Kyungjin Peter Kim â?? CEO, ST Pharm, South Korea

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Peter Kim, CEO of ST Pharm, provides an insight into his expansion of the companyâ??s operations from simply a CMO into a CDMO and new drug development. He also explains his decision to focus on manufacturing oligonucleotides, the potential in that market, and the challenges to the next objectives.

What led you to your decision to move from a lab-based role into business development?

After the financial crisis of 2008, a lot of foreign scientists in US pharmaceutical companies began going back to their home countries. The business strategy of big pharma companies was also changed to contract out some of their functions, such as early-stage R&D and manufacturing. At that time, I was working at Roche in the USA and was forced to consider my next career steps. Initially, I had decided to join the US FDA. However, I was invited by the previous ST Pharm CEO to join the company. When I first visited ST Pharm, I appreciated its potential to become a global CDMO based on its experience and capabilities. I also devised many possibilities of starting up new drug development in Korea. Consequently, I agreed to join the company and commenced work in 2013. Upon joining, I began building up the new drug development platform and I also strongly enhanced the key capabilities of CDMO, which is a global trend moving from simply a CMO into CDMO.

Could you give our readers an overview of ST Pharm and its business?

ST Pharm was established in 1983 as â??Samchully Pharmaâ?• and has been doing business in the field of active pharmaceutical ingredients (API) and it is a key intermediate CMO (Contract Manufacturing Organization). In 2010, we became a member of Dong-A Socio Group, a leading group of pharmaceutical sectors in Korea, and were renamed as â??ST Pharmâ?• (ST stands for Science and Technology). In 2016, ST Pharm was listed on KOSDAQ.

ST Pharm specialized in the nucleotide synthesis and manufacturing. It has also supplied the key APIs of anti-viral drugs globally. In particular, we manufactured the API and the intermediates of Zidovudine for HIV treatment for over ten years and also supplied the API of HCV, a new chemical entity, to a global pharma company. Another speciality of ST Pharm is as a CMO for the manufacture of oligonucleotides, which will be a blooming therapeutic area. As the demand for RNA based drugs grows, ST Pharm has established itself as a major player in the oligonucleotide API

manufacturing industry. Our efforts were recognized with the 2018 Global API Manufacturing (Oligonucleotide) Growth Excellence Leadership award at the annual Frost & Sullivan Asia-Pacific Best Practices Awards banquet held at Singapore on 27 November.

Another pillar of ST Pharm is new drug development. Our strategy is open innovation with â??virtual R&Dâ?• â?? licensing in the very early stages of drug discovery projects, incubating those projects internally, and then licensing out to global pharma companies. This strategy along with the NRDO (No Research Development Only) concept is currently the megatrend within the pharma industry.

It has been only five years since I initiated the strategy, and we have set up more than 7 projects with three currently in pre-clinical trials. Next year, one or two of them are expected to enter the phase I stage.

How much scope is there for development within the oligonucleotide sector? What is the most attractive element of ST Pharm compared with other competitive oligo API manufactures?

The current market size for oligonucleotides is around 7 billion dollars and is growing very quickly. We are the current frontrunner in the industry, and there are high barriers of entry into the market. This is because oligonucleotides have a very high weight requiring a different type of synthesis and analysis compared with small molecules. Thus, it requires deep and specialist knowledge.

As I mentioned, ST Pharm has been specialized in the nucleotide-based synthesis since the 1980s. Our accumulated knowledge and technology over the past 30 years enable us to provide a â??fully integrated systemâ?•. Hence, we can provide a â??one-stop shop CMO serviceâ?•, from starting material (nucleoside) to the final product (oligonucleotide) in-house. The incomparable benefits of this fully integrated system are competitiveness in price, the stability of supply, and continuity of quality. Therefore, I am confident in stating that we are the only company providing such a service globally.

In October, we opened a new oligonucleotide dedicated facility at our Banwol site. The newly expanded facility makes up to 1.8-mol scale feasible and offers over hundreds of kilograms per year. It also has extra space for further expansion in order to proactively ramp up commercial demand as well as provide our clients with a dedicated facility.

The next stage for ST Pharm is to expand into new areas within the oligonucleotide business. In many cases, this is akin to entering into the unknown. However, we view this as necessary since we seek to avoid direct competition with other companies, particularly in markets where there are lots of firms undertaking the same work.

Why did you adopt the virtual R&D strategy for new drug development?

First of all, itâ??s partially attributed to the current pharmaceutical industry environment in Korea. Compared with the US and Europe, Korea is lacking fundamental resources to cover all stages of new drug development. In addition, the high costs of long-term R&D are problematic. I borrowed some ideas from Eli Lillyâ??s chorus platform to initiate the â??virtual R&Dâ?• strategy, in which only key functions are operated without the whole platform of new drug discovery and development. Low cost, high efficiency and agile development processes are key factors in this strategy.

Secondly, it creates a synergistic effect with ST Pharmâ??s CMO business. Once we successfully license-out the new drug project, its API manufacturing rights can be claimed simultaneously. To this end, our scale-up process development of the new drug projects is running in parallel, even at the very early stages. This synergistic advantage distinguishes ST Pharm from other biotech companies pursuing similar NRDO strategy.

Could you tell us more about your decision to set up an affiliate, STAR, in the USA?

STAR is a very specific and focused CRO. This is an FTE-based business with a strong focus on the chemistry driven process development.

There are two key aspects of STAR. Firstly, our strategy is to create a self-sustaining company in the USA. Many Korea companies set up their subsidiaries in the US and Europe which go on to fail. The reason is that they lack a self-surviving entity. In this way, we want the business to be self-sustaining with initially FTE-based CRO service and then conduct process research projects. The second reason for its formation is for education and training purposes. We want to harness the knowledge from big Pharma and transfer it to our company. The current President of STAR has over 20 years of experience working for Merck and is an expert in this field. Thus, we send two researchers from Korea to the US on a quarterly basis to learn from him. This goal is now almost fulfilled

What are the next objectives that you look to achieve?

Two keywords in my mind are satisfaction and wellbeing. Without question, I want to ensure that our clients are satisfied with our work as a CDMO, and also that shareholders are satisfied with our operations. We fell short of shareholderâ??s requirements this year, but we have a well- designed strategy and remain confident that within two years we will gain their approval. Secondly, our employee satisfaction is also very important. We want ST Pharm to remain as a place where our employees enjoy working and want to continue working. Finally, as a pharmaceutical company, we must provide a contribution to mankindâ??s wellbeing.

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