Interview: Gabriel Haering – CEO, Cerbios, Switzerland

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Gabriel Haering, CEO of API manufacturer Cerbios, highlights the importance of "Swiss-ness" to the company's brand, their attentiveness to diversification and scaling the value chain, and the future prospects for Swiss CMOs.

Cerbios is renowned for its expertise in the process development and contract manufacturing of Active Pharmaceutical Ingredients (APIs) and in particular High Potency Active Ingredients (HPAIs). Could you please begin by introducing how the company initially came about and the scope of its operations today?

The Cerbios story in effect starts in the middle of the 1970s when the management of Unione Farmaceutica, a wholesale distributor of pharmaceutical products to the pharmacies of the canton of Ticino, decided to diversify their business by investing in production activities. As a consequence of this decision, three new companies were established. The first was “Cernitin” (1976), essentially a production and marketing vehicle specialed in the production of pollen extracts sourced from different European countries with main production unit in southern Sweden. The products were targeted to the health foods and ethical markets with indications for the treatment of bening prostata hyperplasia. The second company was “Bioferment” (1976) focused on the production of a proprietary, live enterococcus (Enterococcus Faeciums SF68®). Together with Laboratory Giuliani (now Sanofi) the Pharmaceutical Probiotic BIOFLORIN® was launched in Switerland and Austria (by Sanofi) and in other countries by Cerbios. It’s worth to note that Bioflorin is nowadays still number one among the pharmaceutical probiotic. The third company was “SAPEC” (1979) involved mainly

in the production of reduced folates by using in-house developed technology. Cerbios has a world-wide leadership with products that are deployed in the “rescue therapy” when treating solid tumors (colorectal cancer) with antifolates and also as vitamin supplements in folate deficiencies.

Then in 1994 the landmark decision was taken to merge the three structures into a single, streamlined entity creating today what is known as “Cerbios” whereby all our functions are created under the same roof.

How much of an advantage is it to now have all of these capabilities under a single roof as opposed to the more silo-ed approach of the past?

At that time, the merger was driven by organizational needs since all businesses were successfully growing. Nowadays customers are very appreciative of what having both competences under one single roof especially in the field of antibody drug conjugates (ADCs) where both the competences are required, i.e. Biological (for handling the antibody and the conjugate) and chemical (for the conjugation step).

It would seem that attentiveness to diversification and scaling the value chain has always been a defining characteristic of the company’s strategy…

Indeed. As a company, we always have one eye looking towards the future so as to remain at the forefront of the technological curve and a step ahead of our competitors. This mindset had been reflected in many of the strategic decisions made to date. Our offering in the domain of reduced folates was initially difficult to emulate given the complexity of the science and it is no coincidence that we still maintain today dominant positions in the US, European and Japanese markets in this particular niche. Equally, our decision to gain expertise in handling high potency active ingredients is also born out of a desire to focus on the higher reaches of the value chain.

If you consider the new chemical entities, we are talking about more and more highly potent substances requiring advanced levels of containment so as to protect the operator from their toxicity in addition to the cGMP procedures in order to avoid any cross-contamination. The sophisticated containment equipment, which was borrowed from the nuclear science industry, acts as a technological constraint, while the complexities of the molecules themselves represent another barrier to entry for many potential competitors. Increasing needs of super potent compounds (Category 4 SafeBridge) mainly utilized as payload in the ADC represents a good niche of market for us that we have over 20 years of experience in the handling of such type of compounds. Our track record coupled with famous Swiss quality differentiates Cerbios from competitors.

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Switzerland has a reputation as an expensive country. This could be correct in the case of a tourist for example. In our case, and considering that 95 per cent of our turnover comes from abroad, it is a confirmation that we are competitive and our reputation for quality generating value is absolutely essential to our brand. We have to be visibly different and have special technologies at our disposal. We are always keen to make our clients understand that when they work with Cerbios the QOTIF (Quality On Time In Full) promised with the quotation is fully maintained, avoiding any delays in their clinical program. Our goal is always the value for Cerbios and our partner. We set out to surprise our partners that will get more than they expected. Many year ago, I saw an interesting private airline advert saying “Price is what you pay. Value is what you get”.

I liked it and this is what I am also pushing to understand within our company as a strategy. Paying less today, could mean paying much more in the future. And in pharmaceuticals a delay of some months in the clinical trial means a delay of the launch date. Since the patent expiry date doesn’t stop, this means losing millions of dollars of sales. And top management and shareholders definitely do not like this.

Tell us more about Cerbios’ orientation towards innovation and special technologies.

Many companies can make HPAIs. It is “simple” to buy and install a glove box nowadays. On top of the long-term experience we have (over 20 years) in developing and manufacturing these molecules, we can make them differently with a series of technologies. At Cerbios, we have been working hard to create additional value through innovation in processes and technologies. We are proud to be one of the few companies offering HPAI manufacturing of Safebridge category 4 compounds and to possess a variety of exciting technologies on the containment side including:

(1) continuous flow chemistry

(2) chromatography purification

(3) particle size design down to nanoparticles (that can improve solubility and bioavailability)

(4) pre-formulation for lowering the containment class

(5) state-of-the-art spray delivery systems for dermatology drugs

(6) Conjugation for antibody drug conjugates (ADCs).

To reinforce our position in this field we recently joined the strategic alliance PROVEO™ with other three companies specialized in monoclonal antibody production, fill and finish and packaging and labeling.

Our main role within PROVEO is the development and production of payload and performing the conjugation steps. PROVEO enter in force once that at least two or more of the service are needed (antibody and/or fill and finish). The PROVEO full service is offered to our partners via one of these three entry points. From the client's perspective, therefore, they are dealing with a single actor, a "super" coordinator or project manager that supports him in the logistics and sites coordination.

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You mentioned that 95% of your revenues come from abroad. How would you describe the profile of your client base?

Profiles of our customers changes a lot according to the specific types of services rendered. Historically, we tended to work with a large volume of generics clients in relation to our chemical-based products. Nowadays, we work with many different companies from originators (start-ups, large biotechs, top 10 pharma companies) and generic companies. We provide full CMC and regulatory support to partners for world-wide registrations, including the supply of clinical batches, validation and, of course, commercially manufactured APIs that is our core business.

Cerbios' commercial products are indeed marketed worldwide, but primarily in the heavyweight markets of Europe, USA, Japan and India. We work with generics companies in the Japanese market, but not so much originator firms because the cultural preference there is firmly skewed towards local manufacturing. We are looking closely at the Chinese market as well as we are aware that APIs made in Switzerland are very highly regarded all across the Far East but not only.

How important, then, is Swiss-ness to your brand?

Being a Swiss company is a great asset because of the connotations of quality and durability. Coming from Ticino, we are able to blend Germanic rigor with Italian creativity. Ticino's reputation as a top-notch service provider to the pharmaceutical industry is growing in leaps and bounds. Not only is Ticino a good catchment area for stellar talent from Italy, but the local authorities are also incredibly supportive, to the point where we have received financial backing for investments projects that contribute positively to the local economy and employment.

What has been the impact of the strong Swiss Franc, given that the bulk of your business is conducted with foreign clients?

Obviously for a company conducting most of its business outside the home market, the very strong Swiss Franc presents a major obstacle. We have been able to insulate ourselves from some of this pressure through risk sharing of the currency when agreeing contracts so that the quotation is based upon a fixed exchange rate. When the Swiss Franc appreciated, it was of course a big hit for us, just like for everyone else, but, in the end, with innovation and the fine tuning of our business operations we were able to increase productivity and our sales, identify additional ways to add value and plug the margin of price erosion. I am very proud of our employees that supported us in all changes that occurred during the last years and of course our shareholders, the families that created Cerbios and are actively present as board members.

On your appointment in 2009, your instructions were to thoroughly restructure and rebrand the company. Looking back, what would you say have been your main achievements?

When I first joined, Cerbios was well known for specific therapeutic areas and a loyal customer base, but my predecessors had done little to market the company in the sense of corporate branding and outreach. On my first visit to the company, I was deeply impressed by the quality of the in-house infrastructure and realized a lot more should be done to make people aware of the brand. I regarded the company very much as a ‘hidden diamond’ with considerable unfilled potential. Since then we have made great strides on this front.

My other aim was to properly develop the contract manufacturing services. With such state-of-the-art facility and equipment already in-house, it made sense to promote more aggressively to pharma originators needing to outsource these sorts of difficult to make HPAIs and probiotics. Not only we have managed to do this, but we have also flattened our entire organization so as to be driven by cross-functional projects rather than old-style management hierarchies.

How has the CMO business segment been evolving over time? And how has Cerbios adapted to emerging trends?

While once the name of the game used to be all about Big Pharma attempting to do everything in-house, most pharma companies are now tending to concentrate on specific stages of drug development and willing to outsource the other functions. Nowadays you encounter startups focused just on the discovery phases, biotech companies dedicated to moving the candidates through clinical trials, large-scale pharmaceutical companies primarily taking care of marketing and commercialization and others concentrated solely on the development of generics.

Since the development of a new chemical entity or a future generic carries the risk of failure of clinical trials or failure in the launch, production outsourcing to a CMO brings a definite value to the pharma companies. The co-developments model with real risk-sharing resulting in profit-sharing later on is becoming more and more popular. For a small to medium size CMO like Cerbios it is possible to consider this model under certain given circumstances and mainly in the area of future generics or supporting the originator in the “life-cycle-management” phase of his original compound. But have to be wary of instances of risk-shifting. Doing the development free of charge on the basis that the CMO earns royalties on any eventual sales is the dream of some pharma companies, but will probably only makes sense to a CMO if they are a new market entrant and desperate to secure some initial business.

In the development of future generics, however, the co-development model can be sustainable since the compound is known of the market and there is clear potential to attain a market share of say five to ten per cent. The risk is thus, substantially lower than with a new biological or new chemical entity that can fail at any clinical stage.

What are your expectations for the coming three to four years?

I believe there are going to be great opportunities for further expansion. I see us growing organically in areas such as antibody conjugates, and also inorganically through acquisitions of companies with synergistic capabilities of the chemical side. I also have high hopes for our probiotics business, because this is an area for great new scientific potential. Whereas much is already known about the human genome, the human micro-biome and the role of bacteria and microorganisms within the body is much less understood. This could well represent one of the new great scientific frontiers and a source of future medicine pathways.

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