

# BioSpectrum

the business of life sciences

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ASIA EDITION

## HIV Vaccine



# A search for the impossible

Are we a STEP closer?

► Singapore unlocks stem cell potential

► India to get new definition for medical devices

► Thermo Fisher opens \$17 million biopharma facility in India

### Interview



Mr David Ho  
MD, Hovid Berhad,  
Malaysia

### Column

- Pipeline deficiencies in making : Mark Ravera
- Ancient medicines, a source of pharma innovation: David Picard



# Leading from the front

## Quick Take

**Dr Paul LJ Tan** | CEO, Living Cell Technologies, Auckland, New Zealand

“The growing number of publications and reports show how rapidly we are moving into the age of cell therapy. The promising clinical data from our early human trial suggests that people with insulin dependent diabetes should be able to have cell implants producing insulin within a short number of years. We are expanding our facilities to supply our lead cell product, DiabeCell, for larger clinical trial and commercial programs internationally.”



**Dr In-Chull Kim** | President & CEO, LG Life Sciences, Korea

“DNA and SNPs sequencing technologies are improving so quickly and so that the speed and cost for the services will be more practical in the near future. Based on that information, people will want more preventive medicines than before.”



**Mr David Picard** | CEO & Co Founder, Moleac, Singapore

“There are many routes to new emerging therapies—Moleac had a breakthrough in developing and starting to market Neuroaid in only three years. It is the only drug available in the world that helps stroke patients in their independence and neurological recovery. It is also the object of ongoing large clinical trials internationally. While it sounded far-fetched to talk about Traditional Chinese Medicine few years ago, we have shown that this is an effective shortcut to bring new drugs and address unattended needs of sufferers. Moleac is also working on a pipeline of 12 other products, which have traditional origins, and plans to roll out new products in the coming few years. This is our way of thinking ahead in biopharmaceuticals.”



**Mr John Chiplin** | CEO, Arana Therapeutics Limited, Sydney, Australia

“One of the most promising therapeutic/scientific areas in drug development today is the emergence of new generation antibodies. Antibodies are already proven blockbuster drugs and the new generation products look equally exciting. Arana Therapeutics has positioned itself at the forefront of this field, with a broad range of powerful technologies at its disposal for antibody-based drug development.”



**Dr Sze-Wee Tan** | CEO & Managing Director, Rockeby biomed, Singapore

“The market for rapid diagnostic devices is growing very quickly, and the trend towards personalized medicine in this and the next decade, will be the driver for innovation in this field.”







Mr David Picard co-founded Moleac and has served as CEO since 2002. Over the past years Mr Picard has structured the team, identified key scientific, clinical, and business partners in China, Singapore and Europe, and implemented the business agreements. Prior to founding Moleac, he has spent 10 years at The Boston Consulting Group (BCG) where he was a member of the worldwide Health Care Practice Area. He has worked both in Europe and in Asia. He has extensive experience in working in Greater China and in Korea.

**David Picard**

**DESPITE** much effort to streamline R&D operations and lower risk by acquiring promising drug candidates in late stages of development, pharmaceutical companies continue to face escalating costs and risk exposure in drug development. This challenge stimulates innovative R&D routes within the pharmaceutical industry. One route that Moleac has explored is to leverage upon knowledge from traditional medicine.

Traditional medicine is widely used in many developing countries and is enjoying a growth in popularity in developed ones. According to the World Health

evidence and some clinical data. However, the uncritical optimism of the patients and consumers is often tempered by an educated pessimism of the western doctors. Bringing traditional medicine to mainstream practice requires convincing the practitioner with an evidence-based approach.

In the past, there have been some cases of quality issues in TCM, mainly due to non-adherence to GMP on the side of the manufacturers, resulting in negative publicity. These events highlight the need to bring 'safer' medicine to patients. To achieve this, TCM has



# Ancient medicines, a source of pharma innovation

Organization, over 50 percent of the population in developed countries has used complementary or alternative medicine at least once. The global market for herbal medicines was estimated at \$60 billion in 2003 and its historical growth rate of five to 15 percent per annum is expected to continue unabated. This is driven by a strong consumer demand, as more people seek safe and natural alternatives to chemical drugs. With a history that dates back thousands of years, and more than 7,000 plants in its pharmacopoeia, Traditional Chinese Medicine (TCM) will capture the lion's share of this growth.

However, working with TCM presents some challenges. On one hand, the medical promise of TCM is supported by its long history of usage, strong anecdotal

to be modernized in both the scientific and commercial aspects, in order to extend its benefits globally and convince mainstream doctors and consumers of its benefits.

A number of companies are looking towards TCM as a source of new medicinal products. There are two common approaches that these companies are taking to "modernize" TCM. The first approach is to take an established TCM remedy, ensure the manufacturing quality, then repackage and rebrand the product, before marketing it to appeal to a wider audience on the grounds of its traditional health and wellness benefits. This is a fast, low risk model, which requires mainly marketing investment. However, it presents limited growth potential, as it does not go beyond the traditional usage of the treatment.



The second approach is more complex and amounts to applying a full-blown Western pharmaceutical development model to TCM. Potential active chemical compounds in TCM are identified. These are then chemically modified to support new patents. Researchers must also establish their biological mechanisms in animals and identify their targets in particular human diseases. The process is supported by full-fledged clinical trials, carried out over a period of 10 to 12 years. A number of pharmaceutical companies are already taking this approach. For example, Novartis is working with several institutes in China, and has taken its TCM-derived Malaria drug, Coartem, to market with this approach. This Western-medicine focused approach does not require any in-depth understanding of TCM and comes with the potential high returns associated with the classical drug development approach. On the other hand, it also involves

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long-term financial commitment similar to the classical approach, as well as the associated risks.

Moleac, as a small innovative player, is taking a new path that aims to overcome the limitations and leverage upon the advantages of these two common approaches. Moleac is focused on building up evidence in both safety and efficacy of carefully-selected TCMS that are known to work in patient populations across China. Essentially, the company is consolidating existing and building further safety and efficacy evidence, of its products within the rigorous clinical framework of Western medicine. In this way, existing modernized traditional medicines can be brought to additional countries more rapidly, to benefit more patients.

This innovative approach allows Moleac to bring new treatments to market in three years, while at the same time lower the initial development costs to less than \$10 million. Based in Singapore, Moleac is a pioneer in its approach to drug development, leveraging on its expertise in traditional and mainstream Western medicine. The company focuses on therapeutic gaps in mainstream medicine. It works to identify

effective traditional medicines to address these same gaps within a sound scientific framework by establishing robust evidence for the medicines' safety and efficacy.

This approach can be seen in the successful development and marketing of Moleac's first product, Neuroaid, which is the only drug available in the world that helps stroke patients achieve better outcome from stroke recovery. Neuroaid had undergone several high quality clinical trials in China, which established its efficacy and safety. It has received strong interest from the international scientific community and it is now the subject of several ongoing large-scale international clinical trials. One such trial is the CHIMES study, a multi-centre trial being conducted in the Asia Pacific region, with the aim of generating data to support the indication of Neuroaid in the acute stage of stroke, as well as generating pharmaco-economic data. This study is headed by renowned neurology researchers from Europe, Australia and Asia.

Effective traditional medicines often have a long history of application and have established evidence of their efficacy. The work of companies like Moleac aims to bring the science behind the traditional medicines to the next level, and establish their quality and safety through accepted, modern evaluation practices. This process involves stringent GMP for manufacturing, systematic testing of product for quality, documentation of side effects in clinical trials, clear and precise labeling, as well as close monitoring of patients reporting adverse effects. On the commercial front, traditional medicines should be modernized through the use of registration routes for entry into Western markets. Companies can also adopt modern marketing models, as well as sales and distribution platforms to reach mainstream consumers. For example, the Internet is a new channel through which to reach patients who prefer to be in-control and who are more educated and knowledgeable about self-medication.

Although the use of traditional medicine as a source of mainstream treatment was unheard of a few years ago, instances like Neuroaid have demonstrated that this is an effective and viable way to rapidly and cost-effectively bring "new" treatments to the market, addressing unmet needs of patients. Besides Neuroaid, Moleac is also working on a pipeline of 12 other products, which have traditional Chinese medicine origins. The company aims to roll out these new products in the next few years. Through the efforts of companies like Moleac, ancient empirical know how is gaining acceptance and more importantly, it is bringing effective treatments more quickly to more patients.

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