Dean Tsao â?? Chairman and CEO, PlexBio, Taiwan

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Dr Dean Tsao, chairman and CEO of PlexBio Co., Ltd.,

shares the story of his impressive expert background which led him to form the in vitro diagnostics (IVD) company in 2010. Dr. Tsao goes on to explain the companyâ??s unique multiplexing technology based on the Ï?Codeâ?¢ MicroDisc (â??pi-Code MicroDiscsâ??), and its ability to serve as a more convenient, consistent, and cost-effective alternative to next generation sequencing (NGS) in the space of precision medicine and cancer management.

Dr. Tsao, you have quite a bit of experience in the diagnostics sector and as an entrepreneur. Can you tell us more about your background leading up to the foundation of PlexBio?

Prior to founding PlexBio in 2010 and assuming the roles of its chairman and CEO, I came back to Taiwan after having gained over 30 years of extensive experience in the IVD industry in the USA. My background is that of a laboratory and clinical scientist and I have been fortunate enough to leverage that into a wonderful career as a successful serial entrepreneur with a history of launching and leading new companies to grow into successful businesses. Previously I served as the President and CEO of Zymed Laboratories, Inc. which I founded in 1980. Zymed produced antibodies and immune-chemicals for cancer diagnosis and research and was acquired by Invitrogen in 2005. Later, I founded Genemed Biotechnologies in 1987, an OEM for molecular Dx and IHC providers, immunoassay, and reagents which was acquired by Sakura Finetek in 2015. I founded Genemed Synthesis Inc in 1995 in the custom oligo, gene, and peptide synthesis space. I held the role of president until 2007 when the company was acquired by Genomic Resource.

Now please introduce your newest venture, PlexBio, a leading Taiwanese provider of innovative in vitro diagnostics solutions.

Since 2010, PlexBio has been designing, developing, and manufacturing our proprietary cutting-edge multiplexing platform and assays, to enable a broad range of genetic research and more specifically, cancer diagnostics. PlexBioâ??s team of scientists and researchers worked together to develop PlexBioâ??s proprietary Ï?Codeâ?¢ MicroDisc technology which uses a precision image micro disk for the detection of specific molecular targets. Hence the name â??pi-Codeâ??.

We have applied this multiplex detection technology to a variety of molecular targets â?? including infectious diseases, food safety, and general life-science research tools. But our core business strategy rests in developing a comprehensive menu of tests for use in cancer diagnosis and management. In this regard, the current IVD product menu from PlexBio focuses on molecular tests which use tissue biopsy samples for diagnosis and management of cancer treatment. But beyond this, we are working diligently to perfect additional oncology products for so-called liquid biopsy

samples.

The liquid biopsy approach, which uses blood and other bodily fluids that are more easily obtained from the patient, has the benefit of being non- invasive and less expensive than the traditional biopsy approach where samples are removed from the patient surgically or by needle aspiration. Most importantly, liquid biopsy sampling can be done throughout the course of treatment for monitoring the patient for re-occurrence of the cancer or resistance to the therapeutic agent being used.

How do your innovative piCode MicroDisc and SelectAmp technologies platforms differentiate PlexBio as a leading player in precision medicine?

To be clear, PlexBioâ??s approach is a real alternative to Next Generation Sequencing (NGS) and the company hopes to disrupt and displace the use of NGS where ease- of-use, time and cost are at issue. PlexBio believes that performing high multiplex assays does not need to be complex or costly and therefore, we set out to develop a series of products for clinical laboratory use based on our proprietary Ï?Codeâ?¢ MicroDisc technology. Each pi-Code MicroDisc has a distinct circular image pattern and corresponds to the identity of a specific capture agent conjugated to the disc surface. This capture agent allows the capture and detection of targets from a sample.

Virtually any probe used in clinical diagnostics can be conjugated to pi-Code MicroDiscs, including DNA, RNA, antigens, antibodies, proteins, or chemical compounds. The companyâ??s current oncology product line uses oligonucleotide capture probes for single-gene mutations or gene rearrangements. Several of the companyâ??s products also use SelectAmp technology which is a mutation-enriching PCR amplification technique that dramatically increases mutation detection sensitivities. In our gene mutation kits, the achievement of sensitivity up to 0.1 percent is common in many mutation points making this analytic approach ideally suited for liquid biopsy assays.

To bring pi-Code MicroDisc technology to every laboratory, PlexBio offers a series of convenient, pre- activated pi-Code MicroDisc products as a simple solution for the conjugation of virtually any desired capture reagent a life science or clinical researcher may choose. A simple incubation step of the ligand in a buffer under controlled pH and temperature conditions allows anyone to create their own high complexity multiplex tests and can be applied in both molecular and immunoassays.

What are your current priorities to develop PlexBioâ??s positioning within the areas of diagnostics and precision medicine?

Since the founding of the company, one of the main challenges we faced was a lack of publications about our innovative technology. Although we had achieved a very significant advancement in diagnostics, all of the data we had was sequestered within PlexBio and only spread in the research community by word of mouth. Therefore, about two years ago, we began to work in a very focused manner with several European collaborators to perform specific studies using our reagents in their facilities. We saw this as necessary to validate the clinical performance of our products and to establish the necessary brand recognition for our platform. I believe that developing a unique core technology is absolutely essential in the success of any biotech company, especially in IVD as it is necessary to differentiate your products from the offerings of others.

As I mentioned already, we are currently concentrating on diagnostics for use in cancer management. We have specifically focused on identifying a wide variety of gene mutations and rearrangements in our assay kits. Compared to NGS which gives a much more in-depth sequencing,

our offering is positioned somewhat differently. In PlexBio we operate around a 3C philosophy â?? Convenience, Consistency, and Cost. Convenience refers to the ease-of-use, which does not require a high level of expertise to achieve fast and accurate results, unlike NGS. Next, Consistency is essential in ensuring that the results of the same diagnostic sample will be achieved no matter who is conducting the test or where. For example, ten of the same NGS tests sent to different laboratories might not come back with identical results. Additionally, NGS can take up to two weeks or more for results whereas our multiplex platform can provide same-day results in only five hours. Finally, with Cost, we wanted our products to be affordable yet still maintaining a standard of quality. Part of my mission in founding PlexBio was to reduce the complexity of multiplex technology and make it simple and easy to use for just about anyone.

PlexBio offers a range of streamlined multiplexing solutions from diagnostic kits to systems and instruments. Can you elaborate on your entire product portfolio?

PlexBio has committed significant resources and effort to develop products for the early detection of cancer and other diseases. The main focus has been on products for analyzing the status of a wide range of somatic gene mutations or gene rearrangements typically seen in various cancers. These products, which represent the main â??driver mutationsâ?? observed in human cancers, cover a wide range of multiplex analysis capability, ranging from seven to over 40 targets in single tube reactions. All of these tests were CE-Marked for the European market in 2017 and 2018.

Additionally, PlexBio also offers two infectious disease genotyping kits. The IntelliPlexâ?¢ HPV DNA Genotyping Kit is a multiplex hybridization assay that detects and identifies PCR-amplified human papillomavirus (HPV) DNA in cervical specimens. It offers clear and reliable results that can be obtained for up to 96 samples in under 5 hours for high-throughput HPV testing. The IntelliPlexâ?¢ HCV Genotyping Kit is a multiplex hybridization assay that detects and identifies PCR-amplified Hepatitis C Virus (HCV) RNA in serum/plasma specimens. These indications highlight the versatility of our platform.

The PlexBio IntelliPlexâ?¢ instrument platform fits within the general industry trend for increasing automation of routine laboratory procedures by the use of dedicated work stations and software to program instruments. As new solutions like the IntelliPlexâ?¢ system become available to improve reproducibility, increase throughput, and enhance sensitivity for multi-target applications, competition increases. A key advantage of the PlexBio IntelliPlexâ?¢ platform in this market is that it is compatible with a number of â??front endâ?? solutions that already exist in customerâ??s labs. For example, most laboratories already have their preferred sample preparation or extraction methods validated for tissue or liquid biopsy samples and we have made sure these are compatible with our IntelliPlexâ?¢ assays. Additionally, virtually all labs have PCR thermocycler systems already in place for molecular assays, so while we offer this type of equipment, it is not essential for them to use our brand of thermocycler. This allows the end-user to continue to use much of the front-end of their existing workflow while ensuring compatibility with the PlexBio platform for the multiplex detection. This simplified the operation of PlexBio assays and reduced hands-on time for the user â?? giving a balanced degree of automation but which remains compatible with existing front-end solutions. The IntelliPlexâ?¢ 1000 Ï?Code Processor and PlexBio 100 Analyzer also improve laboratory throughput, reduces human error and enhances the quality/sensitivity of results.

Many healthcare systems have yet to fully embrace diagnostics as a core element of its economic well- being with very little money being allocated to the area â?? in Taiwan less

than three percent of expenditure is allocated to diagnostics. Do you see this changing today?

This is an unfortunate situation when it is well-documented that, in general, clinical laboratory test results are indispensable for routine patient management. Imagine attempting to treat a diabetic patient without knowing their blood glucose levels or trying to stabilize a dehydrated patient without knowing of their electrolyte levels. In such cases, lack of diagnostic information can have severe negative, even fatal consequences. Similarly, in cancer management, direct understanding of the patientâ??s genetic status is key. Fortunately, precision medicine has begun to flourish in recent years, and it has attracted more attention in the diagnostics sector than ever before.

Under the umbrella of cancer diagnostics, there are four areas that PlexBio is focusing on: prevention/early detection, diagnosis, treatment, and monitoring. In diagnosis, the information provided by the IntelliPlexâ?¢ system allows proper selection of therapy for the most effective treatment. During the monitoring phase, we can follow the patientâ??s course of therapy to determine how well their treatment is working, their genetic reaction to drugs â?? such as the emergence of resistant tumor cells, and also identify potentially more effective treatment regimes. However, the challenge we still face is that these procedures are not yet reimbursed by national health and insurance systems â?? they must be paid for out of pocket by patients. We believe that appropriate IVD testing enables the correct early-stage interventions and treatment and will ultimately reduce late-stage healthcare expenditures for all stakeholders.

Ultimately, who will be the payer of precision medicine in the long run?

At this moment, tissue biopsies are covered by insurance systems rather than liquid biopsies. However, I believe this will change hopefully within the next five or so years. Due to expensive NGS being the primary platform for conducting a liquid biopsy, healthcare systems cannot afford to cover the four to six yearly tests needed in cancer monitoring. Thanks to PlexBioâ??s Ï?Codeâ?¢ MicroDisc technology, our aim is to reduce the cost of liquid biopsy, allowing for the reimbursement of such an important step in precision medicine.

In addition to PlexBioâ??s HQ in Taiwan, the company also have a manufacturing facility in mainland China and an affiliate in the US. What internationalization strategy do you have for increasing the companyâ??s global footprint?

With the completion of development and the availability of the IntelliPlexâ?¢ system in mid-2017, the company immediately initiated a series of platform placements that ranged from short-term evaluation system rentals, for-sale installations and technical collaboration placements across key geographic regions. By the end of 2018, the company had placed approximately 25 IntelliPlexâ?¢ systems globally. This initial product launch was achieved largely by direct placements from the companyâ??s International Sales & Marketing team without significant reliance on third parties. This was done to gain valuable direct first-hand experience with diverse customer settings globally.

To address the demands posed by different cultures internationally, the company employs a number of customer-facing individuals with multiple language skills â?? including English, German, French, Spanish, Italian, Chinese, Malay as well as several others. This has been another key for the companyâ??s sales and support staff to engage seamlessly with customers outside the APAC region and gain recognition for the IntelliPlex system as a substantial solution for the IVD market. We plan to continue expanding in these directions through 2020 and then we will evaluate our strategy for adjustment and entry into new markets such as North America, South America, and India.

How does building a strong distribution network of partners fit into the business strategy of PlexBio?

Throughout 2018 and year to date 2019, then we began to engage multiple distribution and strategic partners to build out and fortify the companyâ??s supply chain across the globe. PlexBio now has key distributors in Japan, Korea, China, Singapore, Thailand, Australia, the Middle East, and western Europe and is continuing to expand. Earlier this week PlexBio announced a new strategic partnership and distribution arrangement with A. Menarini Diagnostics, a major IVD company with strength in Europe and North America.

Another important business strategy to promote our patented Ï?Codeâ?¢ MicroDisc technology is licensing the technology to IVD, pharmaceutical and biotech companies for different applications. For example, Plexbio licensed the pi-Code technology to Denka, a leading Japanese IVD company in infectious diseases for the development of various multiplex molecular diagnostic products for infectious disease in 2016 and again in 2019. We are negotiating with a Chinese company to license them the application for auto-immune diseases for China market. There are many other diagnostic applications where our pi-Code technology platform provides excellent solutions to meet the unmet needs.

What goals are you aiming to reach within the upcoming five years?

Looking to the future, PlexBio will continue to focus on the expansion of companyâ??s brand image, leading the market with high-complexity multiplex technology, and the promotion of clinical and scientific research to firmly establish PlexBio reputation as a high-quality supplier of key IVD and life-science products. This will enable the company to fully realize its operational goals for its shareholders and employees. We owe deep thanks to all our shareholders for their continued support, our strategic partners for working tirelessly with us to deliver innovative products to the clinical and research markets, and to our employees for their unwavering commitment to creating and delivering truly exceptional products and services for our customers. We firmly believe that by putting high complexity molecular information at the focus of disease management, PlexBio will help transform the delivery of care for patients.

As a successful entrepreneur, how do you manage the successful marriage between business and science in PlexBio?

I do not look at them as separate entities needing to be joined, rather I view PlexBio as simply being in the business of science. From the business perspective, we have focused on unmet needs in the market and then we used our science and technology to develop innovative solutions to meet those needs. It is a simple formula applicable to almost any field. In the case of PlexBio, we see our IntelliPlexâ?¢ system as being the right product at the right time for the market. But as our team and I have worked on this day-in and day-out, it also helps that there is a deep passion for the science and problem-solving. In founding PlexBio, it was part of my vision to develop a core technology which is used around the world to help deliver focused diagnostic information to help improve patient treatment. Now that we are well underway in launching this technology into the commercial space, I am very proud of what we have accomplished and that we are actually touching the lives of many patients.

In business, I believe that having the right team and the best talent is crucial. When you trust your people, they can be given authority to make autonomous decisions in their areas of expertise. My job is to support my team rather than micromanage. Allowing them to feel fulfilled, connected, and responsible for their work is the key to achieving a unified goal.

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