Interview with Hermann Katinger, Founder, Polymun Scientific

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2012 marks the twentieth anniversary of Polymun. Can you describe to our readers the origins of the company and how it compares to your expectations in 1992?

Prior to founding Polymun, I worked as a professor for the Institute of Applied Microbiology at the University of Natural Resources and Applied Life Sciences, as well as working as a consultant for a number of different pharmaceutical organizations. In particular, I had a co-operation with Chemie Linz AG, which was then sold to Hafslund Nycomed in Norway. It was at this point I realized that I could not continue working for such organizations, and subsequently established Polymun. The main activities at Polymun's inception were focused on recombinant products, monoclonal antibodies, as well as some work in vaccines.

What have been some of the key milestones that you have achieved during your tenure at Polymun?

Polymun is well known worldwide as having developed the first human monoclonal antibodies to neutralize HIV in the late 1980s. This development resulted in creating clinical-grade material of these antibodies. A number of clinical trials were run to prove the concept's potency. The idea was to protect neonates by passive immunization from HIV positive mothers, since breast feeding is the main way in which HIV is transferred to infants. This was done in collaboration with Harvard University and Walter Reed Army Institute of Research. During these studies, it was extremely

difficult to raise money, partly because of the lack of organizations that seemed to truly care about this critical issue. Meanwhile, several other institutions have followed our example and established additional broadly neutralizing antibodies. We are still supporting vaccine development with antibodies for research purposes.

Polymun is also known for its pioneering work in the field of influenza in the 1990s, in which we developed an influenza life nasal spray vaccine based on VERO cell technology using protein-free media. This was done in collaboration with Pasteur Mérieux Connaught. Two clinical trials were organized in St. Petersburg by Polymun as there was a licensed life attenuated influenza vaccine available in Russia produced in embryonated hen eggs.

When we spoke to Oliver Szolar of Savira, he expected very strong competition in innovation from China and India. What do you think Austrian biotech companies need to do to ensure their global positioning in terms of innovation?

Innovation is resulting from the translation of research achievements for the benefit of society. Many research achievements that have been originally created in Austria have been fertilizing innovation abroad. I should mention that I engineered a facility for manufacturing interferon in South Korea in the 1980s which is still operative.

Many products that have been created in Austria are now produced all over the world. Producing and marketing biopharmaceutical products creates highly qualified jobs, and Austria can serve as a hub for sustainable innovation. In the biotech field, more than 50 percent of my PhD students are now working outside of Austria. The challenge is how to retain talent in Austria as well as attract foreigners to Austria to work and study. The Austrian biotech industry in general has the biggest manufacturing factories in the world, particularly for antibiotics, citric acid and xanthan. Plasma production facilities are another important area that Austria used to strengthen its positioning worldwide, as the country harbors significant key facilities of two global players, Baxter AG (former Immuno AG) and Octapharma AG. Blood plasma products are of course a door opener for recombinant technologies to manufacture complex proteins such as monoclonal antibodies or various blood factors.

Do you think that this high concentration of plasma activity would serve as a useful beacon for the rest of the world to attract more people to Austria for research?

Unfortunately I see this business in decline, as there is not much research dedicated to plasma-derived pharmaceuticals anymore. The plasma industry started after the Second World War, and now it is perceived more as a traditional treatment, as well as being highly regulated. In the 1970s,

I had the great luck to meet Georg Köhler, who taught me and my students how to produce monoclonal antibodies, a technology for which Köhler won the Nobel Prize. Thanks to Köhler's advice, we were part of the pioneering groups in Europe who could produce human monoclonal antibodies with hybridoma technology. We had ambitions to establish a huge human hybridoma collection stored in liquid nitrogen and prepared from blood samples collected worldwide, in particular from people surviving slums in Asia (India, China and South America) as a general source or treasure for screening of human monoclonal antibodies. We failed the financing of that dream. This would have been ideal, because a healthy human body pre-selects what it is building within itself. Only one percent of the antibodies circulating in the body are selected, and the other 99 percent are eliminated. Now we are rediscovering innate immunity with antibodies developed over millions of years, which can be isolated. At the moment, I am working on a recombinant natural human IgM antibody for cancer treatment.

What is the market potential of such products?

The antibody market is now estimated around $50-70 billion worldwide. It is a particularly interesting market since there are so many clinical candidate antibody products in the pipeline that are waiting to hit the market. An antibody targeted at a specific ailment would have a calculated market. For example, if an antibody against an aggressive cancer like small cell lung cancer turned out to be successful, you would have an immediate and prosperous market as there is no alternative. If you could increase the life expectancy for two to three years with no adverse effects, marketing would be no problem. There is no competition if you can establish something like this.

Partnerships are always required, but what makes Polymun such a good company to work with, and what examples of products demonstrate this?

Polymun communicates, collaborates and works efficiently and it has an excellent team. This is necessary to meet the challenges of the increasing regulations. We have different technology platforms such as recombinant mammalian (CHO, hybridoma) and microbial (E. coli, Pichia pastoris) cell technology. This is enabling us to manufacture any kind of protein under GMP. Furthermore, we have a proprietary liposome production technology for drug delivery and vaccine design. Polymun can combine technologies; for example, the very efficient liposome technology with recombinant antigens for vaccines delivery. Research collaborations with universities in several fields of life sciences are established tradition. We also have expertise in the design, organization and monitoring of clinical trials according to GCP and collaborate with the Medical University Vienna.

Do you think it is becoming more common for big pharma companies to invest earlier in the development of small companies?

I do not. It was far more common in the 1990s to obtain investment for a good idea. Now big pharma companies will only approach a small company if it has a Phase 2A trial with proof of principle that it might work. It is only at this point that such organizations are willing to invest. The industry has changed a lot. Personally, I am not sure of the variety and breadth of the pipelines of big pharma companies. There are only a few that have a full pipeline.

You are very experienced with a wealth of knowledge that you can impart to young students. What piece of advice would you give to someone looking to start up their own company?

I was chairman of the Institute of Applied Microbiology for almost thirty years. We had roughly ten spinoffs during my tenure, eight of which were successful. Most were in contract services, which means they do not have their own product pipeline. One recent spin-off, namely f-star, represents a very good example. F-star was founded by my former student Florian Rüker who is now professor. Florian, after many years of extremely smart and ambitious research, was realizing the breakthrough of a new antibody engineering technology platform with the power to confer additional binding specificities to any antibody molecule without destroying desirable effector functions. Thus several functions can be combined in one antibody-like molecule. F-star found investors as well as strategic investments from several big pharma companies. Projects like these are very interesting for big pharma companies. There are other examples of breakthroughs in technology that were done here in Austria, but many did not have the funding to see a project to its end. This is why I proposed to found a risk fund of €70 million for clinical trials, which would give researchers more reassurance in terms of financing. Of course, convincing politicians of this is another story.

If we were to return to Polymun in five years, where can we expect to see that company at that point?

In five years, Polymun should still be in a very comfortable position in terms of financing and investment. At the moment we supply several clients with products for Phase III, one of which is ready for market authorization. If these products sell well, we will be responsible for the production of the active pharmaceutical ingredients. This gives Polymun stability. We also have several projects in development for earlier clinical trials, both with large and small companies. Polymun’s experience in clinical trials is outstanding. For example, the company is currently serving and supplying 76 clinical sites here and outside Europe for a multi-center Phase III study with a

monoclonal antibody to treat a rare cancer disease of children.

I see Polymun developing very positively over the next few years. We have a very good team, which is more of a family than a company. As long as Polymun continues operating this way I am sure we will be successful. Additionally, my own personal connections through the world of research allows for mobilization of scientific advice and support.

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