

Two executives from Cerbios-Pharma talk to LSKH

With almost 50 years in the pharmaceutical industry, Cerbios is a privately-held company, with headquarters in Barbengo-Lugano, Switzerland, specialising in the development and manufacture of both chemical and biological APIs for its partners worldwide.

The first to answer was Christian Suà, Chief Executive Officer of Cerbios-Pharma.

Q. What do you envisage for future investments and expansion of your CDMO services?

A. Cerbios started their activities in the 70's with one fermenter in a small room. Now we operate ten manufacturing units within an area of 16,000 square metres in all our strategic fields as API, HPAPI and ADC bioconjugations. During our long-standing 45-year history, we have always invested in R&D and new manufacturing plants in order to support our customers with expansion of our capabilities. To give you some numbers, during the last ten years, we invested an average 15% of revenue in new infrastructure. For our future expansion, we have already purchased neighbouring land. We intend to continue investing and consolidating our position in the development and manufacturing of complex APIs and provide high quality services and strong know-how to our customers.

Q. Sustainability is a huge topic worldwide; companies are increasingly adopting sustainability manufacturing practices, but what do you feel are the challenges that Cerbios is facing?

A. In recent years, there has

clearly been an increased awareness and pressure on sustainability topics from all stakeholders, in particular customers and authorities. Cerbios is committed to do its part and last year we already obtained a first objective with the Ecovadis certification as a sustainable company. Our intention is to do more and accelerate the process of sustainable manufacturing practices.

We are currently focusing on three main projects: First, we are installing 5,000 square metres of photovoltaic panels. The second project concerns a new heat pump for recovering passive heat and the third project is increasing the recycling of solvents.



In my opinion, the main challenge will be balancing political expectations and sustainable targets with the needs, objectives and timing of the pharmaceutical industries. Therefore, a strong collaboration with our suppliers, customers and local authorities will be crucial to reach the objectives.



Christian Suà, Chief Executive Officer of Cerbios-Pharma.

With these projects, our intention is to reduce 40% of energy consumption and reduction of 600 tonnes per year of CO₂ emissions. I think they are ambitious, but necessary goals.

Concerning the main challenges related to sustainable manufacturing practices, I believe they are mainly linked to economic and financial factors, as the projects require substantial upfront investments with long-term benefits.

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Next to reply was Denis Angioletti, Chief Commercial Officer at Cerbios-Pharma.

Q. Earlier this year, Cerbios released an article stating that innovation is a mindset. Cerbios has four key values – responsibility, quality, reliability and collaboration. Can you talk to me about those four values and Cerbios' key strengths?

A. When we're talking about innovation, we believe that this is by itself a strength of a company, when it inspires its growth path – as it is for Cerbios. If we look at our past, the company started being in business in the early 30's of the last century, installing a business as a wholesaler, which did not exist at the time, in the South of Switzerland. Then, in the 70's, the company began manufacturing APIs (biological and chemical APIs) for which, still today, we are one of the few making those products in the world. In the 90's, the company moved into manufacturing highly potent APIs, because it anticipated the needs of the market. That's the mindset of the company: innovation with a vision of the future needs of the market. We believe it's a strength for us because when you are focussed on innovation you are ready for making those things that are necessary even when it becomes really complex. It helps you going forward with your clients. That's why we do it. When we speak about our values, which you mentioned, it's the same: those values are in the DNA of the company since the beginning of the story.

We try to apply and extend those values (quality, reliability, collaboration, responsibility) both in the way we work internally, as well as in the way we work together with our clients. That's important because we communicate with the clients and we work together with the clients.

Q. Over the last 20 years Cerbios' value proposition has strengthened in the highly active API sector, continually expanding its offerings for advanced CDMO services. Can you talk to me about the most recent investment for the development and manufacturing of ADCs?

A. First of all, we made all those investments in this single site here in Lugano. We believe that's extremely important because of the complexity of ADCs. During the development and manufacturing of these molecules, including the analytical activities, the processes and logistics may add complexities, which can be easier to manage having all the steps and the team on the same site.

Specifically, talking about the most recent investments, our approach has always been to grow anticipating the needs of the market and the needs of our clients. Therefore, what we did in the last three to five years, was first expanding our capacity for highly potent products, with a larger scale unit to complete our range of batch sizes. Then we built a new conjugation unit that allows us to scale up the manufacturing of the conjugated ADCs for supplying the clinical phases and the commercial scale. We also expanded our R&D and Analytical Development Laboratories to basically



Denis Angioletti, Chief Commercial Officer at Cerbios-Pharma.

double our capacity for the development of new projects.

And finally, the most recent investment approved recently by Swissmedic is a new plant specifically built for the manufacturing of the payloads for the ADC conjugates. That was very important to expand our capacity and to have everything on site to follow the growing demand of our clients.

Q. All of this is within a single site?

A. Yes, all of this is within a single site, which we believe is an added value to what we are doing, as we said before.

Q. Even though the ADCs is a niche market, it represents one of the rapidly-growing segments of the pharmaceutical industry, with a number of technological advancements that have been reported in this sector. What are your strategies to develop this market segment and how do you think Cerbios can make a difference in the global market?

A. Well, yes, it is a niche market, but you can now count 13 molecules, which are out there in the market, and if you look at what is in development, it's more

than 700 molecules at pre-clinical stage and almost 300 molecules, which are in the clinical phases. These molecules are very much different among one another being based on different targeting moieties: it can be not only mAbs, but also fragments and proteins; additionally payload synthesis can involve a different know-how and finally also the conjugation technologies can be very different. In such scope, our decision was not to focus on a specific conjugation technology, but develop our know-how and our internal assets to be able to manufacture as many as possible of those types of molecules and apply as many as possible of those technologies, which are available out there. This is the way we are approaching the market and this gives us the possibility to support as many clients as possible. Even more, to focus our resources to the ADC business, we created a specific division, what we call the PROVEO division, which scope is exactly to manage such a complexity, because our business proposition is that we support our clients from the very early development up until the commercial phases and we do so for all of those single parts of the molecule. That's where the complexity comes and the idea of having a dedicated unit for doing so was exerted to show that and manage the focus, specifically in ADCs or in general conjugates.

Q. You developed and completed a new plant last Spring, full of state-of-the-art technology, can you tell our readers a little bit more about this new facility?

A. The unit is a brand-new building, it features



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two complete lines for the manufacturing of the payload part of the ADCs, the cytotoxic part, and which can host all the different technologies needed. That follows exactly the approach to innovation that we aim for. We needed to have more technology on site, because of the increasing complexities, and we do need more capacity because the programmes, projects or products that are coming from our clients are more complex than ever. So the plant has been specifically designed on the concept we just mentioned, to be able to have the maximum flexibility for making these kinds of products, and having on site all the technologies, which are necessary in such scope. Our customers can benefit from lyophilisation, nanofiltration and all the different types of chromatography, which are fundamental technologies for molecules that are increasingly complex today.