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SALVE THE WORLD

TRADITIONAL CHINESE MEDICINE IS LOOKING TO OVERCOME THE TYRANNIES OF DISTANCE AND DOUBT

By JI XIANG, LIU JIE and WANG HONGYI

Traditional Chinese medicine, or TCM, is now gaining in popularity in Western markets due to the increasing demand for a more modern and nature-friendly lifestyle. The China Association of Traditional Chinese Medicine says TCM industry output was worth \$55 billion (43 billion euros) in 2011 and is expected to hit \$88 billion by 2017, with an annual growth rate of 12 percent.

Tasly Group, a Chinese pharmaceutical company founded in 1994, is a pioneer in the TCM industry. In 2001, Tasly Pharmaceutical International Co Ltd (a subsidiary solely funded by Tasly) was set up to meet the global demand for TCM. After 11 years of international marketing, Tasly has a presence in more than 40 countries around the world.

In Africa alone, it has set up offices in eight countries — Nigeria, South Africa, Cote d'Ivoire, Benin, Mozambique, Zambia, Congo, and Burkina Faso. Its products have reached 14 African countries.

International drug makers have been exploring ways — including joint ventures and co-development partnerships — to use Western

son Whampoa Ltd, agreed to form a 50-50 joint venture to research, develop, manufacture and market innovative nutritional and medicinal products derived from plants.

The joint venture focuses on gastrointestinal health and may later expand into the areas of metabolic diseases and brain health, according to Nestle.

The new partnership gives Nestle access to its Chinese partner's TCM library of more than 50,000 extracts from 1,200-plus herbal plants. Moreover, the Chinese side can offer TCM expertise and a botanical-based research and development platform, including discovery research, non-clinical and pharmaceutical science functions, and an understanding of the botanical guidelines and regulations for the joint venture.

"This joint venture provides us with an opportunity to develop and

commercialize truly innovative and scientifically validated botanical-based nutrition," says Luis Cantarell, president and CEO of Nestle Health Science.

Other Western giants have also sought out TCM opportunities. In

2009, Switzerland-based Novartis AG announced TCM-related R&D in China and plans to spend 500 million yuan (\$80 million; 63 million euros) to merge and acquire Chinese TCM enterprises in the coming years.

UK-based pharmaceutical company GlaxoSmithKline PLC has also established a new research unit in China to carry out molecular study in TCM.

GSK says innovative TCM is an important part of the company's R&D in China, with a strategy of integrating the existing TCM knowledge of diseases with modern drug discovery technology and clinical trial methodology.

In 2011, Hutchison MediPharma Ltd — a subsidiary of Chi-Med — reached an agreement with international drugmaker AstraZeneca PLC for global licensing, co-development

and commercialization of Volitinib, a TCM extract that halts the progress of breast and lung cancer. Under the terms of the agreement, development costs for Volitinib in China will be shared by both sides, with Hutchison MediPharma continuing to dominate development in China, while AstraZeneca will lead and pay for development for the rest of the world.

In addition to creating partner-

approaches to develop TCM drugs.

"No matter the model, we believe this bodes well for the industry in general, as it may help accelerate TCM standardization and modernization, as well as TCM acceptance in overseas markets," says Bruce Liu, partner and co-head of the Pharma & Healthcare practice at Roland Berger Strategy Consultants.

Last November, Nestle Health Science, a fully owned subsidiary of Nestle SA, and Chi-Med, the pharmaceutical and healthcare subsidiary of Hong Kong-based Hutchi-

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ships, many international pharmaceutical companies have chosen to cooperate with Chinese academic research institutes, given the local partners' rich resources of talent, basic research and academic expertise. Chinese companies have also been cooperating with research institutes overseas.

Tasly has worked extensively with the likes of the Harvard University, Aston University in England and Baker Medical Research Institute in Australia, and has formed a huge scientific research system. It has taken on more than 40 key scientific researching programs on the national level.

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France's largest drug maker, Sanofi-Aventis SA, has worked with Hong Kong University of Science and Technology to develop modern versions of traditional Chinese medicine to treat chronic diseases such as diabetes and cancer.

GSK has also established partnerships with academic bodies and TCM experts in China. "We are developing novel therapeutic TCM mixtures as prescription medicines through innovative extraction methods and combinations, and we use clinical data and evidence to differentiate from existing TCM products on the market," says Zang Jingwu, senior vice-president and head of GSK R&D China.

Novartis set up a six-year research partnership with the Shanghai Institute of Materia Medica in 2009 to identify and test the pharmacological properties of some traditional medicines.

The Shanghai institute, a unit under the Chinese Academy of Sciences, is currently the largest natural-herb research base in the nation. A series of multinationals, including Johnson & Johnson Pharmaceuticals and MSD — known as Merck & Co in the United States and Canada — have established R&D cooperation agreements with the institute.

The Chinese government's reasserted recognition of TCM's value and potential is yet another important factor in popularizing TCM's international appeal and enhancing its acceptance.

"This support also encourages foreign companies to join hands with Chinese counterparts," says Liu from Roland Berger. Over the past three years, the government has invested \$2.7 billion in TCM clinical research centers and hospital infrastructure upgrades.

Foreign businesses can invest via merger or acquisition of small businesses. These partnerships are expected to make market registration easier in Chinese and foreign markets.

On another level, the newly kindled interest in TCM may also be attributed to the R&D bottlenecks faced by most global pharmaceutical majors. "In recent years, the global pharmaceutical industry has seen fast-rising R&D costs yet declining R&D productivity and a longer time to market," Liu says.

On average, only about 20 new drugs get approval from the US Food and Drug Administration annually, many of them for rare diseases. Few blockbuster drugs — medicines or medications that can be loosely defined as any chemical substance intended for use in the medical diagnosis, treatment or prevention of disease — have been discovered in the past decade.

As a result, international pharmaceutical companies are desperate for breakthroughs to find new treatments for diseases that heavily affect people's lives and living quality, such as hyperlipemia and hypertension. They have found that TCM is effective in dealing with chronic diseases.

Some foreign firms have already tasted success with TCM. Novartis, for example, has worked closely

with partners in China to use artemisinin, a TCM extract, to make a malaria vaccine that is used worldwide.

On the other hand, it is hard to ignore the restraints that block the internationalization of TCM, including distinctive notions about health-care practice in the West.

Western medicines are generally target-based small molecules or biologics, and their approvals for clinical use are based on clinical evidence of safety and effectiveness by staged clinical trials.

Assessing effectiveness and ensuring safety thus became issues that have inhibited multinational companies' significant engagement with TCM and its global expansion so far.

So far, the State Food and Drug Administration requires TCM man-

ufacturers to follow clinical procedures similar to those required of their Western counterparts. For instance, three phases of clinical trials are required before a new product's approval. However, thorough implementation is impossible given the shortage of time and money, insiders say.

Novartis has spent more than three years on TCM R&D in China. The international drugmaker said it is not yet ready to answer questions related to progress in its ambitious plan announced in 2009.

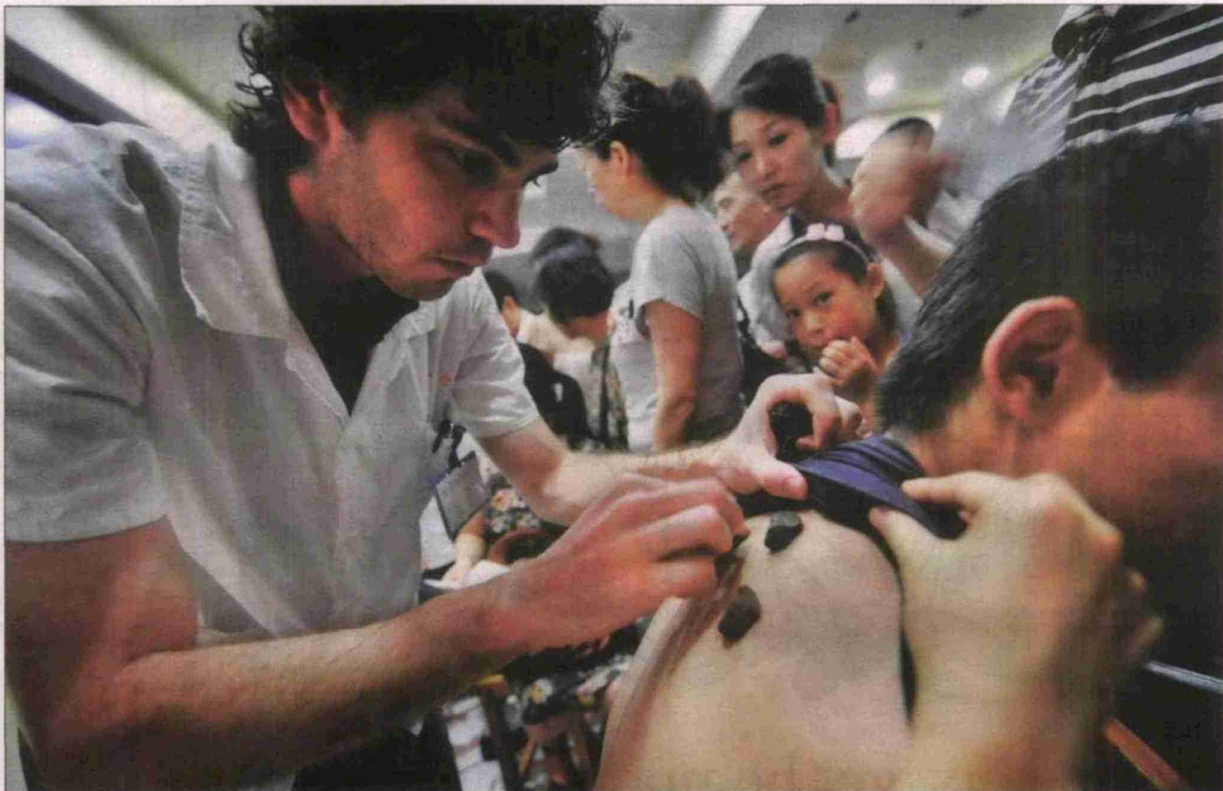
"Drug discovery takes time, money and more importantly, perseverance, TCM or not. We should not be shortsighted and expect quick results," Liu says.

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A foreign traditional Chinese medicine practitioner treats a Chinese patient in Zhejiang Provincial Hospital of TCM.

LI ZHONG / FOR CHINA DAILY



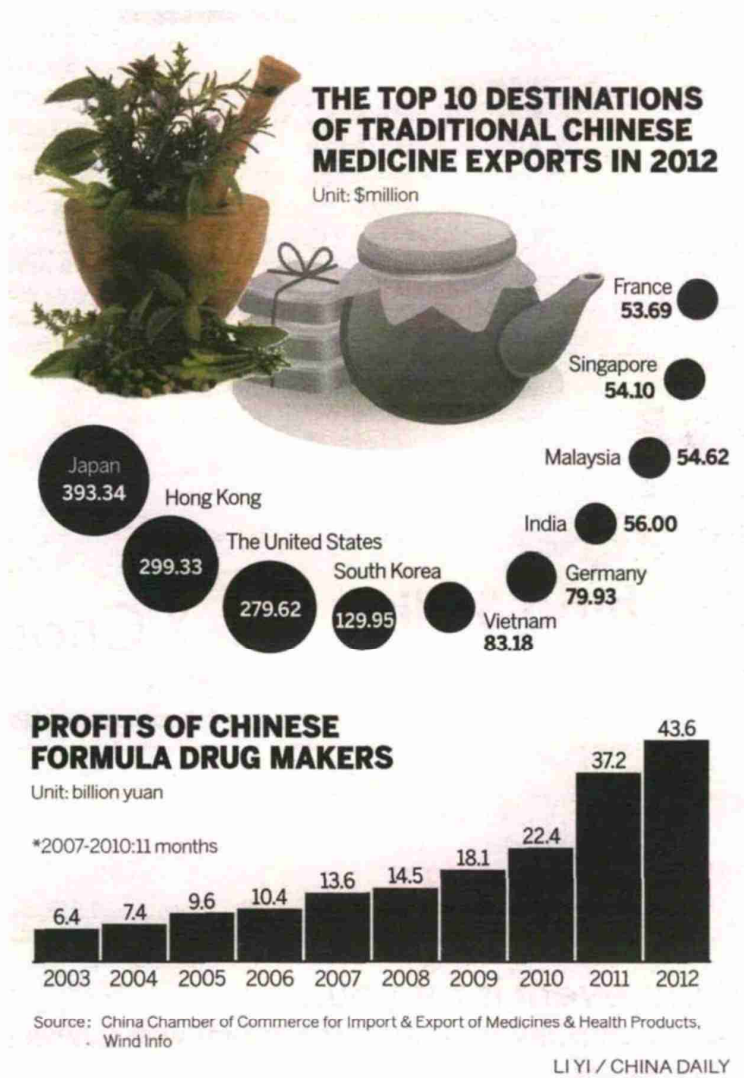
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Foreign tourists check out TCM products in Hangzhou, Zhejiang province.