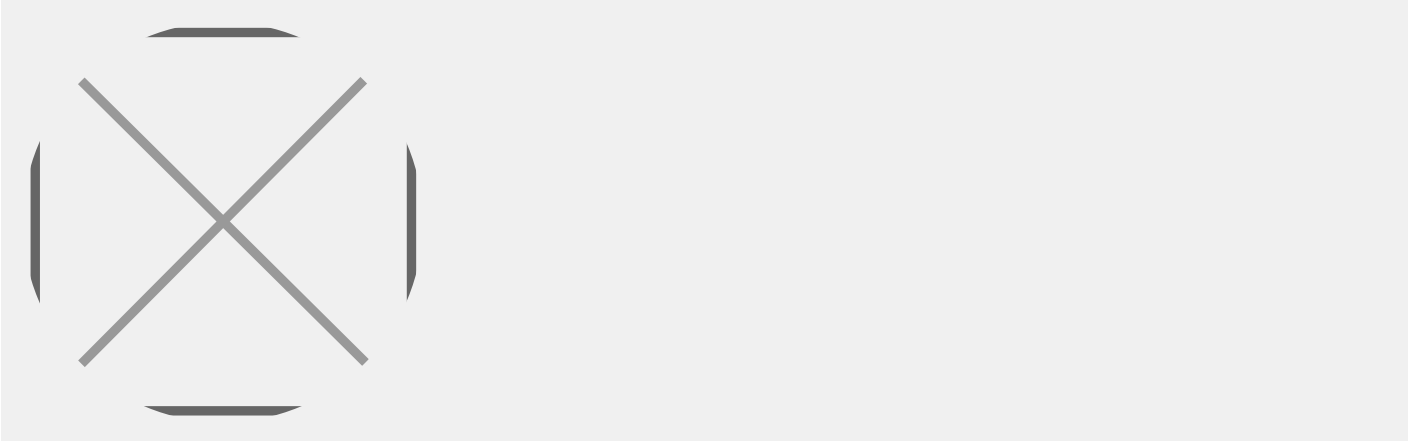
Interview: Johnsee Lee, Chairman, Development Center for Biotechnology, Taiwan



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A leading figure in the Taiwanese pharmaceutical sector, Lee divulges the practicalities behind ECFA, the free trade agreement that was signed between China and Taiwan in 2010 but has not yet come into full force; questions whether a lack of multinational investment has been a major disadvantage for Taiwan; explains the investor mindset towards the pharmaceutical industry in Taiwan, and reveals the mission of the DCB in the current environment.

A recent press release by the Taiwan Bio Industry Organization announced that the market capitalization of Taiwan's biotechnology and pharmaceutical sector has grown a whopping 520% in the last four years. What is driving such extraordinary development?

Indeed, the capitalization of the market has grown from approximately $3 billion in 2009 to approximately $15 billion in 2013. Taiwanese companies across the value chain, from drug development to chemical manufacturing, have participated in the boom. For instance, players like ScinoPharm, whom you interviewed for your first report on Taiwan in 2010, have become leaders not only in Taiwan, but globally. ScinoPharm is now one of the world's foremost producers of Active Pharmaceutical Ingredients (APIs)—and the company's own market cap has surpassed $1Bn.

ScinoPharm undertook an Initial Public Offering (IPO) in the time since you first spoke with their CEO. Their entrance into the public market is part of a major wave of IPOs in our sector. The

number of publically traded Taiwanese biotech and pharma companies has more than doubled in the last four years. Company values have skyrocketed. Revenues, too, have increased quite a bit for most players: from 2003 to 2012, total revenues for the sector have more than doubled.

There are a number of major drivers for this growth. The first is the improved relationship between Taiwan and China—which, by the way, has benefitted not only the drugs market, but also the diagnostics and healthcare services markets. In 2010, Taiwan and China signed the Economic Cooperation Framework Agreement (ECFA), which is being phased in via a series of gradual steps. Because of the complex nature of the relationship between the two sides, it is difficult to introduce free trade all at once, but in five to ten years, ECFA will become a fully-fledged free-trade agreement. A number of Taiwanese government agencies involved with the pharma industry, including the Biotechnology and Pharmaceutical Industries Program Office (BPIPO)—an agency supervised by the DCB—are involved in increasing the level of collaboration between the pharma and biotech sectors on both sides of the Strait.

ECFA, and the changing Taiwan-China relationship, have truly ushered in major change—and this is just the beginning. Our populations and disease demographics are roughly similar, making clinical trial cooperation a logical step. And if Taiwanese companies, or their counterparts in China, develop a new molecule for a condition with high prevalence in Asia, why not benefit a larger population? The two sides are already partnering to battle diseases like Avian Flu, with the Taiwan Food and Drug Administration (TFDA) treating the program as a priority.

Another driver for recent growth is the maturation of company pipelines and service offerings. There was a major wave of investment in the late 1990s and early 2000s that gave birth to a number of companies. I must say that for a decade, the evolution of these companies was not particularly graceful—but development in the pharma industry takes time. ScinoPharm was set up around 2000, as was TaiGen, a company that will likely release Taiwan’s first New Molecular Entity (NME). Medigen, too, comes to mind as a biotech company with a great business model that recently undertook a highly successful IPO. After a difficult growth phase, these companies are in very strong positions today, and they have surpassed the ‘old guard’ in innovation and internationalization—the large, established companies in Taiwan, who have grown over the decades by manufacturing generics for the local market, are now fighting to catch up. It often happens that the larger you are, the more risk-averse your strategy.

In speaking about growth, we also cannot overlook the fruits of government involvement in the sector. Over the last 10 to 15 years, the state has invested very heavily in research, channeled through the universities, hospitals, institutes like Academia Sinica, DCB, and the Industrial

Technology Research Institute (ITRI), and industry. In the National R&D Program for Biotechnology and Pharmaceuticals alone, approximately $100 million in funding is allocated every year from 2011-2016—and there are quite a few programs ongoing simultaneously. The investment over time is very substantial.

70 percent of government funding in this sphere has gone into basic research—something that taxpayers are sometimes wary of, because they do not receive instant economic benefit. And yet, as we are seeing now, 10 or 15 years down the line, basic research can pay great dividends. 'Taiwan Inc.' has a very strong pipeline today, with a lot of high-potential drug candidates.

The government has also recently come out with an amendment to the Drug Act that offers tax incentives to researchers who engage in new drug and device development.

Are there any particular areas of the value creation chain that Taiwan is most disposed to exploit?

In Taiwan, we have taken a more diversified approach. However, we do believe that we have several unique strengths. For instance, Taiwan is well positioned to develop medical devices, because of our long tradition in the electronics and IT industry. As healthcare moves towards an increasingly high-value, distributed-care model—i.e., away from large machines—we can certainly contribute to this evolution by building on our strengths in small computing.

On the drugs side, we have tended to focus on Asian-prevalent diseases. For example, liver diseases, nasopharyngeal cancer, lung cancer, and several other conditions are more prevalent in Asia. While some of the drugs Taiwanese companies are looking into may have little impact in the West, any drug that can impact the Chinese market is in itself a worthwhile business case—the size of the population is huge.

As I began to mention, China also offers opportunities in healthcare services, and, given the high level of healthcare provision in Taiwan, we have a number of organizations that have much to offer in this respect. Taiwanese entities are setting up hospitals and outpatient care facilities in China, duplicating the infrastructure that they have helped develop at home.

Excelsior Medical, another public company, comes to mind as an example of a Taiwanese business that has had a long-standing collaboration with China in the provision of healthcare services and the distribution of medical devices. Excelsior has set up a number of kidney dialysis centers in Taiwan that are doing very well—and they have now replicated those centers five and ten times over in China. The revenue growth that comes from leveraging the Chinese market can be

absolutely huge.

How do you believe Taiwan's biotech and pharma industry compares to that of its 'Asian Dragon' neighbors—notably Singapore?

It compares quite favorably. For instance, Singapore has a large number of highly qualified people from all over the world working within its borders. However, it has few grass-roots companies of its own. The major investors are Big Pharma players. Many of the top researchers, meanwhile, are just visiting—in fact, a number of them come from Taiwan, and they stay four or five years before returning home.

Taiwan, in terms of capacity of research, is perhaps 10 times larger than Singapore. We have 150 universities!

But conversely, is the multinationals' lack of major R&D commitment to Taiwan a drawback for this market?

It is. However, I think the scenario is changing. At the DCB, we are currently discussing several major partnership programs with multinational companies. As our industry has matured, foreign interest in collaboration has begun to pique. Taiwan already has a number of partnerships in place with Big Pharma companies for clinical trials. Now, those partnerships should grow to encompass earlier stages of research. The global community is finding that there are quite a few areas of exploratory research that are really worth pursuing in Taiwan.

In writing about the development of biotech in the Asian Dragon economies, the Asian Century Institute notes, "As the OECD has argued in its innovation strategy, there is much more to innovation than spending money on research and development. In this regard, many Asian economies do not have eco-systems that are conducive to innovation. They put too much of a premium on government controls and planning, and less on individual actions and initiative." Do you feel this is true in Taiwan?

It is true—but just as our level of international collaboration is changing, so too is our answer to this problem. The past few years have done much to improve conditions. For example, in the past, we did not have a good regulator in place. The predecessor agency of the TFDA was quite insular and conservative; now, we are in full compliance with standards like PIC/S. Similarly, the centers and clinicians that carry out clinical trials in this country are now much more proficient.

In the negotiations between Taiwan and China, we have argued that both countries should use the international standard. China is reluctant to do so at the moment, because they would like to

protect their companies, many of whom may not make the cut. Compared to China, therefore, Taiwanese companies are closer to the international level.

Taiwan also has much improved its innovation culture and innovation ecosystem. In the past, we were missing a crucial element of this ecosystem: venture capital and financing. Now, because of the health of our capital market, venture capitalists are quite willing to invest, because they see a way to recoup that investment and exit: through the sale of shares when companies float their stock on the public market. If IPOs weren't so feasible in Taiwan at the moment, investors would be very reluctant to participate in the long-term play that is biotech.

Taiwan has also traditionally emphasized—perhaps *overemphasized*—basic research over applied research. This is still a weak point in our ecosystem today, but it is also another area where we see improvement. DCB, for instance, is a development institution, a compliment to the basic research done in places like Academia Sinica and the universities. Our role is that of the 'second baton' in a relay race—translating from the first baton of basic research to the third baton of clinical trials and commercialization. We have set up a range of facilities and capabilities, including a GLP toxicity facility, a GMP pilot facility, and etc., to fulfill this role.

I have been in my position for just over three years. When I arrived at DCB, I found that there was a focus at this institute on academic research—which is the wrong place for us. We are not large enough to handle that role properly, and our original mission—as evidenced by the fact that we work under the Ministry of Economic Affairs—is to bridge the gap to commercialization. Our scientific work is but a tool for us to build industry and create economic impact.

I believe that this institute never really took its state-appointed mission seriously, until today. It was perhaps difficult to do so, because there was no industry to support in the past. Now, however, we are exactly where we need to be. We need to continue to have a clear focus at the DCB, and ensure that we satisfy our crucial mandate, without overlapping with the activities of other centers. Working for industry requires a different, business-oriented mindset—something I have worked to instill here.

DCB is also much more focused on biologics. We have the best foundation in Taiwan for doing so, because we have been working in this field for a long time. Our biologics pilot plant won a pan-Asian Best CMO award two years ago in Singapore. We also see that in biologics, there is a higher entry barrier than in small-molecule drugs. China and India are very strong in the small-molecule fields, and Taiwan is itself not bad, if we look again at a company like ScinoPharm. Nonetheless, there are few examples of unique competitors in Taiwan for traditional pharmaceuticals. Biologics,

with their rising market need and high technical barriers, are a field where we can offer something unique to the region and to the world.

Having covered DCB, can you leave our readers with a few words about the mission and role of the Taiwan Bio Industry Organization?

We are the largest and oldest biotech and pharmaceutical organization in the country. I am in my second term as president of the association.

Our role is to bring the industry together. We often host meetings that allow our members to network among themselves and with government officials. Communication is extremely important.

Integration and international collaboration are also extremely important. When we travel to other countries, we often travel together as a group to showcase Taiwan’s capabilities in the sector. In the same vein, we organize our own conference, Bio Taiwan, and invite other countries to join us in Taipei. The key word in biotech and pharma is collaboration. Individuals can only do so much—we need to connect. We need to connect for resource reasons, and we need to connect for expertise reasons. Partnering internationally is our greatest goal—with China, but, looking towards the future, also with Europe and the US.

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