Rudolf Hanko â?? CEO, Siegfried, Switzerland

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Developing manufacturing capacity for as yet unapproved drugs can create huge risk on innovatorsâ?? balance sheets, risk which can be mitigated by working instead with a competent CMO â?? a form of insurance as explained by Siegfried CEO Rudolf Hanko.

With over 6 percent growth, the global CMO industry is outgrowing the global pharma industry; what are the main drivers of this growth?

The CMO sector has grown faster than the pharma sector for the last five years and I believe will for the next five years. At 4.6 to 4.8 percent the growth in the pharma industry is already staggering given the under one percent growth environment across the developed world at present; consistently beating GDP growth by 300+ basis points is a significant achievement.

Interestingly, it has been the capital markets which have driven some of the most significant changes in the pharma sector. Whereas the industry was driven by growth investors for many years, in the last decade the industry has shifted to being strongly driven by value-investors. In the past investors were happy as long as they saw strong revenue growth, and paid relatively little attention to risk on pharma companiesâ?? balance sheets â?? this is certainly no longer the case.

The biggest asset-risk for a pharmaceutical company is the risk of non-utilization of manufacturing assets. Given the time it takes to construct a manufacturing facility, the first steps must be taken in phase II of a product development when the risk of failure is still above 50 percent. Thus, if a pharma

company decides to build a dedicated facility to manufacture a given product, then there is a significant risk that any investments made will be have to be written off by the time the facility comes online.

Thus, Siegfried and the CMO industry as a whole has benefited from this shift because we provide companies with an alternative that lets them avoid having to invest in manufacturing assets which might not be used. Instead, we maintain excess capacity and carry the risk of non-utilization for them â?? charging a premium to carry that risk. In this sense, value we create for the pharma industry is by providing back-insurance; by taking on multiple clients, we are able to diversify the asset-risk of non-utilization. If one companyâ??s product fails thatâ??s fine, we can still use the capacity for someone else.

As a â??back insurance providerâ?• to the pharmaceutical industry, how critical is it for Siegfried to be based here in Switzerland?

For us it is essential to be here, Switzerland is the biggest research and administrative hub for the pharma industry in Europe. Most of the major American multinational pharma companies have their European headquarters here, as well as the leading Swiss companies of course, and being close to our clients is critical.

Second, given the type of business that we are running it is important to be financed on a very stable basis, and Switzerland is uniquely stable when you look at the confidence in the economy and the stability of the banking system. This is critical, as our clients need to be able to trust without reservations that we will be ready and able to manufacture their products when they need it.

Of course, there is a cost associated with being based here as well because Switzerland is an expensive country to operate in. However, we have taken steps to try to improve our value proposition by building capabilities in lower cost geographies as well

We understand that when you arrived you introduced a new â??transformâ?• strategy to Siegfried; what were the fundamental aspects of this strategy you introduced?

While I implemented some changes when I arrived in 2009, Siegfriedâ??s major transformation started in 1973. From 1873 until 1973, Siegfried operated as a successful privately held pharmaceutical company. However, in the early 1970s the Siegfried family saw that the pharma industry was consolidating; they could either join the consolidation, or change the company.

So in 1973 Siegfried took the revolutionary step of changing from a pharma company into a CMO, a process which was successfully completed in the early ninties. This was a pioneering strategy because at the time the CMO industry didnâ??t exist and the market was effectively zero, while today the global CMO market has surpassed USD 60 billion per year.

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I arrived 36 years later in 2009, at which point the company was very firmly established as a successful and longstanding CMO. After studying the firmâ??s position for some time, we set targets to drive the companyâ??s growth and development along three lines. First, to drive horizontal

integration of the asset base. Second, we aimed to further develop vertically integrated capacities to allow for the integration of drug substance and drug product manufacturing. And third, we identified a critical size that we must reach to allow us to cost effectively offer idle capacity to our customers and to be fast and flexible in responding to inquiries.

This last step was very significant in terms of our ability to create value through back insurance. To be able to guarantee we can manufacture a product for our clients at any time, we must have significant idle capacity at the time they approach us. The amount of idle capacity you need for a given project is about the same regardless of the size of the CMO. However, the cost burden of maintaining that idle capacity and the degree to which it bites into your profit and loss statement decreases as you grow in size. When we made this plan in 2009, we came to the conclusion that no one in the CMO really had that critical size to efficiently maintain the idle capacities needed for a large volume pharmaceutical product, and we wanted to be the first to reach that size threshold. While not an exact number, we identified that critical size as USD 500 million in sales per year.

With the organic growth and our several acquisitions, we have made since then, we have come from CHF 280 million in 2009 to over CHF 700 million this year. So looking back, we have definitely â??checked the boxesâ?? of the strategy I set out to execute in 2009.

Why did you feel Siegfried needed to develop horizontally integrated capabilities to be successful?

When you look at the CMO industry you will find that 95 percent of companies are vertically integrated in terms of their asset strategy; their entire value chain is usually in one region or at least hemisphere. This means you must carry out every step of the manufacturing process in either the USA, Europe, or an Asian market â?? usually India or China â?? and Siegfried was in this position too when I arrived.

In my view this was not sustainable because our clients want two things; top quality services, and a competitive price position. If your operations are vertically integrated in a single region it will be impossible achieve an optimal balance between these two considerations.

Thus, we decided to transition Siegfried to a horizontally integrated model such that our manufacturing capabilities would not be limited to a single geography. Today, we now have manufacturing capabilities on both coasts of the US, across Europe in Germany, France, Switzerland and Malta, and now a quickly growing operation in Nantong China. This way we can now allocate our supply chain in a way that takes advantage of both worlds, and adjust your value/risk proposition to an individual clientâ??s needs â?? early steps can be allocated to the eastern hemisphere while more critical activities are carried out in Switzerland or other western sites.

As youâ??ve just explained, many CMOs vertical asset structure is now a performance-limiting factor; why then did you see the need for Siegfried to enhance integrated vertical capacities?

The vast majority of CMOs today developed out of either the chemical industry and focus on API manufacturing, or out of the pharmacy industry and focus on finished product manufacturing. There are almost no examples of CMOs developing from integrated pharmaceutical companies â?? Siegfried is a very rare exception. In that sense, Siegfried inherited unique skills and competencies across the entire manufacturing value chain from API synthesis to finished product, while the

majority of the CMO industry has significantly more experience at one end of the spectrum.

This has not been a competitive factor historically, but in recent years the situation has begun to change. Today, most innovative APIs are so complex that they do not easily solidify and are either liquids or glasses at normal temperature and pressure ranges. Most innovative APIs are so complex that no analytical method exists to detect low concentrations of contaminants or impurities unless you know before hand to look for a specific compound. With solids physical techniques can be used to prove if a material has been manipulated â?? this is very difficult with a liquid, compounding these analytical issues.

As such, the FDA has taken a restrictive stance on APIs that are in liquid form, and does not allow you to transport liquid APIs unless they are under your full control. Of course you can transport the material yourself up to a few kilos of product, but this becomes challenging when you must move say 50 tons of material. As a result, today many companies use various techniques to get the API into a physical state in which it can be transported, spray drying or lyophilizing for example; however, these are costly processes not only because of the cost of the technology, but because you always lose material.

Thus, there are significant costs associated with handling and transporting APIs, and this has prompted many companies to look at the interface between drug substance and drug product differently. They must ask themselves how much are they willing to spend on managing this interface?

This is where Siegfried can come in and offer value to our clients as an integrated supplier who can handle the entire manufacturing process. First, it is easier for our clients to manage their relationship with one supplier with one quality system than two suppliers â?? particularly when a products specifications need to be changed in the drug master file. Second, from a technical and cost standpoint it is much easier to handle an API internally than it is when you must move the API between sites which are far apart and deal with separate teams.

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