Jisoo Pae â?? CEO, Genome & Company

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Genome & Company, with a market cap of USD 280 million

, is the highest valued microbiome company worldwide. Dr Jisoo Pae, its co-founder and CEO, sat down with PharmaBoardroom to shed light on the companyâ??s origins, its collaboration with Big Pharma, and the ease of gaining capital investment for a Korean biotech.

As the CEO and co-founder of Genome & Company, what led you to establish a biotech firm specialised in microbiome technology?

I began my career as a psychiatrist, but later took an MBA programme at Duke University, and subsequently worked for Bain & Co as a management consultant, as well as at MSD.

I founded Genome & Company with my friend from Medical school, Dr Hansoo Park, who is the co-founder and current CTO. Having studied as a post-doctoral student at Harvard Medical School, Dr Park continued his research at Jackson Laboratory and became an expert in microbiomes. He approached me five years ago with the idea of setting up the company. Upon explaining the science behind it and its advancements in the US, we agreed to set up Genome & Company.

Five years ago, when I was introduced to microbiome technology, it was almost unknown in Korea. I predicted that interest would expand rapidly in the future, following a similar trajectory to the stem cell or antibody medicine markets. The healthcare industry is a large industry. Many new trends

emerge and establish themselves. I was convinced this would be one of the critical emerging trends. Knowing that Genome & Company could benefit from taking the first-mover position in the market, it seemed like the right moment to make the move and kick-start our operations.

Can you introduce the main activities and areas of interest for Genome & Company?

We are focusing on the microbiome and how to develop this into medicines. Our current most advanced programme is a microbiome immuno-oncology treatment. We have just received clearance from the US FDA for our Investigational New Drug Application (IND) and we are now entering phase I/Ib clinical study. Following this, we will finally have patient data to analyse. We are looking at a timeline of around eight years before approval. However, we will be able to commence discussions on licensing out sooner, depending of course on the findings of this initial data.

We also have a dermatologic and infertility programme which utilises microbiome technology. Moreover, we are developing novel targets within immuno-oncology antibody therapies.

Microbiome treatment, originating from the human body, has several advantages compared to other treatments. Most significant is that it produces little to no side effects, which has very good implications in the development of our anti-cancer drugs. Whereas most anti-cancer drugs have punishing side effects, ours have very little, making it an obvious choice for patients. This also facilitates its use in combination therapies such as with anti-PD-(L)1 antibody treatments. This is just one example of the possibilities at our disposal: the potential for microbiome technology is unbounded.

What is Genome & Companyâ??s strategic business model?

Licensing out is our major ambition and we are actively engaged with multinational pharma in preparation for this. Our ambition is to continue to develop innovative drugs and out-license, repeating this process for every development within our pipeline.

We are currently undertaking a Clinical Trial Collaboration and Supply Agreement with Merck and Pfizer, combining our product with their anti-PD-L1 drug, BavencioÂ®. The success of companies developing anti-PD-(L)1 candidates is very beneficial to our business. The more successful and competitive the market in the PD-(L)1 sphere, the greater Genome & Companyâ??s possibilities for collaboration.

For the East Asian region, we are in also in a partnership with LG Chem for a licensing agreement. The negotiations prior to signing these partnerships has required Genome & Company to make significant efforts to give scientific proof that microbiome can be a viable drug candidate . The stumbling block was the ability to provide the necessary data.

Convincing these companies to undertake partnerships with us was challenging not because of the lack of necessary data, but because the microbiome-based drug candidate was a newly introduced modality.

We had to convince them through a full set of research evidence and references at the pre-clinical level to give them the confidence that microbiome medicine could be applied in human trials. Nevertheless, having overcome this hurdle, it became easier to negotiate.

You mentioned that you filed an IND in the USA. What was the rationale behind targeting the US market before the Korean market?

Naturally, the US market is the largest and fuels our global ambitions. Moreover, one of the intricacies with microbiome treatments is that they can react differently across races. We have sought out, from the outset, to verify that our programme works in Caucasian patients without modifications. That is why we entered the US first. Moreover, the US is an ideal location for this clinical purpose with ethnic diversity.

We are also beginning clinical studies in Korea which will commence next year. This will target a cancer common in Asians but found infrequently in Caucasians. Hence, our studies target Caucasians in the US study, and Asians in the Korean study.

Advancements in microbiome technology are hampered by the insufficient manufacturing capabilities of this new industry. Tell us about your ambitions to expand your manufacturing footprint to fill that gap?

Indeed, the number of microbiome ventures is increasing, and it is becoming popular amongst venture capitalists. Worldwide, there are around 500 microbiome companies engaged in basic research and planning to enter clinical studies. However, this uptake in microbiome venture companies is rapidly outpacing the growth in manufacturers. In fact, Contract Manufacturing Organisations (CMOs) remain hesitant to involve themselves in the market. As a result, demand is far outstripping supply and I see this gap widening even further within the next ten years.

Consequently, we have plans to expand our operations into contract manufacturing to consolidate and safeguard our future capacity. Genome & Company will provide contract manufacturing, not only for our in-house products, but as a partner for other upcoming industry players. Our profits will be reinvested to fund both development and clinical activities.

We are already in the planning stage to explore our contract manufacturing business model. The plan is to reserve manufacturing capacity to serve external customers with the remaining capacity to manufacture our own.

You are also moving into developing nutraceuticals and consumer health products. How does this fit within the ambitions of the company?

We are conducting the launch programme for cosmeceuticals. We expect to launch a first product in the Korean domestic market before the end of 2020. We also looking into functional foods. In Korea, we want to manage the full business for consumer health, from manufacturing to marketing. Cosmetics manufacturing will not be a part of our direct commercialization; rather will be done through CMO/OEM. In Korea, Genome & Co. has already established partnerships with two leading global cosmetics ingredients manufacturers.

My specialisation at Bain & Co was in marketing. While we only have a small marketing team, we are still able to be very effective. In Korea, there are a lot of different channels for cosmeceuticals. Recently, online is emerging as a key trend and sales channel. Hence, we donâ??t believe that a large marketing team will be necessary to support our cosmeceutical operations.

How do you intend to secure sufficient investment to underpin your ambitious projects?

In December 2018, we listed on the KONEX, a Korean securities exchange exclusively for small and medium-sized enterprises (SMEs) and venture companies. Before listing on the KONEX, our market value was USD 40 million. Only three months after listing, our value increased almost seven-fold to USD 270 million, the largest valuation of any microbiome company globally.

Listing on the KONEX made it significantly easier to source funding. As the subsequent clinical studies will require significant financial resources, I want to leverage the financial markets to ensure that we can finance our development.

The KONEX is composed of mainly Korean investors; the next step is to attract international investment. Thus, we are now in the process to move into the KOSDAQ, the major IPO (Initial Public Offering) market in Korea. There are also plans in place for Genome & Co. to attend overseas investment roadshows to attract international investment prior to making the IPO on KOSDAQ.

What is your outlook for the future of the Korean biotech industry?

The Korean bioindustry has come on leaps and bounds in the last ten years, growing rapidly. It is now so competitive that there are a growing number of experts specialised in providing consulting services to the Korean industry. This simply did not exist previously.

Furthermore, the Korean Government has a strong willingness to invest in the biotech industry. The government is raising the initial funds to get the bioindustry off the ground, which is then matched further down the line by the private sector.

Moreover, many of the venture capitalists are young and passionate, studying the industry fastidiously to make the best investments. One of our investors is trying to invest in European, American and Israeli companies. Thus, Korean venture capitalists are experimenting with new investments that never previously considered.

What is your final message to our international audience?

We want industry professionals to really pay attention to what we do and where we are headed in the upcoming years. Our science has already earned the collaboration of big pharma firms, such as Merck and Pfizer as well as LG Chem. Genome & Company possesses unique programmes such as infertility treatments, not covered by any other microbiome firms worldwide. We are innovative, enthusiastic, and committed to our development.

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