Tae-Han Kim – President & CEO, Samsung Biologics, South Korea

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In an exclusive interview, Tae-Han Kim, president and CEO of Samsung Biologics, documents his strategy for expanding Samsung's operations into biologics, and how Samsung Biologics has rapidly become one of the leading Contract Development Manufacturing Organisations (CDMO) in the market in only seven years. Dr Kim also provides his assessment of the CDMO market and the link between insufficient manufacturing capabilities across the industry and slow biosimilar approval rates.

Samsung has a long history of manufacturing, but only entered the biologics industry in 2011. What was the motivation behind this undertaking?

Having joined Samsung almost 40 years ago, I have had gained experience in various Samsung divisions across various industries including petrochemicals, electronics, and textiles. Seven years ago, I was tasked with finding Samsung's next new growth engine. During this process, dozens of candidate opportunities were reviewed, including electric cars, solar panels, and LED lighting. I personally was strongly attracted to the life science and healthcare industries, despite having no previous experience in the sector.

Two tests for selection were set. Firstly, the opportunity had to be "*attractive*": a sufficiently large market size with fast market growth and high profitability for the existing players. Secondly,

Samsung needed to possess the capabilities to exceed the competition within 5-10 years. This reduced the number of feasible candidates. The biopharma industry has a huge market with a high growth rate, and a high profitability margin, meeting our first criteria. While biopharma is very innovative in terms of research and development, it has lacked innovation in plant construction and operation. We determined that Samsung could reduce construction timelines, with higher quality and more efficient operations than available in the market at that time.

How did you mature Samsung Biologics into a global leader within such a short period of time?

My basic strategy was to combine the non-pharma industry and pharma industry best practices. In order to rapidly become acquainted with pharma best practices, I employed around 100 global experts in this field, each of whom had 20-30 years of experience in the sector working with big pharma companies such as Roche, Pfizer, and BMS. We also utilised our past experience in the non-pharma industries, for example, our knowledge from the semiconductor industry, having invested over USD 100 billion and built 25 semi-conductor plants over the years. We not only wanted to build biologics plants better than our competitors, but we were also striving to build biologics plants better than we could produce semi-conductor plants.

In addition, we aimed to align with those who are leading in the world. Therefore, I created global partnerships with vendors supplying key manufacturing components and formed venture partnerships with industry leaders, such as AstraZeneca and Biogen.

Once the strategy was finalised, the next stage was to attract investment, commencing negotiations with the other Samsung affiliates. Eventually, Samsung Electronics and Samsung C&T agreed to invest USD 1.2 billion, to be divided equally between contract manufacturing and biosimilar development. We foresaw the potential in the biosimilar market, and that by mastering the processes for biosimilars, we could eventually expand the scope Samsung’s operations to include novel biologics discoveries. Having grown faster than originally anticipated, the original capital investment proved insufficient. Consequently, we launched an IPO in 2016.

How would you evaluate Samsung’s performance to date?

In fact, the performance of the business has exceeded expectations. In 2011 I made a public promise to build 120,000 litres of capacity by the end of 2020; in 2018, we reached a capacity of

362,000 litres, the largest of any company. We have also cut plant construction timelines by 50 percent. Currently, we have 25 CMO clients for 36 different products.

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Much enthusiasm surrounds biosimilar products, yet their approval by regulatory agencies has been slow, with only 15 approved by the FDA, and 44 by the EMA. In your view, what is the cause of this bottleneck?

It is sometimes thought to be very difficult to discover new molecules or develop biosimilars. This was the case 20 years ago, when Genentech and Amgen were pioneering in novel biologics. At that time, few scientists knew how to develop these products. Today this is no longer the case. There is a new generation of scientists involved in novel biologics who have gained the knowledge and the skills. Accordingly, modern biosimilar production is actually relatively straightforward in terms of finding and developing new products.

In my opinion, many companies either fail to gain approvals, or the process is delayed because of their inadequate manufacturing facilities. There are now 2000 biotech companies in the world, with 500 biologics pipelines under clinical study. Although over 100 companies have products that have received approval by either the EMA or the FDA, most do not possess the capacity for production and have failed to improve their facilities and operation technologies in line with their R&D advancements. The cost of manufacturing biopharma products is extremely small; R&D composes around 90 percent of the total production costs. Hence, companies have viewed their manufacturing development as a low priority area for investment since innovation in manufacturing would only save 2-3 percent of costs.

In addition, the regulatory expectations for products in the pharmaceutical industry are set very high because the products impact human life. While strict regulations are necessary, I believe that the biopharma regulations are at an excessive level. Reviewing and reducing these regulatory barriers would be beneficial to the industry and would speed up approval times.

You mentioned that there is a lack of quality manufacturing, which Samsung have been able to capitalise on. Given the clear demand for biologics manufacturing, what is preventing more companies from emulating your success and entering this market?

The competition falls within two categories, small scale and large scale (above 2000 litres) manufacturing. 90 percent of products do not require large-scale production. However, just ten percent on products, around a dozen in the current pipeline, are blockbuster products comprising 80 percent of the market's total production volume. Looking at the number of high performing large-scale production manufacturing companies, there are only three: Lonza, Boehringer Ingelheim, and Samsung Biologics.

The market is very competitive for small-scale manufacturing: there are over 60 small manufacturing companies with 2000-3000L capacities. These volumes are very useful for producing orphan drugs, which usually require around 1000 litre volumes, and never the 80,000 litres the large manufacturers possess.

However, there is a barrier between small-scale CMOs and large-scale projects, a result of the complexity of large volume projects. To give an example of the complexity, each of our plants has more than 200 segregated rooms where temperature, moisture and pressure differential must be strictly controlled. Moreover, there are enormous bureaucratic hurdles to overcome regarding compliance for large-scale projects. To receive approval from the FDA or EMA for a plant, over one million pages of detailed documents must be completed. There are many companies who try to enter the market but fail as they simply cannot receive the approval. This is particularly the case in more cost competitive markets such as China.

In our interview with Lonza COO Marc Funk, he highlighted the market's growing demand for bespoke custom solutions. How is Samsung Biologics diversifying its offering to meet the requirements of the market?

Indeed, Lonza has been very successful in this regard and possesses the technology for both large-scale process development and small-scale manufacturing. Samsung Biologics, established only in 2011, has a much shorter history in the market. Nonetheless, as we have already established the infrastructure, we are looking at expanding the scope of our services in the near future to include small scale under 1000 litre manufacturing.

With small-scale projects, there is little room for differentiation and it is very localised. Conversely, in large-scale manufacturing, there is much more room to manoeuvre and implement cost-saving strategies; I was able to reduce capital expenditure, production timelines, and operation costs. This provided the rationale behind selecting large-scale projects as our initial focus.

Recently you agreed a deal with Biogen, establishing Samsung Bioepis as a joint venture. What is the mutual benefit you will receive from such an agreement?

Samsung's project has three successive stages: contract manufacturing and development, biosimilars, and finally novel biologics. Thanks to Samsung's strong manufacturing background, it was determined that the CMO business could operate as a standalone company. However, when expanding into biosimilars with Samsung Bioepis, the conclusion was reached that partnering with a global company with expertise in this sector was preferable. Thus, we scouted for global partners and found Biogen, one of the three pioneers in biotechnology with strong biosimilar pipeline and a wealth of industry knowledge.

Initially, Biogen was reluctant to invest in a 50 percent stake of Samsung Bioepis, offering a maximum of 15 percent instead. My ambition was to attract them into a joint venture, so I proposed a call option: when the financial situation became clearer, they could increase their stake. This call option was agreed in 2012, exercised this year following Samsung's success. Biogen now owns 50 percent minus one share of the Samsung Bioepis business.

Where do you foresee Korea's position globally in the biosimilar market?

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The western companies began five or six years earlier than the Korean companies. However, we have caught up and dramatically cut our approval times. People often ask me how this was possible. The answer is that we went "*all in*" – complete dedication to the market. Once we chose to specialise in biosimilars, there was no room to survive if we failed with the few projects we had. Thus, our labs were running for 24 hours, with our employees working shifts. This high-risk strategy invoked the dedication required to succeed. We also benefit from the Korean education system. We have excellent research institutions, particularly for the life sciences. The supply of good quality

employees continues to impress. Here at Samsung Biologics, we have over 2000 employees with an average age of only 29.

The Korean business for biosimilars has already delivered significant results which will be the basis for future progress. Samsung Bioepis has the largest number of approved products by the FDA or EMA, followed in second place by Celltrion, another South Korean company. In terms of company rankings by biosimilar revenue, Celltrion is leading the way and Samsung Bioepis is second.

What will be fundamental for Samsung Biologics' success in the next 3-5 years?

We aim to provide a higher degree of client satisfaction. Clients are requesting not only the CMO business but the development business, so we must provide a one-stop shop service. We are also looking to expand beyond the CMO businesses into the CRO sector, commencing this year. Although we will not be running clinical studies, we will offer QC test services, stability test services, and other high speciality research testing areas, which pharmaceutical companies wish to contract out. As a result, Samsung Biologics will be a CMO, CDO, and CRO company.

We have already built plant number three, which is now operational. For us, this is not the end of the story. The industry requires further capacity, so we are willing to continue expanding our capabilities to retain our position as the number one global service provider.

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