Interview: Daniel Huang – CEO, Genomics Bioscience; Chairman, Pharmigene, Taiwan



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Daniel Huang, CEO of Genomics Bioscience, Taiwan's largest commercial genome sequencing company, and Chairman of Pharm

igene, a global leader in the development and manufacturing of genetic tests, documents how he plans to leverage the combined capacity and expertise of these two companies to form strategic alliances with leading pharmaceutical companies developing targeted cancer therapies, while increasing its footprint in the booming personalized therapies market in Europe and in the US, thanks to Pharmigene's unique genetic tests.

Holding more than 25 years of experience in the genomics industry, you have been the CEO of Genomics, Taiwan's largest commercial genome sequencing company, since 2011. Could you introduce the company to our international readers?

Genomics was founded in 2001 by Dr. T.Y. Chow, a former student of Dr. Frederick Sanger who received twice the Nobel Prize for Chemistry. As the project leader of Academia Sinica Plant Genome Center, Dr. Chow notably represented Taiwan and led his team to participate in the International Rice Genome Sequencing Project (IRGSP), becoming the first to complete the sequencing of rice's chromosome 5. Nevertheless, in the 2000s, genomics was still a very emerging field, whose innovation was mainly driven by academic and research centers. As a matter of fact, a decade ago, an individual genetic sequencing would cost a few millions US dollars.

As a result, developing marketable genomics applications only stood as a promising but very ambitions endeavor, rendering the access to funding particularly challenging.

Nevertheless, 2011 clearly marked a turning point in the industry, as the company Illumina released a groundbreaking sequencing technology, which prompted them to claim they could decrease individual sequencing's cost down to USD 1,000. The launch of Illumina's technology therefore triggered the beginning of a global, industry-wide effort to bring sequencing services from an academic-focused setting to a more clinical-ready stage. In turn, leading pharmaceutical companies quickly understood the heightened therapeutic outcomes that genomics technology could generate, providing our industry with larger partnership opportunities and a greater access to financing, whether through the stock market or institutional investors. In the meantime, some governments – such as the UK – decided to massively sponsor genomics research, while a thriving genomics industry started to emerge in countries like the US, Singapore, China, and also Taiwan.

I was appointed CEO of Genomics in 2011, a frontrunner that holds a solid foundation in existing technology services, with the ambition to develop accurate medical genetic testing. As part of this strategy, our main focus is to service hospital and pharmaceutical companies involved in medical and clinical research, especially considering the skyrocketing number of targeted therapies currently under development, notably in the oncology field.

What does Genomics' service portfolio look like?

An important pillar of our portfolio is our cancer genetic testing. As you know, the development of malignant tumors is caused by gene mutations in the cells, and any aggregation of only seven to eight different mutations will lead to the formation of a cancer. However, up to 3,000 different genes are relevant for such mutations; hence, the total number of combinations potentially driving cancer formation is absolutely huge, prompting all pharmaceutical companies to develop molecular targeted therapies *[drugs that block the growth and spread of cancer by interfering with specific molecules that are involved in the growth, progression, and spread of cancer, e.d.].*

Initially, we were mostly focused on the discovery stage of the drug development process, essentially partnering with research centers and academic institutions, which still make up the largest share of our customer basis in the R&D field. Genomics' portfolio for these customers encompass a vast array of sequencing services, such as sanger sequencing service, peptide, gene, and oligo synthesis services as well as genomics services, ranging from sample preparation, to gene expression analysis, SNP/STR genotyping, DNA methylation analysis, and microbial identification.

As sequencing cost was rapidly decreasing, we started in 2013 to enlarge our customer pool to include companies focused on drug development, such as pharmaceutical companies and CROs. If any company or industry partner is developing innovative oncology drugs based on novel mechanisms of action, then Genomics undoubtedly stands as the best partner to help them identify for which specific gene mutations and patients their compound will be the most efficient, but also what will be the right drug dosage according to genomic specificities. Our main objective at the moment is to develop new partnerships with leading, international oncology companies and CROs, with the clear ambition to become their partner of choice in Asia for sequencing services associated to drug development activities.

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In the meantime, we also decided to bring our expertise to the clinical stage, and we are now servicing major clinical centers and hospitals with a comprehensive portfolio of prenatal genetic testing. For example, our Non-Invasive Prenatal Testing (NIPT) screens for Down Syndrome and certain other genetic conditions caused by extra or missing genetic information in the baby's DNA. Our NIPT notably offers higher rates of accuracy and lower false positive rates than traditional screening tests. Furthermore, unlike invasive procedures such as amniocentesis, there is no miscarriage risk for the mother or baby. NIPT can analyze chromosomal aneuploidy and the major diseases caused by three copies of chromosomes such as trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome) and trisomy 13 (Patau syndrome). The growth potential of this service is particularly interesting as – following the example of the UK and other European countries – an increasing number of healthcare systems are including this testing in their reimbursement listings, creating a global market for prenatal testing that is already worth USD10 billion in 2017.

We understand Genomics now looks at increasing its collaboration with pharmaceutical companies for the development of targeted therapies. Why should leading drug development companies choose Genomics as their partner?

Looking at the global competitive landscape, Genomics undoubtedly stands as the best partner possible, both in terms of cost and performance. Genomics can provide its pharmaceutical partners with sequencing services of the utmost quality at an affordable cost, which is absolutely remarkable in our sector, where technology price remains a critical differentiator.

In the meantime, we can provide our partners with a degree of flexibility and service personalization that most of our competitors – within the same price range – cannot offer. Our cutting-edge laboratory moreover complies with all the most stringent requirements and

certifications, and we hold a deep knowledge of FDA, EMA, and other regulatory agencies' guidance in drug development. Beside a unique flexibility and one of the best cost-performance ratio in the industry, Genomics can then ensure that its partners fully benefit from our genomics service, precisely tailor their drug development approach and produce the data needed to increase their chances to receive market approval, depending on the markets they target.

In addition to your ambitions in the drug development field, in 2016 Genomics acquired Pharmigene, a Taiwan-based company focused on the development of diagnostic tests that enable individuals to know their genomic makeup, allowing healthcare professionals to take the best medical decisions, according to the specific profile of the patients. What was the strategic thinking behind this acquisition?

Since the completion of the human genome sequence, personalized medicines based on individual's genomic profiles have truly become a reality. Following widely accepted research, we know that patients with a specific genetic marker can have up to thousand times more chances to develop severe adverse reactions (ADR) to specific drugs. Millions of people are affected by ADRs in the world each year and more than one million Americans are hospitalized each year due severe adverse reactions. Although most adverse drug events can be avoided with attentive patient care, some adverse events are difficult to detect or to prevent in a timely manner.

In this regard, using a companion genetic IVD test is the only way to identify the safest and most effective drug or drug dosage for a patient. As Genomics was essentially focused on sequencing services, acquiring a company well established in the genetic IVD area then appeared as the best opportunity to diversify our approach, leading us to acquire Pharmigene in 2016.

Pharmigene was founded in 2005 by Dr. Y.T. Chen, a world-class scientist in the fields of rare diseases and pharmacogenomics who discovered the only life-saving treatment for Pompe Disease. Pharmigene holds exclusive worldwide rights for a comprehensive portfolio of technologies in-licensed from Academia Sinica *[Taiwan's national academy of science, e.d.]* for genetic markers associated with ADRs caused by some of the most crucial or popular drugs in the market. Pharmigene also received ISO13485/9001 and GMP certifications, while the sheer efficacy of all our DNA genetic tests was validated by clinical studies involving thousands of patients.

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What are some of the most important drugs for which you hold genetic IVD tests?

We already hold more than a dozen of patented molecular diagnostic tests, including our proprietary and flagship Warfarin dose prediction test, which is one of our main growth drivers. Our product portfolio also comprises IVD kits assessing the risk for developing severe adverse drug reactions like Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) induced by the anti-epileptic drug, carbamazepine, phenytoin and oxcarbazepine, and the anti-gout drug, allopurinol. Those drugs are usually the most widely used first line drugs covered by the health insurance in most countries.

Pharmigene's DNA genetic tests are available world wide, as more than 77 percent of the company's revenues already come from international markets, China being our most important overseas market at the moment. Historically, we have been focusing our efforts on East Asia but we now want to increase our footprint in Western markets, as Warfarin is particularly popular in the EU and US markets. As a result, we are now looking for partners to market and distribute our Warfarin dose prediction test in these strategic countries.

What are the new diagnostic tests that Pharmigene is currently developing?

We are currently concentrating our efforts on developing new PGx tests in the pediatrics and cardiovascular areas. PGx tests help physicians make right decisions in tailored treatment program, allowing them to choose the most effective medication, establish what is the right dosage for each patient, and avoid serious adverse drug reactions. In the pediatrics field, our current PGx panels include the most common drugs that children may encounter: antipyretics and analgesics, gastrointestinal, anti-infective, antipsychotics, and anti-epilepsy drugs. In the cardiovascular area, Pharmigene's cardiovascular PGx panels cover drugs that usually display narrow therapeutic windows, meaning that dosage adjustment based on individual's genetic condition becomes evermore crucial for effectiveness and safety. Our current portfolio notably includes statins-based drugs (cholesterol lowering), antiarrhythmic, antihypertensive, and antithrombotic drugs.

The US market has recently become extremely appealing, as recent regulatory changes have led US insurance companies to reimburse PGx testing for all their beneficiaries. As a company, we then decided to focus our efforts on the generics drugs that are covered by this new policy, whose drug coverage is moreover increasing year after year. Nevertheless, to bring our PGx panels to the US, we will have to receive market approval by the FDA, and we are now evaluating the pros and cons of this opportunity before moving forward.

In the meantime, we are closely following the most recent developments in the genomics area, as new testing devices could allow to provide results for a group of several, different drugs, and not

only for a single product. This new innovation should allow to further reduce genetic testing cost, while better aligning our value proposition with the increase of complex, intertwined chronic diseases that are massively affecting rapidly aging population. In the long-term, as genomic testing get reimbursed by an increasing number of countries, I foresee we could be able to save genetic testing results of all patients on their healthcare cards, including data for hundreds of different drugs and therefore reducing the need to repeat genetic testing for all most common drugs.

As the genomic industry is booming globally, how would you rate Taiwan's competitiveness?

Boosted by strong government support, Taiwan's industry has managed to establish itself as a frontrunner in the genomics area. Nevertheless, this industry has become extremely competitive and no company can afford to rest on its laurels, while genomics still stands as a rapidly-evolving field.

One of the country's main asset probably relates to the comprehensiveness of the NHI's database, which holds digital track records of all people covered by the national health insurance, i.e. more than 99 percent of the Taiwanese population. By associating these digital medical records with genomics testing data, Taiwan could then become a pioneer in the mass implementation of personalized medicines.

What is Genomics and Pharmigene's positioning onto the global stage?

We want to become a pioneer in the pharmacogenomics field, as – by combining the expertise of Genomics and Pharmigene – we now hold a second-to-none capacity throughout the entire genomics value chain, from preclinical, clinical, and drug development-oriented sequencing services to the development and manufacturing genetic IVD tests.

To fulfill our ambitions, Pharmigene is aiming to IPO in Taiwan in the upcoming years. We also want to bring Pharmigene's world-class products to more international markets: in this regard, finding new UK and US partners stands as a crucial priority for us, while we are also expanding our presence in the Chinese market with the upcoming opening of a China-based subsidiary holding a world-class testing lab and a GMP manufacturing facility.

Finally, we want to build strategic alliances with pharmaceutical companies to develop companion diagnostic kits for the development of their targeted therapies, while we also aim to establish ourselves as the best partner in Asia for pharmaceutical companies that would like to outsource

pharmacogenomics projects.

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