Tom Heyman – CEO, Janssen Pharmaceutica & Sonja Willems – Managing Director, Janssen Benelux

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Mr. Heyman, you inherited the chair and management of Janssen Pharmaceutica. What core values and spirit of Dr. Paul Janssen were you asked by the Janssen family to perpetuate throughout the years?

Tom Heyman (TH): Janssen Pharmaceutica is all about innovation—developing, producing and providing innovative healthcare solutions for patients.

When I started here in 1982, Dr. Paul, as we all called him, was still around. And every time I met him dashing around somewhere, he always asked the same question: “what is new?” We could run into each other several times a day and every time he would ask that same question and you had better provide him with a good and different answer each time!

Dr. Paul has always been interested in an innovative approach, continuously asking himself “what can we do to help patients?” and always reminding us that “the patients are waiting.”

In short, this is what we are trying to do at this campus today—saving or improving patients’ lives worldwide with our innovative products. This is the core value of Janssen.

Janssen has grown to have a presence on five continents. What are your key markets today worldwide, what are your prominent growth areas and what are the most

challenging markets for Janssen in the future?

TH: Janssen Pharmaceutica became a member of the family of Johnson & Johnson companies in 1961, which has given this company the opportunity to globalize itself.

The markets in which we have a strong presence include the traditional markets such as Europe, the United States and Japan as well as China. In fact, we started our operations in China in the late seventies, which made us one of the first foreign- owned companies to have a presence in that market. This was only possible through a joint venture with the government, which has been critically important for the growth of our business in China.

Brazil is another market in which we are very successful and have had a long standing presence there. More recently, Russia has become an important market for us as well as it is a rapidly developing market.

Today, our focus is on all emerging markets. This extends beyond the BRICS countries to also include other countries that are becoming increasingly important as well. Fifteen years, ago people talked about the tigers of Asia – South Korea and Taiwan – subsequently however we witnessed the BRICS countries attract the attention of the world. In the same way, we believe that the next wave of rapidly developing economies will include countries such as Vietnam, Philippines, Nigeria, Indonesia and potentially Egypt. Hence, for the time being we are keeping a watchful eye on these countries.

On the other hand, the markets that are becoming increasingly complex are in fact the developed ones. Actually, these countries have already been complex. More specifically, highly developed markets have governments that play a major role in how healthcare is provided and paid for. Of course, this does not mean that a pharmaceutical company cannot be successful in a mature market. Growing by 1% in a G5 country means generally higher revenue than growing 10% in Russia, for instance, due to the variances in base measures.

Janssen has been one of the few companies that really managed to break into the global arena to become known as one of the most innovative companies in the world. What factors would you attribute to this level of success?

TH: Again, it is all about innovative compounds. However, the definition of innovation has changed over time. At this moment, it is not sufficient to merely bring improvement to an existing product. Rather, today it is about innovative products that not only make a difference to patients' lives but

also make a difference to the payers as well. We have to be able to show that we are able to deliver health-economic benefits on top of clinical benefits.

This is something that we have been able to deliver on over the last three years for the medicines that we developed and produced in Belgium. Our advantage is that we also have a strong commercial organization, which is able to demonstrate to the authorities that there is an economic benefit on top of the clinical one. Whether we like it or not, it is not just about the patients anymore. We have to be able to demonstrate through studies, as well as through solid relationships with authorities, that we can help authorities manage their budgets together with providing better solutions for patients.

As Janssen continues to invest heavily in its campus, how would you rate the overall attractiveness of the environment for innovative companies? And what specifically attracted you to the Flanders region?

Sonja Willems (SW): From an operational point of view, I believe Belgium as such remains to be an interesting market. With regard to clinical trials, Belgium is one of the key countries to conduct research in. If we obtain approval for innovative new compounds we already have a number of universities and key opinion leaders who have previously worked with the compound during the clinical research phase. Furthermore, there are patients who have experienced the benefits of the drug already. Thus, there is always a basis of reference that we can start working from when bringing new compounds to the Belgian market.

In addition to this, as president of the board at pharma.be – the association of the Belgian pharmaceutical industry – I feel that there is a good atmosphere of communication and collaboration between the different stakeholders; with government, universities, sick funds, and the industry and especially with Janssen, given our heritage here. I believe that we have contributed considerably in shaping an environment where people can openly communicate in order to bring innovative medication to the market at a reasonable price within a reasonable timeframe.

At the same time, Belgium is certainly not the easiest market to operate in. If you consider the new drug prices for instance, in Belgium they are currently among the lowest in Europe, second only to Greece. The system of price setting and review is amongst the longest and most stringent in Europe. However, we should not necessarily view this only as negative l since it encourages us to do a better job in documenting and demonstrating true clinical and societal value of our medications to our stakeholders.

My only area of concern is in relation to the current cost cutting measures. There is increased attention being directed at innovative in-patent products for additional price measures. This poses a direct threat to our ability to innovate and to continue to invest in R&D in Belgium.

Personally, what's important in moving forward is maintaining this atmosphere of collaboration and open dialogue with our various stakeholders to work together in finding solutions for the health and economic challenges we are facing.

Overall, I believe that Belgium is a country that certainly has its challenges like any other country but in general there is a healthy level of dialogue, a good sense of what is important and the willingness to work together for the benefit of patients.

The global performance for the entire Group has also been strong in the past year, however how would you rate Janssen's performance on a local level with respect to your individual therapeutic areas of focus? And do you feel that your market share levels are where they deserve to be?

SW: Yes I do think so. At the moment our business demonstrating healthy growth results as a result of product innovations we recently brought to market. We firmly believe that if we continue to bring value to society and answer the specific clinical needs of patients, our success will be carried into the future. It is for this reason also that we have experienced difficult periods in our past since we refused to make a number of obvious and easy choices and instead opted for a more challenging, yet rewarding approach. In other words, because we did not want to make compromises we had to endure some tough times but I believe that today we are reaping the benefits of those choices as we are now capable of delivering true value and innovation to our patients and society.

For instance, with regard to the treatment of Hepatitis C, we are now able to cure patients while a short while ago this was not yet possible. At the core of this ability is the power of innovation for the benefit of patients and societies.

What would you say are your strongest therapeutic areas in Belgium?

SW: At the moment it is Hepatitis C because that is where the innovation is, an innovation for which we received the Prix Galien earlier this year. In addition to this, in oncology we have been

extremely successful having launched Zytiga® – a new and unique compound for the treatment of prostate cancer. We have also been very successful with respect to Velcade® for multiple myeloma as well as with supportive cancer therapy in pain and fatigue management with Eprex® and Durgesic®.

Again, this success relates back to the spirit of Dr. Paul where we always start by considering the patients clinical needs. In oncology we have a broad portfolio but from an operational side, we also look at care in general such as better diagnoses, better compliance, irrespective of the drug. We sometimes see that when we bring innovation to the market, the environment is not ready for it and the outcome less than optimal. This can be because of insufficient communication and collaboration between universities and primary care physicians or of patients simply getting 'lost' in the system. We therefore try to have networks and services in place in order to ensure that the benefits of our innovations can be maximized to the benefit of our patients.

The success of Incivo® was partly due to the use of an innovative spray-dry technology in your production methods used to obtain better solutions of the active substances. What are the implications of these new production methods for future medicines and how do you go about ensuring a spirit of ubiquitous innovation in your activities?

TH: The spray-dry technology was first applied in one of our HIV products. This HIV product would not have come to the market without this technology, which was interestingly derived from the foods industry. For patients suffering from HIV, they were previously required to consume up to 40 pills a day. However, since we implemented this new technology, we were able to bring the dosage down to as little as 3 pills a day – a significant leap forward. Subsequently, we used this argument in our discussion with Vertex, the originator of Incivo® and were able to convince them to partner with us.

This undoubtedly demonstrates yet another example of Janssen's ability to innovate. This technology was sourced initially from the milk industry in Denmark where we sent our people to learn about it. Moreover, we brought people here and built collaboration between our pharmaceutical industry development, chemical development and production facilities. This resulted in the development of a system which we implemented first in our HIV products and now for Incivo®. Needless to say, the spray-dry technology is an interesting and effective technology that we will certainly apply in the future to other products.

One of our objectives is to learn from each other on our campus. The challenge of having so many different functions on our campus is to have them talk to each other in order to nurture new opportunities and ideas. Coming back to Dr. Paul's spirit and philosophy, we are constantly trying to foster an environment of collaboration and communication which results in synergies and innovation. Moreover, I want people here to understand that their contributions at Janssen have an impact on patients' lives because everyone who works here touches people's lives.

Janssen is engaging in open innovation through internal and external partnerships. Can you elaborate on the strategic motivations driving this relatively underexplored initiative and highlight some of the most notable partnerships or advancements that have resulted since it was implemented?

TH: It is rather simple in the sense that the amount of money spend worldwide across universities, governments, companies and other institutes in R&D is a drop in the ocean compared to the amount of money that we as a pharma group spend, which is highly significant. Likewise, the fact that we have come to the realization that innovation does not stop here at the boarders of our Beerse site. We are well aware that there is a lot of innovation going on outside this campus. For us to get access to that innovation we need to understand the medical needs, the new approaches to medicines and start looking at medical solutions which are of utmost importance. We do not possess the capacity to develop all of this on our own. Thus, we are creating collaborations with other parties and have been doing this for a long time now.

More specifically, we have relationships with every university in Belgium and conduct research with other academic institutions across the world as far as China. We also have partnerships with all sorts of biotech companies on a global basis. This is a way of living for us at Janssen.

Furthermore, we also have for example a German company, Biocartis, which we are also working closely with on our campus. Likewise, we have a university center specialized in Alzheimer disease with a laboratory here. For us, it is not just partnership in the sense that you strike a deal; rather it is about increased interaction by bringing scientists together to create an environment where ideas are exchanged.

Mr. Heyman, you were previously quoted saying that the changing pharmaceutical environment demands a proactive shift in the research model to cope with this trend.

Can you elaborate to our readers what you meant by this and provide us with an insight into the future direction of Janssen's research model?

TH: You have to shift your focus in R&D to those products that bring health-economic benefit. Very early on in development plans you have to think that through. Today, it is no longer sufficient to show that your product works and that is has a reasonable toxicological profile, but you also have to demonstrate that it is better than the current standard of care. This needs to be built in your clinical studies at an early stage otherwise you are going to miss the boat.

Furthermore, we have to open ourselves to the external environment and realize that there is more innovation going on outside our walls. Solving diseases such as Alzheimer is a very complicated process. In Schizophrenia, for instance, we have been investing in R&D for sixty years now and although we know how to treat its symptoms, we do not yet know how to treat the disease. Similarly, we do not have solutions for an array of oncological diseases as well.

On the other hand, I would say that the disease we have achieved the most progress in the over the last 30 years is HIV. In the early eighties this was a deadly disease but now, at least in the developed world, it is a chronic disease. Life expectancy of an HIV patient is more or less the same as yours and mine.

Going forward, what pipeline prospects are you most excited about?

TH: We have a new product for the treatment of type 2 diabetes—an SGL 2 inhibitor. The phase III trials have been highly positive. An interesting feature or side effect of this drug is that it promotes weight loss and also has a positive impact on blood pressure. This is of course highly positive for diabetes patients since obesity and diabetes are closely linked.

We also have a Hepatitis C product in phase III that we are excited about.

In collaboration with the Gates foundation we are also developing a tuberculosis drug. This represents the first tuberculosis product in 40 years that will be introduced to the market. This might not be as important for Europe or the United States but for less developed countries it could make a significant difference.

Also, we have a series of important cancer products that are currently in development for different types of cancer—primarily for blood cancer.

SW: One of the risks we face today is the probability of success for new compounds. For instance, we recently had a compound in development for dementia where we entered phase III studies following ten years of research and much investment, but the phase III studies unfortunately turned out to be negative. With the high need for innovation and clear added value, clinical trial programs are facing higher risks compared to before and this will likely be one of the big challenges our industry will face in the future.

In early 2011, J&J finalized the acquisition of Crucell—a Dutch biotech company focused on vaccines. How do you go about ensuring a seamless integration process of these newly acquired companies into Janssen's corporate and business culture?

TH: One of the key elements for J&J is its decentralized model because it understands that local companies have a better understanding of the local market's needs. So whenever we acquire a company such as Crucell, there are certain aspects that are integrated such as financial or HR systems. But with regards to R&D activities, we do not meddle with their affairs since they are far more experienced in their activities than we are.

Crucell was acquired because we believe it is important to have an additional platform in prevention of diseases. We believe that preventing disease is one way in which we can help governments control their budgets since prevention is always better than cure. Furthermore, Crucell was one of the last independently standing companies with strong expertise in vaccines.

SW: When you buy a company you also buy culture. In my experiences with Janssen, I have integrated a number of companies and what surprised me most was that the culture always fit seamlessly with ours. This indicates that not only do we consider a target pipeline and portfolio in our acquisitions, but also its culture and expertise.

TH: As I am also leading Business Development in the pharmaceutical team for J&J and having done this for over 20 years, I have been involved in most of the group's acquisitions. Since it is impossible to integrate culture, we included it in our list of criteria for acquisitions alongside with financial and other obvious metrics. Similarly, another criterion is talent because we try to bring in talent that can have a future outside the company that we acquire.

Looking ahead, where would you like to take the Belgian operations of Janssen in the next 1 to 2 years and what goals would you like to achieve?

SW: We need to intensify the dialogue with our partners in the market such as government, sick funds and universities to see how we can all better prepare ourselves for the future. With respect to Belgium, the main challenges we are looking at include the aging populations and tightening healthcare budgets. The industry is not able to solve this alone so has to sit with partners in order to find the right solutions.

From our point of view we have to continue looking for innovating solutions not only in medication but also in services and support to patients while also becoming more efficient and effective in everything we do, like everybody else at the moment.

TH: Considering that we launched eight new products over the last two years, we should be safe for the medium term. However, the challenge for us is to recreate a new pipeline of highly innovative products that meets patients' needs while offering well balanced health-economic benefits to secure our long term ambitions.

For the campus particularly, we need to ensure that investments continue to follow here. We have a dedicated and professional workforce here and the Belgium government has created a good environment especially from a fiscal point of view to conduct R&D. However, we would hope that they will also create a better environment for our local commercial companies here with respect to access and pricing.

Nonetheless, for us it is important to continue to invest in the country as it represents the very roots of Janssen. Moreover, Belgium boasts a good infrastructure, high standard of education and academic institutions and is an attractive destination for clinical trials and we need to ensure that we maintain this competitive edge and continue to attract investments.

If you could go back to the day you left university, would you have made the same choice and put your life in the pharmaceutical industry?

TH: I am a lawyer by training. My dream was to enter the diplomatic service of Belgium but I quickly came to the conclusion that Belgium is too small of a country to have a real impact on foreign policy. I therefore started to get more and more interested in international law and economics. Following my military service I came across an announcement seeking law candidates specialized in international and commercial law to join Janssen Pharmaceutica. That was when I joined the Janssen team, beginning in the law department which eventually led me to the place I am in today. I would attribute my success to a little bit of luck and to the guidance of great mentors around me.

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