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The silver lining of the crisis is that it has provided opportunities for small companies to work together and perhaps grow together

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Taiwan Bio Industry Organization Chairman Dr Johnsee Lee outlines the Taiwanese biopharmaceutical industry's rapid and coordinated response to the COVID-19 crisis and also explains how Quark Biosciences' diagnostics and precision medicine expertise is aiding this effort.

Johnsee, with the world facing the challenging COVID-19 situation, as chairman of the Taiwan Bio Industry Organization, how have the situation in Taiwan evolved in the past few months?

Generally speaking, most sectors of the economy – especially the transportation, food & beverage sector – have seen a significant reduction in activity and consumption, and accordingly, there has been a negative impact on the Taiwanese economy. However, the internet-related sector has been growing significantly. As an indication, for Taiwan BIO, we organize a biotech conference every July and this year, we will be holding the conference online. This would save us a lot of expenses in terms of eliminating the need for physical venue and travelling costs, and we are subsequently investing these resources on various digital and virtual conferencing tools to prepare online content as well as filming capabilities.

As chairman of Taiwan BIO, we are also trying to mobilize our members to coordinate responses to the COVID-19 situation. For instance, we have one team focusing on diagnostics. For instance, some of our members work on reagents, some on assays, some on instruments – so by bringing them together, we can work on developing and offering a total diagnostic solution to institutions in Taiwan as well as globally. The short-term goal is to offer a better supply of the necessary COVID-19 diagnostic tests. We have another team working on R&D, comprising both academic and research institutions as well as vaccines and drug development companies. There are many different projects in progress, including vaccine development, new drug development as well as the repurposing and investigation of already-approved drugs for the treatment of COVID-19. This is a longer-term undertaking since vaccine and drug development have longer timelines than diagnostics but the critical aspect is mobilizing and connecting the different parts of the biotech industry.

Since the pandemic began, I have received a lot of calls from our members to coordinate such efforts. The silver lining of the crisis is that it has provided opportunities for small companies to work together and perhaps grow together. Such collaboration and consolidation could result in Taiwanese companies becoming stronger and more competitive. There may also be opportunities for M&A activity between Taiwanese companies and international companies. In fact, one of my companies, Personal Genomics, has received interest from both American and European companies.

We are also working with the Taiwanese government to accelerate regulatory approval processes. Unlike in the US, Taiwan did not have any Emergency Use Authorization frameworks, but following our advocacy, on 26 March 2020, the Taiwanese government issued a new regulation for the emergency use of necessary healthcare innovation to combat COVID-19. Already, one company has been approved under this new regulation. This is a positive step. In this way, the pandemic has also encouraged regulators around the world to be more flexible and change their approaches to managing regulatory processes. Many companies have been able to bring their products to market in a shorter span of time.

Taiwan has always had a vibrant biotech industry, which receives a lot of governmental support. How have these strengths been deployed in the fight against COVID-19 as well as more generally in healthcare?

One of Taiwan's competitive advantages has been our unique healthcare database. Virtually all of Taiwanese citizens are registered on our compulsory National Health Insurance (NHI) system, and we all carry a NHI card with our electronic medical records on a chip. This card allows us to access our prescriptions at pharmacies and hospitals. Pretty early on in the pandemic outbreak, Taiwan connected travel and immigration data to this card so that medical and other relevant personnel could see your travel history and assess your potential exposure to COVID-19. This was extremely helpful in terms of managing the outbreak quickly and effectively.

Other data generated by the NHI include testing results, treatment outcomes and so on. With the use of AI, we would be able to extract more and more information. This is definitely an area where Taiwan has a unique opportunity to leverage our strength and develop into a precision medicine hub.

Last year when the U.S. Biotechnology Innovation Organization (BIO) President and CEO James C. Greenwood was in Taiwan, he believed this was one area the government has to try to balance here: reduce healthcare expenditure while continuing to introduce more new drugs and support the biotech industry. This is a dilemma but the government is becoming more and more understanding. For instance, in 2018, the NHI started to reimburse cancer immunotherapy, which is very expensive. Our member companies are working to support the government as well. QuarkBio has developed a product to identify the patients most suitable for immunotherapy. So far statistics have shown that only about 25 percent of the patients receiving immuno-oncology treatment through the NHI respond positively. The system is currently using only one marker based on tumor mutation burden (TMB) to evaluate which patients should receive IO therapies, but we have developed a genomic test to also evaluate the tumor microenvironment. Based on early data, we believe this test can select patients more accurately and generate savings for the government.

What more do Taiwanese biotechs need to accelerate their advancement, whether in response to COVID-19 or more generally?

For Taiwan, one of the most important factors is to work with companies and partners in other countries. While the population size of Taiwan – 23 million – is not small, it is still too small for new drugs or inventions to be commercialized. We need to work with other partners with different capabilities to expand the market size. This is why we organize our BIO Asia-Taiwan conference with global BIO each year in order to connect Taiwanese companies to international communities. Last year, we had over 2,000 one-to-one partnering sessions.

Secondly, money is always important. There are sufficient resources from both the public and private sectors in Taiwan but the main challenge is the investor interest in the biotech sector, which has longer investment timelines, especially for new drug development. Investors are still not as willing to take risks or wait ten to 15 years for returns. I have been advising our government to implement policies and provide incentives to encourage investors to invest in higher-risk sectors like biotechnology. It is not as easy because Taiwanese investors are more used to manufacturing-oriented sectors where the investments and products are far more tangible.

However, with the COVID-19 pandemic, we must take advantage of the situation and capitalize on available opportunities. One piece of positive news I have seen is that the pandemic has inspired many students in Taiwan to enter the fields of biomedicine and public health. This will hopefully grow our talent pool in the future.

As president and CEO of Quark Bioscience, a diagnostics and precision medicine company, how has your company reacted to the COVID-19 crisis?

QuarkBio has focused on real-time precision medicine. For conventional DNA sequencing technology, you have to wait three weeks for analysis results. Cancer patients do not have time to wait that long, especially if you also want to test regularly to monitor disease progress and treatment outcomes. This applies also to chronic diseases like diabetes or various cardiovascular conditions, as well as neurodegenerative diseases like Alzheimer's. For this reason, we have developed our PanelChip^{TM} Analysis System which uses a real-time PCR array assay that can detect over a hundred markers or genes simultaneously within two hours. This allows real-time monitoring and fairly comprehensive analysis of the patient's genomics.

We have adapted this instrument to also test for COVID-19 and it has worked quite well. The key feature of our COVID-19 diagnostic test is its high sensitivity, with the lower detection limit being as low as two to three copies per reaction. This is extremely sensitive – at least an order of magnitude more sensitive – compared to the standard RT-PCR assay typically used for virus detection today. We are trying to reduce the rate of false negatives so that we can firstly identify those infected earlier, and secondly, avoid release infected patients prematurely. This would help the fight against COVID-19 significantly. It can also be used to monitor patients' disease progression in real-time. This data could then be used to evaluate how patients respond to different treatment regimens and standards of care.

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