

West Pharmaceutical Services: Former CSO on Destocking Concerns and the Growth Outlook

Former Executive



Moderated Call

Moderator: Leroy Rogers

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Fran DeGrazio, Former CSO - West Pharmaceutical Services

KEY QUESTIONS

- "How can we have confidence that destocking won't get worse and when can we expect to see improvement?"
- "Do you personally believe that Q4 2024 is when things will truly start to improve, based on your experience and knowledge of the situation?"
- "Can you provide any additional insights or thoughts on the destocking issue and its impact on West?"

HIGHLIGHTS

“Lead times have normalized from 30-50 weeks to 8-12 weeks, affecting ordering patterns.”

"New regulations like GMP Annex 1, effective August 2023, impact contamination control strategies, encouraging the use of barrier isolators and potentially increasing demand for West's high-value products (HVP)."

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Leroy Rogers: Hi. Good morning, and thank you for joining us for our call around West Pharmaceutical Services. Before we get started, if anyone in the audience has any questions, feel free to email me at LRogers@Guidepoint.com, and I'll be happy to pass along those questions to our Advisor.

With that, Fran, it's a pleasure to have you here today. To begin, would you mind introducing yourself and providing us with an overview of your professional background?

Fran DeGrazio: Thank you. As you introduced me, I'm Fran DeGrazio. Currently a consultant in the parenteral packaging and delivery system space. For about 39 years, I worked at West. My last role was as chief scientific officer at West.

During my tenure there, I worked in leading various roles, everything from the analytical laboratories, regulatory organization, quality organization, global R&D for packaging systems, marketing, scientific affairs, and many various technical and commercial roles. I retired in March of 2022.

Leroy Rogers: Just for a bit of context for this call. West Pharma reported earnings last week and may cut their guidance which was driven by continued pressures, particularly around destocking.

Just to set the stage here, Fran, are you surprised that there hasn't been any improvement in the destocking? Is there any way to speculate as to why visibility is so poor here and why things haven't improved because it's been an ongoing issue as you know for more than a year now?

Fran DeGrazio: It's not a total surprise that this is dragging out a little bit longer than expected. Based on my experience, the forecasting and demand from the pharmaceutical companies at times is not very accurate. I'm sure that has played very significantly into trying to understand better when things will fall back to normal.

From, again, what we're hearing generally in the space that certainly by the end of the year, Q4 things should start to return back at least closer to normal. Many times, West or other similar companies can only forecast based on the quality of the information that they're given from their customers. That can be a challenge at times.

Leroy Rogers: Let's take a step back here and just examine the destocking issues that we'll talk a bit about the customers themselves. First, the common explanation that's been given for this destocking is around COVID essentially as the company describes it.

As they were going through COVID, that's why they saw the most pressure around lead times where customers really had to manage their supply chains. That's where the safety stock was built up over time. That's why West has seen destocking in particular areas.

First, do you believe that explanation? Is there anything to poke holes around in that logic, or does that sound sensible? Is that in line with what other market participants are saying?

Fran DeGrazio: Yes. It does make sense. One of the things that I was at West for as long as I was, we actually lived through several other destocking kinds of situations, of course, not due to a pandemic, but due to other reasons, so that I know that realistically, these things can happen. Again, that it's not always clear exactly the exact time that you're going to pull out of some of these things.

It is consistent not only at West, but across the industry that they're struggling with some of this same issue. The destocking really occurs because of the over-ordering to begin with by major customers especially. They over-ordered to make as much as you tell them not to. They will over-order and end up with too much product in their inventory. They're trying to bring that down.

Now, also on the other side, you have the fact that lead times are now back to normal or improved even more so. When customers order, they will typically do that based on the lead time for the products. Back when COVID was occurring, lead times were greatly extended to many customers.

In order to overcome that, they would order, of course, whenever they could get their hands on product. Now that that's coming back to or has come back to normal that this is really a result of that.

Leroy Rogers: This question of lead times and how it impacts ordering, can you maybe walk us through an example? As you said before, West, they talked about at one point their lead times or 30-50 weeks, and then now they've reached this level of what they call consistency of 8-12 weeks for lead times.

Is that a normalized level of lead times and also, how much do you manufacture lead times really drive pharma companies ordering patterns? I just want to understand that relation a little bit more if possible for him.

Fran DeGrazio: Lead times can definitely have an impact on the majority of ordering. There will be some larger companies that may come in with a full-year order if it's something that they've been ordering for forever. They know and they're very consistent with what they're going to need. They may come in at the beginning of the year with a year's worth of orders.

But more typical is the kind of thing that you see. They'll order based on the lead times. 8-12 weeks is the normal lead time for Westar products or the HVP-type product lines. As you mentioned, those were out some past 30, 35 weeks when COVID had hit. Now they are back to 8-12, which is very typical lead time.

The customer will typically knowing that then come in with their order right before that, place that knowing that they're getting that product in very close to when they're going to need it, depending on how much they were typically hold in their own inventories.

Leroy Rogers: Fran, how much visibility does West themselves have into their customers' inventory levels?

Fran DeGrazio: Unless it's changed recently, they don't have direct insight into their customer inventory levels.

They're really going by historic demand and then interaction with the purchasing teams and supply chain teams at their customers.

Certainly, West's planning and supply chain organization will work directly with the customer's organization. That's how with certainly the larger companies, they would have that type of relationship in setting up their orders. They're really going by what they're being told by the customer on the most part.

Leroy Rogers: Fran, West did talk about seeing promising signs from their customers to indicate that destocking is at a turning point. Could you speculate on what are the signs they could be seeing? What could they be meaning by saying promising signs? Is that just commentary around maybe the pace of orders or developing order book or what other signs could you point to to maybe indicate a turnaround?

Fran DeGrazio: They should be tracking their backlog of orders. They should, assuming if they're saying that they're seeing an increase in orders coming in for Q4. That would be the major indicator that things are starting to return to normal.

Typically, you would track that and track that in comparison to prior years. Of course, they would have subtracted COVID out of that, anything that was directly related to COVID so that you'd understand what's the ordering versus your normal baseline for Q4 of the year.

Leroy Rogers: Fran, just from the customer perspective now, can you explain to us, once again, how far the pharma companies stink in relation to orders, how much are they planning ahead? Does it differ if it's a large pharma company versus if it's a small biotech?

Fran DeGrazio: With the larger company, they would typically have a certain quantity of stock in-house in inventory. That could be anywhere. I would say under normal circumstances, most are within three to six months holding inventory. It all depends on also their own risk mitigation plans because each major pharmaceutical company would have risk mitigation plan were they to run into any issues so it could be anything like, geez, we order further ahead of time than what the lead time is or we want to hold double our normal inventory.

It really all depends on what their own internal risk mitigation strategies are. Smaller companies quite often don't realize that they may need to come in earlier. West is a built-to-order business. There's not necessarily a lot of product that's made and that's laying around in inventory. They're really producing based on the orders that are coming in.

Leroy Rogers: Fran, I know we talked about the COVID dynamic, but I do want to run this idea by you and see, does it sound reasonable, or do you think it's not exactly how things work in the industry? What about the idea that large pharma has upgraded their inventory tools then possibly using AI, for example, to better manage inventory? Now they can comfortably manage with lower inventory days on hand.

This expectation to get back to the pre-COVID mentality maybe that's not the right way to think about things. Maybe this type of inventory management among customers is the new normal. Maybe do those tools that I referenced. What are your thoughts on that idea?

Fran DeGrazio: Yes. That's an interesting concept. I would think that many of these larger pharma companies are certainly looking at doing that to help with the management of their inventory. It's quite amazing, though at least historically and not that long ago, say, 5-10 years ago that there were some major pharmaceutical companies that were still challenged with their demand and forecasting knowledge and being able to convey that.

One of the biggest areas of challenge would always be when they're introducing a new product. They may think this new product is going to be a real blockbuster. Then it turns out it's not. Or it's just the opposite. Or maybe they think it is a blockbuster, but it's bigger than they thought it was going to be.

That's where, and again, AI today could play a role in improving that. The reality is it's never going to be perfect. Those are just the normal challenges that suppliers to the industry have to deal with.

Leroy Rogers: What about the concept of vendor-managed inventory? Is that just an impossibility for especially these larger farmer companies? Does that already exist with some customers?

Fran DeGrazio: It is doable. From a West perspective, I know they may have been working with a couple of key customers on something like that, the vendor-managed inventory. However, my guess is they have not done it broadly with their customer base. Again, I'm only guessing at that.

Leroy Rogers: When we think about the destocking, is it reasonable that this is being driven really by those large customers, the large five or six customers that are being responsible for this destocking, and this isn't like a trend that's spreading to the smaller customers and small biotech? Is that the right way to think about it?

Fran DeGrazio: Yes, that's what I would guess, because, quite frankly, when you're in a crisis situation like they were with COVID, it's those large customers that are going to have the ear right of the company and the power to be able to adjust quantities and move timetables around and things of that nature.

Smaller companies are just fighting to try to get their hands on some product. Most of them are not going to have too much product at hand. They're just hoping to make sure they get their hands on something.

Leroy Rogers: Fran, can you help me understand the average shelf life for some of these products? Can these products sit on the shelf indefinitely, or do they have a limited shelf life? Is there maybe an average shelf life that you all references? Is five years maybe the right number? Just trying to understand the destocking in relation to shelf life.

Fran DeGrazio: The rubber elastomers themselves, the formulation, they have a five-year shelf life. However, if the product that's purchased is ready to sterilize or ready to use, or already sterilized, they go through a different post-process and are in different packaging. That packaging typically has been validated for a two-year shelf life. Meaning the customer would have to use the product within a two-year time period.

Leroy Rogers: Is that possibly why destocking at West might not be at the same level as a company like Stevanato who might be more involved in glass bottle making?

Fran DeGrazio: It could be. That could be. Because, again, I don't know exactly what Stevanato or the glass manufacturers are all conveying for their shelf life of their ready-to-use glass. The other thing is that typically, historically, it's been easier to be more flexible and changing up glass, too.

For instance, if you were short on one supplier, maybe utilizing another supplier's glass is easier than doing that with elastomers. From that regulatory perspective, that could have something to do with it, too.

Leroy Rogers: Fran, when I think about potential market share loss for West, do you think that's an issue, or do you think it's simply or you think this is an industry-wide phenomenon and it's not indicative of any share losses by West?

Fran DeGrazio: My thought process is that it's indicative of the industry and it's not something that's specific to West of any significant volume losses. Frankly, yes, I don't know why there would be any significant move if you take a step back and look at it objectively.

If a company was having trouble getting their hands on West product during the COVID time period, then that would have been most likely for a new product. Those products would be very low from a volume standpoint at this point in time. I wouldn't expect that what you're seeing is due to any kind of significant loss of volume.

Leroy Rogers: Fran, what about the end markets themselves? Do you have any concern that any of the end markets could possibly be weakening? Any concern, maybe large molecule or biologics demand, or do you think once again, that's not the core issue here?

Fran DeGrazio: No, I don't think that's the core issue. If anything, the biologics continues to grow. That's where a lot of the development activity is occurring. I really haven't seen anything that's an indicator that's trailing off anytime soon.

Leroy Rogers: Fran, what about these new regulations like GMP Annex 1? How does that relate to demand for West Pharma's services? I don't think it has any relation to destocking, but just in general, how our regulations may be shaping trends.

Fran DeGrazio: Annex 1 certainly is one that can have a direct impact on the packaging components. Just to maybe give a little bit of background on that. Annex 1 has been updated several times through the years. This latest update, which became effective, I think, August 2023 is really about all the pharmaceutical companies needing to update their contamination control strategies.

In particular, how that impacts West is in relationship to microbiological contamination and particulate contamination. The objective with Annex 1 is to get companies to minimize the potential for those kinds of contaminants.

That means that they're encouraging within the actual Annex 1 document itself, encouraging industry to move toward the use of barrier isolators or RABS systems which would be in essence, to put it in non-technical terms, you're taking a clean room that would have the fill-finish equipment for the drug product and shrinking it down

into a closed system that only has access through glove ports.

For instance, everybody in the industry knows that the thing that contaminates sterile drug product is typically people. If you have people in the environment, whether it be skin flakes or hair or anything else, those are the things that can contaminate the drug product.

By shrinking it down and using these barrier systems, then what you do is to have a direct connect access of, for instance, ready-to-use closures, and they go right into this barrier isolator.

Typically, the bags that are used, so this now is the secondary packaging that the components would come in instead of coming in the more traditional plastic bag or even a Tyvek sterile bag, they would actually come into what's called a, there are different kinds of port bags.

These port bags connect and keep a sterile connection between the sterilized components and the entry into the barrier isolator. What that does for West is really encourage customers to move up that HVP curve. If they weren't using product that was already washed and sterilized, maybe they would decide to do that going forward.

One of the other reasons is not only because the product will be pre-sterilized then, and this would just be easy access to these barrier isolators. West tests every washer load for things like particulate contamination.

That's one of the advantages when you purchase components from a supplier versus washing them within the pharmaceutical company itself because they will not test every washer load for things like endotoxin removal and particles.

These are all things that if you're using a Westar product or a Nova pure product that you'd get much better quality data and quality product and then that would be part of their improved contamination control strategy.

Leroy Rogers: We can go back to destocking. One question that we've gotten in, it's pretty simple. How can we have confidence that destocking won't get worse? How can we tell if we are at the bottom, given what you've described around visibility from West?

Fran DeGrazio: All I can say is I don't think there's anything that's 100% guarantee, would never tell you that. West, you've got to look at it this way. One of the reasons West recognized what was happening this year was at the end of last year. Because that's when their customers went back and really figured out, hey, we're not going to use all the product that we have.

That's one of the reasons why it was what the end of '23, beginning of '24 when they really came out and said we've got this destocking issue. My expectation would be they're doing their best to figure it out as to when the improvement is coming. They're projecting Q4. Ultimately, it would be the end of the year when they really get everything cleaned up and analyzed from their customers going into 2025 as to probably when your assurance would be at its greatest.

Leroy Rogers: You personally, Fran, you would still lean toward Q4 2024 as being when things truly start to improve and you don't believe this stretches out into 2025 based on maybe similar situations you might have had in your career or what now that's obviously in the public domain.

Fran DeGrazio: Yes. Correct.

Leroy Rogers: Any final thoughts before we close out?

Fran DeGrazio: Not really. I've addressed everything you've asked. That's it.

Leroy Rogers: Thank you so much for your time this morning, Fran. For those on the line who would like to follow up on a one-on-one basis, please get in touch to your Guidepoint representative. Otherwise, have a great day.

Fran DeGrazio: Thank you very much. Bye-bye.