something in, especially a syringe system and the auto-injector, that's one dosage. You go from a vial that's probably holding five dosages at least, there's going to be even more units being produced and more components, packaging components that go into that.

David Windley: Just while we're on the topic, in that vial configuration, is it likely that Eli Lilly would use-- let's just insert, say Eli Lilly's using FluroTec in its auto-injector single-use syringe format, now adds vials, would it also use FluroTec on that vial, or would that be an independent decision?

Fran DeGrazio: Most likely, my guess is they would be consistent, and they would use the same because that would help facilitate getting the approval from the regulatory agency.

David Windley: Then the syringe used to draw a drug out of that vial, is that a high-quality syringe with a high-quality component in it, or is that a piece of plastic -- because it's drawn out and put it in right away that there's not a lot of concern about the quality of that syringe?

Fran DeGrazio: Yes, that, we would call a disposable syringe system. Yes, the makeup of that is totally different than a prefilled syringe system.

David Windley: Okay. Not likely a big revenue opportunity for a FluroTec plunger or something like that?

Fran DeGrazio: No.

David Windley: Okay. Another way to come at this GLP-1 question, how big is the GLP-1 franchise for West at this point? Do you have a sense of that? Is that something you can comment on?

Fran DeGrazio: No, not really.

David Windley: Okay. Then in terms of other form factors, as this evolves, as you highlighted, you've got the glass of the-- we'll deal with autoinjector, but you've got the glass of the syringe, you've got

a plunger that needs to go in the syringe, the syringe then goes in the autoinjector. The autoinjector has a needle shield or something of that sort. You've got all these different pieces that I think the blossom just continues to unfold. Are needle shields something that West focuses on historically, or is that a market that they haven't really tried to address?

Fran DeGrazio: West does have their own what's called a rigid needle shield which is what's on those types of products for the autoinjector, but typically they were not the ones that introduced that. The leader in the rigid needle shield space is Stelmi (Aptar).

David Windley: Okay. That's consistent with what we've heard. I'm realizing I did want to ask a question or two about Annex 1 before we run out of time. Again, a little bit of a long preamble, but we've had other calls focused on Annex 1, where the expert has emphasized to us that in reality, soft as it may be, the deadline was August or September of 2023. I think there's broad acceptance that the regulators have said, "Yes, we understand that's too short, and you need to be in compliance. We're not going to look the other way, but we are going to be a little bit [lenient] in expecting you to have a plan, but maybe not have that plan fully implemented yet," and that's the state of play. Is that your understanding? I guess in addition to that, why is it that in 2024, after this deadline was supposedly passed for compliance, that only now is it becoming a talking point as a driver?

Fran DeGrazio: Well, let me address that first. I don't know why just now it became a talking point because it's certainly something that everyone should have been aware of and could have an implication. It actually becomes an opportunity. This is how these regulatory things become opportunities for the companies to leverage. Now, as far as your point of, "Yes, it became effective in 2023," it will take time for companies to upgrade and get to where they need to be. I'm sure some may be there already.

This is all around contamination control strategy, and so the real drivers there will be a couple of things. When inspectors go in to inspect, they will tag these companies at that point with 483s or whatever, and that is what will continue to really drive this. PIC/S, which is the Pharmaceutical Inspection Co-operation Scheme, which is what trains all the regulatory inspectors, that is used by-- I think there are 56 countries that are tied into PIC/S. They have sanctioned Annex 1. That's how now they've set up the training to train these inspectors who will go in, and they will be looking for these improvements to be made.

Now, that will be a driver for this. The other thing that will be a driver is the time these companies have to make decisions about capital equipment purchase because then that's an opportunity for them to decide, "Do we want to buy certain equipment so that we can clean stoppers better," or-- when that's not really their core business, and then typically, they will make a move up the chain then to a ready-to-use product, for instance, or a NovaPure.

David Windley: Got it. Fran, like I said, I could go on for another hour. Unfortunately, today, I don't have it. You probably don't have it either. I'm sure you're busy, and our clients have got to move on, too. Thanks so much for your insight and your time. Our paths are probably going to cross again in the future. Thanks so much.

Fran DeGrazio: Take care. Bye-bye.

James Vane-Tempest: Thank you.

Company Valuation/Risks

Eli Lilly & Co
Valuation: Our PT is supported by DCF valuation. Risks include commercial, regulatory, and clinical.

Stevanato Group SpA
Our $21 PT is based on 18.1x STVN's 2025E EBITDA, a discount to peer WST. Risks include: 1) Slow RTU uptake in vial and cartridge markets, and 2) share loss to peers in HVS.

West Pharmaceutical Services, Inc.
Our $345 price target is based on a 45x multiple on 2025E EPS. Risks include customer inventory volatility, HVP product uptake, uncertainty surrounding key drug launches, and FX.

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(Article 3(1)e and Article 7 of MAR)

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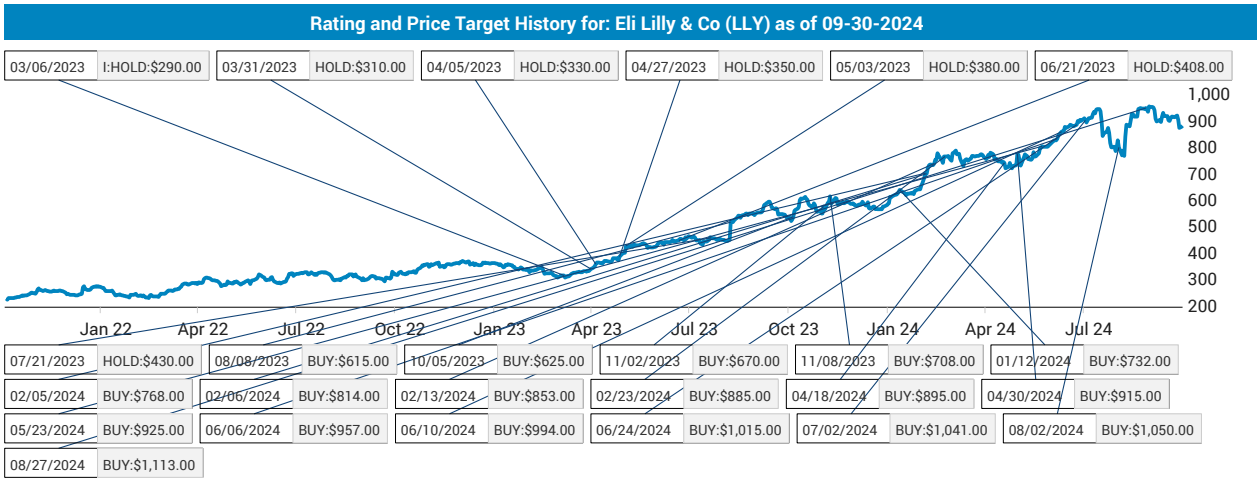
- West Pharmaceutical Services, Inc. (WST: $299.80, BUY)



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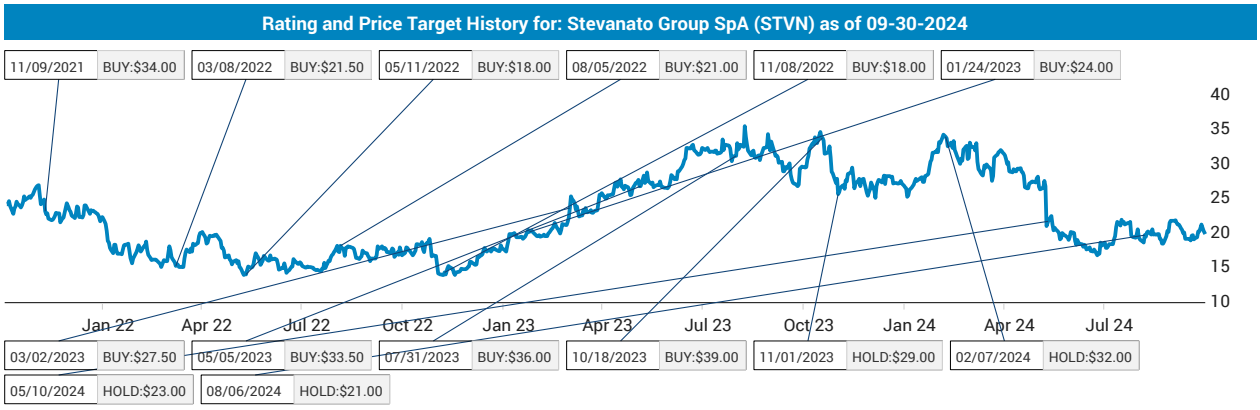

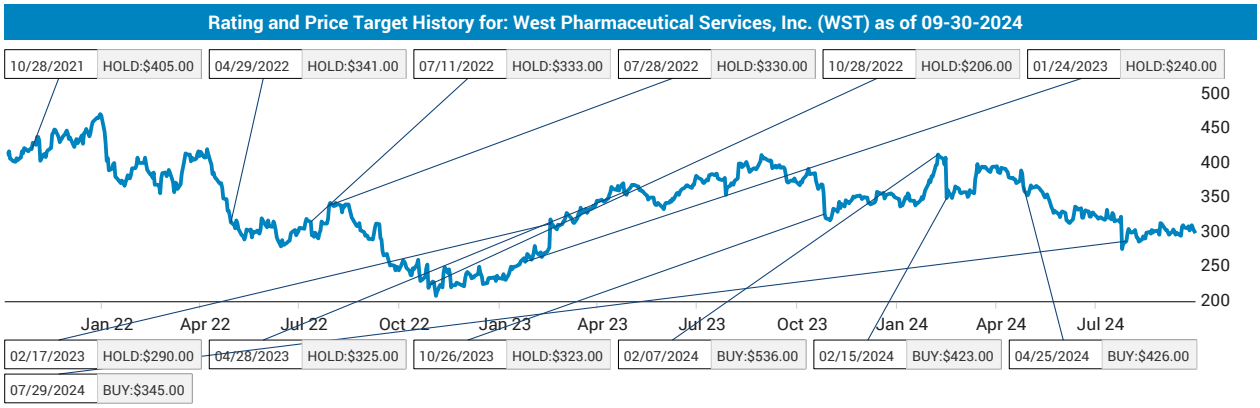

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