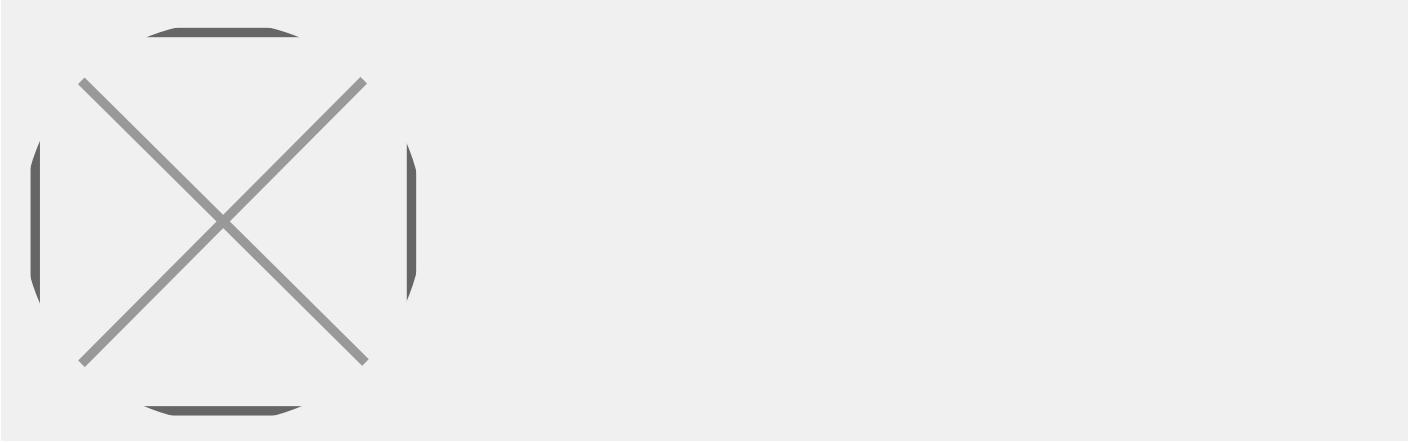
Interview: Ellson Chen, President & CEO, Vita Genomics, Taiwan



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The President & CEO of Vita Genomics talks about the advantages that genomic testing offer both to sick and healthy patients, as well as the opportunities to catalogue the science behind Traditional Chinese Medicine.

What is the vision behind Vita Genomics?

Vita Genomics was founded in 2001. At the time, we were supposed to be a downstream collaborator of an early mover in the genomics field: Celera Genomics. Celera's business model was to sell genomic information. Dr. Craig Venter, the founder of the company, was successful for a year or two, but eventually, genome sequencing data entered the public domain—so Celera's business model did not work, and the company essentially disappeared from the map.

Nonetheless, Vita Genomics pressed on. Our idea was to bring the benefits of genomics to ordinary people. When Celera folded, that turned out to be an uphill struggle for us. And yet, 12 years later, the environment has improved considerably.

Allow me to explain in more detail what Vita Genomics does. We have been quite low-key over the last dozen years, but now we are about ready to reach out.

We have three major focuses, the first of which is our specialty CRO service. Since 2004, more and more clinical trials have included genomic information. In 2003, the US FDA announced a program

for voluntary submission of such information, and essentially told pharma companies that, in clinical trials, they could no longer simply report, say, that 60 percent of patients responded well to a drug, 30 percent did not, and ten percent displayed harmful side effects. The FDA wanted to know more about those patient subsets.

The best way to know more is through so-called 'pharmacogenomics.' The idea is simple: as I noted, in clinical trials—particularly during Phase II—drug companies will usually find one subset of patients for whom a drug works, one subset for whom it does not, and a third subset that displays an adverse reaction. Using genomic tools, researchers can look into the genetic makeup of each subset, and with enough data pools they may be able to pinpoint specific genes, or gene mutations, that explain why the patient responded positively or negatively to the treatment.

You are speaking of the road to personalized medicine.

That's absolutely right. Most pharma companies do not have the internal capabilities to conduct such analyses themselves, so they will typically contract out. These are the kinds of services our specialty CRO business offers. Of the top ten pharma companies, three or four are already our customers.

The road to personalized medicine is fraught with challenges. Firstly, we do not expect the pharma industry to change. Indeed, in the pharma business, change is painfully slow—we might say it is nearly impossible. So our approach is the following: during clinical trials, if pharma companies want to include genotypes in their patient profiling data, we provide that service to them. This way, when the drug is ultimately approved, companies like ours can go on site at the point of care and screen patients.

One good example is AstraZenca's Iressa. Iressa is indicated for late-stage lung cancer treatment, and was launched about ten years ago. When it was sold in the Western world, the efficacy rate was less than ten percent—actually, AstraZeneca was forced to pull the drug from the market. However, when checking over the trial data, the company noticed that Japanese patients had a much higher rate of positive response. Further research was conducted, and it was determined that if patients had a particular EGF-receptor gene mutation—as many Japanese people do—then they would respond particularly well to Iressa. In total, studies showed that about 30 percent of Asian people, including Chinese, Japanese, Taiwanese, and others, carry the right genotype for Iressa treatment. Vita Genomics' subsidiary in Shanghai participated in the genotyping work when this research was carried out, and currently, in the Chinese market, we are selling EGR-receptor detection services alongside AstraZeneca's drug.

Our second focus is on diagnostic tools. We offer diagnostic checkups for two different profiles: healthy individuals, and sick individuals. For healthy individuals, the purpose of our testing is preventative. A recent champion of this approach is Angelina Jolie, who opted to undergo a preventive mastectomy when she learned that she had a high risk of developing breast cancer. It was certainly a bold move, but there is also no doubt that the science behind her case has accumulated strong data—the test that formed the basis of her doctors' recommendation has been around for more than 20 years, and more than a million people have been tested.

Unfortunately, the findings of certain other genetic tests are not as clear-cut, particularly in the case of complex diseases like diabetes and asthma. Nonetheless, getting the test done is much better than the alternative. Vita Genomics offers a range of such diagnostic tests in Taiwan and China—much like 23andMe, our peers in California. As I mentioned, our customer-facing partner for these diagnostics is Gene Health, which has designed a number of packages that can help people determine their risk of contracting particular diseases. As the China market picks up, the opportunities in this niche are huge. Certainly, the growth of China provides an opportunity for all Taiwanese biotech companies!

Many experts have commented that the promise of genomics for personalized and preventative medicine has been slow to develop. What bottlenecks do you see?

I'm glad you asked this question. As I mentioned, on the diagnostic side, we offer two types of tests: the first is similar to the offering of 23andMe, and is for preventive purposes. The second test is for personalized medicine, and an example is our work with Iressa. Here, we must work hand-in-hand with hospitals and doctors.

I believe that currently, doctors are most interested in two areas of genomic testing: oncology and psychiatric care. In oncology, we find that the average efficacy rate of most drugs is only about 20-30 percent. At the same time, doctors tend to use the drugs that they are familiar with. If one approach doesn't work, they doctor shifts to a different drug—but too often, if two or three consecutive products don't work, the patient is gone.

Vita Genomics is collaborating with local hospitals to screen patients that might be good candidates for some of the better-known oncology drugs, such as certain generic chemotherapy products. Because the genotypes that respond well to these treatments are quite well known, we can easily conduct a genetic checkup and provide doctors with potential efficacy rates. The first hundred patients that we tested demonstrated that, if gene profiles are used to match them to the right drug, efficacy rates more than double.

It took us ten years to get here, and the biggest bottleneck was this: most doctors had little idea of what genomics was. Doctors see patients day in and day out, and in many cases they have little time to catch up on new information. There are a number of doctors that conduct advanced research, and are well versed in genomics developments—but research-oriented healthcare professionals are the minority. The biggest barrier, then, was education. More than that, we needed to help in application, because knowledge is one thing, and application is another. Healthcare regulators also had little idea of how to set up rules and guidelines for genotype screening.

Education, methods of application, and regulation: these are the challenges we have been addressing.

In the US, the FDA has ‘recommended’ that doctors employ diagnostic testing when prescribing medications, but they have not required it. Taiwan, which follows the US in many healthcare matters, has a similar approach. Interestingly, it is Mainland China that has had much more guts in pushing the matter forward—largely because the CFDA has a much larger market to look after, and is more willing to try something new in this dynamically changing world. The CFDA is behind the FDA in matters of health, and has a desire to catch up. But they do not only want to catch up. They want to jump ahead, and they want to learn from others’ mistakes. Regulators in China have seen that the US is resistant to advancing genomics, and see their chance to lead.

This brings me to the third aspect of our business: herbal medicine. In Mainland China, many consider herbal compounds to be one of the greatest treasures of their society, passed down from a tradition that stems back thousands of years. In China, there is a very vague line between a ‘drug’ and traditional herbal remedy. Many doctors in the country—especially herbal doctors—did not undergo what is considered modern medical education. Rather, they came up under an apprenticeship system. This is particularly true in the countryside.

As Vita Genomics, we are proposing the following. We believe that the best way to combat illness is to prevent it from happening—because, particularly in the case of a chronic disease like diabetes, the damage is very difficult to reverse. How can we prevent diseases from happening? In most cases, we cannot give healthy people drugs, because drugs should only be given to disease sufferers. However, what we *can* do is give them herbal treatments, which are generally much milder and have fewer side effects. The idea here is similar to food additives and vitamins in the West, whose sales currently rival those of prescription drugs.

Vita Genomics is working on what we call a ‘Herbal Connectivity Map.’ following the method developed by scientists at Broad Institute. The Broad Institute in the US, which also wants to bring genomics into action, has been developing a library of how chemical drugs work. They have catalogued close to seven thousand different FDA-approved drugs so far, recording the gene expression changes that they induce. The result is a library that shows which drug brings which gene up and which gene down. A second library, meanwhile, has documented how gene expression changes in the presence of a disease. Broad researchers are working to connect the two databases with a connectivity map. If a particular drug affects gene expression in a diametrically opposite way to a given disease, then the drug should be effective in combating that disease.

The Institute is now spinning out a company to offer services to the pharma industry. As we know, new compounds are getting harder and harder to find, so the name of the game now is to find new uses for existing drugs. A connectivity map can suit that purpose perfectly. Until now, drug development has been based on a series of guesswork and practical checking. With this method, researchers will have much more concrete evidence of potential efficacy—and they will very likely find that many drugs can have positive effects beyond their current indications.

We have been collaborating with the Broad Institute, and want to use the same technology for herbal medicines and food additives. We can use herbal profiles to compare against chemical drug database, and compare against disease databases. Thereby, we may be able to gather enough evidence to demonstrate their potential as preventive tools.

In many cases, these herbal compounds are not considered ‘botanical drugs.’ Many of them have not passed through modern standardized clinical trials. And yet, people have been using them for millennia. They are considered safe and essentially classified as food—this is where we get the name ‘functional food.’ We are trying to catalogue these compounds, and give them new life through new evidence. Eventually, our goal is to develop a new paradigm: rather than doing traditional clinical trials, we are hoping to use genomic tools to bridge existing herbal therapeutics. We hope regulators will accept this paradigm.

Dr. Chen, what is your final message to our readers?

Innovative drugs are getting scarce. I think what we are doing with genomic tools—bringing people to the right drugs, and also working on prevention with our connective database of herbal remedies—is brand new territory. Most people in the biotech industry are working within the confines of three-phase trial designs, and we can help in those efforts as well. But we want to offer something revolutionary to the market. We want to help people in a new way.

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