Transcript

J.P.Morgan

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David Adlington: Good afternoon, good morning, everyone. Thanks for joining us again today. It's my pleasure today to host Fresenius CEO Stephan Sturm. I'll hand over to Stephan in a moment for some introductory remarks before we go to the Q&A. If investors would like to e-mail in questions, please feel free to do so to david.adlington@jpmorgan and with that I'll hand over to you, Stephan.

Stephan Sturm: Thank you, David. Good afternoon, good morning, warm welcome, and, as always, we appreciate your interest in Fresenius SE. We also appreciate your interest in Fresenius Medical Care but today, I guess, the focus is going to be on our Kabi business.

And whilst we have quite an array of formidable businesses and there also Kabi is so much more than just IV drugs, I guess the elephant in the room, and that is what we should start with, at least for now, is pricing in the injectables market in the US, and let me start by saying that I am keen to confirm all of the statements that I made during our Q3 earnings call on 2 November and specifically I'd like to assure you that pricing environment in the US injectables market from our perspective has not changed and that we are not seeing anything out of the ordinary. In fact, price erosion for Fresenius Kabi in the US is very much in line with developments in recent years and there is nothing that we have not seen before.

And as I tried to do on our 2 November call, I'd like again to caution you to do a straight read-across from the dynamics in the oral solid space. What has been the case, what continues to be the case, is that sterile injectable drugs have substantially higher barriers to entry in comparison to oral solids. There is just a much more complex manufacturing process, more expertise, more experience, more capital required and from our perspective the evidence of that is the consistently high number of injectable drugs that are on the FDA's drug shortage list. By the way, the number of drugs on that list has started to increase again over the last couple of months.

So, when you study statements of our competitors, I would urge you to pay very close attention to their specific drug portfolio and product mix and that may be substantially different and that may flow the read-across to what we are exposed to. And also when you monitor the dynamics surrounding individual larger generics, I'm keen to point out that price decreases, price developments there from our perspective are neither representative of a generic manufacturer's portfolio, let alone the entire market.

When we look at individual injectable generics, then you are generally aware of the dynamics. At the outset a steep revenue ramp-up, when the generics market is forming, with relatively few competitors and at an attractive pricing level and I'd like to remind you of neostigmine and daptomycin in this context. And then thereafter quite a number of competitors tend to come into that market, tend to put pressure on the price in order to gain market share and once we have reached a certain level of maturity, then this is by and large a sideways development with very little changes and I'd like to mention our propofol in this context.

And, again, please don't mistake the normalisation towards maturity as general pricing pressure in our part of the market. From our perspective, the normals as far as pricing points are concerned, aren't lower than they used to be.

As a matter of fact, over the last five years the average selling price across our US injectables portfolio, that has decreased in low single-digit percentages per annum and that is also in line with what we had seen before.

And that is also the magnitude that we do expect for the current year and, frankly, when you look at the first three quarters at Kabi in North America, our year to date data, that very clearly supports that projection. So, a slight price erosion but coupled with very meaningful volume growth and therefore what you see in our year to date numbers is 6% organic revenue growth and, frankly, I can't see in those numbers anything that would be out of the ordinary as far as pricing pressure is concerned.

Talking about volume growth, well, first and foremost that is driven by our new drug launches and I would like to remind everybody that our ANDA pipeline is at a record level. As of today, we're looking at 55 ANDAs that are sitting with the FDA and are waiting for approval. Secondly, we have done the right thing, we believe, vis-à-vis the GPOs in the past. We have never taken undue advantage of our superior supply position during times of shortage. We have acted as very responsible market participants and based on that track record, we have formed very strong close relationships with these GPOs and they generally do value, as they should, responsible and, first and foremost, high quality suppliers.

Lastly, on volume growth, you will recall the transaction that we entered into with Becton Dickinson where we acquired their portfolio of prefilled syringe injectable drugs and that Simplist range is very much living up to our expectations and is driving a very meaningful part of our overall volume growth. The market for injectable generics, from our perspective, will continue to increase.

That is against the backdrop of constantly increasing price pressures and budget constraints in any market, also in the US, and, as I said on our 2 November call, generic drugs in America represent 89% of prescriptions but just 26% of the costs of pharmaceuticals and generic prices tend to go down, as I said earlier, in our particular case in the low single digits. So, we would clearly expect that also going forward we're much rather going to be considered part of the solution than part of an issue.

In order to stay competitive in this market... And that is the minimum target. In an ideal case we would even succeed in further enhancing our already strong position. So, in order to do that, we'd believe that we have got to grow further. Size matters. Size is a key success factor in this market and we believe that it will be increasingly tough for smaller manufacturers and suppliers to keep up with the growing capital intensity in our business, capital intensity because manufacturing entities will have to grow and because we also believe that quality as a matter of course will continue to matter also going forward.

And capital constraints, they are also bound to trigger capacity constraints and are more than likely to trigger quality constraints and on that basis we do feel very comfortable with our competitive situation, given our size and diversification within North America Kabi, within Kabi globally but in particular then also within Fresenius. We have a track record and we have also a strong belief going forward that we can generate reliable and strong cash flows

and so that therefore we are in a position to implement the necessary capex that will help us to capitalise on these market trends.

And so I continue to believe that when we want to be successful in the injectable generics market in the US, that we have got to manufacture there. Labour costs have never played a major role as a success factor there. It is much rather down to a manufacturing-friendly environment with a stable supply of utilities, a stable supply of clean water and a well-educated workforce but that also going forward we would try to improve our overall quality situation by going about further automation.

And, as I have talked on a variety of conference calls and investor meetings already, we are in the process of substantially expanding and upgrading our Melrose Park facility with an about $250 million investment. We will spend substantial amounts of capital also at our Grand Island facility in upstate New York and do expect some further announcement for further capex measures for our North American drug manufacturing processes.

So, all in all, we continue to be upbeat about this market. We are looking at a pipeline that is stronger than ever. We are looking at a competitive position that is stronger than ever. We are looking at a quality track record, I need to touch wood, a quality track record that is stronger than ever and therefore we feel well equipped to deal with the challenges ahead of us and, David, that's my intro and happy to take now your questions or any of the other questions of the participants. Thank you.

David Adlington: That's great, Stephan. So, that's a very thorough coverage of an area that everyone's been focussing on for the last little while. So, maybe I'll just expand on that and just get you to address some questions that I think people have had. So, maybe just to start off, and obviously this concerns coming away from the oral solids, like you mentioned, and the perceived risk, that it might switch across to the injectables.

I think you addressed the reasons why it might not but maybe just dipping in here to start off with, obviously a lot of that was driven by an acceleration in approval times, more products getting approved on your side. Are you seeing any acceleration in approval times for the injectables side or is this just the hopper of more products that went in 12/24 months ago just starting to come out at the other end?

Stephan Sturm: We're seeing a little bit of an acceleration but, frankly, nothing that would be material and, from our perspective, when we are seeing, from our perspective, also only a slight increase of the number of approvals, relevant approvals, then this is much rather the result of enhanced R&D activities elsewhere. More filings result in more approvals and then subsequently also more launches.

Mind you, I was making reference to our ANDA pipeline of 55 individual compounds but still you have only heard us talk about six to ten launches per annum over the years and this year we were saying we would expect to be more at the upper end of this. I am at least quietly optimistic that we would be able to top this year's number next year but, look, if this were really a massive acceleration, then you should expect substantially higher numbers from us, and that is not our working assumption right now.

David Adlington: Perfect. And the products that are coming through, are these done on a first come first served basis or are there some products that are being approved more quickly?

Stephl·n Sturm: Well, the FDA, as they should, prioritises those drugs where there is a shortage and also those products where there are less than three market competitors and that is something that has come about only recently. The effect of that it is too early to say. In general my statement would be that there are only a few situations where we are one of these less than three competitors and in those situations, yes, we may expect a bit more competition a bit earlier than originally anticipated but I would also encourage you to work on the assumption that we have ANDAs filed with the FDA where we are targeting situations where there are less than three own market competitors.

David Adlington: Perfect. And one of the arguments out there is actually we're seeing new entrants coming to the market and get approvals. Is that something you're seeing in the marketplace?

Stephl·n Sturm: Here and there, yes, but, from our perspective, when you look at it, the vast majority of approvals is with the current incumbents.

David Adlington: Maybe some context would be useful in terms of if a new entrant was to enter into a market like this, in terms of the amount of capital and time required to build a facility and get the various approvals, what sort of timeline and expenditure would one have to be thinking about?

Stephl·n Sturm: Well, setting up a new manufacturing plant that is FDA-registered, from my perspective, would be at least four years and it would very easily be a capex amount well into the triple digits. Look, we have had our own fair share of issues with overseas plants when we were trying to supply products into the US. That generally hasn't worked that well for us and that is why, as I said in my prepared remarks, we continue to believe that manufacturing that in the US for the US is the right thing to do.

Others do view that differently but I would also encourage you to look at the relative share of 483 findings or warning letters, product recalls or even temporary plant shutdowns abroad relative to what is going on in the US market, you will find a confirmation of what we also very strongly believe in. It pays to manufacture in that market where you also want to sell.

David Adlington: Understood. And obviously we've seen a lot of consolidation both in the US hospital sector and in the GPOs over the last three to five years. You even alluded to this in your opening comments but it doesn't sound like that's changed much in the way of the pricing environment and you don't necessarily expect it to. Is that fair?

Stephl·n Sturm: We're now down to the last three GPOs. I find it hard to believe that another step of consolidation would be permissible and that situation that we're looking at right now with those three large GPOs commanding around 95% of the market, that has been around for almost two years now. I would work on the assumption that the effect of those mergers were basically we were asked to adopt a best price policy. Whatever

the lower of any price for the various same generic has been, it had to be adopted vis-à-vis the merged larger entity. I would expect that that effect has rippled through and is behind us and I cannot see why now all of a sudden that GPO consolidation would trigger any completely changed market dynamic on the pricing front.

David Adlington: Yes, that makes sense. So, in terms of how the markets will forecast your numbers, certainly historically we've pencilled in a fall in US margins this year as we expect the shortages that you've benefited from to resolve but generally that's been too conservative and that's certainly how you give your guidance at the start of each year - you assume that the shortages resolve through the year and you guide on that basis but, actually, as the shortages get pushed back, it's allowed you to get more positive on your guidance as the year progresses. Do you expect that to continue in terms of both how the shortages have taken longer to resolve but also how you plan to give guidance?

Stephan Sturm: Yes, to both questions and, David, when we were getting into that business we were saying that a normalised margin would be in the low 30s and over time, given the unexpected drug shortages, we were seeing margins that were well north of that. All over the years we were saying that whilst it is a much more complicated business than dressing pills, at the same time it's not rocket science and therefore, from our perspective, it would have to be a temporary phenomenon and with drug shortages receding, we would also see margins normalising.

However, at the same time we were seeing a bit of market consolidation already kicking in. We were seeing capital intensity growing. We were seeing quality requirements moving up and we were also seeing us ourselves making use of our good fortune by entering into substantially more contracts on substantially more individual molecules, with the GPOs, and on that basis we were saying a normalised EBIT margin was probably rather in the mid-30s.

More recently, given everything that we have seen going on and us also further strengthening our market position, I even got comfortable saying that from the mid-30s there may be a tiny little bit of upside. Obviously, there is downside from where we are operating right now but as far as the normalised structural margin level is concerned, we have gradually but steadily become more optimistic over the years and I would still stand by that perspective.

When you look at the shortage situation, then, yes, from a peak well into the triple digits, we had a gradual decrease to around 50 and for the last two months, as I said in my prepared remarks, we were even seeing an uptick. So, for those who listen to me more frequently, you will know that it is my hypothesis now that drug shortages are unlikely to go away completely and that I much rather think it is realistic to work on the assumption that there is a fairly solid base layer of drug shortages that will be with us for good.

Now, is that base layer at the level where we are right now or further down? It's a bit too early to say but at the very least, given the development of the last quarters, I would argue that there is something to that hypothesis and I would like to think that given our track record, given our manufacturing skills, we are more likely than many others to take advantage of these drug shortage situations.

But back to your question about guiding, we will do the very same thing as we did in the past. We will be building a bottom-up model, trying to take in market intelligence as to where we believe competitors are working on an alternative launch. We'll try to anticipate launch time and aggressiveness with regard to pricing and market share ambitions and we'll try to give you a very realistic guidance for the year next February.

At this point in time that is very important to me. I don't think that the theme that we have seen over the years, price erosion in the low single digits, that there is something that we need to change as far as this basic assumption is concerned.

David Adlington: Understood. And so big picture here, if we did see high pricing pressure, presumably we could end up increased drug shortages. So, I suppose perceptually how does the FDA think about this? Does it let the free market set the price and therefore it drives effectively lower prices by increasing supply through, obviously, increasing approvals? Or does the FDA have a strategy of maintaining quality over the medium to long term which will obviously require a return on investment? How does the FDA square the circle of price versus quality and need to invest?

Stephl·n Sturm: Look, that is basically a question for the FDA to answer but let me give you my observation and from my perspective the FDA has a dual mandate and on the one hand they need to protect the American patient by safeguarding quality standards in the manufacturing process and, on the other hand, they are meant to support the American taxpayer by making sure that we have the right level of competition in these product markets and, fairly obviously, those two mandates are in a certain conflict with each other.

My observation over the years is that there is a bit of a pendulum between those two aims that is swinging back and forth over the years and whenever there is too much of a focus on pricing competition, we may see a slippage in quality standards but the FDA is very quick to fix that and on the back of that you will see increased scrutiny with a substantially higher number of inspections and, consequentially, findings with drug shortages as the end result and from my perspective, I don't think that temporary relatively small swings of that pendulum do alter the underlying structure and the general dynamic in this market.

David Adlington: Perfect. And then in your remarks earlier on you said that, obviously, consolidation... you should expect consolidation, that size matters here, but clearly you could get bigger organically as well. How do you balance the prospects of your capital allocation there between organic and acquisition growth?

Stephl·n Sturm: Yes, we do believe that size matters and that is, on the one hand, as far as sizing of your manufacturing plants is concerned. We need to get to a situation where our cost of production is the lowest in the industry whilst, at the same time, reliably manufacturing a very high quality. And on that basis I was making specific reference to the various capex programmes that we have launched already quite a while ago, ground-breaking for Melrose Park was just this last quarter, and we are making good progress in the expansion and also the upgrading of our equipment.

At the same time, when I'm saying that size matters, I'm also referring to the depth and breadth of our product offering and we really are keen to cover the entire waterfront as far as injectable generics are concerned so that we are a one-stop shop for the GPOs going forward and make them ever more relevant, ever more comprehensive product offerings.

And against that backdrop you need to see our announcement to acquire Akorn, relative to the size of their product base and the size of their product pipeline, the number of overlapping drugs is negligible and so therefore the key aim, why we went about this acquisition, is that it should help us, first and foremost, with the pipeline to further complete/near complete our product offering in the injectable generic space.

So, to answer your question, ideally we'd do both, facilitate further organic growth on the manufacturing side but also further go about organic revenue growth by broadening our product offering.

David Adlington: Perfect. And you brought Akorn up, which is actually my next question. Obviously, they faced some issues themselves this year. Maybe just touching on what's been happening and the outlook there, once you get your hands on the business, presumably by about the end of this year I think you guided to.

Stephl·n Sturm: David, for the avoidance of doubt and to spell it out very clearly, yes, we have been and we are disappointed with Akorn's current trading and it is not what we did expect. It is not what Akorn expected itself, if you look back to their 2017 guidance that they issued end of April when we announced the transaction. But in a fairly volatile market where I was trying to convey the general dynamics about the effect of individual drug launches and then a ramp-down toward maturity of individual drugs, individual drugs in a portfolio and in a pipeline can make a very meaningful difference.

I would like to remind you of vasopressin, of neostigmine, of daptomycin where I would bet that very many of you hadn't heard about these drugs before we had launched them and where they made all the difference - neostigmine in '15, daptomycin in '16 - and where we continue to look at a pretty healthy pipeline in that regard. And therefore I was saying in our earnings call, 2 November, whilst we are disappointed and whilst the stretch towards reaching our expectation for 2018 that we communicated end of April is larger than I had hoped for, it is too early to revise that.

I would like to go about this once we are the proper owners of this business, once we are a bit clearer, and, as you know, you asked me about our guidance setting process before, that is what we would also like to do for Akorn next February.

David Adlington: Perfect. And your expectations around closing, is that still before the end of the year?

Stephan Sturm: That's the target. What I was saying is that I do believe that Akorn could quite take advantage of some of our help and that therefore I'm generally keen to close the transaction as soon as we can. We have done everything we could vis-à-vis the FTC. That antitrust process is running. Again, we're targeting the end of the year. I cannot say with conviction whether we are actually going to be successful there.

David Adlington: Okay, perfect. Maybe if we move on from the injectable space but still in the central area, obviously you've made a move into the biosimilar space early on this year, around the same time as the Akorn transaction. What made that particular transaction interesting now and how should we be thinking about the phasing and the ramp of costs with respect to revenues?

Stephan Sturm: We have been looking at biosimilars for about a decade and at the time when many of our competitors or those companies that are currently active in this space entered into it, so 2007/2008, we were constrained. We had just done the largest acquisition in Fresenius's history, namely APP, which, by the way, was off to a pretty rocky bumpy start at the time. And then we had the world financial crisis.

So, we were very much constrained as far as our financial and our management capacity was concerned and so the question just didn't ask itself but that didn't mean that we were not generally interested in that space and over the years we continued to monitor developments in there and, frankly, we were also approached on quite a number of occasions by corporates who had started off pretty hopeful but had either run out of capital or run out of qualified staff or had also seen that distribution was increasingly important also in that space.

We couldn't make ourselves comfortable with an investment in biosimilars because we felt that the regulatory space was still way too opaque and fluid and, look, if we couldn't say what we would have to prove in order to demonstrate similarity, it was very difficult to build the business plan. But we had never lost sight of this space and then, I guess, two things have happened.

One, regulation is substantially crisper, more crystallised now and we are comfortable putting together a business plan and, secondly, we found also a partner with Merck that was willing, on the one hand, to sell the business but, on the other hand, in a transaction structure that, from my perspective, much rather resembles a joint venture than an acquisition. The purchase price is very, very back loaded and it essentially consists of milestone payments that are very strictly tied to further development success and on that basis we could make ourselves comfortable getting into that space.

Now, rewind to many of the dynamics that we were discussing in the injectable generics market in the US and remember that I said we have got to become more comprehensive, we have got to be able to offer a broader and deeper portfolio and I have no doubt that, given time, biosimilars can be, arguably even will be, the anchor product in any more comprehensive product offering vis-à-vis a GPO.

And the point in time when to go about these challenges and opportunities is when you are in a position of strength. We are on our way to achieve yet another record result in 2017. Arguably, the strategic posture, the financial position of the Group has never been stronger than right now. Arguably, our market position in the US injectable space has never been stronger than right now. This is the time to prepare ourselves for the next decade. That is why we also got into biosimilars.

David Adlington: Perfect. Now, I am slightly mindful of the time and I've got quite a lot of questions coming in as we speak but I just want to make sure we at least do touch on the other part of your business which we haven't

talked about at all so far which was the hospital business at Helios. Just focussing on your home market first, obviously some political uncertainty, unusually, in Germany at the moment. I just wanted to check there was nothing you were seeing there that could have any impact on the German pricing environment.

Stephł·n Sturm: I would expect that whatever government we are going to have and irrespective of whether or not we are going to have a government in Germany, the appetite for further privatisations in general and hospital privatisation specifically is going to be extremely muted.

In particular at a time when the German economy is flourishing, there is just no room for restructuring transactions in the hospital space and what that, in turn, means is that the reimbursement environment has got to be accommodating for those public hospitals that have a substantially higher exposure to labour cost than we have and so in order for these public hospitals to make ends meet and to stay afloat, they have got to get quite meaningful support to their top line than falling through to the EBIT line so that they can minimise, ideally avoid, those running losses and therefore, again, irrespective of the overall political uncertainty temporarily, I would work on the assumption that we will continue to see a more accommodating pricing environment.

Evidence of that is the close to 3% DRG inflator that has been announced for 2018. Again, most of you will know that, we mentioned it on numerous occasions, caution, not all of the 3% will accrue to us. We work on the assumption that only about half or two-thirds of that headline inflator is going to end up in our P&L. But still it is a positive pricing effect and, as we just discussed, that cannot be said of all the markets that we are active in.

David Adlington: Perfect. And then just quickly, before we move on to investor Q&A, Quirónsalud, just maybe if you can give us an update in terms of how that's panning out and, again, any potential fallout from the Catalonian situation, which I think you covered on the Q3 call as well but just to square that out.

Stephł·n Sturm: We are generally extremely happy with the Quirónsalud situation and acquisition and we are on our way to make our numbers there. The guidance that we had given of €300 million to €320 million of EBIT, if I recall correctly, Rachel, on our Q3 call already pointed towards the upper end of that range and that bodes extremely well. I had to be a bit of a spoilsport in our Q2 call because after two strong quarters, we did get the impression that some of our investors were being carried away and had forgotten about what we had said in February about a much more pronounced summer lull in Spain that what we are used to in Germany.

And also the performance in the third quarter was very much in line with our expectations. Yes, very meaningfully below quarters 1 and 2 but, again, just as we had expected. Did Catalonia help? No, it didn't. Did it have a meaningful effect? Also, no, it didn't. We had a few general strikes, you will recall, in larger Barcelona. Again, that wasn't exactly helpful but at the same time we were very much in line with our earlier expectations.

As far as potential structural consequences out of the Catalonian situation are concerned, I continue to be fairly relaxed. You will recall that public hospitals are only about a third of Quirónsalud's revenue. Within that third we have a dominance of the Madrid region and Catalonia is relatively small within that and the contracts that we do

have in the Catalonia region continue to enjoy a long maturity. We have the regional government as our counterpart and therefore I lack the imagination to see what negative consequences there could be.

David Adlington: Perfect. And then last question from my side before we open it up, obviously you've got two businesses here that can both benefit from further capital being allocated, when you think about allocating capital between the two, how do you think about that question? Who gets the majority of the capital or is it going to be split equally?

Stephl·n Sturm: David, I appreciate the question but please appreciate my answer, that further capital allocation is a very low priority at this point in time. We have done with Quirónsalud the largest acquisition in our corporate history very recently, we're in the middle of the integration process, we're in the middle of trying to generate synergy benefits whilst at the same time we are trying to deliver relative to the acquisitions that we have raised.

And as far as Kabi is concerned, I think we have made two, or we at least announced two major strategic moves with Akorn and with us venturing into biosimilars. So, coming back to what I was saying a bit earlier about the 2007/2008 timeframe, I believe that first and foremost with regard to our management capacity, we should be well advised to digest what we have taken on and therefore my appetite for near term M&A is relatively limited.

Also, please don't forget that as far as Fresenius Medical Care is concerned, we have also made a strategic acquisition with the announcement of us acquiring NxStage and, as I alluded to in our Q3 call, also for Fresenius it's small but for them very meaningful additions to their portfolio of services businesses and therefore everybody in the Group is very busy integrating those strategically important acquisitions and reaping synergy benefits.

David Adlington: Perfect, great, thank you very much. Operator, could we open it up to questions on the line there, please?

Operator: Of course. Ladies and gentlemen, if you would like to ask a question, please press star followed by one on your telephone keypad now. And if you change your mind and wish to withdraw your question, it's star followed by two. As a quick reminder, that's star followed by one to ask a question. At this moment we have no questions registered, so I'll hand the line back to you, David.

David Adlington: Thank you. I've got a bunch of questions that have come in on e-mail. I'm just going to read them out in the order they've come in and, again, we've covered some of these off, so I'll try and read them very quickly. So, firstly, on Venofer and Diprivan, are the competitive dynamics changing as it relates to these two drugs? [INVESTOR QUESTION]

Stephl·n Sturm: I'm not going to comment on Venofer. That is in the FMC space. On Diprivan/propofol, we continue to enjoy a market share in the mid-70s and with fairly stable pricing.

David Adlington: Perfect. Can you confirm that the number of suppliers of your IV generic drugs in the US is up significantly, in brackets three times compared with a year ago? [INVESTOR QUESTION]

Stephl·n Sturm: No, I cannot confirm that. I'm not sure where that statistic is coming from.

David Adlington: Okay, perfect. And if there are more suppliers coming to the market, why over time would there not be more pressure on price? [INVESTOR QUESTION]

Stephl·n Sturm: At the risk of giving away too long an answer, I still would like to remind people of the transaction that we have entered into with Becton Dickinson. The key reason for them selling their prefilled syringe business to us was that even after quite a number of years they hadn't managed to get a portfolio of drugs that was as sufficiently broad to be of interest for the GPOs.

We just believe that the market is calling for ever broader and more comprehensive portfolios of drugs and ideally, and that is what we are preparing for portfolios/product offerings that go beyond just injectables and here I have been talking about our infusion pump, infusion solution, parenteral nutrition, all our medical devices. That is what we would like to offer and therefore we, from our perspective, continue to have our very strong doubts that a small player with a very limited portfolio will be successful vis-à-vis the GPOs.

David Adlington: Very fair. So, another question here, would you agree that the FDA under Scott Gottlieb seems to have a more liberal view on those barriers of entry that historically have protected the Kabi business? [INVESTOR QUESTION]

Stephl·n Sturm: I am not saying that the FDA under Mr Gottlieb has lowered their quality requirements. If that is meant to be implied with that question, no, I would dispute that. I much rather would argue that the FDA will continue to work to increase quality requirements to live up to one of their two important mandates, namely to protect the US patient. What Mr Gottlieb is on record is that he is looking for more competition in this market and that is why he has gone about singling out those situations where there are less than three competitors for a drug. So, if that is meant with the question, then the answer is yes.

David Adlington: Perfect. So, next question, is generic Restasis against dry eye disease one of the key drugs currently in Akorn's pipeline and could that be granted approval in 2018 and, if so, could you assess the opportunity? [INVESTOR QUESTION]

Stephl·n Sturm: I'm very sorry but we're generally hesitant to comment on individual drugs. We tend to give comments for those that are on the market and that are more visible, in particular in IMS statistics. As far as individual drugs in the pipeline are concerned, we've got to protect our competitive situation. I'm sorry.

David Adlington: No, sure, they knew they were chancing it by asking that question anyway. Are you comfortable breaking out your expectations from where the accretion from Akorn will come from, what is the risk to these and has that changed over the last 12 months? [INVESTOR QUESTION]

Stephl·n Sturm: We have acquired Akorn, as I said, first and foremost for its injectables portfolio. We have also gone about the acquisition with a view that synergies on the manufacturing front but obviously also on the administration front can be had and when I was saying earlier that we are disappointed with the development in the second and the third quarter and that the stretch towards our original 2018 expectation is larger than I would have hoped for, then, yes, there is a bit of a change but, again, quite a lot of things can happen also as far as individual drugs are concerned and therefore I'd like to reiterate that it is way too early to go about the potential revision of our original expectation for 2018.

David Adlington: Sure. Another one here again, unsurprisingly, on Kabi. So, what is the spread of erosion that Kabi has experienced in the past? Is it always based, presumably correlated, on the number of competitors? [INVESTOR QUESTION]

Stephl·n Sturm: I don't think we have ever gone into double digit space but, as far as percentage price erosion in a single year. We were also in the mid to high single digit in individual years, namely in 2009/2010, and that was, interestingly, exactly the opposite situation because after the Heparin crisis we had the first meaningful wave of drug shortages on the back of an elevated level of FDA scrutiny and therefore the drug pipeline was completely clogged.

And also we at APP couldn't get a larger number of desperately wanted new launches into the market and therefore the installed manufacturing capacity in the market, that was very much focussed on those drugs that had already been launched and that therefore led to a higher level of competition and a higher level of price erosion. So, it is the opposite in a sense of what many of you are assuming today. Ever since, by and large we have been in the low to very low single digits as far as annual price erosion is concerned.

David Adlington: Perfect. And then just two more questions here. So, on Akorn is there any potential for you to renegotiate the price, given the issues the Company's had this year? [INVESTOR QUESTION]

Stephl·n Sturm: We have entered into a customary merger agreement and, just as for any acquisition, we obviously continue to track whether our expectations and whether the representations and warranties that are a part of the merger agreement do turn into reality and if there was a deviation, then that could be the basis for a breach of these representations and warranties but, frankly, as of now I have no reason to believe that that is the case.

David Adlington: Understood. And then final question, some of your competitors have had supply issues, given they're manufacturing in Puerto Rico. Are you seeing any benefits from this and how long could they last? [INVESTOR QUESTION]

Stephl·n Sturm: Frankly, Puerto Rico is a terrible situation for the island itself but also for certain parts of the industry. We had a good fortune. We have two relatively large manufacturing sites for Fresenius Kabi there and when I'm saying now that they are largely unaffected, my dear colleagues and friends in Puerto Rico will probably

hate me for saying that but I'm saying that on a relative basis, relative to what has happened to other manufacturing sites there.

So, we have done our utmost to get back to a relative normal. We have been shipping in diesel to drive our generators and to get back to electricity. So, again, a pretty catastrophic situation but as far as our manufacturing output is concerned, we are not constrained in a major way and that is first and foremost, because our colleagues on the island have done a stellar job.

David Adlington: Stefan, that actually takes us to the top of the hour and that's the last of the questions, so thank you very much for joining us once again this year and we look forward to seeing you in San Francisco.

Stephl·n Sturm: Thank you, all, for your attention. Thank you, all, for your ongoing interest in Fresenius. As I said at the outset, we're so much more than injectables in North America but, at the same time, I do appreciate that this is the focus of your attention right now. I hope I was able on the one hand to convey a bit more of transparency but, on the other hand, also a bit more of confidence in that particular piece of our business. Thank you very much for now.

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