Kris Sterkens – Company Group Chairman, Janssen EMEA



We have managed to build a truly robust and enduring business

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In this exclusive and wide-ranging interview, Janssen's EMEA head Kris Sterkens outlines the company's strategies in Europe, its increasing embrace of digital solutions, and the shift toward pre-emptive and precision treatments. Sterkens also highlights how Janssen is positioning itself in the emerging markets under his remit and how the ongoing integration of Actelion stands to benefit patients across the region.

So far this year, J&J has been registering better-than-expected financial results (3.9 percent operating revenue growth) largely on the back of a surprisingly strong performance by Janssen. Just how influential is Janssen EMEA's contribution these days?

It has to be said that Jansen EMEA has been enjoying an incredibly successful run over the past couple of years whereby we have been outpacing the market with double-digit growth, which in the prevailing economic climate certainly cannot be taken for granted.

I think this performance is a testament to the fruition of the decade-long strategy of positioning ourselves as a truly transformational medical innovator, which entailed scoping in upon and prioritizing a handful of core therapeutic areas where we aspired to assume real leadership. Ultimately this game plan has been paying off handsomely and we have been managing to scale the rankings and assert ourselves as a heavyweight player.

The really welcome fact is that this growth occurred more or less uniformly across all our main therapeutic areas and major geographies. It was not just a case of relying on one or two flagship brands or depending upon the over-performance of a couple of powerhouse markets. All of this demonstrates that we have managed to build a truly robust and enduring business.

There's been a lot going on for Janssen in the EMEA space over the past couple of years – both internally with the integration of Actelion and externally with developments like Brexit. What have been your core priorities and achievements since assuming the role of Company Group Chairman two years ago?

First of all, I have been very keen to preach that we must not take the successes of yesteryear for granted. The biggest risk when you have been doing well is to succumb to the temptation to rest on one's laurels and to allow complacency to set in. The reality is that we are the target of some very strong and well-equipped competitors who would jump at any chance to chip away at our competitive advantage and therefore it is vital that we maintain our current momentum.

To that effect, we have been making some important changes to how we go to market and focusing heavily on optimizing our execution capacity. We believe that seamless execution hinges upon customer interaction excellence so have set ourselves a number of criteria to measure and track our performance in that area. Every year we try and re-calibrate these criteria and raise the bar with an emphasis on enhancing both customer perception and brand resonance. We really try to fine-tune the entire commercial mix and improve on that year-on-year.

Products at different phases of their life cycle need to be handled in different ways

You mentioned the primacy of 'prioritization' and 'specialization.' How has Janssen EMEA gone about making these important choices?

When it comes to resource allocation, Janssen has started to make much tougher trade-offs than we would have done in the past. There is a recognition that the "one-size-fits-all" formula has become redundant in the new era of medical science in which personal precision therapies are gradually going mainstream. We cannot treat every therapy in the same way and position ourselves to try to be everything to everyone.

Moreover, products at different phases of their life cycle need to be handled in different ways. We have now set up intricate models that track the performance of each individual product while simultaneously monitoring the contextual landscape such as where the science is going and what the competition is up to. Armed with this intelligence and the awareness of how each specific product in the portfolio falls into this segmentation, we have been shifting over resources from one brand to another in the direction of where we identify the potential to be most pronounced so as to accentuate our impact. A prerequisite, of course, to being able to perform all of this has been Janssen's getting up to speed with the digital revolution disrupting our industry.

We have noticed Janssen's involvement in collaborations such as "Big Data For Better Outcomes (BD4BO)". What steps have you been taking to prepare Janssen EMEA for digital disruption?

One has to be blind to not see how digitalization is shaking up our industry, which we once all considered to be more or less digital proof. Other industries such as entertainment, travel and media have all been thoroughly disrupted, but Pharma has been sluggish to embrace the inevitable. This is historically down to a number of reasons. Firstly, we are working in a highly regulated industry where there is considerable risk adversity and conservatism around enacting changes that may adversely impact human lives. Secondly, the data that does exist tends to be fragmented and locked in silos. Thirdly, privacy issues are especially acute when one thinks about the sensitivity of personal medical records. Finally, let's not forget about the legacy of face-to-face interactions with medical practitioners and how direct relations through medical representatives has always been a hallmark of our industry. That said, little by little, we have been witnessing the erosion of each an every one of these barriers.

Disruption is always about new entrants arriving on the scene and seeing new value propositions that will change the rules of the game so there is always the threat of the incumbent being left behind if it doesn't adapt. That is why it is imperative that Janssen doesn't sit on sidelines waiting for the dust to settle. Instead, we have to be proactive and that is why we have already teamed up with IBM Watson to integrate blockchain technology and artificial intelligence into R&D processes.

Within EMEA, we are also applying predictive analytics in our 'go to market' strategies so as to enhance our interactions with our customers and other stakeholders. We are even running pilots where we create digital landscapes in which we simulate specific interactions with stakeholders with a view to ascertaining possible impacts.

> Unlike some of my peers, I am optimistic that [the entrance of tech giants into the healthcare space] will ultimately result in natural partnerships

How concerned are you about the prospect of parts of your business being superseded by new entrants such as the big technology giants?

There's absolutely no doubt that the landscape that we used to inhabit is becoming radically recreated and we see global technology players making their entry into what was traditionally our exclusive space. Amazon, Google, Microsoft, IBM are just a few of the tech giants that are now making incursions into the territory previously reserved for Big Pharma. However, unlike some of my peers, I am personally optimistic that these developments will ultimately result in natural partnerships. These new market entrants, namely the software and tech leaders, bring to the table completely new capabilities such as the access to and ownership of data combined with the interpretation and translation of that data into insights. Drug developers like Janssen, meanwhile, deliver the understanding and knowledge of the progress of science which is something that is exceedingly hard for an outsider to master. These technology companies sit on the vast mountains of data and have advanced analytics and AI to drive insights, but we, the pharmaceuticals developers, remain the most able to apply their insights to the science

Clearly, neither side can go the full distance without the other, and that is why I am confident that the future will be more about collaborating with these entities in win-win partnership than competing with them.

Just how easy do you anticipate collaboration to be when their mindset and behaviour is so fundamentally different from yours?

It is absolutely correct that these technology players approach issues from an entirely different start point and perspective compared to the way with which the pharma industry is familiar. Tech companies generally start from unique customer issues that they strive to resolve. Once they have identified those issues they move very fast in coming up with creative fixes. They have adopted an entire philosophy and methodology around the concept of the "minimum viable product."

Drug developers, by contrast, tend to gold-plate solutions and address problems that the customer doesn't even know exist. In that sense, the pharma industry can find itself building Rolls-Royces

when the client might really just want a VW. Honestly, I don't think that we have yet identified the perfect way of collaborating together, because we inhabit very different ecosystems, but the more that we become familiar with each other's work styles, the more we can potentially learn a great deal from one another.

You are a big proponent of algorithmic medicine. What headway is Janssen making in its attempts to transition the business model from "treating" disease to "intercepting" and "pre-empting" illness?

Predictive technologies, machine learning and artificial intelligence all underpin a revolution in medical science. A decade ago, when we started searching for a breakthrough against prostate cancer, we commenced with developing therapies for patients at the end-stage of the disease. These were instances in which everything else that had been tried had run its course. However, as we became more and more knowledgeable about the specific disease pathways we were gradually able to work our way backwards, coming up with medications for non-metastatic prostate cancer as well. The ultimate aim is, indeed, to travel back to dealing with disease prevention and interception. It's almost a case of travelling "back to the future" like in traditional Chinese medicine where the emphasis is firmly on maintaining a state of wellness rather than curing illness.

CAR-T is perhaps the ultimate precision medicine to date

Technologies like digital biomarkers should help us to work through the symptoms and determine when a disease like this might start to manifest itself before it actually occurs. If we take an example from cancer, sometimes what is known as "smouldering multiple myeloma" will show up almost as a precursor to the arrival of the real disease and that's exactly the point at which we'd ideally want to be taking action. Moreover, if we can identify the cohort of people who are most likely to be afflicted with a specific disease, we can then take preventative and mitigating steps. This is where the digital science combo can really make a difference and the bold new era of personalized precision medicine (PPM) starts to become a reality.

CAR-T is perhaps the ultimate precision medicine to date, in which companies like Janssen can harness a patient's own cells to combat the disease. The future vision of healthcare is very much about ultra-customized treatment and bespoke solutions for each and every patient. When someone like Jeff Bezos proclaims that our margins are his opportunity it is not surprising the Big Pharma gets the jitters, however, my reading of the way things are going is a bit different. If drug

makers can get our own houses in order and then join forces with technology companies then we can end up with the sort of “dream team” that can usher in PPM.

Just how momentous a milestone is the fact that the EMA has granted a PRIME designation for Janssen’s CAR-T therapy, JNJ-4528? And what does this say about Europe’s continued openness to breakthrough science?

This is a hugely important signal on how these latest generation biologics are being perceived by the external environment. We have already received similar sorts of designations from the FDA in the United States and PDMA in Japan, so it is reassuring to know that Europe is also in the game for this type of novel therapy. The responsibility now falls to us to develop and deliver it properly. There are huge expectations riding on this breakthrough treatment and, as a company, Janssen has to be attentive to managing these expectations and delivering on the trust this is been placed in us.

In today’s context of cost-containment and increasing stress on healthcare systems, what role can companies like Janssen play in ensuring the long-term sustainability of healthcare provision bearing in mind that therapies like CAR-T are hugely expensive?

There are actually a lot of misconceptions about what pharmaceutical products really cost to society. If you look at that share of the medicines bills across Europe, you will actually discover that in many instances they have remained stable or even reduced over the past decade. It is not the pharmaceuticals that are bankrupting healthcare systems.

What tends to happen is that people will see in isolation the costs of some of these sophisticated therapies and believe that that is what is blowing up healthcare budgets. Let’s remember that the greater share of health spending goes on aspects like hospital care which has gone up considerably. Commentators formerly predicted that statins would bankrupt hospitals, but that, of course, never happened. CAR-T comes in for the same kind of mostly undeserved negative publicity. CAR-T, if introduced properly, can alleviate large costs of care in hospitals and play a role in curing patients to the point that they can return to economically productive healthy lives. Meanwhile, the patent system introduces an important element of self-sustainability into pharmaceuticals with generics and biosimilars freeing up budget for fresh innovation.

That said, I do agree that the sticker price on certain oncology medications is doing a lot to tarnish the public reputation of the pharmaceuticals industry. I am not blind to this public debate. As an industry, we have to take this very seriously. Clearly, the pricing model as we know it today is running towards the end of its useful lifespan. Industry actors, in tandem with governments, urgently need to be transitioning over to outcome-driven, value-based healthcare.

Regulators, payers, policy makers and drug developers seem to have been discussing the transition to "value-based care" for a long time without very much to show for it. How can this switchover be practically achieved?

For a start, governments can revisit their methodologies and criteria for health technology assessment. So much of the systems and processes currently in place are no longer really fit for purpose. The QALY (Quality Adjusted Life Year) system that was used in an era when cancer treatments were all about prolonging life for a few more months is still in effect today although the medicine around it has completely changed and cancer has taken on the characteristics of a chronic disease that people can survive.

Many of the HTA criteria being used today were around in the 1990s when HIV constituted a death sentence and medicines were thus judged on the merits to prolong life. Nowadays diseases like HIV can be managed and priorities revolve around other criteria like quality of life, side effects and patient satisfaction. Governments need to move with the times and drop some of those outdated methodologies. Also, 30 years ago hospitals used to be rewarded by perverse criteria such as according to the number of beds they could fill rather than getting people released back to society sooner and still many of these obsolete practices remain. These are the sorts of frameworks that hold back and slow down the transition to value-based care and performance related contracts.

We keep on hearing that Europe is ceding its competitive edge not only to the United States, but also to Asian power markets like China. Just how relevant is Western Europe to companies like Janssen anymore?

> Where Europe really does excel is in the existence of universal healthcare coverage systems

Having been managing the Asia Pacific region before taking over the reins at EMEA, it is clear to me that Europe's record is quite mixed. On the one hand, I see the evolution of stimulation of innovation and the venture-capital infrastructure around that not only in the US, but select Asian markets such as China and Singapore, and to a much lesser Japan and Australia, and it becomes obvious that Europe is lagging behind. This isn't just limited to healthcare but applies more generally. I think it is no coincidence that apart from a few outliers like Airbnb and Spotify there is nothing much of size that has come out of Europe in the last couple of decades in terms of disruptive tech entrepreneurialism.

On the other hand, certain European markets like Switzerland and Belgium perform admirably when it comes to transitioning to value-based care, and where Europe really does excel is in the existence of universal healthcare coverage systems. The US market, by contrast, is entering a danger zone when you consider the unsustainable share of the healthcare burden costs and, at some point, something will simply have to give. It's only a matter of time.

For Janssen, EMEA remains a very important growth driver. 2019 was initially expected to be a "trough" year with our Chairman, Jennifer Taubert, predicting as much as a USD 3 billion hit to sales due to the coming off of patent and subsequent generic erosion of two star products in the United States: namely prostate cancer med Zytiga® and immunology blockbuster Remicade®. In actual fact, Europe, where the patent cliff is still to happen, has been registering robust revenues and has largely managed to compensate for any shortfall. We are now contributing more to growth than we did in the past. Moreover, the future looks very bright with new drugs set to come on-stream in the coming months such as our ketamine derived drug, Spravato®, which constitutes an exciting new prospect for treatment-resistant depression. There are equally high hopes riding on new indications for drugs like Tremfya™, which we are currently expanding into ulcerative colitis.

And how do the non-European regions of EMEA fit into the mix?

These are very much more long-term plays. There is often a lot of media hype about the growth potential of emerging markets, but our portfolio in places like Africa and the Middle East looks very different from that of Europe with much more of an emphasis on legacy products, though we do try to secure patient access to more innovative therapies through pricing structures that take into account the GDP capabilities of a nation.

Our priority in these markets is to stay the course. Aside from the obvious ethical need to do so, experience tells us that "staying-power" pays off in the long run. For example, we were one of the

few pharma MNCs to remain in Russia during the turbulence of the mid to late 1990s, with most of our competitors pulling out. This was hugely appreciated by the full range of stakeholders from the authorities to patients to practitioners. Then when our competitors tried to reenter the market they found it very difficult to reestablish their original foothold. Janssen's message to the emerging markets of EMEA is that we are always in it for the long haul and not just a fair-weather friend.

To wrap up, what has been your experience handling the integration of Actelion?

I'm happy to be able to confirm that we are now nearing the completion of this process. We actually had a twin-speed sequencing for absorbing the Actelion portfolio and infrastructure. This has been a major undertaking with PAH becoming Janssen's 6th therapeutic area. The first step, which was finalized mid last year, was to carry out the integration in what we call the non-G4 markets, that comprises everywhere other than the very sophisticated markets of France, Germany, the UK and Italy. Then the second stage, this year, has been to tackle these more complex G4 markets.

The entire process has been proceeding very smoothly, and I think that is a testament to how we go about this type of operation. Janssen is quite different from many of its peers when it comes to M&A activity. Many companies, as soon as they have made an acquisition, try and drive immediate cost-efficiencies often by having a fire sale and downsizing staff. Janssen, by contrast, tends to look much more for synergies than pure efficiencies and endeavours to rock the boat as little as possible by keeping the best elements of the acquired entity intact including the original corporate culture. If we look at past acquisitions like Centocor, the philosophy has always been about conducting very thorough due diligence to ensure the target will be the right fit and then "going slow to go fast" when it comes to absorption.

My belief is that Actelion brings with it a lot of added value besides just the product portfolio. They operated almost as an orphan drug company with in-depth knowledge and understanding about the patient that we can learn a great deal from. Their customer interaction is excellent. What we then bring to them is a far more extensive and robust launch capacity and market access infrastructure. When you combine these two elements it ends up a very good marriage.

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