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Albert Liou discusses the success of the government's investment in clinical trial infrastructure, which has triggered the rapid growth and advancement of the Korean clinical trial market and spurred innovation in the local life science industry.

What have been some of the main changes for PAREXEL in Korea since 2009?

Back in 2009, we were just finishing the integration process with PAREXEL, which had started at the end of 2007. We had fewer than 70 employees in Korea, and were just getting used to working with the PAREXEL global network in terms of operations. Once we finished this process, we returned our attention to growing and developing our business in Korea.

This process enabled us to expand beyond our clinical trial services. First, we have greatly developed our role as a healthcare consultant over the past few years, and now have a very active consulting business unit that works with local companies who are trying to bring biosimilars and innovative products to the global market. Taking on this global advisory role has required our organization to develop and mature substantially. Prior to our acquisition by PAREXEL, Apex’s perspective was limited primarily to the Asia-Pacific region; now we have a truly global outlook and are part of a global organization. The second aspect of our growth has been in our PAREXEL Informatics (PI) business, which is a part of our technology group. Our PI unit has come to play a

very important role in the Korean market, and many of the top local firms have benefited from these services over the last few years. In fact, APAC eClinical solutions market is expected to reach 662.8 million by 2018, with a CAGR of 19.5 percent per annum.

Several of the top Korean CROs have become significantly more sophisticated in recent years and are offering quite comprehensive 'full services'. How has the increasing competition from these players affected PAREXEL Korea's position in the market?

The clinical development industry in Korea has become more competitive, but also more collaborative. Local CROs have their own strengths, including government support and a general 'home team advantage', while we have different strengths and assets as a global CRO, specifically our technological capabilities and global drug development experience. With regards to our top of the line project management systems and PI capabilities, we can support local CROs that need these systems to handle multi-country or global clinical trials, as many of them are seeking to do – and in fact, several of them are using our products at this point in time.

Another pattern for our collaboration with local CROs occurs when they are working with a local pharmaceutical company to bring a product to other markets. Often, the Korean CRO will manage trials conducted in Korea, PAREXEL provides eClinical trial technology, safety monitoring, and project management for trials conducted in other countries, and we work together to maximize the returns from our shared clients' resources.

We are of course engaged in other types of partnerships as well. One of the more interesting possibilities is with regards to some of Korea's leading hospitals and medical centers who are starting to focus on early phase development. As a global company, PAREXEL is interested in brining high quality early phase studies to these state of the art medical centers around the world. Over the last few years, we have experienced success with some of these Korean medical facilities and look to continue participating in these opportunities.

There is an industry wide trend towards earlier phase trials, with some firms considering bringing first in human trials to Korea. What is driving this trend and how has it affected Korea's strategic position within the region?

First of all, the Korean government deserves recognition on this subject, as I admire their foresight, policy and execution with regards to the clinical development industry. Many years ago, the Korean government had the ambition to develop Korea into a major clinical trial hub. Originally, this was by attracting population-intensive trials, however as Korea cannot compete with China or India in this area, they have focused on bringing more knowledge-based early phase trials to the country in

recent years. These types of trials are very valuable in terms of talent development, and have acted as a catalyst for local biotech and pharmaceutical companies to engage in more innovative R&D. They have made a lot of progress in this regard; in 2000, the year I founded Apex Korea, there were only five multinational studies and 28 single country studies being conducted in Korea. By 2010 there were 448 studies being conducted in total, roughly half of which were multinational.

The government made a lot of regulatory changes and investments in medical infrastructure during the 2000s to make this possible. Not only did they adopt the ICH GCP guidelines, but also separated the IND and NDA application processes which was a substantial reform. Furthermore, the Ministry of Food and Drug Safety system were adjusted significantly to align with the FDA or EMA requirements. KoNECT was also established in 2007 for improving clinical infrastructure, including the 15 regional clinical trial centers, also known as GCP sites, and five global innovative drug research centers. The Asan Medical center is foremost among these facilities, as it is a truly world-class medical facility, not just in terms of equipment, but also the knowledge and experience of the investigators, and we are honoured to be working with them.

By 2010, many of the studies taking place here were phase III or IIb, but today we are seeing many phase II and Ib studies, with some in phase I. The industry has grown so much that for the last five years, many of the clinical trial facilities at major hospitals have been fully saturated, in part motivating the development of these GCP sites. Korea is at the point now where it will be the major hub in Asia-Pacific for early phase trials within the next three years. Not only does the country have the necessary infrastructure, facilities and regulatory environment, but also the expertise and world-class investigators to plan and conduct these studies for a wide array of therapeutic areas – oncology and hepatitis for example. With the government’s continued support, I have no doubt that Korea will continue to develop into one of the premier markets for clinical development in the world, and the government deserves recognition for having the necessary foresight, commitment and planning needed to successfully promote this industry’s development.

What are your thoughts on the Pharmavision 2020 policies and the objectives of the Korea Drug Development Fund, regarding new drug development potential in Korea?

Similar to their vision regarding Korea’s potential for clinical development activities, the government has a very long-term vision for the pharmaceutical and biotech industries. The potential to achieve the goals referred to by the Pharmavision2020 and the Korea Drug Development Fund (KDDF) is certainly there; half of the top 10 companies in Asia are Korean, and all of the companies such as Samsung, LG Life Sciences and Hanwha have invested heavily in the life science industry. With the support from the government, Korea’s largest companies, global key

opinion leaders in several fields, and an increasingly experience community of researchers, Korea has the ambition and commitment needed to achieve these goals given time.

PAREXEL has made an alliance with the KDDF, as our corporate mission to help bring the best medicines to patients around the world is aligned with the spirit of the Pharmavision 2020 objectives. As a result, we are providing strategy consultation and other advice to the companies that the KDDF is supporting. In fact, since 2012 we have regularly brought our U.S. based global consulting team to Korea to work with several Korean clients. This has been highly productive for all parties involved, as it has provided some variety to the advice and a fresh perspective to many discussions, which has in turn helped to bring us new clients and more business.

What would you like to see accomplished in terms of drug development in Korea over next five years, and what will PAREXEL's role be in this?

While there has already been a lot of progress made with regard to drug development in Korea, at PAREXEL, we would like to see the country continue its work on knowledge-intensive early phase studies.

For PAREXEL, it is a priority to help the Korean industry break onto the global stage. Primarily, this will mean encouraging a paradigm shift, so that life sciences companies can adopt a more global outlook, and helping them to design their global drug development plans from the beginning, to reduce unnecessary investment on clinical trials and increase efficiencies.

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