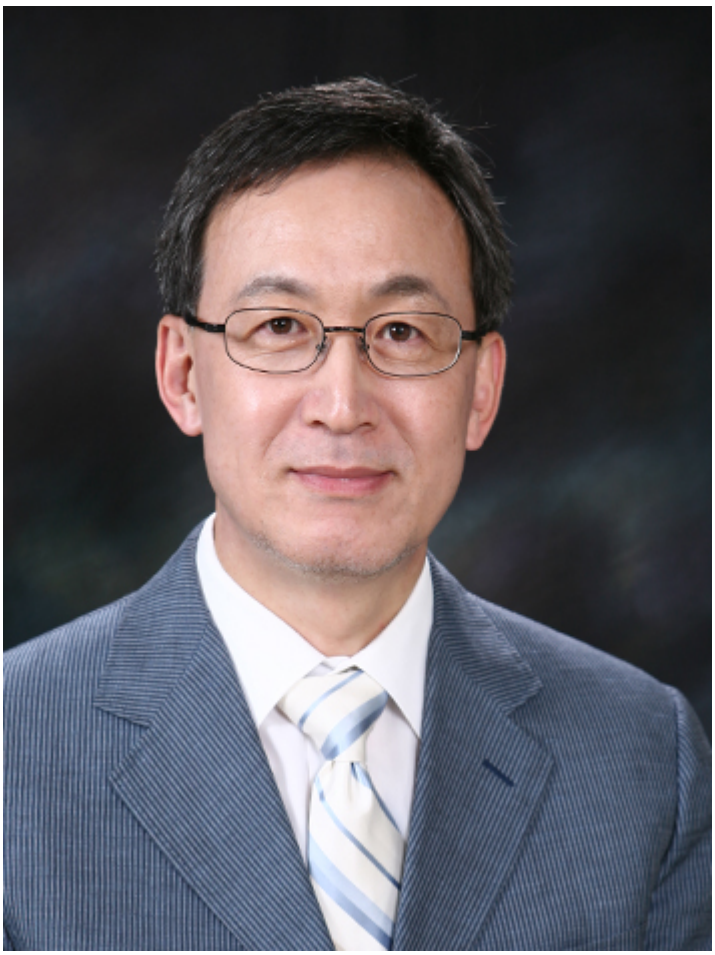
Sunyoung Kim â?? Founder and CEO, ViroMed, South Korea



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Sunyoung Kim, CEO and founder of ViroMed, reveals his strategy for conquering the US market and the feasibility of his ambitions for ViroMed to become the biotech company with the largest revenues from gene therapy by 2025. He also discusses the areas within the Korean biotech sphere that must develop to truly entrench the country as a dominant player in the global market.

ViroMed differs from many biotech ventures in that it has a much wider focus of operations. What led you to take this more unorthodox approach?

After founding the company, my strategy has always been to develop platforms for technologies and target indications. The majority of start-ups and small biotech companies like ours are generally built around only a single product or a single technology. When this fails, the company collapses. Furthermore, at the time of founding the company in 1996, the term â??biotech ventureâ?• was new to the Korean investor community, even amongst venture capitalists, and, not surprisingly, the investors were conservative and reluctant in risk-taking. Therefore, I had a strong need to minimise the level of business risk while maximising investment opportunities by focusing on developing multiple technology platforms.

With our scientific and technological platforms in place, we established a conceptual disease platform, where we work on a variety of target diseases that have similar underlying pathologies, instead of one disease in isolation. This way, we can use similar techniques and methodologies for research and experiments. For example, the protein produced from intramuscularly injected VM202, one of our flagship gene medicines, can interact with endothelial cells and smooth muscles cells to make new blood vessels, and also can interact with muscles and neurons to improve pathologic conditions and symptoms. Using these effects, we have been conducting clinical trials for four different diseases using one product, in this case, VM202. This is what I call the disease platform.

In short, our technology and disease platforms allow us to develop a number of different products and to target many different diseases. As such, our R&D programs are run very cost-effectively and swiftly.

How has ViroMed maintained the financing required for its operations throughout the development stages?

Based on my experience, it takes about 15 years and at least USD 200 million (excluding pre-launch related expenses) for one product to get BLA approval after one or two Phase III studies. A majority of the money, say about 85 percent, seems to have been spent during the last three years.

In the case of VM202, it will take 20 years, assuming we obtain BLA approval in the year 2020, and that is because we just did not have enough resources to push forward according to our schedule. The first nine years following our inception saw investment coming from venture capitalists and institutional investors. From 2006, after the company went public, we were able to raise capital through the stock market.

Meanwhile, being a company developing a variety of new drugs, ViroMed was barely able to generate meaningful revenues and thus had to stay in the red virtually every year. Thankfully, however, we have continued to receive investments over the past 12 years and ViroMed is probably the first company of this kind in both the KOPSI and the KOSDAQ. I believe this was possible for a number of reasons. Firstly, we were undertaking something genuinely meaningful, developing the worldâ??s first gene medicines in several different disease areas. Secondly, I was able to convince investors by presenting the significance and the scientific, clinical, and commercial potential of our products. Finally, we fulfilled the promises made to our investors by progressing and delivering results. For these reasons, our credentials have been quite strong in the public market, which is often not the case for many small biotech firms.

This year you set up a legal entity in the USA and acquired a production facility in San Diego. What made now the right time for overseas expansion?

It was a natural evolution for the company. Based on our experience, we had reasons to be optimistic about the outcome of the phase III trial that will conclude next summer, and we had to be prepared for commercial-scale manufacturing. The first product is made of plasmid DNA. Plasmid DNA has never been commercialised as a medicine for humans. Most of the contract manufacturing organizations we have worked with thus far for our clinical studies are not large enough for commercial supply, and the production cost and schedule have always been challenging. For months I searched for manufacturing sites across the world, eventually finding a production site in San Diego. This site already had experience in producing phase III DNA, so we acquired the asset and established an entity called Genopis Inc.

I am planning to utilize this facility not only as our commercial production site for our first plasmid DNA product but also as a CMO for other biotech companies. This site will also become home to ViroMed-USA, the HQ for our North America operations and also possibly provide an incubator function for other early-stage biotech companies in the US and Korea.

In terms of your flagship platform VM202, could you give our readers an overview of the progress and timeline of this project?

VM202 can target a wide range of indications in the area of neurological and cardiovascular diseases. Initially, we are conducting clinical studies for painful diabetic peripheral neuropathy (PDPN), amyotrophic lateral sclerosis (ALS), diabetic foot ulcer (DFU), and myocardial infarction. For PDPN, the first readout from phase III will be available next summer.

There are huge unmet medical needs for all of these four diseases. For example, regarding PDPN, only a couple of prescription drugs are available to patients, of whom only around 50 percent can use the medications. Our phase I and II studies for PDPN indicated that VM202 is very safe, showing virtually no drug-related adverse effects. Most importantly, our data reveals that VM202 works even more effectively in patients who do not currently use available PDPN medicines like gabapentin or pregabalin. The implications are obvious: VM202 will provide hope to those patients suffering from pain that is unbearable. Looking at the list of phase II and III clinical trials being conducted for PDPN, I can hardly see potential competitors over the next 7-10 years as all of them are using candidate medicines based on small molecules aiming at just pain reduction.

The results from this ongoing phase III will be made publicly available between June and August 2019. We hope to bring this product to the market in the year 2020 to 2021, and to capture at least 10 percent of an estimated 1.8 million chronic PDPN patients in the US alone. While we base our clinical trials in the United States given our ambitions to establish ourselves there, the worldâ??s largest pharmaceutical market, we plan to do bridging studies in other territories such as EU and Japan once the market approval is obtained in the US.

Being the third largest market in Asia, Korea constitutes only two percent of the global market and thus operating only in the Korean market could barely recoup the USD 300 million already spent on VM202 development. Moreover, meeting the US regulations and launching our product there will provide a springboard to enter the European and Japanese markets at a later date.

Where are the main shortcomings within the Korean market?

The pharmaceutical market in Korea is small relative to the amount of money that we have to invest in the development of a new drug. Secondly, Korean physicians are highly skilled at following well-established protocols, but very conservative in the case of novel concepts and new approaches that may require designing new protocols and new endpoints or parameters. In addition, for this type of innovative medicine, Koreaâ??s regulatory agency also becomes highly restrictive, asking to address various sorts of hypothetical issues and situations. Therefore, for truly new and innovative drugs, we do proof-of-concept studies in the US, and then find a local partner in Korea for marketing there.

What can be done so that Korean biotech can make breakthrough discoveries and inventions in pharmaceutical areas?

Korea should take two approaches. The first is an in-house approach, that is, nurturing and using made-in-Korea sciences and technologies. Given the short history of science and start-ups in Korea as well as the relatively small size of the venture companies, I reason that Korean ventures have performed relatively well. ViroMed is a good example. Looking around, I see great potential with Korean universities. I hope that the Korean government more aggressively promotes start-ups by providing them with appropriate legal and financial infrastructure. There is two type of start-ups; those established by university faculty members and their associates or those by people who have left their jobs to set up their own business. I see great potential in the former case. The only bottleneck is the conservative academic culture which resists any changes in the traditional roles of the university.

The second approach is the use of technologies developed in other countries like the US or Japan or European countries. The size of the R&D budget in Korea is small. To make matters worse, the budget execution is poorly managed by bureaucrats and amateurish academics. Thus, the potential for producing truly meaningful discoveries and inventions in Korea is slim.

However, Korean scientists are very good at converting early-stage technologies developed overseas into tangible products. This approach is already being undertaken. Many remain unaware that recently highlighted two gene medicines from Kolon Life Science and SillaJen are actually foreign-born products. Kolonâ??s allogeneic cell/gene therapy product, Invossa was originally developed by TissueGene founded by a Korean-American scientist in the US, while SillaJenâ??s oncolytic vaccinia virus was originally developed by North American scientists and their company. Kolon and Shillagen brought these products into Koreaâ??s financial market, secured money from Koreaâ??s stock market, and conducted their phase III trials. I have long advocated this approach, but the patriotic or nationalist culture of Korea does facilitate this.

You are striving to become the biotech company with the largest revenues from gene therapy by 2025. How realistic do you believe this goal is?

We hope to achieve this by 2023, even sooner than the 2025 target. This is dependent on when VM202 is going to enter the market. Last year, we asked an outside consulting firm for an estimated drug price and market size for PDPN, who suggested that given the medical need and seriousness of the disease, VM202 can begin to generate USD 10 billion-plus revenue from the fifth year after market entry. The revenue will continue to grow till until plateauing several years later. This is only for the PDPN indication in the US market. Although merely an assumption, it is consistent with estimates by other independent sources. For example, GlobalData based in London also reported that by 2026, more than 45 percent of the global PDPN market might be captured by VM202.

There are 23 candidates listed in phase III. Almost all of them treat rare genetic diseases and quite restricted cases of cancers that are markets limited in size. Therefore, I am comfortable with my goal of having the worldâ??s best-selling gene medicine.

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