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# West Pharmaceutical Services, Inc. (WST)

Analyst and Investor Day

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## MANAGEMENT DISCUSSION SECTION

### Quintin John Lai

*Vice President-Corporate Development, Strategy & Investor Relations*

Good morning, everyone, and good morning, everyone on the webcast. My name is Quintin Lai, Head of Investor Relations at West Pharma. And on behalf of all the team, thank you for coming. We've got a great day planned.

We will start with presentations from our CEO, Eric Green, and then our commercial team. We'll have a break at 10 o'clock. If we have time before the break, we'll take a few questions, but if not, we will have another question-and-answer session at 11:45. We have question cards on the table in front of you, and so if you want to write down your question and give it to anybody with a West badge, we can address it after the break, otherwise we'll take them from the floor at 11:45.

So, before we start, I refer you to our Safe Harbor statement, please take a look for at our recently filed 10-K for a more detailed discussion of risk and disclosures.

Before we start today's meeting, we're going to start with a little video and then after the video CEO, Eric Green will kick-off the formal presentation.

[Video Presentation] (1:22 – 3:28)

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### Eric M. Green

*Chief Executive Officer & Director*

Great. Good morning to everyone. It's a pleasure to have you here in New York in the auditorium to talk about the West business and how we're – with a bright future ahead of us. I also want to welcome those on the webcast, and so just [ph] stating (3:42) today's Investor Day. That video is a great reminder of why all 7,000 employees are engaged at West each and every day. We're supporting since Herman O. West started the firm in 1923, over 90 years we have been supporting the pharmaceutical, the biotech industries and med device industries to really help solve problems and bring solutions to their drugs with the patients. We're committed to quality. We're committed to service and we're committed to the patient's experience when they're using West products.

When we take a look at our goal at West is to become the world leader in integrated containment and delivery of injectable medicines. And today, we're going to talk to you in greater detail on how we're going to achieve that goal.

West has the right to play. Over the last 90 years, we have built relationships with numerous customers and helped them able to take their injectable medicines into the marketplace. When you talk about the top 35 biologics in the marketplace today, the injectable drugs, West or our partner in Japan, Daikyo are on all 35. When you talk about the top 75 pharmaceutical and biotech companies, the injectable companies in the space, all 75 West is working with – worked in the past, we're currently working with them, and we're pretty confident we'll work with them in the future. And what's interesting, when you look at just the sheer volume of components that our facilities around the world produce, 40 billion components are produced on an annual basis.

After this discussion today, for the next two hours or three hours, the number of components our facilities will produce will fill this auditorium. But more importantly, it's the commitment to the quality. So let me tell you, in the last two months, I've had the opportunity to go to a number of our sites, our manufacturing sites and hold

town halls. And really talking about where we are and what the vision is for the company and how each and every employee contributes.

What fascinates me in these town hall conversations is when our operators, that are producing these products every day, are really [ph] connect in (6:12) realizing, it's not about the volume. It's about each and every item that goes out the door, that they realize, they themselves, their families, their friends, their neighbors, somebody will be benefited by our product working with the primary container of an injectable medicine going into a patient. And that's how real the organization looks at 100% commitment, every dose, every time at West. It's a remarkable feat.

The business is extremely diverse. Take a look from a geographic point of view. Asia Pacific and Latin America is approximately about 12% of our sales. The U.S. roughly around 50% and the balance is in Europe around 40%. We are diverse, we're – most of our customers are in the global base. And we see future growth opportunities in all markets. But more importantly, we do feel that we have the active base in Asia to allow us to grow, continue to grow quickly.

Just to put in perspective, last year our Asia and Latin America business grew well in the double-digits, while our U.S. and European business were mid-to-high single-digits, very strong growth in every geography that we're represented. From a product point – portfolio point of view, we're very well diverse. Our largest SKU is less than 5% of sales at West. That gives us the ability to have a broad range of products in the portfolio to really support our customers. What's interesting dynamic that's happening, if you look at the pie chart in front of you today, the high value component is growing well in the double-digits in the last several years. And that's becoming a larger piece of West portfolio. The future growth in addition to high-value products is around our delivery devices. And little bit later today, you're going to hear more about, not just what we're doing today, but what we're working on with next generation of new technologies.

And we have a very important business called Contract Manufacturing, roughly around 20% of our business that again is supporting several pharma and biotech customers, around the globe. Looking forward, we have a new lens on the business. We reorganized around – become more market led as a company. In 2016 we believe, we'll achieve around \$1.5 billion of revenue of which, it's 20%, 20%, 30%, 30%. 20% biologics and also in Contract Manufacturing and 30% pharma and generics.

[ph] We're seeing and you'll hear (8:56) more from Karen Flynn and her team, around the growth drivers of each and every segment. But we're seeing that the biologics and generics are growing faster than the pharma and the Contract Manufacturing space. In all four cases, we're growing attractively in every – each and every market that we serve. I just want to remind you, our largest customer is less than 8% of sales. Again, back to diversity. We have several customers, several products, to support the marketplace that we serve.

As we looked forward into our business, Proprietary Products are all products that we have either designed, we have IP, we have patents, we have knowhow. We manufacture these components that are going into our customer's manufacturing process. It's about \$1.1 billion of revenue. The other \$300 million business, is Contract Manufacturing. And when you listen to Mike Treadaway talk little bit later today, you'll see a shift and that shift is moving more towards the pharma and the med device space versus being somewhat agnostic in servicing multiple industries. And because of that focus, we can leverage our commercial engine to drive more value. In the Contract Manufacturing space, the way to look at this – the IP's owned by our customers, but we help design, we help manufacture in large volumes on a global basis.

The company has sustained consistent growth, top-line our constant currency growth about roughly 7%. If you look at last year's results and you're quite familiar, we grew a little bit faster than that in 2015 on a constant

currency basis. From an adjusted diluted EPS perspective, we're roughly around 12% CAGR over the last five years. Again, last year our growth on EPS was slightly faster than that. Again, momentum going forward.

Last year we were added to the S&P MidCap 400 Index. And part of that group, as a peer group, if you look at our performance as a comparison of cumulative five year total return, we have outperformed our peers within the S&P MidCap 400 Index. In fact if you put other indices in there, you'll see West continue to grow quite nicely.

Using of cash. We do generate quite a bit of cash at West. What's interesting when you ask, what are our priorities at West? The first priority is continue to reinvest in our business. We're investing roughly \$150 million to \$175 million of capital this year to continue to build capacity and capabilities to support the demand of our current business. But more importantly what you'll see going forward is that – and that's roughly around 10% or 11% of our sales. What you'll see going forward as a percentage of sales, we want to bring that down slightly, but in line with build, support our customers demand. The second area is dividends. As you know, we continuously spend roughly around \$30 million or \$40 million back to our shareholders. And the third area [ph] we clear on (12:03) is inorganic growth strategy. We have a clear line of sight, where we want to play at West we have the right to play in the injectable medicine space from the elastomers all the way to the auto-injectors. We are going to continue to look at both opportunities, anywhere between \$50 million to \$250 million, to bring new technologies into our portfolio.

In addition to that, if there are opportunities at larger amounts, West is at a very good position because of the strong balance sheet to identify, if it's strategically makes sense, we will act. Debt repayment as you know, our leverage – debt leverage is very low, it's roughly around 2%. And stock repurchase, we take a look at that as an opportunity to keep our share count neutral. This year we have authorized up to 700,000 shares to be repurchased in 2016, depending on the conditions of the market.

Third quarter of last year, as you know, I've been with the firm now for nine months or 10 months, and I couldn't be more proud of it standing up here today. About six months ago, we pulled together 14 individuals throughout this organization, different geographies, different disciplines, different functions. Typically we build business plans based on divisions. What we've done is, we assigned 14 individuals under the leadership of Karen Flynn and myself, and Bill Federici to take a deep dive in this organization to determine, what is the right enterprise and strategic plan to drive this company forward.

We have a great – we're from a position of strength. We continue to grow. We have a great opportunity to continue to exceed the market expectations. And I'd like to share with you, what the key levers will be for the growth of this business. And as we get into further discussions throughout the day, you'll get into the details, you'll hear from our business leaders on how we're going to execute. The first and the foremost is this company has been reorganized in the last three months or four months to be market led. And that means that we are – organized ourselves around the customer segments, the biologic, the pharma, the generic, the Contract Manufacturing because each and every customer segment has unique needs that [ph] we need to be addressed (14:08).

We believe we'll continue to have a strong base of organic sales growth. We articulated about 6% to 8% organic this year, in 2016. With that, there's a natural margin expansion because our high value product portfolio continues to grow at high single-digit and low double-digits.

We also believe we hold our global operations from a site regional business unit approach to one global operations. You're going to hear more about that today. That gives us the ability to leverage our operations if you look at expanding capacity and also utilizing the existing capacity. It's optimizing our network, but more importantly globalizing the procurement organization, which is now in place, so it can have lean manufacturing

and supply chain efficiencies. We believe we'll continue to drive margin expansion, in addition to the product mix shift. You will see margin expansion through our global operations.

The third area I'm really excited about is strong innovation and technology. This is about building for the future. This is about working with our customers. This is about building next generation, whether it's in the containment or in the delivery devices. And we've taken a business unit [ph] slight (15:20) R&D focused organization and now we have one global innovation and technology team, and this is mirroring our customers. By the way, our customers are building containment to delivery R&D engines in their own organizations and we have mirrored that, so we can better work and partner with our customers.

We're confident in our [ph] 2012 (15:40) projections. We believe we're going to grow our sales, continue to high single-digits here at West on an organic basis, and we also believe we can continue with the margin expansion. And this is showing a 600 plus basis point expansion since 2015. It starts with people. This company has \$1.5 billion assets in the organization around the world and we put \$600 million in the ground in the last five years for building for the future. We have great customers, diverse customer group and they look at West and bring West to the table to have conversations to solve complex problems. It starts with the people.

We have a very talent leadership team. There's been some changes with retirements, obviously I've stepped in for Don Morel, but more importantly we have a healthy mix of existing leaders that are running key commercial operation and innovation technology areas. We've brought in experts – domain experts from large multinationals. They'll help us drive more around the talent acquisition, around more of our legal compliance, M&A engine, and also around IR.

So today I'm excited. I'm excited for you to hear from the team. We've met – I met many of you on the last nine months in different conferences. I know Bill has been out there meeting with many [ph] with (17:03) you also. I want you to hear from our leaders. You're going to hear from our segment leaders. They're driving biologics, pharma, generics and Contract Manufacturing globally. Also our operations, our innovation and technology, and we'll wrap it up with the financial view of the company, and I'll close it off before we do the Q&A. So I'm excited that you're here today. Thank you for your attention and we will turn this over to Karen Flynn. Karen?

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## Karen A. Flynn

*Chief Commercial Officer & Senior Vice President*

Good morning, everyone. My name as Eric said is, Karen Flynn. I have responsibility for the new commercial organization at West. But I've been in and around the pharmaceutical industry for 30 years. It kind of scares me even to say that out loud, 30 years, sounds like a long time. 22 years of that with West. I started in R&D. So I had a number of opportunities to work with customers, sitting across the table, and trying to understand technically what their needs were, so that we could bring new products to bear in solving their problems. I've spent 15 years of my career in sales and sales management functions at West and with other companies. And there's nothing like that as an opportunity to really sit across from the customers and understand uniquely what their challenges are. And it's this experience that really makes me excited about the new direction that we're taking at West to become even more customer and market focused. Really excited today to spend some time talking with you about how we're going to execute that strategy.

So first let's start looking – with a look at the total injectable medicine space. It's a very large market about \$300 billion in sales. If you look at the space where West plays, it represents sales about \$7 billion to \$8 billion. So these are products that are used in the containment and the delivery of injectable medicines. It includes vials, prefilled syringe systems, vial closure systems, pen systems, injectors. These types of products make up global sales of \$7 billion to \$8 billion currently.

Not only is the market large, but it's growing. And I was just having a conversation this morning with one of you about how do we measure the progress of the injectable space and one of the ways to do that is to look at the number of novel medicines that are approved as injectables. What you see here is just the last three years in the data that we've been following. In 2012 and 2013, many of you probably know that there was a bit of a slow down in terms of FDA approvals. But we're seeing a nice recovery from that and the pipeline is very strong particularly in the biologic areas you'll be hearing from us later today speak more to. So you see here just biologics approvals went from two to 13 in the last three years, and the number of approvals in general for injectable medicines almost tripled.

It's also interesting to note how these presentations are coming to market. What we're finding is that more and more of these are being introduced with delivery systems. So of the last two years, the 38 approvals, 16 of these have been introduced with a modality that requires the use of a device. That could be a vial adapter, a prefilled syringe system, a pen system, an injector, any of these types of modalities that help to enable a better patient experience.

Of course West is always interested in knowing how are we participating in the approval of these drugs. Eric mentioned that – the top 35 biologics that are currently on the market use a West containment system or delivery device. And here is the adjusted statistics for those drugs that have been approved in the last three years. So it says here known West participation. We don't always have complete visibility to the selections that our customers make.

We fortunately have very good relationship with the major pharma, biotech companies and so often we're privy to this information. But sometimes, we don't know, if they're using a contract manufacturer for example, we might not have complete visibility. And sometimes, they like to keep this information confidential. But we're very proud of the fact that these statistics certainly favor West, that we are participating in between 80% and 100% of the novel medicines that have been introduced into the market in the last couple of years.

Talk a little bit about the customers that we serve. Eric showed this graph already, this shows the split of our current customer base and the revenues generated from these markets. We have about 20% as he said with Contract Manufacturing and 20% in the biologic space. And the others are split between generics and pharma.

Now, the three market segments of biologics, generics and pharma, those customers also buy Contract Manufacturing services from us. We proudly serve more than 2,000 customers globally. West truly serve global markets. We have direct sales and also with distributor network in some of the smaller countries, but we do have a deep global presence.

These companies have more than 2,400 injectable molecules that are intended to be delivered via injection in clinical development currently. Of the 2,000 customers that we serve, the top 125 represent about of 95% of our sales. So, we do have very long standing relationships with these companies. These are the typical large pharma, large bio, mid-tier pharma and bio companies. We obviously spend a lot of time, put a lot of resources to keeping these relationships strong and growing.

However, we've got a long tail of customers as well that represents only 5% of our current revenues. We feel it's also important to have a relationship though with these customers. What we find is that, these – this is really the engine of growth for the pharma injectable industry in the future. Some of these companies are just one. They're working on one or two molecules and as they [ph] speck in (23:23) the containment systems that are used through the clinical development of these products. It's important that West is represented and that West becomes part of that system.



It's often we find that, these molecules are purchased by large pharma or large bio companies. If we can make sure that our components are utilized in the clinical phases, we find that they normally stay with those drugs even if they're acquired by another company and that they'll come to market using a West containment or delivery device.

Now for those of you who follow this industry, these market drivers will not look surprising to you. In fact, West has talked about many of these drivers over the years. We see that the bar continues to rise on many of these, and also there's emphasis on new market drivers.

So now, we're saying how do these market drivers keenly affect these markets that are a focus to West. And we're aligning our commercial resources around developing even a greater understanding of the markets that we serve, the pharma, the biologics, and the generics markets.

If we look at how West can meet the needs of these markets, we see that there is a high quality bar set across all of the markets that we serve and this is no different. But there are some [ph] uniquenesses (24:58) of the individual segments. Generics, for example, there is a keen need in the generic space for customers to be – to rapidly be able to enter that market space. Sometimes, [ph] there are tender bids (25:10) or an opportunity for a generic company to jump in and capture some market share. And so, they're looking for support in the marketplace to enable them to react rapidly. They also need very efficient manufacturing because it's a competitive space as we all know.

Traditional pharma companies who have a portfolio of small chemicals in their portfolio are facing patent situations, right. Many of these drugs are nearing the end of their life cycle, so they're very interested in life cycle strategy. What can they do in order to maintain the profitability of their portfolio of products through their life cycle and really maximize those opportunities? They also may be facing situations, where they're losing volume. They've got to install manufacturing. They have installed manufacturing assets and they need to efficiently utilize these assets and maybe [ph] shedding (26:14) some of these assets even.

So they're very focused on total cost of ownership and being sure that they're very efficient in what they do. The biologics is a unique space, especially, when you're thinking about monoclonal antibodies. These are unique molecules and unique drug products that are very sensitive and often require specialized packaging for the containment in order to be sure that there's no interference between the materials that are used to contain the drugs and the drugs themselves.

So their – the quality standards are extremely high. [ph] Also that we find (26:48) many of the drugs that are being developed for therapies that are based on biologics are for chronic diseases. And our customers are looking for these types of therapies to be delivered outside of a traditional hospital or clinical setting often administered by the patients themselves. And so, they're much more interested in utilizing devices to make it easy for the patients to take and adhere to their therapies.

When companies are faced with the need to procure Contract Manufacturing services, they're driven by the need to find companies to support them in the design for manufacturability and also to have very high quality standards. Why is this important? When you think about a device that is used to for example deliver insulin, each and every device has to work every time. It's got a patient associated with it. That patient relies on that device. That device needs to be able to be manufactured. It's comprised of multiple components. So, you need to design that device in a way that lends itself to a high quality manufacturing. It can be assembled very effectively in the manufacturing environment and then work each and every time.

So, it's this patient focus. The patient focus is not just for manufacturing services but it's on all – across all the markets that we serve. Our customers are keenly interested in developing therapies that serve their patients. And



this is what West is interested in doing as well. We're interested in partnering with our customers in order to serve their patients. And it's through the unique understanding of patient needs and also through the unique understanding of these markets that we serve, that we can bring value to the market.

So how can we do that? We can do that with this portfolio of products and service offering. It starts with standard product. Eric showed you the sort of the split of our sales by standard products versus high value products and services. That's not to say that our standard products don't provide value. They certainly do.

Elastomers for example that are used to contain medicines are based on the intellectual properties that West has for the elastomer formulations. Also there is proprietary knowledge in being able to manufacture billions of these annually. But if you think about how West can go up that value chain and provide even more service or value to our customers, in maybe in the form of us taking on manufacturing processes that have traditionally been done within our customer's wall. This could be pharmaceutical washing or sterilization services and that – when we do that, we provide those services for our customers. It creates more connectivity between West and the customers we serve. We also can provide services around inspecting components and through doing this inspection, the quality of the component reaches a whole new standard and at our customer's location then we find that they have a reduction in their fill – the level of rejects after filling. And so that obviously reduces their total cost of ownership.

We provide administration systems. So these could be in the form of – for example, vial adapters. We use a vial adapter with a vial, with a stopper and a seal. It helps in administration of that drug and it improves that patient experience.

You'll hear a lot today about Crystal Zenith. Crystal Zenith is a material that is used in order to manufacture vials, syringe systems and cartridge systems. It's the material that we find is important for use with those drugs that have very sensitive aspects of their molecular structure. It makes it difficult for them to find a compatible containment system and CZ fits the bill there very well. And again, it lends itself to more customer intimacy because in these cases, we're providing the primary container and the closure system.

The ultimate in terms of customer engagement would be West providing a device, and this device is comprised not only of the mechanism in order to deliver the medication, but also the primary container and it's the marriage of this containment system with the device that sets West apart and creates this high-level of engagement with our customers.

So, I'm going to turn this over to my colleagues and we're really excited to share with you an even greater understanding of how we're partnering with our customers, putting these products to use to solve their challenges.

I'll turn this over to Mr. Chris Ryan. Thank you.

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## Chris Ryan

*Vice President & General Manager, Global Generics, West Pharmaceutical Services, Inc.*

Thank you, Karen. Hey, everyone. I'm Chris Ryan. I'm the Vice President and General Manager for the Global Generics segment at West. A little quick bio on me, I'm a chemical engineer from Villanova University. I'm also have an MBA from University of Chicago. I'll take a really important pause here to note that there's kind of a couple of basketball games going on at the Garden right now and if anyone is a Villanova fan, or even a Georgetown fan because it's Villanova, Georgetown, I'd be happy to share cab with you after the conference.

So, a little bit more about my background, I'm actually also one of the newer people at West. I've been here one year, but I come with over 20 years of experience of leading market-led global businesses, businesses that are performance products, businesses in the B2B space, businesses that are highly branded. And very pleased to be here at West, extremely collaborative management group here, and I appreciate all the support I've gotten in the last year from the group.

But I can also tell you, I'm really excited about this switch to a market-led organization. It's really what I've been comfortable working in the last 20 years and I see tremendous value for that going forward for West. So, what I want to talk to you about though is the generic space, why West now after many years and putting a really significant focus on this. So, that's what I hope to get across to you today.

So, you know the market is a large market and it's growing. There is also a very good set of trends behind it that indicate the growth is going to continue. For example, right now, there's over \$200 billion in drugs that are expected to come off patent in the next five years and move into the generics space. There's really so much activity that the FDA and even the CFDA in China had to really significantly increase their staff to deal with this. And they've been working with the industry to make that happen.

But despite the number – the increased the number of licenses, they've been able to allow the number of requests for licenses continues to outpace that. So really, we feel pretty good about the potential for that to grow in the future.

So for West and Generics, as mentioned earlier, looking on a forward basis, it represents about 30% of our sales. And from a revenue growth point of view, it's kind of in that we're calling a mid to high tier single digit performance. So it's right in line with the enterprise, so a strong contributor to the enterprise going forward.

And when we talk about generics, we're really talking about almost two completely different worlds. One is the developed markets for generics and one is the emerging market for generics. So quickly on the developed markets, we will see from West as we are growing a little bit faster, you can see, than the industry in terms of drugs. And a lot of that has to do with what I'm going to talk about later, which is this HVP adoption rate. So although our units are more growing in line with the market, our revenue is growing faster than our units because of that.

And [ph] then I'm going (35:04) to talk about emerging markets. So emerging markets is basically the indications are that it's going to be about 80% of the global demand in the future for generics. So emerging markets are really important for us and we participate in emerging markets today. As we know the – Asia and China and India are some of the biggest components of the growth of emerging markets.

Today, that's a very, very small base for West and it's a small base for West because the premium part of that market is very small. But over time, we expect that to grow. So we're really investing in all the capabilities and infrastructure necessary to grow in that market in the future and it's going to grow as regulatory forces are put in place there and even more importantly they're enforced. And there's going to be a lot of multinational companies that follow in there. So over time that'll grow, but that's a longer-term horizon for us but we're investing in it now.

So really an importance for generics customers is really a robust operating network and really what they need is speed and they're looking for faster time to market. They're looking for shorter lead times, and this is very, very important for them. In the U.S. for example, if you're the first one to register your generic product, you can have an exclusivity period. This is very important, very important they work with the vendor to get that position and be early on in that space.

Additionally, you can see some unforeseen spikes in demand [ph] than the suppliers may be (36:34) ready for. We can have a drug shortage. You could require the generics company to respond within two months of that shortage and if you back that up to the supply chain, that's a lot less than two months for the vendors to respond to that. So they want all this, but they really don't want to take a lot of risk and that's very indicative of our industry, so they want these high performance – increasing performance product for regulatory but they also want low risk. They want low supply chain risk and they want lower regulatory risk as well.

This is a really important slide for me as the Generics leader because Generics is really the one part of West that has the most global reach. We're talking about South America, we're talking about Asia Pacific, we're also talking about all the developed countries, but there's a lot of global reach here. So, this network that we're creating in West is absolutely critical for the Generics business. So, as was mentioned earlier and will be discussed later with Don McMillan, who's Head of our Global Operations.

This network is really important and Don and I will be working very closely together. Don, whether you like it or not, I'm going to be seeing a lot of you in the future as we really develop, really develop this network. But the network is really not just on the operating footprint that we already have in place, but it's developing our footprint around sales, service, regulatory.

Speaking of regulatory, I was at the PDA Conference this summer and there was a lot of very interesting topics and with the packaging side, but the one thing that really surprised me was the presentation that was on the multinationals moving to the Asia-Pacific region, and this really was the dominant energy of that conference and the number of questions we had in that conference. And if you start to look into it, it's kind of a moving target and it's very complex. West knows that. Many of the leaders you're going to see today – actually, three of us spent a whole week in Asia last week just working on that plan and how we're going to move that forward, very important to us.

In the last year, West established a regulatory office and staffed it in Beijing, China. These are all steps we're taking to prepare us for the future in those emerging markets. When you look at what's going on with the companies in the generics space, there's a lot of consolidation going on. I also talked about all the growth opportunities, the things coming out of the funnel. So, what's happened with these companies as many of them are getting bigger, very big very fast and there is some degree of consolidation. So that's kind of one driver they're looking at. Another driver is, because they're getting bigger and faster, there's also some more competitive forces for them, so some of them are looking for differentiation.

Both of those are important and both of those play in this value chain that I'm going to talk about here at West. [ph] Well, (39:24) most of the generics are playing kind of on the lower end of the spectrum, but there are customers, who reach all the way across [ph] even the devices (39:30) in a generics world.

So I'm going to talk to you next about a case that's very typical for West that's taken place in the last three years that kind of plays to this trend that we're seeing. So, we have an important customer in our generics space. They were really only buying what you call standard products from offices, a very good business. As Karen said, this is a good business for us, but they had a problem, the problem was twofold.

One was very common in the industry and that's increased regulatory pressures, which means they had to start performing from a quality point of view at a different level. And the second is this customer could see what was going on in the marketplace and they were looking to make a real step change in terms of the size and growth of their business. So, they were being very, very aggressive in their strategy.

So that led to a number of issues for them. And those issues include – hey, I don't really have the capabilities in my current process [indiscernible] (40:32) the quality I need. I'm not really sure what process I need in the future. I don't really have the capacity in these processes to grow like I need to grow in the business and also I've got only so much capital and I really want to put that capital in my core, which is making these drugs versus working on the packaging and washing systems.

Additionally, they weren't able to respond fast enough on their supply chain to the needs of the market going forward and they had some other unforeseen problems that they had [ph] that they never were going to (41:04) face in the future. So, three years ago we started this discussion with this customer and we started working through these issues one by one. In the end, we were able to convert them to our industrial washing – pharmaceutical washing system and RS. We immediately converted all their products over.

So what did that do for them? It took away their problem of how do I deal with this issue or I'm having yield problems and things like that, how do I improve my process to get there. It took away all their capacity needs because we could leverage our network in our global network to meet their capacity and demand spikes. And it also allowed them to refocus their resource, not only the resource they spend on doing that internally, but their capital resources for them.

Additionally, after just two years, they could see the value [ph] of this (41:58) and they started to move a large part of [ph] the rest of their (41:58) portfolio to Westar RU, so it's the same story, but now they don't have to wash and they don't have to sterilize their products. So that means that comes in the door already done for them. That increases their speed dramatically from their end in terms of what they can do and how fast they can come to the market. We also [ph] partner (42:19) with these guys. Very, very difficult sometimes to understand the demand in the generics market and it can have a big [ph] pay out (42:22), especially if you're a big customer in terms of what it means from a supply chain point of view, when that unexpectedly slashes down.

So we work with them very closely to understand their market not just today but tomorrow and what type of issues to come in the forefront. And we've been able to put them into the position to respond much more quickly to market needs and we developed an R&D funnel together with them, which is also critical. So at the end of three years, instead of having a customer, we have a strategic partner. We've allowed our customer to meet all their quality requirements, grow significantly in a much more [ph] effort (42:58) for them and we've also developed the funnel for the future and I really expect future growth. And the nice thing for West is we're able to grow our revenue 50% in just three years, which was really significant [ph] and I will (43:10) share with you where we started with this customer. That's a very normal story that's going on right now in the generic space and it's really a big win for the customer and for West.

So, my last slide here just wrapping up, some of the big pathways to success for us in the generic space, one is to continue to grow these high-value solutions. For folks who are following West, that's probably – you've heard that many times. In the generic space, I think there's a really long runway for us in this area. But it's going to come [ph] and (43:44) really with much bigger customers as these things are consolidating and these partnerships that we form with these customers are going to be incredibly important going forward.

The other thing we did was we talked about the emerging markets and we really want to work on expanding that premium space that's in that emerging market, which is really a populated initially mainly by multinational customers, and we have to make a pathway for them to get there and build the infrastructure for them to get there. And establishing ourselves, our brand and our presence initially through the generics segment into the emerging markets is critical. That's going to create a gateway for all the West portfolio in the future.

And finally, thirdly, we want to leverage our global network. This is critical. This is actually for me one of biggest assets that I have in dealing with this space. This global network that we have is something that is very valuable. It's a win for our customers because of what we can do in their supply chain. It's a win for West [ph] it says (44:43) we can leverage our assets and prove our return on invested capital. And it's a win for me as the leader because I don't know [ph] that anyone else in industry (44:50) can respond to these kind of needs.

Finally, as we look at these market-led teams – and you'll have Graham Reynolds come up here to talk about biologics and you hear my story and you hear the generics story and you hear how different they are and how different the markets are. This market-led focus is going to lead to [indiscernible] (45:10) much more tailored products and services for each segment, the things that are really valued by these segments. And I have no doubt today we have a beautiful portfolio, but there's more things in the portfolio that we can sell into the generic space.

There's also additional products and services that are extremely valuable that under this new organizational structure, we'll start bringing to market and will really make much more difference for us in the future. So thank you very much for your time. I'm very happy to speak to you about Generics. My cab leaves at 12:00 if anyone wants to talk about generics. But the next thing to do is introduce my colleague and friend, Heino Lennartz, to talk about the pharma market.

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## Heino Lennartz

*Vice President & General Manager, Global Pharma*

Thank you very much, Chris. Good morning, ladies and gentlemen. My name is Heino Lennartz. I'm European-based Vice President and General Manager for the Pharma business unit. I have more than 20 years business experience like most of us have and that also in different industries and in most of the times in business management roles and also in technical roles, where I have been also really banging on on my education. I'm holding a degree, an MBA degree and also a technical degree from a German university.

I'm very proud to be part of that excited team here to now be a little bit more focused even on customer and market-led initiatives for West. Important for us I think is that we also look a little bit about deeper into the different segments and I will give you an overview about the Pharma segment.

The pharma market when you really look into that, it's at this point of time one of our backbones of the business and that's representing roughly 30% of our forward sales as you have heard already today. We are facing a little bit [ph] the midterm (47:16) or single-digit growth from the market perspective, but as you know, we are really banging on our – an adoption of our high-value product, which is really helping us to outpace the normal market growth, also in the pharma market, which is very important.

As [indiscernible] (47:36) Chris Ryan's saying, emerging markets are very important for us, that's also valid for the pharmaceutical environment and especially for the Pharma segment. And when you look [ph] to that, (47:42) what we have on the slide, by 2020, the market expects that the seven countries are representing 20% of the market. So it's also very important for us to really look and take care after that.

We see a lot of trends that the blockbusters are getting less, and Karen has shown that especially also on the slide for the small molecules, but also we see that we have patient-focused medication and prevention coming downstream, means that the patient focus and the customer focus, that's even more important for us, and West is uniquely placed in that space. So, the pharma environment is now changing due to that whole environment being more patient-focused, smaller batches and smaller products coming upstream, means the pharma base is really focused on total cost of ownership. It's focused on differentiation. It's focused on really life cycle management.



We have a lot of products, which are already longer in the market, where we can have our customers to differentiate, to stay in that maturity curve, and I'll come to that in one of my case studies later on, which really makes a difference for us. That's really important that we can help also our customers. And when you look to the partnerships, we were able in the meantime to really bang on and really create wonderful relationships with our customers. We can help our customers to bridge the gap between that product and the customers' final patient expectations. So we are aligning with our product portfolio and our offerings and integrated solutions the problems of our customers. So we are really [ph] helping that (49:35). That's important.

Total cost of ownership, a very important area in this pharma market. We see that a lot of healthcare systems are changing. Preventive medication is getting more into the focus. The life time and the maturity curve of the products are really effective. So quality, reliability, and especially also pressure of the financial system, it's giving our customers a big problem and we can help them. And I'll give you one example when I come to the slides with the product solutions, where we can offer solutions and help the customer to avoid even their investments and we can utilize that better with our established network.

When we look into the introduction of new products, I think it's also, in the Pharma segment, important that we have a faster market capability. When we look into West product and in the pipeline you have seen that slide with the arrow. I will show you that again. That is really bringing us the capability to bring customers early into the game, and especially from the pharma perspective, that's important because they need to be also, like in the generic field, very quick in the market.

Partnership for life cycle management and I think we will hear a little bit more about that in my case study. When we look into the solutions, what can we do in order to help the customers for these market drivers, we see that we have – coming back to what I said, expectations in the market are different to what the patient is seeing at this point of time from our customers. There we have particulate problems. We have delamination problems. You see a video screen in the back where you can see also some of the examples, which you can really understand there where the delamination plays a problem in the [ph] black (51:35) cycle of the individual patient.

[ph] Think about (51:35) we're dealing with individuals, patients. We need to be very patient-focused. So, our West Envision product can help to reduce particulate directly from square one when the customer uses our products or even for delamination problems, we have a Crystal Zenith polymer structure, which can be used instead of glass, avoiding delamination. So we have a lot of portfolio in our, what we call, high-value product portfolio.

Another one is like we are seeing in the market more and more, avoiding investments. We can bring customers together in order to get into their value stream from their particular production. We have a lot of activities done with our customers together, what we call value stream mapping, so helping the customer to optimize the entire supply chain. There are sometimes simple things, which can help both companies to avoid costs in the whole system, and West is uniquely placed in that. For example with our washing capability, ready-to-use product, the customers don't need to sterilize that themselves.

And then, I think addressing also what we would like to see the market's performance in order to have really a very quick start when customers are facing problems with particulate. We have a product like West FluroTec, where extractable and leachable profiles are much easier to handle because of the barrier coating than some of our competitors can offer in that market.

But not only HVPs are important. From a product perspective, it's the integrated system; the integrated containment and delivery, which is very important. And we see that West is uniquely placed there also and you've heard Chris already talking about that and Karen has given us a deep insight into that, but I want to take our one

specific example, which is the containment of the injection pens, what we can offer is, together with our Crystal Zenith solutions, a very important offering we can really bring into the market.

So, coming to my case study, thinking about differentiation, life cycle management and also total cost of ownership. We had a customer really having problems with some of the products, which are lyophilized powder products and these needs to be administered from nurses into the patients. So, the nurses needed up to 17 steps in order to reconstitute that powder into a liquid form and bring it into the patient. So the reconstitution is very, very difficult, especially when you think about – sometimes powders are very difficult to reconstitute because they can foam. And then, you can't bring it back into the syringe and then you potentially fail the full dose to apply to the patient.

So, we have worked with our product life cycle team and the customer together and have developed a different solution, what we call a vial adapter, a vented vial adapter together with the FluroTec component, which you'll see on the screen here. And you can see that also back in the video screens how we can use also this administration product. This has helped to reduce the whole cycle up to five cycles that nurses needed to do instead of the up to 17. So that was very important in order to have the customer, in order to have a product, which is now much better placed in the market because that's a differentiator in the market compared to others, and it bought a little bit back the maturity curve to a longer, stable environment for our customers to be sold in the market. So that's very important that we can help our customers to avoid also [ph] an early (55:48) going down from the product life cycle.

So when we really look into the environment, what is in summary important for the pharma market? Strong customer relationships are very important for us and we have a lot of very good relationships, which really brings us forward also to understand the customer and patient needs and you've seen that in some of our product that we can bring that into our development. A very strong patient focus, which is helping us to be very clear in our product development and even being better in the development of smaller batches, helping the customers to be very differentiated compared to their competition.

Risk mitigation is very important in our environment at this point in time. So West is uniquely placed in the environment. Because we have a global footprint, customers are looking for dual sourcing opportunities, but due to the situation that they fear that one supplier might fail and we need another manufacturing side. West has a global network. We can help the customer by really bringing upstream different sites in the sourcing. And then when we look into the differentiation, as I mentioned already that's very important that we help our customers [ph] the (57:13) unique opportunities in order to stay longer into the maturity curve of our product.

And lastly, the emerging seven countries are very important for us and drives the value upstream for us in the future, which we can generate really nice business also in that market environment. So thanks very much for your attention. I will hand over to Graham Reynolds, the Vice President for Global Biologics.

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## Graham S. Reynolds

*Vice President & General Manager, Global Biologics, West Pharmaceutical Services, Inc.*

Thank you, Heino, and good morning, everyone. It's a pleasure to be here, and I think it's a great opportunity and I'm very proud to be part of this management team at West. I'm also proud to have the opportunity to talk to many shareholders, investors, and I'm sure there are many of us in the room who look very excitedly at the future of West.



I can also probably guarantee that everybody in this room at some point in their life or in the future will be a patient and will use West technologies and products. So you'll hear a lot about the focus on the patient. It's really about us, our families and our people that take care of us, so I think we should keep that in mind as we go through.

So a little bit about me, I guess I officially have the honor to be one of the old-timers at West now. I've been with West for 35 years. I joined as a trainee Rubber Technologies when I had no clue what rubber was. I spent 25 years of my West life in Europe, and I had the opportunity to work on many different things, including closure technology, sales, marketing, et cetera. The last 10 years, I've had the opportunity to move here to the U.S. and that's really – I want to just put a frame of reference around the last 10 years at West.

There were some very significant things that happened 10 years ago. One of them was I moved to the U.S., but that's probably more significant for me and my family personally than anybody else, but there were several key things that started. West took a direction to say we need to focus on broadening our portfolio and think about delivery devices as it relates to injectable products.

We made an acquisition of The Tech Group and you'll hear from Mike Treadaway, who really has led that organization since the acquisition, and that has become such a key part of our business as we move further into delivery systems and devices.

We acquired a company called Medimop, who took us into the area of proprietary technologies for delivery devices. We started an initiative around innovation, and you'll hear from John Paproski, who I've had the honor to work with for the last 10 years, who is riding off into the Arizona sunset on retirement, but leaving a legacy of products that we've created in the last 10 years.

And bring us to today, I'm so proud to be part of this team, and also leading the biologics effort, because one of the key things that we'll learn about biologics, first of all, it's a very significantly growing market. We'll talk about some facts and figures, many of the new drugs today are biologically derived, many of them need to be self-administered.

West has a unique position in that marketplace. I often get asked about competitors. Who are your competitors? And I guess my first answer is there is no one in this world that can do everything that West does from start to finish.

We have competition at different stages of our process, but when we think about the ability to go from two men and a molecule developing something with a dream of a lifesaving drug, right through to the patient, helping patients, helping our customers to contain their drugs, to deliver them, helping patients with adherence solutions, better devices, there's no one that can do all that. We don't do everything ourselves. We have great alliances and partnerships and collaborations in the industry and I think our depth of knowledge brings us to that point.

So, I'm going to talk a little about biologics. I'll have a couple of case studies that really show the importance of those key factors of understanding devices and the container, bringing it all together and that's really where West has a sweet spot.

The biologics market is growing as we know. It's growing a little faster than the rest of the pharma market. That reflects on our business also. It's about 20% of West sales today relate to biologic activities. We expect that to grow and we expect it to grow a little faster than maybe the rest of West business. If you look at the pharmaceutical market today, five out of the top 10 drugs are biologic. Two years ago, the ratio was much different and in the future, who knows, we expect that there'll be more biologics that are representing again our blockbuster products.

But if you look at what's coming, we did an analysis recently and we found 7,000 molecules under development in the biologics space, 7,000 drugs that are at various different stages of development, some in very early phases, some close to reaching market. The good thing from a West perspective is virtually all of those are injectable. 98% of all biologics today are injected. It'll be great if we could find a magic pill that people could swallow and it would replace the need for injections. But the fact is most biologics today are injected and we see that continuing in the future.

The other thing to recognize is that those 7,000 drugs are being developed by a combination of the big biotech companies and very, very small companies. The two men and a molecule that maybe working on the next lifesaving or therapeutic drug, but there are many, many small companies, and I think, the good thing about West is that we target not just the big companies and you'll hear a couple of case studies that relate to those big biotech companies, but the small companies as well, because those small companies may turn into big companies at some point. They need more help in some ways than the bigger guys because they have real needs and they benefit from West understanding.

So, when we think about the needs of our customers today, and I think as Karen said, I think, one of the good things about being this market-lead approach is it allows us to really focus on the markets that we serve. So, the needs of my segment in biologics are much different than they are for generics or for pharma or contract manufacturing, so by really understanding the needs in those areas.

So, what are some of the key things? Many newer drugs, many new biologic drugs are very, very complicated molecules. That makes them very sensitive to interaction with their containment systems. It also makes them to a point where you need to deliver a high volume of dose to get an effective therapy. So, we're seeing a lot of new drugs, where you need to deliver not just 1 ml, which is typical for a syringe, but 2 ml, 5 ml, 10 ml in order to get an effective dose.

But also the focus on the patient, what if you could say to a patient, instead of taking a daily dose, you take a weekly dose, but it's a higher volume. Maybe you go to a monthly dose and that's an even higher volume. How do we understand the needs of those patients to make sure that we can provide them with delivery solutions that work for them?

So, we're not going to see huge blockbusters in terms of 100 million units of product in the biologic space. We're starting to see drugs, and I was talking to one of my colleagues recently, that working with a small biotech company in the Pennsylvania area or Philadelphia area, they're talking about the potential for a \$1 million drug. One shot of a drug could be a million dollars. Now, if that cured blindness or cured some disease, who is to say what the value of that drug should be. So, there are going to be smaller units and that drives our needs to be able to support that.

We're also seeing a trend away from the hospital environment to the home environment. So, I think the fact is that if you have a patient who is treated in a hospital maybe with infusion therapy, they have to travel to the hospital, they have to sit in the doctor's office, they have to get wired up for an infusion. What if you could say to that patient, you can treat yourself at home, you can take this medicine through a device that's been developed specifically for you, it's very easy to use? So, we see this trend from the hospital to the home environment.

But what that's driving is the need for devices and delivery technologies that are really focused on those types of therapies where you can give something to a patient and say, here's how you can take your medicine very simply and effectively. And John and Eric and his team will talk a little more about these technologies in detail and would be happy to talk a little more at the back of the room as well.

This is a chart you've seen throughout the presentation, but what it really represents is the breadth of West capabilities. And from a biologics perspective, we have many customers, they start with FluroTec. If they have a new drug, they wouldn't consider anything other than FluroTec with the highest possible level of cleanliness and quality. They also start on many occasions with a Crystal Zenith vial system, because as you'll see from the case study, they learn the benefit. So, they start their process with what they believe to be the optimum container system. And then, we can help them through that journey to lead towards more delivery technologies.

So, let me tell you a little story about one of those 1,600 companies that we talked about. So in 2004, so 11 years ago – 12 years ago, one of our technical sales specialists had a meeting in Massachusetts with a company called BioVex. BioVex at that time were just setting up an office and he relays the story that he walks in, they have one conference table and folding chairs. That was the nature of their business at that time, that they started their business, they had a dream, they were developing a new product to treat melanoma, they thought it would be great, but they needed some help.

We helped them, we helped them to select the container system. When they had interaction problems with glass, we provided them a Crystal Zenith vial to overcome that. When they had issues of low temperature storage and they wanted to make sure that they retain the sealability of the unit at a cold temperature, we provided them that. We'd already started with FluroTec because we knew that, that was going to be the lowest risk solution to help them to get their drug to market.

So, we helped them. From 2004, they went through Phase I, Phase II, Phase III clinical trials, all the way we were helping them with consultation. We helped to advise them on filling processes, who could do that for them, et cetera. And the net result was that in 2011, BioVex was sold to Amgen for \$1 billion. So, Amgen saw this product that it reached a certain level of effectiveness, and it was launched by Amgen last year. The drug name is [indiscernible] (01:08:48). We have a press release that indicates that. So, that's out in the public domain.

This was the first biologic approved in a Crystal Zenith vial. There are many other drugs approved in CZ, our Crystal Zenith, but it was notable because it was the first biologic. But it started 11 years ago. And I can tell you, we have a very strong pipeline of other bio [ph] access (01:09:12) that we started 11 years ago, some sooner, some further in the past. But this is really where we see a lot of our future. So, we were able to provide a CZ vial with FluroTec stopper, ready-to-use seal and that product is now on market.

Second case study is – it's a little different. In this case, we started to work with the large biotech company. And again, this is in the public domain. This is Amgen. One of the things I would say is that there are many other companies, the fact that I give you two case studies on Amgen is the fact that we have a very good relationship with them and we were able to use their name publicly to highlight some of these innovations.

So, back in around 2007, I think it was, we started to have early discussions with Amgen about the ability to deliver a high dose of a new category of drugs, the PCSK9 drugs to treat cholesterol. The challenge they had was it was a very sensitive molecule but they needed to deliver a high dose to get a monthly dose into the patient. They saw that as a real competitive differentiator, instead of having multiple injections just one per month would be beneficial.

So, we work with them very actively for many years developing not just the SmartDose technology but also the container system having a validated Crystal Zenith FluroTec container that was ready to fill. We helped them set up filling capabilities to make that happen and that product was filed for approval in October last year, so we look forward to next steps on that.

So, just to conclude. Biologics is a really significant growing opportunity for West. And when you think about the combination of drug containment and drug delivery devices, you'll learn a little more about some of the newer technologies, how we're getting into adherence solutions around digital technologies, more patient-centered design. This brings us to a unique space that we can go on that journey with the BioVex or a similar company for 11 years, 12 years, 20 years, however long it takes to get those lifesaving medicines to market.

We're in a great position. We have technologies that really support that process in that journey. We're seeing the evolution of new therapeutic areas. Who would have thought that we'd be treating cholesterol with injections or asthma with injection, dermatitis, et cetera? So, there's a huge pipeline of these types of new drugs that are coming through the system. So, we do see some growth, but it's really about understanding the patient needs, providing the right solutions, being prepared to take that journey with our customers, and ultimately, we can all be successful and treat patients like us in the future.

So, with that, thank you for your attention. I'll pass over to Mike Treadaway.

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## Mike Treadaway

*Vice President & General Manager-Contract Manufacturing, West Pharmaceutical Services, Inc.*

Thank you, Graham. Good morning, everybody. My name is Mike Treadaway and I am responsible for the contract manufacturing division within West. Little bit about me. I've been in the industry – manufacturing industry for 35 years. 19 years with The Tech Group and we were acquired by West 10 years ago.

The contract manufacturing operation operates out of eight facilities in North America, Puerto Rico and Ireland. Within those facilities, we have about 1 million square feet, 300 injection molding machines, and 50 high-speed automation systems.

The contract manufacturing business, as was pointed out earlier, is about a \$300 million business, about 20% of West overall sales. We've had modest growth over the last four years, adding about \$30 million in new business and about 4% compounded annual growth.

We really concentrate our business into four markets: drug delivery systems, where we make injection systems for insulin, auto injectors; we have diagnostics business, where we make consumables for point-of-care diagnostics and also devices for the continuous glucose monitoring segment. We have medical disposables, where we make lab filters, blood filters, disposable surgical equipment, and then we have a consumer division that makes oral care products, nurser assemblies and some beverage products.

If we look at the growth of the business, we're going to grow about the rate of the rest of West over the next five years and continue to be about 20% of the overall business. Two areas that we're really seeing significant growth in, Karen talked how self injection is a growing industry, also you heard Graham talked about it, and also a lot of the new drug approvals are being approved with the device.

So, we're seeing significant growth in that area, but another area we're seeing even higher rates of growth is in the diagnostics area. Point-of-care, where you're looking for more rapid tests that are less expensive, but also in the continuous glucose monitoring area, we're seeing very significant growth there.

So, what are our customers looking for? They're trusting us with making their devices to deliver their drug or perform a test and they are under very heavy regulatory scrutiny. So, they need to make sure that their suppliers understand how to navigate that regulatory field. They're looking for manufacturing excellence. They need predictability, they need quality, and they also need capabilities. They want a one-stop shop. They want to go to a

supplier that has design capabilities, that has manufacturing capabilities. They can deliver a finished product sterilized to their customer.

And they're really looking for depth of experience. There are a lot of contract manufacturing companies that have been around for a long time, that are making a big push in the medical industry. They are looking for those contract manufacturers that have years and years of experience and with the West contract manufacturing, we have over 30 years of experience in the medical industry.

If we look at our business, 90% of what we do is in the medical market and that makes us unique. And the last five years, 100% of our focus has been on the medical industry, and there are just a handful of contract manufacturers out there like us, but we're the only one that has such a high concentration in this area. We are the world's largest manufacturer of auto-injectors. And that became very personal to me a couple of weeks ago when my granddaughter had to go to the hospital with a peanut allergy. My daughter now carries an auto-injector for her in her purse. So, it became very personal for me here recently. We're also the world's largest manufacturer of continuous glucose monitors, which is a very rapidly expanding area.

We have compliant and tested quality systems. Last year, we had more than 50 audits from customers, from the FDA and happy to say no 483s, no major findings. So, we're fortunate that we have a very sophisticated customer base. It comes in on a regular basis, checks our quality systems and we know that they're very compliant.

A quality culture. From our standpoint, quality is number one and in the contract manufacturing division, we have over 100 either certified Master Black Belts, Black Belts or Green Belts. 44% of all of our employees have either been trained in Six Sigma or Lean and that system ensures that we're constantly improving processes and improving quality.

Advanced manufacturing systems. About five years ago, we began investing in a system to monitor all of our production equipment. We're getting two main benefits from that. The first benefit is from a quality aspect. We now have every single manufacturing machine within tech group hooked up to this system, we're monitoring 15 variables on each molding machine making sure that every single part we make every day meets the highest level of quality standards. The system also provides us significant data for manufacturing to make sure that we're utilizing the equipment as best we can and we have no unscheduled downtime, so we can have reliable deliveries to our customers.

Every day we take over 10 million data points with this system and analyze them to make sure that we're making quality product. That system received the Frost & Sullivan Manufacturing Leadership Award last year. And we call that our E2 system or our digital factory.

Full-service provider. We have capabilities to help our customers design product for manufacturability. We have the capabilities to design high-speed automated systems. We have the capability to handle drug and assemble that into a device. We also can finish package and sterilize product for customers. We can provide all the full services that our customers need.

I'll give you a case study here. We had a U.S.-based customer that was developing a novel medical device. And they wanted to have an engineering team near their team here in the U.S. to develop a product that was going to be marketed in Europe. So, they also needed a supplier to have capabilities to manufacture that in Europe. So, we helped them design this product. We transferred the technology to our facility in Ireland and got it underway.

Shortly after that product was introduced, the customer realized that the market was much bigger than they anticipated. So, we had to scale up our operation in Ireland to increase our output by 20 times what was originally

anticipated. We're able to do that in a very short period of time, and get the customer the product they needed for their market.

Just to summarize quickly here, what do we need to do going forward? We need to continue to drive manufacturing excellence. The contract manufacturing world that we live in is highly competitive, and is very cost-sensitive. We need to make sure that we have systems in place that not only provide the highest levels of quality, but also the lowest possible costs.

Full service provider, we need to make sure that we continue to add those capabilities that our customers are looking for, so we can provide finished product for them. And then, we need the global West network as we move forward and work with customers in emerging markets.

So, that's a very quick overview of contract manufacturing. I'd like to introduce Mike Schaefer, who's our Vice President of Product Management.

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## Mike Schaefer

*Vice President-Product Management, West Pharmaceutical Services, Inc.*

Thanks, Mike, and good morning, ladies and gentlemen. As Mike indicated, my name is Mike Schaefer and I'm in charge of global product management at West. And it looks like I'm the guy between you and the break, but I promise you I will keep it interesting and entertaining.

First of all, a few words about myself. I'm with West for now almost 16 years in customer-facing technical and commercial roles, and I've spent all my professional career in pharma and related industries. I worked in during that time with patients, healthcare professionals. Have worked by serving clients in pharma and biopharmaceutical industries as a contract manufacturer. And finally, I'm now with West.

I have the pleasure to give you some deeper insights in to our portfolio of proprietary products and services. And I would really like to share my excitement about our strong portfolio, our capabilities, because they really serve as a strong competitive advantage and as a future growth driver as we have seen before from Karen and Eric.

As you heard in the previous presentations, you know now what are the markets that we are focusing on. You heard about different customer needs and challenges that we are facing and how we are also able to address the different needs with our products. I would like to bring it now one level higher and really show you a more realistic picture of our portfolio and how these different puzzle pieces fit together, because it's important to understand that West is really uniquely positioned to address these different market and customer needs to our tailored products and services. The portfolio in itself can be basically split in two categories, one is around component and containment solution, and the second category is around contract manufacturing and proprietary delivery devices.

It all starts with component and containment solution, and here the portfolio starts with standard packaging components for basic customer needs and more importantly, our high-value products and the Daikyo portfolio, because they are really addressing key customer needs to support for example, the trend towards outsourcing to help customers to lower the total cost of ownership in their production, while at the same time, addressing the steadily increasing quality expectations.

It's always important, if you think about the component or containment solution, to keep in mind that these components and containment solutions are essential for the drug quality, for the patient safety and in combination with an injection device, they are also important for the functionality and performance of a device.



That leads me to the second category, contract manufacturing and delivery devices. Here we are really able to provide differentiated solutions to patients and customers, always with the objective to increase patient adherence, patient safety and also therapeutic outcomes.

What is really important for West is the capability to provide integrated component and containment solution, by really merging the portfolio we have around component, containment and delivery to provide these integrated systems and that goes hand-in-hand with our in-depth knowledge of the drug material device [indiscernible] (01:24:30), and that's really a very unique competitive differentiator for us and really allows us to play this role in the market.

When you think about the different market and customer needs, we need to understand that this drives also definitely different needs in terms of products and services. But at the same time, also different drug products have different needs in terms of containment solutions and device solutions.

A last but not least, also customers have different maturity levels. Some customers are staying with basic solution and try to keep their process as in-house, whereas others and that's turning to become a majority, are more open for outsourcing solutions and are also very interested in innovative device technology. So, within the next couple of minutes I will give you some deeper insights how we are really able to address these very different customer needs with our portfolio.

It always starts with standard packaging components, and here we talk about stoppers, plungers, Flip-Off Seals that you can see also during the break in the displays that we have in the back. And of course, disposable components like [ph] blood tubes (01:25:39), stoppers, like disposable syringe plungers.

These are quality components for basic customer needs but require at the same time still in-house processing at a customer. Because of increasing quality and regulatory expectations and also the continuous trend towards outsourcing that you heard about already a couple of times today, customers tend to favor now more and more our high-value product portfolio as their prime choice.

Typical examples of our high value product portfolio are FluroTec, that's our really proven barrier coating for demanding drug compounds, and this has become really the gold standard for packaging of biologics as you have heard from Graham already.

On the other side, additional examples are Westar RS or Westar RU as you can see here, Flip-Off Plus, Flip-Off CCS representing ready-to-sterilize and sterile closures and seals to support the trend towards outsourcing.

Last but not least, the latest addition to our portfolio, NovaPure, that's really a product line designed and manufactured around using and applying QbD, Quality by Design principles. We see objectives to provide to customers the product that has minimal variations in quality, with the objective to maximize patient safety, which of course is of utmost importance in our business.

The portfolio of our partner, Daikyo, is very nicely complementing our high-value product portfolio with another set of component and containment solutions of unrivaled quality. West and Daikyo are partners since 1973, and we are working collaboratively together on the commercial and also technical side to provide best possible solutions for our customer base.

Examples of Daikyo's component innovations are Daikyo RSV and Daikyo RUV. These components are representing 100% camera-inspected FluroTec components, which are in a ready-to-sterilize and ready-to-use format to meet the needs of very demanding customers or very demanding markets, like for example the Japanese



market. As you know, the Japanese market is driven by perfect visual appearance and perfection. So, that's an offering that really place very strongly in this market.

Another product portfolio we have is around Daikyo CZ, you heard that already in previous presentation. This is really a high-end, polymer-based containment solution in the form of vials, syringes and cartridges, which represents the low risk as relative to glass, especially when issues and challenges like drug stability, protein aggregation, glass delamination or breakage kind of [indiscernible] (01:28:26). So, as you've seen, this is really nicely complementing our high-value product portfolio.

Mike talked already about our contract manufacturing capabilities and services, so I'm directly moving on now into our proprietary delivery devices, where we are also able as I said before to address very different customer needs and I would like to take an example out of the world of reconstitution, mixing, and administration of [ph] live-to-life (01:28:53) product, and a lot of drug products out of the bio area first get into a [ph] live-to-life (01:29:00) format, because it allows customers to get very fast into the market.

Patients in the oncology and hemophilia area heavily depend on product solutions like vial adapters, Mix2Vial, Vial2Bag in order to get their therapies. Imagine hemophilia patient. The hemophilia patient can't afford any needlestick injury. So they really rely on solution like a vial adapter or Mix2Vial to allow a very smooth, efficient and safe reconstitution, mixing and administration of the lifesaving factor VIII product, instead of fiddling around with multiple vials, multiple syringes, multiple needles, always and permanently exposed to the risk of needle injuries.

Another example that you see on the slide is Vial2Bag. It's widely used in hospitals to allow again reconstitution and transfer of drugs into an IV bag, which is then infused in the patient and it really helps in the healthcare environment to allow these therapies in an effective and safe manner.

In the area of self-injection devices, we have multiple options to address really the needs of [indiscernible] (1:30:11) different drug products, because you can imagine drug product has different [indiscernible] (1:30:14) volumes, et cetera. On the other side, different patient and therapies also require different self-injection devices. So, it all needs to be very customized and tailored to the patient groups of the drug product and the therapy.

And two examples I want to highlight here are SelfDose, that's our patient-controlled self-injection system; and on the other side, SmartDose, you have already heard about that in Graham's presentation, that's our leading-edge electronic wearable self-injector. But it's very important to still put it into the context of our capability and our strength to offer integrated component containment solution by really – sorry, containment and delivery solutions by merging the components, the containment, and the deliverable device, and our strong know-how around the drugs material interface and also the impact of component on the device performance.

Another key aspect I want to highlight is our scientific expertise. We are continuously providing technical, documentation, studies, application, we host conferences, et cetera, to discuss hot topics within the industry, so we are really turning into opinion leadership and evolve as a company to a scientific destination that our companies are turning to, if they have questions about our product, but also about industry issues and hot topics.

This, as you have seen, is a very strong competitive advantage but it's also very interlinked with our analytical laboratory testing, because a lot of these scientific materials need of course studies, testing, et cetera. With our analytical testing capabilities, we provide support to our customers during the drug development cycle, but also during the product lifecycle and that can be for example in early development compatibility tests where we help customers to find device container for the drug products that can be extractable/leachable tests, container closure

integrity tests, design verification studies, during customer development and registration phase and even continues after the launch into services like particle testing, compendial testing on commercial products.

So, as you have seen, we are able to address steadily increasing customer and patient expectations in multiple ways, and by doing so, we are upgrading customers more and more to our proprietary products and services. By being able to provide these superior solutions and especially as I said before to provide integrated containment and delivery solutions to customers, we provide more value to the customer, more value to the patient, but finally also to us.

It is important that it is a very high value for our customer to be fast-to-market, to have a very safe way of administering a drug product, to ensure the patient adherence is high, et cetera, and then of course is a key benefit and the key value driver [ph] for them. (1:33:18)

Having said that, we need to keep in mind that this journey of course requires also investment in infrastructure and in capacities because all of this proprietary products require [ph] cleaner (1:33:30) manufacturing space, some of them require [indiscernible] (1:33:34) space, some of them require [indiscernible] (1:33:38) et cetera. So, we need to prepare and invest early enough in infrastructure and capacities, and Don McMillan, our Vice President, Global Operations will talk more about after the break.

So to wrap it and release you into the break, you have seen that our portfolio is, I would say, very well balanced, acts as a very strong competitive differentiator, especially the benefit of us being able to provide integrated containment and delivery solution placed to our strength. However, we need to leverage the opportunities that we have at hand, we need to leverage the strengths, but also need to continuously refill our pipeline and that's another area I want to draw your attention to because by our close customer context and relationships and partnerships, we are also able to hear and get information about unmet market and customer needs and then can collaboratively work with customers on finding solution. [indiscernible] (1:34:35) portfolio as you see it here are working with customers closely to find new innovative solutions.

And after the break, you will hear from John Paproski, Eric Resnick about our pipeline, some of these new solutions that we are going to move forward with. And with that, I thank you very much for your attention. Apologize for the few minutes delay, but hand over back to Quintin.

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## Quintin John Lai

*Vice President-Corporate Development, Strategy & Investor Relations*

Thank you, Mike. So, we're about five minutes behind or in West time about 420,000 products have been made. Please, if you have questions, please give it to any West person and we'll accumulate them. We'll have a formal Q&A at the end of the presentation. The display cases are open and after the presentation – after the formal presentation, we're going to have lunch and the display cases will also be available, so please join us after this. So, for everybody on the webcast, we will reconvene again at 10:20. Thank you.

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## Eric M. Green

*Chief Executive Officer & Director*

Okay. Thank you. Hopefully you enjoyed the few minutes on the break. And also, I'm pleased again for the folks on the webcast coming back talking about around innovation and into the global operations and Bill Federici will bring this together from a financial perspective. But before we get started, I just want to thank you for the folks that are here in the auditorium, participating in the West Investor's Day.

As you noticed, I think several of you received a bracelet this morning. Just to let you know, every participant, we are donating to, on your behalf, to the Leukemia & Lymphoma Society for your attendance here. And the reason why we do this is because, at West, we have a very important element and culture around philanthropy, and we have this group called West Without Borders. In the last 15 – I'm sorry about last 12 years, we donated – raised and donated over \$3 million from the employees, so that speaks volume. And in 2016, we're going to focus on supporting LLS and also Fox Chase Cancer Center in the Philadelphia area. So, I just wanted to thank you, again, for your participation and a little donation will be going on your behalf to LLS.

So, without further due, I do want to introduce this next gentleman, 36-year tenure with West. It's been a pleasure working with John for the last 10 months, he's show me the way at West and what West really means. He has his fingerprint on all our plants. He has his fingerprint on all our products, many of our customers, but more importantly, he has his fingerprint on a number of the people that you've been listening to for the first couple of hours in this company. He is retiring. He's been looking at retirement for a while, and now it's an opportunity for him to move on.

But more importantly John has, with my support, we've been looking at who is going to be able to fill his shoes, and with – because he's really developed a lot of good people in this organization, we're really proud to be able to bring Eric Resnick into the organization – I'm sorry, move up in the organization to be our Chief Technology Officer. So, you will hear from both of them today, but I just wanted to highlight John's accomplishments and really thank him for his many, many contributions that supported our employees, our company, and our shareholders around the world.

So, thank you, John.

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## John E. Paproski

*Chief Technology Officer & Senior Vice President*

Hello, everybody. It's my pleasure to be here, and it's been my personal blessing to spend the last 36 years at West. It's – I hope you all have careers that allow you to invest the kind of energy and enthusiasm into your companies that I've had at West, and to see the outcome materialize in the form that it has today where we have so much impact on the world's health, it's really a blessing from me to be able to participate in that way. As Eric said that, to see our pipeline, to see our products, to see our people, and to see the passion of what we do is, it just makes it all worthwhile. It's a wonderful way to retire and it's been my blessing to work with everyone at West.

So, this slide is one that I'm sure that you're all familiar with. It's the kind of traditional form of pipeline, and I think it's – a couple messages here that I really want to leave with you. It's obvious that these products take a long time. It's obvious that West is by our customer side throughout this process. If we don't start early with them, when it comes time for their products to commercialize, it's not ready. And the good news is we have a nice long string of deliverables that roll throughout the year. So, I mean, if you go back to our high value product performance of today, it's rooted in what we did with West 15 years ago. I mean, to see these high-value products roll out and grow and grow and new platforms take shape is really about how you pave the way decades ago, and West has been particularly good at that.

If you – later, you'll hear a little deeper about some of our device strategies and how they marry with primary container. I think as you keep that in mind and consider this pipeline and the number of biologics that are coming out and the importance of West in that, you can see that we're not just going after another stop for sale. We're trying to change the way patient is treated and we're trying to have an impact on their health in the long run, but for our shareholders and what we're trying to accomplish is a higher value for each injection that we participate in.

You'll see we can easily move – we can easily move the value of West revenue from participating at the sale of a single component to full systems. And these systems are very complicated and very valuable.

So, where has this taken us, at this stage of time? So, our traditional business in the primary containers, you heard a lot about NovaPure and some of our Westar history. Over the last years, we've been happy to see NovaPure really take hold in the industry. There's been a lot of interest in the effect that our NovaPure plungers can have on devices. So, we've had cases where customers would want to switch from existing plungers that they've done an enormous amount of work on to NovaPure, because they find that their auto injectors don't work on the plunger choices that they've made. NovaPure has changed that for them.

As we see customers think about large volume injections, the 1 ml to 3 ml NovaPure syringe opens up new categories for us to take NovaPure on. So, I think the theme to keep in mind here is that our high-value products aren't limited to what we see today. It's not just what we sell, it's what we will offer in extensions to these areas and later. And based on what West has done for decades, you go to the delivery system side, you'll see SmartDose, for us, really a super exciting product. I think for patients a super exciting product. I mean, imagine if any of you have dealt with loved ones or yourselves having to go to the hospital to get IVs and to find an option that would actually allow you to treat yourself at home, it's an enormous change.

I mean, it's an enormous change in many ways. And what's you'll find, when you look at SmartDose is, we start to understand the patient at levels that West never had an opportunity before. I mean, so much of our work with pharma customers has been with a bit of arm's length to the patient and that's changed now. What we find is as we get deeper into understanding how multiple sclerosis patients work, how [ph] cholesterol (1:42:28) patients will work, we start to think about how we can change these devices and integrate the primary container with these devices to change how treatments get. It's a big deal for people. It's a big deal for all of us in the way we'll be treated in the future and especially as it connects the biologics drugs.

One of the things that we have been particularly successful at is taking advantage of innovation that we have landed in Israel. The SmartDose technology was based there. We have enjoyed advancement of the assets that we have in Israel and they continue to provide promise for new ideas in the future. In a few minutes, we'll share with you the outcome of some of those ideas.

And as I said earlier, really the patient-centric approach, when we – as a technologist, I thought that I was going to be worrying about pressure, what pressure [indiscernible] (1:43:26) how much [ph] volume (1:43:27) can you push in the subcutaneous tissue? What do we do about motor energy? How long can batteries last and how can we get the most energy out of the batteries? And we do worry about that stuff, but the irony is the tough stuff that we ran into is what happens when your patient is fat, what happens when your patient has a six-pack abs, what happens if they're hairy, right, those things suddenly matter to you.

It's – and it's not an easy problem to solve when you think some of these through. Simple examples, how do you train? We find ourselves, when we – helping our pharma customers think about the training techniques that they're going to use with their devices right down to providing trainers work, so we will have simulated versions of our products to help them step their patients through the process to ensure that it's easy for patients to use these things.

That patient-centric approach changes the game for us in so many ways. It's not just the impact that you have on your products that you take to market, it's the way you approach what you do. And suddenly every one of us can say, I can imagine myself using this thing on my body or [indiscernible] (1:44:40) see one of my kids doing this, right. It's going to happen. You will see our products used that way. You will be worrying about whether the button

I push is this. Those things suddenly become part of West place to participate and that lets us help our pharma customers and our bio customers be even better and serve their patients better.

So, how we do all of these? We are very fortunate to have an enormous space of long-term people in our presence. We have employees that exceed probably over a third of our employee base that had been with us for over 10 years. That ability to draw on experience is beautiful. There is nothing that I enjoy more. We have tremendous interim programs where we bring youngsters in from college settings to participate at West, and when you see some of the old-timers kind of working hand-in-hand, and some of the new ideas that come out of that interchange with the millennial generation, it's a beautiful thing. It really is exciting to see how these ideas propel themselves.

850 issued patents. We cover ourselves with intellectual property protection on every front. We have done an enormous number of patent applications and continue to do that, protect ourselves well ahead, but there is an important piece of IP to West that again decades older, it started with H. O. West and that is how we protect ourselves through the regulators with trade secret knowledge. When I started at West 36 years ago, it was a manufacturing plant. We literally still make the same products that were on the plant for the day I walked into this place 36 years ago, we still make today. And what our customers want from us is the same product, only better. They want it cleaner. They want it reliable, but they don't want us to change it. They want what they did their studies on and West can do that better than anybody in the world.

65 projects in development. We've talked about our pipeline. You can see our pipeline in the back of the room. The stoppers were settled, but we have fed the industry with our closure systems for decades and we continue – we'll continue to see the fruit of that be borne for a long, long time. We have 12 R&D sites. We haven't been afraid to grab expertise wherever it shows up. We've acquired a whole series of businesses around the world. Typically, we try to keep the entrepreneurs in place. Typically, we try to keep the creativity that goes with those acquisitions in place and have been very effective with that. I would say that we can put a team together at West to do anything that any perennial drug company needs to have done. We can do it for them.

But the organizational changes that we just made make it almost fundamental and make it happen without bringing teams together, so we just shared in our first meetings of the broad integrated R&D team what we saw was people that know each other and had worked together in the past suddenly sharing each other's problems. It's different, go back feeling that your colleague has a problem you can help them with than just going back to your job. Right now, that integrated measure is really an advantage for us that we'll capitalize on for a long time.

So, we talked about the patient focus, so important to us. The ability to be market led, this market segmentation that you saw through our Commercial group, again, allows us to focus very precisely. We continue to increase investments in both people and in our installed based, manufacture of these products, and really the key is collaboration. I think, as I look around that, West [ph] tendencies, (1:48:23) we are a naturally collaborative team. We work together hand-in-hand and you can put West people together anywhere in the world and they will make something happen, but when you see us with a customer, it's a beautiful thing. I mean, it literally – there are certain teams that we had that we participate all with our customers where we'll bring together 20 or 30 on each side and by the end of the meeting, you can't tell who is on which side. The collaboration is so deep and so intense that the two companies move together at a really rapid rate, it's really an impressive capability that we have.

So, with that, I'm going to turn this over to my colleagues both of which have spent the last over 10 years in Eric's case and over 20 years in Scott's. And it's, for me, a pleasure to hand off to them, what has been literally a dream of mine to see innovation become alive, well, and mature at West, and you'll see it in the back of the room in the form of products and you'll see it in our revenue growth in the form of revenue growth in the future.



So, with that, let me turn it over to Scott.

Stay right there. Can you turn me back on? Sorry about that. Something I don't want any of you to miss, okay. Before you leave, go back to the center of the room, there is a – under one of the – under the center display, I know you can't see this thing, but what it is, is kind of a crazy shaped-syringe, okay. It is the fundamental change; it's going to take SmartDose to the next level. We have wanted to put out a pre-loaded version of SmartDose. Preloaded means that the prefilled syringe is already embedded in the device before the patient gets it, and this is the way we're making it happen. Okay.

We talked about some of the technology centers that we had – that's where this is coming from. Okay. The combination of West closers on [ph] this site (01:50:30), CZ molding in our Scottsdale operation that we've grown, the Daikyo plunger that closes it, the technology that's come from our Israeli center that has – that's making the SmartDose delivery system happen, integrated into a system that is phenomenal. It changes – it will change the way patients use SmartDose, it's going to change the way delivery systems are made and whether it's a large volume or a smaller volume, we have versions of that coming that's going to – it's going to change that reality for folks. So go check that out and don't miss the opportunity as Eric described to you.

### Scott Young, Ph.D.

*Vice President, Primary Container Technology, West Pharmaceutical Services, Inc.*

Thank you, John. My name is Scott Young, and I'm Vice President of Primary Container Technology. Just a little bit about myself. I have a PhD in Chemical Engineering with an MBA and compared to John, I'm considered a junior employee in that I only have 22 years here at West. So it's been a pleasure working with John, and we're really going to miss him. But boy, we got – John developed a great team and we're going to keep moving this forward.

What wakes me up in the morning and gets me to work every day and it's really the investments we made through John's tenure. 10 years ago, 5 years ago, that – we're now seeing the fruits of that investment. Graham talked about two of those [ph] on (01:51:53) objectives, one example, that was a CZ vial with a West stopper, with a West closure. What Graham didn't mention was, while this for a – it's an oncolytic drug, it's for melanoma, it's the first viral oncolytic that's on the market. And they went with these components for they knew they get better compatibility and really to lower the risk to make sure when they got to market, they would have something that would be effective. And REPATHA, it was the first time where we took a CZ container integrated into a device, into the SmartDose device, and now that's becoming commercial also. So these commercializations are very, very powerful. I mean, at the end of my short presentation, I'm – give you two case studies of two more that are going to be pending moving forward.

So, why does containment matters? This is sort of a fundamental basis of West products. It is really the elastomer, how it reacts with the container and the drug, and how do we have something that is really safe. It's going to give our customer drug stability, and really, allow our customer to feel like they're going to get something that is going to be run through the stability trials, it's going to be the same every time. There is not going to be any part-to-part variation, lot-to-lot variation, and this is something where we really built a strong business. But what we're trying to do now is, now, traditionally we looked at elastomers at single components. Now we're integrating them into systems, okay. It's whether we are selling the container, we could – most of our components still work with glass. Glass isn't going away. But we need to understand how it functions with glass better and our customers are asking for data there.

They want us to be more involved. They want us to collaborate, and we do a lot of collaboration. They're asking for functional data. So they want to have more functional data, because now they're taking these systems and putting

them maybe in their own auto-injectors [ph] other (01:53:53) devices, and they want to have that data and that confidence that it's going to function and it's going to be reliable. And then you heard a lot of – mention of easy use for the patients. There's a lot of patients that are dexterity-impaired, they might be elderly population, they might have rheumatoid arthritis, and how do we design devices and the containers that go into those devices, so that the patient isn't going to have any issues delivering this especially with the advent of more and more home healthcare and we're on the forefront of doing this. And we actually, now have a group of people who actually are experts in [ph] human science (01:54:29) understand this and how we can design products that will actually help our customers and help the patients. So, they're more compliant and they will have effective use of the device and pharmaceutical product.

So, customers hear about clients, you heard a lot about clients and performance to-date this morning. And there is really getting to be a heightened bar for chemical incompatibility. When you look at biologics, as Graham Reynolds mentioned, there is really a lot of the traditional containers, a lot of traditional components, really have incompatibility with some of the existing systems.

And we want to be involved with delivering products that can actually – are solutions to these, and variability and quality, there is a lot of issues with particulates, there is – customers want lower and lower particulate levels. I saw just yesterday there was a major generics company that actually had glass particulate in a vial where they had a recall and due to glass contamination, something like a Daikyo Crystal Zenith will – can solve that problem, and I'll talk about glass delamination, in a case study. Visual defects, cosmetic defects, customers are asking us to have a 100% camera vision inspection, down to almost the sub-visible level to reduce any kind of contamination that handles [ph] their drug part (01:56:01) and the reliability with the device delivery, things like dimensional control and functionality can affect the injection time. You can imagine if someone's given themselves an auto-injector at home and one day they get a 5-second injection, the next day they get a 12-second injection, they're going to wonder if something is different with the drug and they're not going to feel comfortable knowing that they see that kind of variability. So, this is something where we collaborate with all of the major customers to really get the best delivery device and delivery systems for our customers.

So matching innovation and containment delivery, there's a lot of different aspects on how we're matching innovation, containment and delivery. The common theme is sensitive protein drugs, this is a very, very technical aspect where proteins are very, very – have some incompatibility resisting system. I mentioned reliable auto-injector delivery, this is something where not only auto-injectors, but all devices, how do you make them more reliable? How do you make them so that if a clinician uses it or someone at home uses it, you have the same type of delivery?

We want to be a global leader in quality whether the product is manufactured in one of our European facilities, in our Japanese facility or European facility, there's expectation that you're going to have the same quality across the product and then lifecycle management. Customers want to, maybe first in the human go from a vial to a syringe to an auto-injector, but when they put it in initial syringe for delivery, they don't want to have to develop another product when they go into an auto-injector. They want to be able to use that same syringe, same component to utilize the lifecycle management of their product without having to go back and reiterate in terms of design and development of the packaging component.

One example that you heard [indiscernible] (01:57:51) and a number of other people is West NovaPure. This is something where – it's one of many, our last number of programs, as John mentioned, we have over 65 programs in development, most of them in elastomer technology where our customers, there's expectations to have better characterization of how that particular piston and design the piston to the glass syringe. And this is everything from particulate control, extractables check, it utilizes FluroTec film, how does it perform after steam sterilization, and actually supply that as a whole data package that we give to the customer. And what's interesting about this is



– as we increase that knowledge, and increase that data package, we get a lot more value out and actually can then get more revenue and more value and our customer embraces that. And so this is something where we're going to see more and more solutions that involve the functionality and the data package associated with the entire system.

Now, I just want to tell a little bit about glass. Glass isn't going away, glass is something where – most of our elastomers are associated with glass, either in a vial or a container, but our concern's with glass. There is interactions with sensitive biologics, there is breakage. I mentioned before [ph] Onlogec (01:59:18), that Graham highlighted in his case that you can imagine if you have a live viral oncolytic and you have a breakage situation in a clinic or in a hospital, that's a serious situation. So why would you even take a chance of having any kind of breakage associated with a product that is a live virus, but an extremely valuable product for melanoma.

Things like dimensional variation, you get dimensional variation in glass, you put it in devices, you can end up with breakage, different performance, you can't get the same tolerances on glass as you can with plastics and some other containers. And there is things like variable silicon distribution. The coatings they put on, if you can really get rid of those coatings, you don't have to worry about variability of the coatings. And then just general glass quality. And many of you heard the solution is our Daikyo Crystal Zenith, what we call CZ. So, CZ containment is really getting more and more used really across the whole lifecycle of our customers. And it's used from everything from screw-top containers, the first-in-human in vial. Currently we have vials anything from 0.5 ml for stem-cell-type therapies up to 100 ml for IV-type solutions; to syringes, whether it's Luer Lock, Leur Tip, inserted needle and then take it – take these containers and then design for devices like the SmartDose cartridge with – Eric Resnick will explain in a little bit more detail next.

Now one example of – probably our flagship product is the 1 ml [ph] IN (02:01:03), and you can see an example of this in the back, but this is something where it doesn't have silicon oil, it doesn't have tungsten that is currently in a lot of glass syringes. There's no glue associated with the cannula, and a combination of all those is, you have more suitability for sensitive proteins, and I'll talk about this in a – more detail on one of the case studies. They're break-resistant, because you don't have a – really the break problems that glass has, because you're on silicon oil, you have high functional consistency. John talked about design flexibility, this is huge, and this is huge because glass can only be formed in certain shapes. And when you take the plastics like CZ and you're actually – put the functionality into the container that you currently used to have in the device, you can make the devices easier to use, you can make them easier to manufacture, you can make them easier to sterilize and you get a higher quality product in general. And this is something that really our customers are really, really embracing and we're beginning to collaborate more and more on – let's make something that doesn't look like glass, and you'll get a better product.

So I'm going to talk about two case studies now. So the first one is – I had a question from one of the participants about, do you have CZ that actually has replaced glass on an existing product? And this is an example of that and the next case study is going to talk about how we worked with a major biopharm customer on a pipeline product.

So what this was was a major pharma company had a 50 ml vial that – on a mature product that was facing regulatory hurdles because of glass delamination. And what glass delamination is, is certain compounds, especially high pH, over time you will get glass that actually delaminates off the surface and you will get sub-visible glass particles and glass particles in the area of maybe 500 microns to a 1,000 micron. And there's an illustration here and there's some videos in the back that actually explains this in a little bit more detail.

What was also interesting about this was, we have a good collaboration with a lot of machine vendors. And most of them are based in Southern Germany that supply a lot of the fill finish. We're working with them and our customers and collaborate, we actually participate in the design of how to introduce that into their operation. And now, that particular vendor also is selling that to other companies around the world on how to introduce CZ into

their existing lines, which is a little bit of a hurdle because it's not exactly a drop-in, but this was extremely successful.

So what was the solution? It was Daikyo Crystal Zenith, they didn't have to worry about delamination. They knew they had to do the work for stability, but because of the endurance of the CZ material, they got very, very good stability and so they went through their trials filed with the regulatory agency and are planning on launching later this year in all the major markets worldwide. The second case study is what we call protein compatibility challenge. This was something where there was a very exciting monoclonal antibody from a major biopharma company and they were having some issues with glass compatibility.

So, again due to silicone oil, tungsten, metal extractables that come out of glass, they chose CZ, the other thing that was interesting is they required a 1.2 ml fill. Glass currently you can only fill because the dimensional tolerance is up to about 1 ml and because of the solubility of the protein they needed to have a larger dose so they could give a monthly delivery and because of the enhanced cleanliness, they went with the Daikyo Crystal Zenith 1 ml Long. This is something else where they're just pulling together the final documentation. This is something we collaborated very closely with our customers and they'll be filing later this year for regulatory approval.

So, this is something very exciting – it's another very exciting therapy that could be a big product for West and for our biopharma customers. So with that I'd be happy to talk to any of you at the displays, more about Crystal Zenith and about containers technology. We have a lot going on, it's just not about Daikyo Crystal Zenith, but it's also about enhancing our existing elastomers portfolio and really getting the best system overall for our customers and integrating those with the devices.

I'd like to introduce Eric Resnick, he's our new Chief Technology Officer and he is going to talk to you about more other exciting developments that we have moving forward.

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## Eric Resnick

*VP & Chief Technology Officer, West Pharmaceutical Services, Inc.*

Good morning, everyone and thank you Scott. I want to start by echoing what Eric Green said about John. It's an honor to be literally and figuratively following him both today and into the future. I always often refer to John as the engineer's engineer, whether he's on product, equipment or factory, he is the guy that you look up to when it comes to just being truly innovative in being the engineer, but it's more than that, great leader, mentor, coach for me personally over the last 10 years and it really is an honor to be stepping in to this role.

It's been 30 years since I graduated with a Plastics Engineering degree and perhaps inspired by the [ph] graduation (02:06:46), maybe it was the 100% job placement record that the university I went to. And the first half of that career was spent in consumer products, which was rewarding, to be able to walk down the aisles of the supermarket and department stores going, see that camera, oh yeah, my team was involved with that one. But see how that film gets packaged, that's – we did that. It is rewarding but it wasn't everything. So, I moved over to the healthcare side and did some work in clinical, chemistry and diagnostics. That wasn't very rewarding after a few years later. And sitting in a hotel room I called Mike Treadaway who was leading The Tech Group at the time and said, you guys hiring? He said, you want to come work for us? I said yeah. He says, how about the end of January? I said perfect, I'll be down there. Didn't tell my wife of course we were moving to Arizona. But it started off really the last 15 years and it's how I ended up where I am today and through a number of just jobs in R&D and engineering and operations, the West acquisition of The Tech Group in 2005 really leading us up to today.

And when I got that excitement of seeing consumer products in the store, was rewarding. But now knowing what we're working on, what we're part of, you heard what Graham said about cholesterol lowering. We're involved

with our products, our devices, our containment systems, and whether it's immunological disorders, Alzheimer's, cholesterol lowering, muscle wasting diseases, to know that you are now part of making people's lives better. Lifesaving quality, life-improving, it doesn't get any better than that, and that frankly is when people say to me, god, you work a lot, you travel all over the world. Doesn't that get tiring? I said, no, I actually love what I do and I'm not lobbying for the job. I got the job, but it is, I tell you, I actually love what I do.

I'm going to talk to you about some products that we have in development, some things that are going to be ready to launch in the near future. It's rewarding to see when Karen Flynn's talking about those products, the things that Mike Treadaway's factories are making. When I was in engineering, we were working on those things and now seeing them come to fruition for our patients and our customers.

Lyophilization is basically freeze-dry. So, if you're aware of freeze-dry foods, so why do we have to freeze-dry a drug? Well, frankly it's about liquid stability. Some drug biologics just aren't stable in the liquid form. They don't have shelf life. So a common thing to do is freeze-dry them, bring them down to a powder. So, just as it applies or suggests, you freeze it and you dry it, you stopper it, you cap it. And then it can be reconstituted, diluent or liquid can be added in, and now you have what's really a reconstituted drug.

The problem that exists today and really what we're about is really getting to solving problems with customers and patients, really understanding what the unmet needs is, the drug is still filled as a liquid, but the stopper is not permanently set, because we still have to dry the liquid off when we do the lyophilization.

Metal seal that you see in the photo here is made of aluminum, aluminum causes flaking. So, that process of capping leaves to aluminum flakes. Now, it's not just an issue. Scott talked about glass contamination. This is not just something that's nice to have. European regulators have now just passed the new law saying when it comes to particulate from capping, there's new regs in place in terms of driving to do basically the elimination of that particulate.

So we came up with a solution. Our R&D team in Europe has been working on is what if we get rid of the metal, why don't we go with the plastic seal. Instead of just having a loose-fitting plunger or seal in place, so I'm going to put a plastic cap over it. That way we don't have potential for contamination of the drug container. We'll definitely get lower particulate from the plastic versus the metal. And then we can combine filling and capping into one step. So, from space of having to separate capping and filling, we reduce the footprint. We have regulatory pressures coming in to reduce particulate, and honestly, we can eliminate or certainly reduce the possibility of contamination between filling and lyophilization. So three improvements that we can bring to the market and bring to our customers.

The product on the other end is another plastic cap that we're working on with our partners at Daikyo. Graham talked about the idea of the big blockbuster, the \$1 billion drug really isn't there with the biologics. They are much smaller in quantity and the annual demand, while maybe in different format, still isn't going to rival the big blockbusters of yesteryear. What the – leading to is our pharmaceutical partners [ph] really likes (2:11:33) flexible manufacturing, the idea of having these massive filling suites, for me doesn't make sense when you have to do constant change over some drug to drug. So they're going to really flexible manufacturing and – coming up with this plastic seal, plastic capping and using a glass or CZ Vial, while we are enabling the use of flexible manufacturing. And it's part of the project. There are two distinct products that we're working on, clearly both serving important needs that are in the market.

We've seen the slide today, why delivery matters? Differentiation, and it's differentiation on two levels. The first level is customer is going to want to buy our technology. We can use SmartDose or SelfDose as an example. They may want unique branding. [ph] They may – don't want to have – they're identified (2:12:16). They're going to

want to make sure it looks like their products with their drug. We certainly can do that. It's part of what we do for customization. But also differentiation when it comes to us. You've heard today about seals [indiscernible] (2:12:31) at the elastomeric level, the component level has been what – has been West business for decades. The global leader in innovation, in technology of sustained quality. Scott talked about container systems with Crystal Zenith as well. So we have now a differentiation. We go to the component for the glass container and now with delivery solution.

John touched on a really round of delivery device. C. Everett Koop was famous for saying, drugs don't work in patients who don't take them, okay. Pretty simple statement, drugs don't work in patients who don't take them. So why doesn't a patient take their drug? Maybe it doesn't feel good from the side effects, maybe they are unconsciously forgetting to take the drug. Either way, we got to get to what causes someone not want to take their therapy. And it's important for a number of reasons, certainly as – in altruistic sense, we want to make sure people get better. But also from a business sense, there's – when customers are buying products from us with delivery systems, the intent is that when it's matched up with their drug, it's going to be sold to a patient who needs it. We have to understand why they're not taking that potential drug, not that we're going to start selling directly to a customer, that's not what we're doing. But it's a lost opportunity. It's bad for the outcome. It's bad for the individual. And we're losing basically the potential for a sale. So we have to make sure our drugs – I'm sorry, our devices are matched up with the drug in mind, and that we understand what the patient is going to be going through.

Karen talked about just the increase in biological approvals in the recent years, and we're seeing this on the device side. Larger volume, more frequent injections, higher viscosity drugs, the demographics of what's going on the population, aging population. I talked about some of the conditions where new drugs are being developed, all require some sort of injection device. The pen injector, we're deeply engaged in the Contract Manufacturing business. Mike Treadaway talked about how he's the world's largest manufacturer of auto-injectors right now.

On the wearable injectors, [ph] we're going to talk (2:14:38) about SmartDose, but the large volume, where asking a patient to give himself multiple injections with a syringe, just isn't going to be feasible. And that's not good for the patient. We talked about adherence, no one's going to want to have to inject themselves three times with a 1 mL syringe. So, the wearable pump, we can deliver a higher volume, higher viscosity drug, one time in a monthly dose.

So, SmartDose, we announced last August that we're investing in our Scottsdale facility getting ready for launch of the existing embodiment. And it's not just putting equipment in and hiring operators and technicians to man the line. We had to put in our redundant supply chain. So we have manufacturing capacity now in Israel. We have it in Scottsdale. We have [ph] standing-by (2:15:24) technicians to understand, when complaints come in from patients, it's a new novel technology. While we're not going to deal directly with the patient, it will go through the pharma partner, those complaints will come in.

Nothing's perfect when it goes out the door, but we have to understand, is it use, is it design, is it reliability. Everyone expects safety. They expect efficacy. They expect sterility, and they expect reliability. We're now trying to make – take it to the next level, understanding beyond usability. So we talked about adherence. John talked about building a training system. He talked about a number of projects that we have in place. We have seven active developments with customers right now on their specific needs. On top of that, we have eight of our own internal developments, one of them is our training device. This became evident that on a new technology patch injection is new. We just saw the one that was approved last year. So, being able to take patients through to open up the box, give them that same feel of when they get their new iPhone. They can open up and see, easily understand, have it work out of the box, bring technology into our training devices, so that we can get a better patient onboarding and adherence.

My personal story, why I love what I do is I have to self-inject. And my onboarding consisted of here's your example, we'll send the prescription to your pharmacy, and there you go, enjoy using your new device, and that was it. So imagine someone who is unfamiliar in the technology being asked to get onboard. What are the odds that [ph] they stay adherent to their regimen (2:16:56)? I talked about the basic needs. It has to work, has to meet specification. And that's always the way devices were developed. 10 years ago, 15 years ago the idea of usability, human factor study, people are going to want to have to use the device. The regulators demanded. It just made sense. Well, we moved from usability to what we call affinity. And Chris Evans, our Vice President of Innovation is with us today, and he's the guy who's been preaching for this for years within the organization around the globe saying, we've got to get to the point where you're never going to have adherence unless people actually want to use their device. No one's happy about having to give themselves a drug. No one's happy about the condition they may have. But if you can make it such that, okay, I understand it, I have it. But this treatment that I have to go through, whether it's monthly, weekly, biweekly, at least, I get it, I understand it. It doesn't hurt. I'm okay with it. Then you get adherence, you get outcome. Outcomes are important because that's what ends up on the formulary, that's what ends up when you see an actual clinical benefit having that in place means a lot to the patient, certainly means to our pharmaceutical partner and to us.

The smartphone is showing our HealthPrize interface. HealthPrize is a company that we have a relationship with. They have developed really in terms of an ecosystem, tying in the patient to the pharma company, to a reward system. So we are equipping our devices. We also offer it as a solution to other devices as well, where a patient will give themselves their administration, take their drug, and then will get recognized by this system to, okay, you've got a reward for staying on your regimen, it leads to adherence. It's been proven in clinical studies, psychological studies. We're now equipping all our devices with this technology.

John talked about the preloaded SmartDose and bringing back the true idea of innovation. We were kicking around the idea of trying to come up with preloaded. We knew it was good for two reasons, one, out of the box, patient doesn't have to do anything, it's ready to go. Also for our customers, making it easier for them to do the final assembly, filling, put it together and distribute themselves. We got hung up on a number of areas, and finally had a group of folks together and say what is the problem. And so we eliminate the fluid path and we got a sample of it in the back. We're always going to have a question of what we call preloaded assembly, maintaining sterility. So we said did you know what, let's call the guys in Scottsdale, and I'm sure they can come up with a solution for us. And in a matter of weeks concepts were created. Something we had put on hold so we can get past this major roadblock suddenly was opened up for us.

So five years of working on SmartDose, we're now launching or getting to ready to launch with the current configuration. We have eight other independent projects going on from preloaded, 1 mL, 5 mL, 10 mL, a training system, a clinical configuration. So while we've been getting ready to launch and getting facilities ready, we haven't been sitting idly by. We are spending significant resources, opened up a new innovation center. Our inventor of the original SmartDose is still working with us coming up with new solutions and new technology. But it doesn't happen overnight. And so four years of development is now finally leading up to the point where we go into manufacturing, knowing that it takes that long is why we constantly have to stay ahead of what we're doing, understand the market's going to evolve, how the drug's going to be developed, and leveraging our market knowledge. Karen's team, especially Graham on the biologics. They know exactly what's going on in the market. We have to leverage that information, make better products, [ph] get the voice (2:20:45) of the customer, voice of the market.

On shareholder value, the work that we're doing right now in our current product, those high value products that were the innovation projects 10 years ago are now driving the revenue that we're seeing today. The stuff that we're working on, the innovation of technology today will be that next step. So what's going to happen with the



company? That's why it's exciting to know when it comes to the future, the products that we have, meeting those unmet needs, solving problems, getting closer to patients and getting closer to customers is the exciting part of what I do.

So, with that, I'll turn it over to Don McMillan, our Vice President, Global Operations.

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## Don McMillan

*Vice President, Global Operations, West Pharmaceutical Services, Inc.*

Thanks, Eric. Good morning, everybody. You've seen a lot of really innovative products, delivery systems, complex assemblies. And one thing that West does better than anybody in the world to the markets we serve and the products that we build is we design those products and we give that one product to our customer. And then we make 10 of them, and then we make 1,000 of them, and then we make 10,000 and 100,000. And in some cases, a million, tens of millions, a billion. So our ability to scale up – and you heard a lot about the quality demand for particulate, for performance related to the design of the plunger and the container that, that plunger is in, in a heavily regulated market, in a safe and compliant manner.

So the sun never sets on the over 5,000 West team members around the globe that are making those 110 million products a day. One of the strengths that we have is our global presence. We have 12 elastomeric facilities around the globe. We have six facilities that make our seal products that go over those elastomers at least [ph] when they're a stopper (2:22:43). We have eight facilities that are either making the plastic components or assembling the devices in our Contract Manufacturing business. We have distribution center, distribution network. So we have that presence around the globe.

Two years ago, I was actually here in New York at our Investor Day Conference and was talking to you about what we were going to do to bring operations together on a global basis. Our historical regional model served us really, really well. I mean the relationships that our factories had with the customers and often located in the same country where they were. We're fantastic. We learned a lot about their needs. And over time, those needs were specific to the individual side of manufacturer, but that became more and more of a global need. So that model was in – I guess it gave us a lot of insight, little thing that happened in the marketplace. Chris was talking about the global generics business, their need for the same product from a facility, so that equivalent product for multiple sites. So there was the site level customer intimacy that we had, we needed a global market intimacy with the needs of [indiscernible] (2:24:00).

We had regional capacity planning. We had really good programs for lean, for safety, but in a lot of case, those were done on a site level basis. In some cases within a region, we shared some of our best practices. And what we ended up with was a network of hybrid facilities. So, as the market demands became global, and what do customers need? We talked about multiple sites making equivalent products for risk mitigation. Many of our customers are 100% full sourced on West for their product. So for us to offer them risk mitigation of products for multiple sites is a tremendous value driver. The value of having the ability to leverage our network when we get a surge in orders for a certain product like what happened in the generic market recently, to be able to leverage our entire network to serve that need is really, really important.

So, over the last couple of years, we formed a global process engineering organization. We've actually done this [ph] to all of the account neutral (2:25:02). We took existing resources and we realigned their responsibility. And if you think about that, if you're a process engineer sitting in a plant, and Le Nouvion, France, St. Petersburg, Florida or Singapore, and you're working on a process, and you're improving that process in your facility, that's a fun job. Think about how much more exciting it is to be working on that process across the global manufacturing network and spreading your influence across the globe with these things that you do and the things you design.

Think about [ph] attacking or tracking (2:25:34) – attracting good talent, think about the opportunities you can give to your high potential performers. And we've seen that as we gone around the globe, we've indentified tremendous talent that we've been able to give more responsibilities to.

We've built out global supply chain organization, IT enablement for understanding global demand, IT enablement for understanding global supply. Eric talked a little bit about our global sourcing and procurement team that we've brought together, immediate benefit as we indentified, we're buying similar equipment in all three regions. When you combine that to one purchase order, you obviously gain some leverage, and then dedicating some of our resources to kind of that higher end of the manufacturing, that next-generation manufacturing.

Some of the benefits we've already seen, last year 2015, we delivered 30% more lean savings across our global network than we had in our historical run rate over the last five years. When we had the bottleneck situation with our Westar process in the United States, we worked with customers to qualify Singapore and Asia, and also our facility in Germany to actually fulfill some of those needs. Those customers now receive risk mitigation and multiple supply from our network. So we're starting to see the benefits, the ability for us to use our resources more effectively, apply best practice solutions to get more throughput. When you go around and you look at 12 plants, you do find the best practice.

Now implementing that and telling 11 plants that yours wasn't the best, here's the best, it's coming in as a change management challenge. But that is happening across our network. We're seeing increased throughput through assets. And if you think about our business, there's growth in all of the product segments. But the CapEx required for these higher end products that you saw, as you go up that that arrow in the curve. Those are very capital-intensive and require us to invest ahead of the curve. We want to channel our investments to those next-gen products. So being able to produce more with existing assets for our standard products is absolutely a goal of ours.

I talked about this hybrid network. We pretty much made a lot of our products in all of our facilities. And we realize that there were certain products that we didn't really make much volume of anymore. There were old products. They were legacy products. But, in some cases, that product may actually go on an orphan drug that one of our customers have to make for the FDA. They don't want to reopen their filing, our actual components that are in direct contact with the drug are included in the filing with the regulatory agencies. You open the entire filing, when you open that backup, even if you just want to change the stopper. So they really want to buy the product that's on that drug for 20 years, 30 years, 40 years, 50 years, and in some cases, goes back that far.

Now we're not going to make that product, six weeks to eight weeks make to order. We might make it once every two years. We're putting those products in dedicated facilities with a high flexible manufacturing network. There's cost competitiveness for the – components we make for disposable medical devices. We need to let our customers be more competitive. It's a very competitive marketplace [ph] to price buy (2:28:57). Having dedicated facilities, they're focused in on high throughput, still high quality, quality is everywhere.

And then taking a few of our facilities, where we're investing in clean rooms, and vision inspection equipment, and water for injection systems is really what we need to do. And we need to do that in fewer facilities, but do that as a network to offer that risk mitigation to our market.

The other area Eric talked about was the Scottsdale facility and this next new product introduction center, I mean that's clearly an area we want to free up CapEx to be invested in, and that's part of our capacity expansion. So, the takeaway, we're investing our CapEx for, into expansion of capability for growing market on the highest end of our products. And we're leveraging our network to get the most out of it on just the legacy and standard products that we continue to make.



Now when we decided to go into Waterford, Ireland with the Greenfield site, it was a unique opportunity for us to actually establish that next level of quality, that next generation facility. So, we designed the facility in a way that we have never designed a facility before. It is a campus design. The center of the facility kind of that little S-shaped portion in the middle is where all of the employee services are. So, the employees will enter there, go down there, the canteen is there, the production offices are there.

If you go off to the right and kind of forward, or I guess down on the slide, that's the central utilities building, and that is in the very center of the facility. Off to the upper right is, I call it our next-generation finishing facility. It's really just the best of what we do now. We have growth in Westar RS, Westar RU and Envision, and we needed to have capacity for that.

Now, we are implementing best practices for material handling, for cleanliness, eliminating clean rooms, putting in more micro environments, trying to do some of that activity. So, it's a best-in-class finishing center. We also have our advanced manufacturing engineering group working on that next-generation processing to meet the needs of the markets.

And then to the left of the facility is dedicated to the production of components we make for our insulin customers. It's a very highly engineered rubber laminate; it needs a very inert layer that contacts the drug. And then, because of these pen systems, there can be upwards to 50 punctures, you need superior functional capabilities and that's what that top layer of that elastomeric portion is. By having dual site risk mitigation for these products, we eliminate the incentive or the need for our customers to qualify [indiscernible] (2:31:42). And we have the ability to expand out. You can take that insulin building and picture it expanding down and up, and we've designed it that way such that we can meet the growing needs of that market. It's a huge growth opportunity.

And then the finishing area, you can go back, you can go forward, we can come down the slide here, and we could also go off to the left. It's on 44 acres. So we bought the land. We can expand to do anything and everything we need to do whether it's SmartDose, whether it's contract manufacturing, whether it's elastomeric production, whatever. It's going to be our campus in a country that's incredibly friendly to business and really is dedicated to the life science industry, [indiscernible] (2:32:27) talent is wonderful.

Quality and safety, just it's in our blood. It's foundational. And talk about bringing our engineering group together and having this best practice solution. Well, the other thing we've done is, we've launched a companywide quality awareness initiative. We talked about, and Eric talked about what he learned and saw down to the actual molders and production people on the shop floor, is every one of our employees connects that one of the millions of pieces that they're making is going to be a product that could be used on their loved one, their child, their grandmother, one of their friends. So connecting what we do toward the patients through our customers is a really, really important initiative. We had 130 programs of best practice solutions. We actually put a database together and captured every single project going on around the globe in our manufacturing network. It's over 500 projects. Some are for sustainability. There were 130 that were focused on particulate. You – the lot of the analysts in this room covers the pharmaceutical industry, you know about the issues with particulate, some of our folks talked about that.

We've had Westar RS, very heavily regulated product, has a very strict regulatory requirements. In fact, one of the reasons our customers actually buy Westar RS, I mean, we do it a lot, we do it to many, many of our products, so we can have [ph] inefficiencies (2:33:56) there. But one of the real reasons they buy it is compliance with regulatory standards for component preparation. We can keep track of that on a global basis.

We have a [ph] stack (2:34:04) on that product for particulate and we've been able to reduce that across our entire product portfolio by 20%, some products even better. So, taking the best of what you do and making that available to other people around our network and working together as a global team is really, really playing some tremendous benefits.

Safety. Same thing. Every one of our factories, have a very, very robust safety program, safety audits, they have incentives, near misses, they engage with the employees. But there's best practice ways to do that, and we have factories that have better safety records than others. We're taking the best of what we learn and we're applying that. Our 10-year safety record is on a fantastic trend. Coming down every year, we feel we can even make a quantum leap and a step change improvement in that as well.

So, before I turn it over to Bill, 32 years ago, I hopped in an M.G. Midget and drove from the Midwest in America to St. Petersburg, Florida and joined West as a Plan Engineer. I lived for eight years in Florida, spent three years in Singapore, was in international business development when we first looked at India and China. Came back, I worked in sales in California calling on biotech for four years, I was in a marketing organization and I've been with this company for 32 years. And to see that our dream of creating a global integrated network come together and pay dividends for our customer and for us, it's incredibly exciting. It's very much what John talked about. And I can tell you in my heart and my soul, to line that up now with the way we're structured on the commercial side with the market focus, it's going to enable us to tailor our product and service offering to better serve the customers we serve and the patients. And then partnering with Eric on the R&D side, as I tell him, somebody's got to make all that stuff that we design, and they got to make a lot of them. We're prepared to do that as well. So, thank you for your time and attention.

And I'll turn it over to Bill Federici, our CFO.

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### William J. Federici

*Chief Financial Officer & Senior Vice President*

Good morning, everyone. As you've heard today, West is well positioned to become the world leader in the containment and delivery of injectable drugs. When we look at our business, Eric showed you this slide earlier, we've been able to grow organically over the last five years at a compound annual growth rate of 6.7% currency neutral. Really being driven by, as you heard, increasing demand through our high-value product components, which over that same five-year time horizon, grew in excess of 10% per annum.

The favorable mix shift that we talked about with those high-value products, modest price increases and operational efficiencies has really allowed us to expand margins, and that margin expansion has translated into adjusted EPS CAGR of 11.8% over that same five-year time horizon. Our ability to grow organically and expand margins has allowed us to post a five-year total shareholder return of approximately 200%, way in excess of their – of our peer group, and has allowed us to increase our market cap to north of \$4 billion.

When we think about our business going forward, the long-term growth drivers, favorable growth drivers that have been moving our business over the last five years remain unchanged. Growth in biologics and generics will continue to fuel demand for our high-value products and for our proprietor delivery systems.

And from a market segment basis, we continue to believe that we're going to continue to grow our businesses in excess of the underlying markets that we serve.

So long term, we expect to organically grow in the near term, 6% to 8% and expect margin expansion of on the order of magnitude 50 basis points per year in the near term. We expect higher organic growth rates in sales and

larger margin expansion opportunities in the back half of our five-year plan. And that's all based on the expected commercialization of CC and SmartDose.

Over the last five – oh, well, since the beginning of the company, we have invested \$1.5 billion in our unmatched global footprint. As it says on the slide, nearly \$620 million of that has been invested by us over the last five years. We continue to expect that we'll invest between \$150 million and \$175 million per annum in our CapEx to support the continuing demand for high-value products, the capacities to put those high-value products and the proprietary delivery systems over that time period.

We believe that those investments represent the best allocation of our capital in the short term. Over that five-year time horizon, we expect that \$150 million to \$175 million of CapEx per year that we're going to invest will actually decline as a percentage of sales. And we believe that those investments will continue to build the moat – the competitive moat around our business that we enjoy today.

So what we've done in a couple of the slides that you'll see in the book is provide you with a takeaway bridge between our old reporting segments and our new reporting segments to help you with your modeling efforts. We're doing that both for you on a historical basis and then we're also doing it as relates to the 2016 guidance.

What I'd like to do now is to turn the meeting back over to Eric for some wrap-up comments. Eric?

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## Eric M. Green

*Chief Executive Officer & Director*

Great. Thank you, Bill. Excellent. So you've had an opportunity to hear to the message from many of our leaders throughout West and hope you got a good insight of where we're going as a company and share the enthusiasm that we are operating from a position of strength. We talk about moving our organization to be more market-led, and that means focusing the biologics, the generics, the pharma space, and also in contract manufacturing. When you take a look at our position of strength, it comes because we're in a heavily-regulated industry across the more around the business. And we take a look at our products that are designed through regulated products respect in. If you take a look at the – what Bill is just talking about the \$1.5 billion of assets we've put in place takes several years to get up and running, validated within each and every customer. And that mentioned, the talent we have in this organization it is about the science, it is about the engineering. It's very difficult to replicate. I'm really pleased about it that we have an engine that's continued to grow or driven by high-valued products. We have new innovations that are gaining acceptance with our customers CZ, the SmartDose and the additional new products.

And Don talked about operational excellence. While we're growing the top line, mid - to high single-digits with the natural margin expansion on the high value product mix, we're driving our – going forward driving our operational excellence continue to drive margin expansion to better utilize our assets, better utilize our infrastructure and better utilize our facility to drive service and quality to our customers.

Innovation. The journey getting more exciting through bringing containment and delivery together. And, that's going to allow us to think about new innovations, better solutions to our customers, and more importantly, we're better aligned with our innovation groups with our customers' innovation groups. And at the end of the day, when we look at the results, we're looking at very strong P&L, strong balance sheet, that enables us to continue invest in the business, inorganic opportunities and our investment in the future.

But what I like to do is bring up for Q&A. The team that – most of the team represented, Eric, John, Karen, Don, and Phil. We have others that also presented when – if you have a question will love to answer when we get into Q&A.

## QUESTION AND ANSWER SECTION

Eric M. Green  
*Chief Executive Officer & Director*

A

Do you have microphones? Okay. I think everybody has a microphone. So we get started. We do have – yeah.

A

[indiscernible] (2:43:22) and please announce your name and affiliation.

Paul Richard Knight  
*Janney Montgomery Scott LLC*

Q

Hi, it's Paul Knight at Janney Montgomery & Scott. One of the things we worry about with the lack of biotech financing right now in the next five years, you see 2,500 products in the pipeline. What happens with your pricing versus volume mix in the future, Eric? What happened – or do you have more pricing flexibility going forward if volume is in jeopardy due to lack of...

A

[indiscernible] (2:43:54) I'm not going anywhere.

Eric M. Green  
*Chief Executive Officer & Director*

A

I think if you look at our existing portfolio, we have strong [indiscernible] (2:44:03-2:44:17) with pricing capabilities whether it's an existing portfolio or the new portfolio because what you're seeing here especially the high-value products, you're talking about similar number of units, but the added benefits and features is capturing more value from our customers, therefore gain more margins.

In regards to new innovations within biotech, those innovations will continue to flourish, whether they're in large pharma, small pharma, they'll find a way through the innovation pipeline, and we'll be there to support them. So I don't know. Karen, you want to talk about pricing?

Karen A. Flynn  
*Chief Commercial Officer & Senior Vice President*

A

Well. I think John used the term of value per injection and that's really our strategy. It's not as much on pricing. Certainly there is some pricing leverage, but it's more about adding the value. And if we can combine the components that are used for the primary containment with an injection device, then we're going from selling a single stopper and driving value from that to a complete system, and certainly there's a lot more value to left, and pricing leverage that we can bring to bear by providing a complete solution.

Paul Richard Knight  
*Janney Montgomery Scott LLC*

Q

Last question I have, you are recently – you talked about today about the biological effort, you are trying to put into Asia, specifically. What's happening there that we hear that [indiscernible] (2:45:36) production, is it more of

funding that [indiscernible] (2:45:40) in China that you just don't hear about, could you talk about what seems to be new news regarding your Asia initiative?

Eric M. Green

Chief Executive Officer & Director

A

Yeah, it's a very good question. So, we have a tremendous footprint already in Asia with a number of assets, both in China, India and also in Singapore. And what we're seeing is a mixture of – as Chris mentioned earlier, it's the established multinationals continue to build out their own capabilities, but there is another fundamental driver that you turn [indiscernible] (2:46:08) take office more on the biosimilars, and we have the right to play in that space. And it's not just in China, you're seeing this in South Korea with the Samsungs, the LGs, the Celltrions type of organizations and we're very well positioned. We're having those conversations because they're being supported by the large multinationals also. So, I think if we look at our initiative in Asia [indiscernible] (2:46:32) resources today, we just invested heavily in a regulatory affairs group in Beijing. We didn't have presence before, now we do. We can engage customers, engage with the local regulatory authorities to really enable the process to be conducive to use multinationals. So, I think we're very well positioned both on the asset base and the talent base.

Paul Richard Knight

Janney Montgomery Scott LLC

Q

[Question Inaudible] (2:46:55-2:47:16)

Eric M. Green

Chief Executive Officer & Director

A

[indiscernible] (2:47:12) but it is again off a very small base. Yes, Derik.

Derik De Bruin

Bank of America Merrill Lynch

Q

Hi. Derik De Bruin from Bank of America. So a couple of questions. So, we cover the stock for roughly eight years now, I remember the very first meeting we ever had together. You guys said one of the things that you got to watch for West is that, in terms of new products, that always takes a little bit longer than you thought. [indiscernible] (2:47:35). So sort of looking at the plan and sort of looking at your trajectory there, I guess, relative to where [indiscernible] (2:47:45) looking at this timeline is like, are you confident, what's your level of confidence in sort of that back half acceleration of the business [indiscernible] (2:47:54)? And I guess, is it – is there any one program or project that you've got going on with some of your customers that would really be a SnuFu or something [indiscernible] (2:48:04) I'm going back to even more ancient history when you had some customers [indiscernible] (2:48:08).

A

Yeah. Well, I'll start with this, with your question. If we look at the current five-year plan today, you're absolutely correct, there's more growth in the back half than the front half. And right now today is the growth that we're seeing in the mid to high single-digit is really driven by the high-valued products, yes, we're driving growth of standard products, yes, we're gaining business [indiscernible] (3:48:32) contract manufacturing. But the real growth double digits is in the high-valued products.

When we take a look at the customer acceptance of the new technologies, specifically around the Crystal Zenith, and we highlighted a couple of recent announcements and acceptance of the market, where we're positive [indiscernible] (2:48:54) pipeline being developed. And as customers get approval in line, we will – we do believe

[indiscernible] (2:49:01) as a runway ahead of us. Now, the SmartDose is an interesting launch that we have right now. We believe we'll be the first commercial launch wearable injector, [ph] a pas injector (2:49:12) that will go in place sometime this year with our customer. And it's like anything else that we've done over the last decade, which is [indiscernible] (2:49:22). It just continues to accelerate after that. We have several in the pipeline that we're talking about, but I am more excited about also as we've been working on for several months is actually more than a year on the next generation. So, I do believe there's a higher degree of confidence, a better [ph] line of sights (2:49:38) now of acceptance of the new technology can be more back ended.

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Eric M. Green

Chief Executive Officer & Director

A

So Derik, one of the things we've talked about a lot and you saw it on the slide with the 2020 numbers, expectations for us \$2.2 billion to \$2.4 billion, that \$200 million range is reflective of the fact that we don't control the timing. And we know it. We know we're not going to be exactly right about the timing, but everything that we've been hearing leads us to believe that these things will be successful in the marketplace.

Your point about timing, so if we took the growth that we expect from CZ and SmartDose, which just a reminder, it's less than \$30 million of sales today. So, if you fast forward to 2020, our aspirations are to have that be somewhere from a – if you look at that \$100 million that are proprietary devices are today in 2015, and you try to look at that going forward, there's a couple hundred million dollars of growth in there, relative to those two product portfolios.

So if they are wildly successful, we'll do better than that. If the timing is such that things are delayed further than what we've anticipated, then we'll do a little less than that, but it's still within those boundaries that we've set up of the \$2.2 billion to \$2.4 billion, and the margin between 19% and 23% is reflective of that one thing.

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Derik De Bruin

Bank of America Merrill Lynch

Q

Yeah. Great. That's really helpful. So, speaking about SmartDose and some of the other ones, can you talk a little bit about the competitive landscape in terms of that product? And also, I know BD has something, and they're also – you also have an interesting relationship with BD in terms of being both a customer and a competitor.

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John E. Paproski

Chief Technology Officer & Senior Vice President

A

Yeah.

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Derik De Bruin

Bank of America Merrill Lynch

Q

And is there any potential conflict with them that could make them go less of using you as a partner?

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Eric M. Green

Chief Executive Officer & Director

A

Sure. John, do you want to take that?

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John E. Paproski

Chief Technology Officer & Senior Vice President

A

Yeah. Sure. I think we have many partners that we work with, and obviously the syringe manufacturers that have been long established remain important to us, and we want to help them be successful as well, but we do believe



that we have a significant advantage, especially with the rubber base that we [ph] had (02:52:02), the knowledge base that we have is very unique, and it is one of the more challenging aspects of the container closure challenge. And by putting that together with delivery devices, it's a real advantage, and we don't anticipate giving that advantage away, anywhere that we can avoid it.

A

Talk about BD potential confrontation.

John E. Paproski

*Chief Technology Officer & Senior Vice President*

Specifically BD, I would say I was...

A

Karen A. Flynn

*Chief Commercial Officer & Senior Vice President*

From a wearable...

A

John E. Paproski

*Chief Technology Officer & Senior Vice President*

Yeah. From a wearable standpoint, we worry about everybody. We do believe we have a significant time advantage over everybody who's in [ph] sight (02:52:30). We have product offerings that align with – [ph] or were (02:52:41) exceed the performance of others that are out there as well. And I'd say the one place where we would be concerned about a BD, they have real manufacturing ability. Most of the competitors that show up don't really have that capability in place and aren't manufacturers at heart. So we have that advantage BD shares, we have the major jump on them.

A

Yes, please.

David Howard Windley

*Jefferies LLC*

Hi, Dave Windley at Jefferies. Thanks for taking the questions. My first one is – using the example given in the Chris' Generic presentation on the client that grew 50% over three years. So I'm curious in situations like that, presume there's high-value product upsell involved in that, is the client seeing a hard dollar ROI from that or are they accepting a hit to COGS because of regulatory pressure and it's just a factor of being in the game or maybe a third alternative being they've had historical pricing power and they can pass any of that regulatory additional cost through which then becomes pertinent for the current political situation? Will they continue to have that and was that due to [ph] your price (02:53:59) environment?

Q

Eric M. Green

*Chief Executive Officer & Director*

Yeah. It's a good question. I want to have Karen answer it but before I turn it over, real quickly when you look at the cost of the drug being administered to the patient, we're a very small fraction of that, whether it's the standard products or the high-value products. And because we're able to go to the market faster with the high-value product portfolio, they are looking at it as a strategic advantage which ultimately lowers the total cost of ownership. So that

A

has been one of the major drivers, [ph] when you see that (02:54:26) transition from the standard products to the high-value products.

Karen A. Flynn

Chief Commercial Officer & Senior Vice President

A

I think it really is a combination of that, the need to in some cases drive down their cost of goods. In other cases, the customers are motivated by the fact that they can achieve a higher level of consistent quality by having West do the processing of the closures. If you think about the numbers of stoppers or plungers that West washes day-in and day-out through our network, it's very large compared to a single manufacturer of drug products, who they just do this because they have to, right? We do it because we excel at it. So we can achieve very consistent levels of washing siliconization particulate level. So sometimes it is driven by a need for an improved compliance or just addressing quality needs. And sometimes it's related to the fact that their assets have reached the [indiscernible] (02:55:20) systems and they want to avoid [indiscernible] (02:55:25). So it's an opportunity for them to just kind of look at their own network and say do we really want to invest our capital here, do we turn over these manufacturing processes to a supplier such as West. That's driven by a number of different areas.

David Howard Windley

Jefferies LLC

Q

Thank you for that one. My second question and my last question is you've talked a lot about quality, leverage of the network of facilities, things like that. And we also then separately have your five-year plan and the margin expansion embedded in that. Could you give us a little bit of an intermediate step? How much more product can the network manufacture, what percentage increase in yield can you get, some kind of intermediate step that helps us to translate improvement in productivity in the plans to margin? Thanks.

Eric M. Green

Chief Executive Officer & Director

A

Right. It's twofold. One is you're absolutely correct. You can leverage our existing facilities through productivity gains, even though we might be running at capacity there's opportunities to leverage with new innovation. There's new [ph] process closed will (02:56:27) support our customers. [ph] Technically (02:56:29) as the expansions that we have invested over the last five years has been giving us more capacity available at this point. For example, Kinston, North Carolina has given us the ability to expand further. Don, do you want to dimension this a little bit?

Don McMillan

Vice President, Global Operations, West Pharmaceutical Services, Inc.

A

Yeah. Where we've implemented some best practice solutions, we've been able to increase our throughput through those assets 20%, 30%, big, big numbers. Now, we've gone after our bottlenecks first. So, as we get more and more into this and we start to really gain traction, we're kind of at that turning up of the curve. Last year was a wonderful year for that. I do believe that there's a lot of opportunity for us to really get more throughput and higher quality through what we have.

Larry S. Solow

CJS Securities, Inc.

Q

Good morning. Larry Solow, CJS. Can you talk about a little bit on the competitive side, on the high value packaging? Obviously, the macro environment is very favorable. You guys are doing a lot. With that, what are competitors doing? Have you seen any change in that competitive dynamic?

**Eric M. Green***Chief Executive Officer & Director*

A

Okay. Karen, I'll let you handle that, the high-value product competitive landscape?

**Karen A. Flynn***Chief Commercial Officer & Senior Vice President*

A

Right. I mean it's a challenge for us to continue to address market needs and that's one of the benefits that we really see about keenly focusing on the markets. Chris mentioned the benefit that we expect to see by understanding more deeply the Generic segment and bringing new products in that high-value portfolio to bear and solving their unique need. We're not alone in some of the high-value product offerings that we have; washing, for example, sterilization. We do have competitors that provide those services, but where West really excels is in anticipating what's the next level of quality that's going to be required and that was really demonstrated by our introduction of the NovaPure family of components.

West is at the forefront of delivering systems like this that were designed with Quality by Design principles and the whole data package that Scott I believe spoke to, that's real value. It's not just the component that they're buying, but it's the knowledge and the consistency that goes along with those components. So I think it's up to us, our whole organization to bring back those insights from the market and to continue to see that pipeline stay ahead of our competitors.

**Eric M. Green***Chief Executive Officer & Director*

A

And, Larry, one more thing on that. Just think about the scale, okay? These other competitors happen to be not nearly as – have the type of scale that we have.

We talked about \$1.5 billion that we invested in our platform. You look at the other two competitors and they're primarily European based. They do have other operations. And we've talked about this before but for someone to actually get to our level of capacity, these plants aren't cheap they're hundreds of millions of dollars and you would take years and years just to finish the plant. And you'd have to have customers actually go through all the process of qualifying their products through that plant. It's a great deterrent for people coming into our business, but it's also a deterrent for everyone in terms of their ability to grow the business.

**Larry S. Solow***CJS Securities, Inc.*

Q

Right. And just a follow-up to that, your five-year plan is clearly backend loaded but more on the delivery side, with the strong competitive position and biologics seem to more and more need these high-value products and a great pipeline on the industry side. What prevents the packaging side from not also being backend loaded?

**William J. Federici***Chief Financial Officer & Senior Vice President*

A

It is. It is.

**Eric M. Green***Chief Executive Officer & Director*

A

Well, I think – just a quick comment, though. It's not just the biologics space, but also we're seeing this with the generics space moving into the high value price. So if you look at the combinations of those two units, it's about

50% of our business, biologics and generics. So half of our business is high single-digit market growth and then actually in biologics, low double-digit. So that macro trend is really assisting us to continue to the growth that we're having now, but continue on as that base gets bigger. And that's the benefit, not just top line, but also mix.

Quintin John Lai

*Vice President-Corporate Development, Strategy & Investor Relations*

A

Well we do have one question that came on card. The 2020 target, how much acquisition dollar are in those numbers?

William J. Federici

*Chief Financial Officer & Senior Vice President*

A

Zero.

Eric M. Green

*Chief Executive Officer & Director*

A

Yeah, exactly.

William J. Federici

*Chief Financial Officer & Senior Vice President*

A

The plan that we've presented with a top line of 2.2% to 2.4% is an organic business plan and with the margin expansion up to 19% to 23%. It doesn't mean we're not going to be acquisitive. We are looking at opportunities, but that is – we'll take a look at both on opportunities and see how we can bring that into the fold. But that is a growth rate from the – to the top-line organic.

Q

Thanks. The shift to a more customer-centric strategy strikes me as a little bit similar to what Sigma-Aldrich did shortly before it was acquired. And I guess two questions. Is that the right analogy? And secondly, if it is, I think that the point of that was really, to kind of reaccelerate growth. What is the goal of moving to this structure that this is more customer-centric focus?

Eric M. Green

*Chief Executive Officer & Director*

A

Yeah. It's a good question. There is some truth to the fact that my past life we actually migrated toward the customer-centric approach, really heavy manufactured, product-focused organization and the growth was observed. I looked at West as a team collectively as we went to the enterprise strategic plan. What we really realized was we're really focused on a couple of areas of growth like the biologics, we knew pharma space really well.

We knew the generics space [indiscernible] (03:02:25) in depth is now we're learning. And so when you take a look at these markets with a different lens, we do believe we're able to maintain if not accelerate some of the growth. And that's really this period of – the reason it's going to become we're going to become more market led does not mean that we're going to take the focus off of manufacturing. It does not mean we're not going to know our products and know the deep technical aspects for the products. But it is aligning our commercial organization around the customers' savings.

I'll give you one example. And it's not a negative comment, but you can go to a large pharma and we have three to four different parts of our organizations, we've talked to that same customer. Whether it's contract manufacturing, it could be they have a biologics arm, they may have another site that the elastomer and then the delivery devices from a product [indiscernible] (03:03:16).

By really focusing on that customer, whether it's a pharma or a biologics, we're actually – we have an owner of that account that's working, bringing it back into the organization from the portfolio perspective, from the manufacturing perspective, and also innovation. So, I do believe it's an opportunity for us to continue the growth that we're seeing more recently, but also potentially accelerate some of that opportunity.

Q

Thank you.

William March

Janney Montgomery Scott LLC

Q

Hi, Bill March at Janney Montgomery Scott. Could you just talk about 2020 guidance? And as you think about that margin expansion, where is that coming from in terms of proprietary products versus contract manufacturing?

Eric M. Green

Chief Executive Officer & Director

A

Yeah. I'll start and Bill will get into the numbers...

William J. Federici

Chief Financial Officer & Senior Vice President

A

Please don't call it 2020 guidance...

Eric M. Green

Chief Executive Officer & Director

A

2020 target. So when you look at it, naturally what we're seeing is there's really a combination of three aspects to that margin expansion. One is there is some price built in there, and we typically see about net price contribution about 1%, so give or take.

Second really is the financial product mix that we're experiencing, and seen in the last several quarters actually by the last couple of years, but more pronounced recently. We have seen the margin expansion because we're selling more high value product based on one of the charts that Bill talked about, we typically see around almost a 60% range of margin for high value products, standard products around the 28 or 30. So it's almost double for the same volume.

And then the third aspect, we strongly believe by – for globalizing the operations. This is the first time in a long time that we've actually globalized a procurement organization. And by doing that, we're now able to leverage our spend. We have a global network that we've been working on, but now it's strictly – it fell under one leadership where we can start looking at how do we move the assets more effectively. It's built – again, maintain the quality of service and safety levels that we expect, but also look at how can we leverage the cost more effectively. So those are the three levers that we're looking at right now on this mix.

**William J. Federici***Chief Financial Officer & Senior Vice President*

A

Yeah, and it's really – a way to look at this is, you have – in the first half of the plan most of what Eric is talking about the mix shift to higher value products, a little bit of price and this operational efficiency will drive margin expansion, but marginal margin expansion, to say it plainly. We think that order of magnitude, 50 basis points per year on average, in the near term. There's an inflection point out there, where we believe that we'll start to see the commercialization of some of these proprietary devices kick in.

We don't know exactly when that is. We think the timeline is somewhere in that 2017 timeframe. The – once that happens using what Eric talked about, even before selling our very, very highest high value product, we might be selling that for \$0.50 a piece. If we're now going to be selling not only that component, because each one of these devices that we sell has those components in it and if the biologic, they tend to have our very highest value of products in there, the component.

But we're also going to be selling the device and those devices range from multiple dollars a piece to \$30 a piece for something like a smart dosed at volume. So you can see that there's a multiplying effect on the revenue line in the back half of the plan, and as Eric said, as we move migrates from just having contract manufactured devices to devices that are our own proprietary products, and with still those factories, the Scottsdale location, and we start to actually generate a lot of throughput through those new capacities that we have for these devices. We'll start to see an expansion in margin from – in the kind of 20% range to now we're going to see it going into the 30% and 40% range.

So, there's an expansion on the revenue side. A very high expansion on the revenue side that drags with it a pretty big expansion on the margins side. And that's what allows it to get to those kinds of rates. If you do the CAGR on the \$2.2 billion to \$2.4 billion in the 19% to 23%, it's a hell of a lot larger than that 6% to 8% we talked about. And that's a held a lot more than 50 basis points.

The problem is that it's almost – you really have a more level mature business. Not mature in that it's slowly declining, but it's more of a like Queen Elizabeth. It moves slowly and you can't really steer it a lot, that's our components business. But once we get out into that point in time, when we hit that inflection point and we start to see those proprietary devices kick in, that's where we'll start to see that super charged growth.

**William March***Janney Montgomery Scott LLC*

Q

And then maybe just a follow-up on that. In terms of SmartDose 2.0 or other devices, how does already being in the market with an initial product speed up commercialization or adoption of next gen?

**Quintin John Lai***Vice President-Corporate Development, Strategy & Investor Relations*

A

I want to turn that over to Eric...

**Eric M. Green***Chief Executive Officer & Director*

A

Yeah.

**Quintin John Lai***Vice President-Corporate Development, Strategy & Investor Relations*

A



...if you don't mind talking about the new generation.

Eric M. Green

Chief Executive Officer & Director

A

Sure. Well, these eight internal developments that we have, our [ph] generation two (03:08:47) and our preloaded SmartDose, some are in different stages of development right now. Some are still early concept, some are in feasibility and some will be entering formal design development, all of which we have active communications going on with leading companies right now who want access to that technology.

I would just add to that kind of the basic principle that our customers love to see the product on the market before they jump on it themselves. So we think that having our product hit commercially will assure them that the other customers – that they'll be able to get through the regulatory pathways without complications that they don't understand. That's a big deal for them.

Quintin John Lai

Vice President-Corporate Development, Strategy & Investor Relations

A

Yes?

Q

Yeah. Hi, regarding your 2020 targets, how does your free cash flow or the timeframe feed into those numbers?

William J. Federici

Chief Financial Officer & Senior Vice President

A

Excellent question [ph] Mike (03:09:35), thank you. So when we think about our operating cash flow, you use the metrics we just talked about, the mix shift towards higher value products and then eventually towards these proprietary delivery systems. We expect that portion of our cash flow to go up very, very nicely, the operating cash flow number.

In the near term of our five-year plan, most of that will get eaten up by this \$150 million to \$175 million of investment we will be making back into the business to enable us, as these guys have described, to get ahead of the demand curve on our capacity. We can't just overnight flick a switch and all of a sudden have a new line for CZ or SmartDose, it takes longer than that. Same thing with clean rooms for our high value products or new visions, inspection systems for our high value products. So we're investing two years to three years ahead of where we think the demand will come in.

So [ph] Mike (03:10:33) in the near term, literally what I see is I see very limited free cash flow, free cash flow being defined as our operating cash flow less our CapEx and the dividend. Once you get out into that past that inflection point, not only are you going to see that the other cash flow starts to increase. But as we said, as a percentage of sales, the CapEx goes down. You're staying in that same [ph] 150 to 175 (03:11:03) band, and therefore, you're going to see a lot more start to flow through to the free cash flow line.

So don't expect anything, it's not a free cash flow story today. And it won't be for the next couple of years. But we certainly expect that as we continue to grow the business and we see that inflection point kick in, we will start to generate real meaningful free cash flow.

## Quintin John Lai

*Vice President-Corporate Development, Strategy & Investor Relations*

Okay. That's been great. I think we covered all the questions. Now we are going to be here. In the back, we have our products available. We also have lunch. I want to thank you for your attendance. It's been our pleasure to have you with us today. Please let us know any additional questions, but we're excited about the future and thank you of your interest. Have a good day.

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## Eric M. Green

*Chief Executive Officer & Director*

Thank you.

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