BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

“The Open Innovation Program has become a trend in the molecular diagnostics industry”

11 January 2024 | Opinion | By Ayesha Siddiqui

Established in 2000, South Korea based Seegene Inc is a leader in molecular diagnostics and achieved remarkable financial success with over $1 billion in revenue and 65 per cent gross margins. With a mission for a disease-free world and proactive pandemic prevention, Seegene seamlessly integrates high multiplex diagnostic assays with automated testing systems. In an interaction with BioSpectrum, Dr Seong-Youl Kim, Seegene's Senior Vice President, shares insights on the company, the molecular diagnostics landscape, challenges and opportunities etc.

Molecular diagnostics (MDx) is a powerful tool in healthcare. Could you explain why it's considered the most effective method for accurately diagnosing ailments and the importance of early diagnosis?

With its high accuracy, sensitivity, and rapid testing capabilities, MDx enables early detection and thus leads to appropriate treatment. Particularly, among MDx technologies, Polymerase Chain Reaction (PCR) is a powerful tool for detecting minuscule amounts of biological material in a sample. This allows the early detection of pathogens in asymptomatic patients, COVID-19 being one of many examples. Early diagnosis can also reshape how we deal with diseases. For example, if we can detect cancer at very early stages, far before symptoms start to show, treatments can make a real difference.

Seegene, a leading South Korean company providing a total solution for PCR molecular diagnostics, has pursued to further refine this technology. Unlike conventional technologies that can detect a few pathogens at a time, our syndromic quantitative PCR (qPCR) reagents are highly multiplexed which can detect up to 15 multiple pathogens in a single tube using Seegene’s proprietary technologies. For example, our Human papillomavirus (HPV) products can test for 14 high-risk HPV types and also provide quantitative information of types in a single tube. We have four key technologies such as DPO, TOCE, MuDT and 3Ct.

Seegene is known for its industry-leading intellectual property (IP) in molecular diagnostics reagent assays. What sets your technologies apart, and how are you leveraging them to expand your product portfolio and market

coverage?

Seegene has been building a comprehensive patent portfolio covering all aspects of multiplex PCR testing including oligo chemistry technologies, reagent development solution, testing instruments, as well as manufacturing system. We have all key proprietary technologies required for development of multiplex PCR reagents. We developed the DPO primer technology for multiple gene amplification in 2006, the TOCE technology for multi-target detection in 2012, and the MuDT technology for quantitative analysis of multiplexed real-time PCR results in 2014. In 2022, all these technologies were integrated into 3Ct (cycle threshold) technology that can simultaneously detect up to 15 targets with quantitative information based on Ct values in a single channel without compromising sensitivity and specificity simultaneously. This achievement marked a new era of 'real' syndromic PCR-based molecular diagnostics. Going forward, under the Open Innovation Program and OneSystem business, we plan to develop a vast array of new products based on these technologies with our partners.

Seegene has achieved remarkable financial success with over $1 billion in revenue and 65 per cent gross margins. What factors have contributed to this success, and what role does international expansion play in your revenue generation?

We responded promptly to the initial reports of the virus and made diagnostic kits available before COVID-19 was declared as a pandemic by the World Health Organization (WHO). It took just two weeks for us to develop the diagnostic kit. Performance evaluation and regulatory approval by the Korean government were obtained the following week. Our COVID-19 assays were designed to detect multiple target genes of SARS-COV-2 virus using our innovative technologies. Excellent performances of these assays were validated in several international studies and publications. As a result, 350 million tests were delivered worldwide during the pandemic. Our global network comprising nearly a hundred of distributors contributed strongly to our $1 billion annual revenue generation during the COVID-19 pandemic.

Seegene's world-leading technologies and dedicated presence in global markets are some of the key factors that led to our financial success. We have eight subsidiaries in Europe, North America, South America and the Middle East and North Africa. Although we had been exporting our products for much longer, our first subsidiary in Italy was established in 2012. Other subsidiaries were established subsequently and built from the ground up. Our drive for product innovation and long-term dedication to Europe and other export regions resulted in Europe having the largest contribution to our overall sales (55 per cent in first half of 2023). Other large regions included Asia (24 per cent) and North America (8 per cent). All in all, exports accounted for 87 per cent of our first half of 2023 revenue.

What are some of the key challenges and opportunities that Seegene anticipates as it continues to work towards its mission of making a meaningful difference in the world through molecular diagnostics?

Over the past 20 years, Seegene has been building itself with an end goal in mind: creating a society where everyone in the world is able to live a happy and healthy life, free from all diseases. This vision can only be realised by channelling the collective wisdom and capabilities of scientists, experts, and companies toward this single goal. As we've experienced from the global COVID-19 pandemic, it is crucial to develop diagnostic products for all diseases in every field. Nevertheless, due to hurdles in menu, regulation, manufacture and distribution, it is difficult for a single company to develop ten new products per year. To overcome such challenges, Seegene is introducing a global OneSystem business for global democratisation of PCR in all fields. We believe that companies and scientists worldwide participating in our Seegene OneSystem business can develop hundreds or even thousands of diagnostic products annually. Seegene OneSystem business is a new business strategy where representative companies from each country develop qPCR products localised to its need through Seegene's standardised technology. Under this plan, we will establish new companies in over 100 countries with leading companies in each country to develop diagnostic products.

Seegene started its One System business by signing strategic partnerships with top tier MDx companies in Spain and Israel. As part of Seegene OneSystem business, the company recently launched the 'Open Innovation Program powered by Seegene' in partnership with Springer Nature. The programme enables scientists and experts worldwide to develop syndromic qPCR assays across all fields.

What are the current trends and emerging technologies in the molecular diagnostics industry that are driving innovation and improving diagnostic accuracy?

The Open Innovation Program has become a trend in the MDx industry. Yet, Seegene's approach stands apart from its competitors. As Open Innovation in general allows companies to cooperate with external professionals and organisations, we stay ahead of the curve with our Seegene Digitalized Development System (SGDDS), which provides support for researchers

to easily develop syndromic PCR products, even to those with limited development experience. It consists of two key systems: SG in-sillico that automates oligo (primer and probe) design, and SG IDEA that automates the entire experimental and documentation process. With our automated systems, a wide array of participants can easily contribute to our open innovation ecosystem which eventually will lead to a world free from all diseases.

Ayesha Siddiqui