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Johnsee Lee, chairman of Taiwan Bio Industry Organization, gives an update on the major developments of the country's biotech environment over recent years, speaking about its new areas of focus, unique strengths, and the remaining amendments necessary to realize the industry's global ambition. Lee also discusses the organization's upcoming event BIO Asia-Taiwan in partnership with the Global

Biotechnology Innovation Organization (BIO).

How has Taiwan's biotechnology industry landscape evolved in recent years – particularly regarding the Biomedical Industry Innovation Program?

After the two stock market crashes of Medigen and OBI, in which their clinical trial results caused many controversies among investors, the market has since been slowly recovering but still not to the same level as it had been previously. Currently, the investment environment of Taiwan's biotech industry is not very optimistic, but we do see the government making efforts to help the industry. However, investors are still motivated by performance indicators, and active results are necessary to win their confidence.

That being said, the industry itself has made improvements in its ability to produce results. Before, many companies were stuck in a purely R&D stage, but today several companies have gained market approval and are now generating revenues. Six drugs from Taiwan's biotech industry gained FDA approval and even more medical devices, between 20 and 30, were approved by the FDA as well. Despite this, the challenge remains in having the capital market of Taiwan reflect this success. Therefore, many Taiwanese biotechs are looking outside of the country to attract cross-border investments and industry partnerships.

The problem in Taiwan is not a lack of capital funding, but the reality that investors are wary of the risk that comes with the biotech industry. The question we have to consider is how we can lead the

industry in the right direction to yield solid results and see another boom of the capital market in the near future?

In what areas of biotechnology is Taiwan aiming to take a strong positioning?

In regard to government policy, many positive changes have been made in Taiwan's innovative biotech. For example, the administration has recently passed new regulations to allow the use of cell therapies for cancer patients. For now, this is limited to autologous cell therapies, but this could be expanded later down the road. Along with Japan, Taiwan has taken the lead to develop this area and we have seen several cell therapy companies working on CART and stem cell popping up within the last two years.

Precision medicine is also a growing field in Taiwan, especially in molecular diagnostics and the use of new precision medicine drugs. In this area, we are building more collaborations with multinationals and Taiwan is moving from a traditionally generic positioning to new drug discovery. Furthermore, Taiwan became a member of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) just last year.

Additionally, several big projects within the current administration aim at building Taiwan's capabilities in smart healthcare and medical artificial intelligence. Taiwan can leverage the big data from National Health Insurance and its strength in ICT and semiconductor industries to take a lead in this field.

While in the US or Switzerland is very much bottom up, Asian innovation dynamics seem to be different with government guiding the industry. Who would you say is driving innovation in Taiwan?

While the government still has a strong role to play, investors and the private sector are key drivers of innovation in Taiwan. Innovation does not need to come from grassroots domestic sources either, it can come from international collaboration as well. For example, out of the 15 to 20 cell therapy players that exist, several of the most advanced come from institutions overseas such as MIT and Harvard. Many of our scientists will go abroad to study and conduct research, then return to Taiwan to start their own biotech companies. Taiwan is also able to attract expatriates to come set up their business here also.

Speaking of the public sector, Taiwan's life science innovation is driven primarily by five key organizations – Academia Sinica, the National Health Research Institute (NHRI), the Industrial Technology Research Institute (ITRI), the Development Center for Biotechnology (DCB), and the university network like the National Taiwan University. Nevertheless, it has been some years that the private industry has been able to create its own innovation success stories without coming from government programs. Even still, as the private industry, we maintain a positive relationship with the public sector and each month TBIO meets with the Ministry of Health and Welfare, the Ministry of Science and Technology, and the Ministry of Economic Affairs to discuss key issues facing Taiwan's biomedical sector.

Taiwan is in the heart of a very dynamic biotech and R&D ecosystem with close proximity to countries like Japan, China, and South Korea. What are some of Taiwan's key strengths

compared to regional competitors?

Thanks to Taiwan's NHI system, patient records have been collected digitally over the past 30 years or so. We have an abundant amount of data linking treatments with disease outcomes etc., and this is a resource that is to be explored. Many MNCs are trying to tap into this data because compared to countries like the US where health data and records are very fragmented among insurance carriers, Taiwan has a unique advantage of having a single point of connection for the data.

Another strength we can leverage is our proximity to major markets like China. Taiwan population's genetic blueprint is almost the same as the Chinese, so all the precision medicine, diagnostic, and treatment technologies developed in Taiwan can be used in China. We also have an advantage over China when it comes to IP protection, transparency of financial accounting, and corporate laws. For that reason, many companies are now choosing to conduct early-stage clinical trials in Taiwan when IP protection is essential, then moving to another Country for phase III trials when they approach commercialization.

What is the relationship that exists between Taiwan and its next-door neighbour China?

China is a large market, so it is always attractive to enter such markets. The previous administration set up a mutual recognition of clinical trial data in eight designated hospitals between the two countries. While Taiwanese companies still need to apply for CFDA approval and vice versa, clinical trials do not have to be repeated which saves time and money when bringing new products to market.

Although there are some political tensions between the countries, there are close business and investment ties between us. In fact, after Japan, China has the second highest number of delegates attending the BioTaiwan conventions last year. However, there still are a few issues and barriers between Taiwan and China. For example, Chinese investments in Taiwanese companies are not allowed to exceed over 30 percent of shareholding.

Furthermore, to balance out Taiwan's relationship with China, President Tsai has implemented the South Bound Policy to encourage collaboration with other Asian countries which has many components related to health and biomedical. We work with Southeast Asian countries to export Taiwan's products and services, especially in emerging areas like personalized and regenerative medicine.

Looking forward, where do you see the room for improvement in order to continue driving Taiwan's biotechnology industry?

The most important thing to have is the passion and enthusiasm of the capital market. Not only is there a need for results, but there are necessary changes which should be realized from a regulatory viewpoint. The government should not always be so focused on trying to protect all investors - they should be free to make their own decisions. Yes, the industry information should be made to be as transparent as possible but not putting up too many barriers to stop venture capitalists from investing.

What message would you like to deliver about the Bio Asia Taiwan 2019 event will be taking place this coming July?

For the past 16 years, BioTaiwan has established itself as one of the largest annual biotech events in Asia. Expanding on this legacy, the Biotechnology Innovation Organization (BIO) and TBIO have come together to present BIO Asia-Taiwan, taking place July 24-28 in Taipei. Themed “Biotech as the Next Growth Engine for Asia”, this year’s event will attract more than 1,500 attendees from 25 countries representing biomedical, pharmaceutical, genomics, biotech services, equipment and instruments, academic research, and bio-based healthcare. Look forward to seeing you in Taiwan in July.

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