Yoji Yuki – CEO, UniBio Corporation

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Yoji Yuki, CEO of Japanese regenerative medicine company UniBio, recalls the roots behind the venture and its plant-based technology. He also sets out his ambitions to expand and develop greater manufacturing capabilities in order to meet UniBio's future ambitions.

Can you start by introducing yourself to our international readers and Unibio's origin?

Previously, I had been the President of the tech transfer office of the Niigata prefecture for 16 years. Niigata University initiated the idea to form what we call Niigata TLO – Technology Licensing Organisation. As part of our activity, we made an agreement between 11 universities along Japan's north-eastern coast and transferred technology from Niigata university's life science industry, involving 2500 life scientists.

We took some of this technology to demonstrate at the BIO innovation trade show in the USA, the biggest biotechnology trade show in the world. During the show, we were introduced to Plant Biotechnology. After hearing the news that Dr Yamanaka received the Nobel Prize in 2012 for discovering iPS cells, a ground-breaking discovery in regenerative medicine, we came up with an idea of using this technology to produce regenerative medicine materials. We then made an agreement with Medicago and Kentucky Bioprocessing Company, now a subsidiary of British American Tobacco. The deal with Medicago was designed to promote Medicago's technology in

Japan and signed an exclusive deal with them. We began transferring their vaccine technology based on transient expression technology. Mitsubishi Tanabe then acquired Medicago.

Up until now, the raw materials for regenerative medicine were all imported from the USA and Europe. They are mainly from animal cells which are higher risk as they contain parts which are infectious to humans. Moreover, processing animal cells is very complex and expensive.

We sought to neutralise the risk by utilising plant cells. Moreover, plant-based technology is very easy to scale up or down. At that time in Japan, we were still using chicken eggs to make influenza vaccines. It would take up to ten months to make the vaccine because the manufacturing process is very slow. Using our plant technology, we can do it in two months, a big difference. Moreover, the initial investment cost for plant processing the *Nicotiana benthamiana* plant is one tenth of that for a bioreactor system.

In 2005, the Japanese government began looking for innovative ideas across Japan in the field of regenerative medicine. By 2011, the timing was very good to establish a company as the Government enacted new regulation to give conditional approvals and shorten the clinical testing period for stem cell products. They had also conducted comprehensive market research, both in Japan and abroad. As a result, UniBio was established in March 2011, coincidentally on the same day as the Great East Japan earthquake.

You have a partnership with Mitsubishi. What has been the impact of collaborating with a large conglomerate?

In fact, it was Mitsubishi who contacted us looking to invest into regenerative medicine. We were in discussions with Mitsubishi for two years before we came to an agreement. We like to say that our technology is “SSS” – safe, swift, and scalable. We now have a joint global patent with the Mitsubishi Chemical Corporation in addition to our Japanese patent for the EGF method of manufacturing through a transient expression system.

Together we have developed two or three items, but we must still develop many more protein growth-factors over a five-year period, creating perhaps 10-20 new products. 90 percent of the growth factors are from the US or Europe, so Covid-19 is damaging our supply chain. However, this gives us an incentive to produce in Japan to secure our supply chain, and also demonstrates our importance to the Japanese industry.

What are your current capabilities at UniBio?

Currently we have a small manufacturing capability. We are renting the space in part of a factory but are now expanding. This will be completed by the end of the year. Our material can be frozen and preserved before becoming part of a cell culture, so it can be transported from our base in Japan. This can enable us to become a regional or even global supplier.

We need to expand our portfolio of proteins and growth factors very quickly. Despite the fact that there is a downward pressure on cost, there is an upward pressure on quality. Unlike pharmaceuticals where only one compound needs to be produced, in regenerative medicine, growing a whole new organ for example, the manufacturing process is very difficult, requiring many proteins simultaneously. If one material fails or is contaminated, it all fails. It is even more difficult and high risk if the material is sourced from the patients themselves. Thus, our manufacturing must be of the highest quality, while scalable to match our future production ambitions.

Both large multinationals and small bio-ventures across the world are facing the same problems vis a vis manufacturing within regenerative medicine; no nation is able to claim leadership in the regenerative medicine manufacturing sphere. This has become our ambition, which is why we need a factory that is capable of achieving that goal. We know that the large-scale factory is coming, and we believe that it will become profitable within 3-5 years, generating USD 40 million annually.

Where is the main source of interest for UniBio's technology?

Internally, we are prioritising regenerative medicine raw materials, which is quite a different offering. When thinking about regenerative medicine, every protein is unique. However, we have the potential to make many kinds of protein drugs and are not limited to regenerative medicine; currently the industry is looking at our technology and products with a view to producing antibodies and vaccines. There are three companies in the USA that are developing Covid-19 vaccines using plant biotechnology. Of these three companies, Medicago was a former partner and KBP is a current partner. This widens our ability to form partnerships.

At this stage, our main partnership interests are from domestic Japanese companies. However, large multinational companies can take advantage of the favourable Japanese laws towards regenerative medicine.

What has been UniBio's experience in raising revenue and attracting investment?

While we are keeping the majority of the shares amongst the Niigata prefecture, the remainder will be open for outside investment. We have been very lucky that the presidents of the Japanese food industry are interested in regenerative medicine, and some have begun investing in UniBio. Furthermore, the Japanese local government has some small venture capital projects that it has invested in. We have also received investment from a very good IT company which has been growing significantly. Their chairman, foreseeing the future lucrative nature of regenerative medicine, has also decided to invest. While we have been successful in attracting investment, we are still not rich and are always seeking to find more funds.

What would be your final message to our international audience?

We are open to collaborating with any large company and are particularly interested in sourcing investment to help us create a GMP plant in the future.

Moreover, we welcome partnerships not only financially, but also technologically. We are specialised in manufacturing proteins, so we need to find a way to place it into cells to create organs that can be transplanted into patients. Only then can we file an IND (Investigational New Drug) application to the PMDA, EMA, or FDA. We are in the early stages, and we cannot achieve this with only one single material (although the PMDA is reviewing the system to become more accommodating).

Consequently, we are interested in collaborating with pharma companies and research institutions who want to use our technology to produce a full organoid or use it as bioink for a 3D printing process. What is most important to stress is that there are many different applications for our technology, particularly in the field of regenerative medicine.

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