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The Pharmaceutical Strategy Institute (PSI) is a Korean consulting firm helping local biotech companies reach success by providing strategic and legal counsel all along the value chain. Its founder & CEO,

Dr Jung Yunâ??Taek, explains the different services his company provides, his role in shaping government policies to foster the biotech ecosystem, and discusses the potential of Korea to become the next Switzerland of pharmaceutical innovation.

The last time we met you were heading the pharmaceutical division of the *Korea Health Industry Development Institute (KHIDI)*. What prompted you to leave KHIDI and set up a consultancy company?

I worked at KHIDI, a government-affiliated organization, for ten years during which I was in charge of promoting the Korean pharmaceutical industry through policy recommendations. About three years ago, I founded the Pharmaceutical Strategy Institute (PSI), a company with a pharmaceutical development organization (PDO) business model.

What are the main operations of PSI?

PSI promotes the pharmaceutical industry. Our mission statement is to support the local pharmaceutical industry, especially biotech companies, through three main activities. First, we try to foster an environment conducive to innovative new drug development by advising government bodies on policies and regulations, for example regarding clinical trials and approval procedures, as well as research investments. These include the Ministry of Food and Drug Safety (MFDS), the Ministry of Science and ICT and the Ministry of Health. We also collaborate with private research institutes. Secondly, we help local companies reach global commercial success by providing strategic and legal counsel for in-licensing, out-licensing, joint-venture or M&A agreements. We also assist them in their R&D strategy and planning. Most of the companies we assist in that way are biotechs. Finally, we create links between biotech companies, traditional pharma and venture capital funds through forums and symposiums.

How do you determine the best strategy for Korean biotechs to make it on the international stage?

In general, biotech companies first license out to a big local pharmaceutical firm such as Yuhan which takes an equity stake in the biotech. The next step is reaching an agreement with a global group. There are three reasons why an MNC might decide to license-in an asset from a Korean biotech company. The first is when the asset is within a specific category the MNC is interested in. The second is when the asset is a first-in-class drug. And the third case is when the drug presents robust scientific and clinical evidence with a clear mechanism of action.

I advise biotechs by benchmarking successful companies such as Celgene. In the beginning, these companies were focused on new drug development in oncology and rare diseases. Indeed, orphan drugs can receive approval after Phase II with fast-track priority review. Subsequently, these drugs can be extended to new indications. I think the global trend is in specialty innovation for secondary care market. ABL Bio is the latest example of a successful business model. In the space of only three years, the company launched an IPO in Korea. I advise biotech companies on how to replicate these kinds of success stories.

PSI also assists local companies in their R&D process by advising them on how to comply with global standards and regulations. This can come in the form of new business models. For instance, recently three companies, a CRO, a pharmaceutical company and a lab formed a joint-venture.

How can a Korean company realistically become a top 50 global player if licensing out becomes their main strategy?

Japanese companies were the first to license-out and collaborate with international groups in order to enter global markets. The rationale was that they did not possess the capabilities or language skills necessary. Nowadays they are starting to employ foreigners to take care of global sales and marketing and acquiring foreign firms. Takeda is a good example of this trend. I think the same will happen with Korean companies. They will progressively move away from a licensing business model and start marketing their own drugs.

In addition, I think that it is very likely that a Korean biotech company will license out a drug to a global company that will go on to achieve more than USD 1 billion in sales. Now that the government is investing in oncology and rare diseases early-stage research, the likelihood of that happening is increasing. In fact, public R&D expenditure relative to GDP is the highest in the world. Moreover, even though Korea does not have natural resources, it boasts strong human resources thanks to top-notch education as well as good infrastructure, especially when it comes to clinical research. Thanks to these strengths, I think Korea can become the next Switzerland. Even though it is a small country, it is home to some of the largest pharmaceutical companies. It exports 40 percent of its manufactured goods to other countries.

What we could see in the future is a convergence between IT companies in the field of AI technology for example and biotechs such as gene and stem cell therapy companies. The government is trying to make this happen through strategic investments and incentives.

How do you assess the government's willingness to support pharmaceutical innovation?

The government has made the development of the healthcare and life sciences sector a priority, along with IT. However, the local market size is quite small. The government's budget dedicated to IT is the largest, but the healthcare budget is growing. The healthcare development public fund of USD 0.5 billion was created in 2013. After that, private funding started coming in, further developing

the local innovation ecosystem.

What is the comparative advantage a consultancy like PSI compared to the likes of more international consultancy players?

These international corporations obviously have extensive consulting experience globally. However, they lack the experience of dealing with the local government that I accumulated during my ten years at KHIDI. Therefore, I am uniquely positioned to bridge the gap between the private and public sectors. Moreover, PSI is not a CRO but a Pharmaceutical Development Organization (PDO) that provides consultancy services all across the value chain, from R&D to commercialization.

What are the key milestones you want to achieve in the next few years?

In the future, I would like to advise companies on new business models and participate in the creation of new joint-ventures to drive the local biopharmaceutical company to the next stage.

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