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Hakhyun Nam, co-founder and CTO at i-SENS,

Inc. a developer of glucose sensor devices, reveals his path to running a globally successful medical devices company, and how i-SENS overcame early challenges in manufacturing and marketing to establish its reputation within the Korean market. Professor Nam also discusses the factors that are delaying other Korean medical device manufacturers from becoming global success stories.

Professor Nam, as a co-founder of the company, how did you come to move from academia into the world of business?

I returned to Korea from post-doctoral work in the USA to work as a professor at Kwangwoon University. There I met another professor, Dr Cha, working on the same project into analytical sensors. Together we published a number of papers together. This made us well known within the industry.

In 1997, Korea suffered a financial crisis known today as the IMF crises. President Kim Dae-Jung decided to advocate for new technologies to be developed in the country as a way out of the economic difficulties and encouraged anyone with valid technology to start a company. Professors like myself were permitted to hold two jobs, as the CEO of a company, and as a professor. Three years later in 2000, Dr Cha and I took this opportunity and founded i-SENS.

The initial idea of the company was to commercialise the research projects we conducted in the university through licensing out. After presenting our technology, and leveraging the reputation we had developed in academia, we successfully secured venture capital funding of around USD 500,000 dollars.

What was the rationale behind your decision to focus on the glucose sensor market?

Soon after founding the company, it became obvious that simply conducting and selling research would be impossible in Korean culture, and thus our company had to develop a product that could generate revenue. Despite my preferable project being in cancer detection sensors, it was determined that only in glucose sensors could we be profitable and gain a market share. In 2004, after pooling our scientific knowledge, and with the assistance of external mechanical engineers, we were able to create a prototype for our product and develop manufacturing capabilities to produce a

small quantity â?? 35,000 strips per day which would cover part of the Korean market.

The global market for glucose sensors when i-SENS entered the market was 6-7 billion dollars. Given the size of our operations, achieving just 0.1 percent of the market would suffice for the company to sustain itself. Moreover, 95% of the Korean market was controlled by four major companies: Roche, J&J, Bayer, and Abbott. There were no local competitors. I determined that i-SENS could produce a product that was more advanced than the competition available. The other products require larger amounts of blood and had slower measuring times, for example requiring five microlitres of blood and 15-30 seconds for the measurements. We believed that we could create a product that required less than one micro-litre, for less than a ten second measuring time. Hence, i-SENS developed the most advanced 0.5µL and five-second glucose sensor on the Korean market using only our own patents.

Given that you now also act as an OEM, how have your manufacturing capabilities evolved?

After launching our first products, we were approached by other companies outside of Korea, to act as an OEM. This enabled our sales to surpass 11 million dollars within three years of launching the product. During that period, we had to increase our capacity from 30,000 to 300,000 strips per day to meet worldwide demand, requiring ingenuity. By 2006, we established a manufacturing facility in Wonju which could produce one billion strips per year. Today we have expanded to 1.5 billion strips per year. We now have two facilities in South Korea, and a third in China. One of the issues in China is that their regulation is very complex, but we are hoping to get registration early next year.

Where are the main markets you are targeting globally?

At the moment it is evenly distributed. In Korea we have 30-35 percent of the market share. We are also selling well in international markets, and through a distributor in the USA. Our revenue in total is now USD 160 million dollars, divided half and half between products and OEM. In 2012, we also won a national tender in New Zealand to become the sole supplier until 2017. We won this tender again in 2017, so will remain as the sole supplier in New Zealand until 2022.

In our overseas work, we collaborate with distributors and establish our own offices. If there is a high-quality distributor, we are more than willing to work with them. However, if there is the possibility to establish a presence there, we would prefer to make our name known. That being said, it is not possible to open every market. Moreover, without having a renowned brand, it is not possible to attract the best OEM partner. This balance is very important. Opening a market with one's own brand will bring higher revenues but will also carry with it higher costs for marketing and general maintenance.

How did you establish your brand name?

Dr Cha and I never paid attention to marketing, coming from an academic background. This became a challenge for the company. Nonetheless, we encountered some good fortune during our early years. As the large companies in the market, such as Roche, determined that the Korean market was very lucrative, they decided to close their distribution channels and set up their own offices. Hence, many Korean distributors lost their jobs. These people were highly knowledgeable about the market, and subsequently came to work with us. In the beginning we could not supply the quantities

demanded.

We were able to develop our reputation in Korea by monitoring all of the discourse around our products, especially on mediums such as the internet. Thus, we could quickly solve any complaints or issues that developed. Moreover, a member of the team checked with every hospital or clinic using our product, to see if there were any complaints or claims of inaccuracy. This helped to ensure that we could maintain our quality standards; this effort has been rewarded.

How easy can Korean companies become global exporters of medical devices?

I believe it is extremely difficult. There are two problems for the Korean medical device market. When operating in another country, companies encounter many barriers, such as registration and market recognition. Moreover, some countries, for example, Vietnam and Indonesia, require that the distributor is of the nationality of the target country, or alternatively, the exporter opens an office in the destination country. Finding the right people and setting up this new infrastructure takes 1.5-2 years. Moreover, it is extremely difficult to switch to an alternate distributor at a later date, which can impact the effectiveness of sales.

In some European markets, diagnostic devices, such as glucose monitors are of national medical concern, given the growing incidence of diabetes. In these markets, the devices are paid for either by the government or through insurance. Securing this funding and supply from government healthcare demands a very different approach compared with ordinary marketing. Koreans have very limited experience in negotiating with these agencies internationally. The regulatory burden and bureaucracy are huge, and the successful completion of these procedures can be at the mercy of the chosen distributor. Koreans have experience in selling large manufactured goods such as electronics, but not more complex items for the medical sector.

Moreover, the language also remains a barrier to overseas markets. Even those who speak English well do not always understand the marketing structure, customer's needs and service channels. Finding talent who possess these skills and knowledge is difficult in Korea.

Despite these challenges, Korea is technologically very advanced and has a well-developed infrastructure. Thanks to this, we were able to develop our manufacturing facilities in such a short period of time. This would not have been possible in other developing countries. Any new device of technological innovation can be easily developed to compete in the world market. The final step is to have the capabilities to internationalise and understand the world market. I believe we need to reach a threshold of human resources who understand the world market. This will obviously take time.

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