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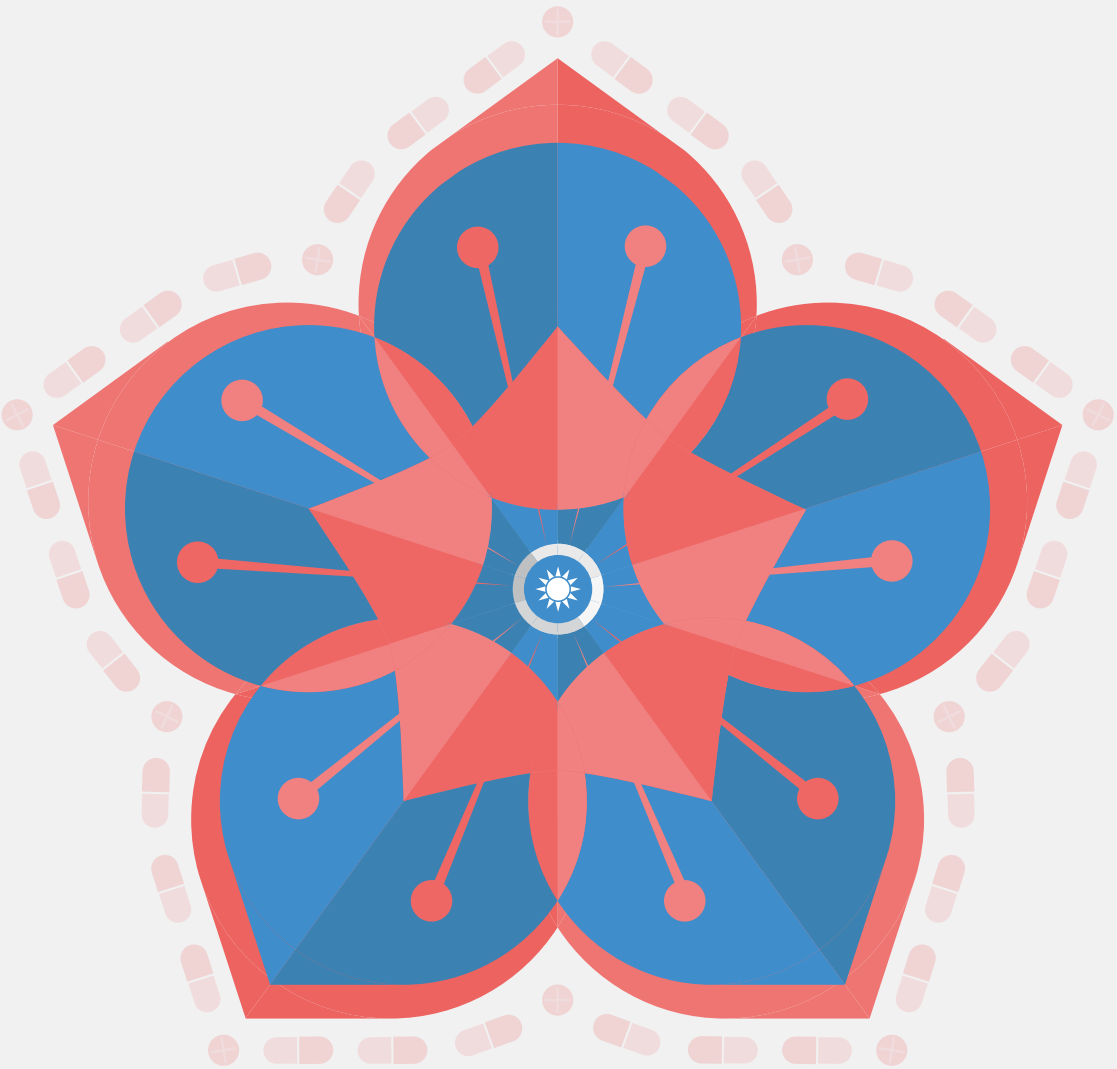

INDUSTRY EXPLORATIONS

Taiwan Pharmaceuticals & Biotechnology 2015

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01 South Korea's generic market is projected to grow on average 5% per year between 2013 – 2018 to a staggering $23.84 Bln.

02 South Korea closely ranks after China and India as the third "best outsourcing destination" in Asia.[1]

03 Korea Drug Development Fund (KDDF) will promote the development of the Korean biotechnology sector in the Asia Pacific region aiming to produce 10 new treatments by 2019.

04 Investment in R&D and related facilities is very active and establishment of plants according to the international standards is increasing.

[1] The changing dynamics of pharma outsourcing in Asia, PwC.

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Dear Readers,

Our team at Global Business Reports has been delighted to discover one of the most innovative and promising pharmaceuticals and biotechnology hubs in Asia – and perhaps worldwide – all while being regaled with copious amounts of green tea and insightful perspectives from some of the country's brightest minds.

One of the "Asian Tigers," formerly known by the name of Formosa (Portuguese for "beautiful island"), Taiwan is a small island to the east of the People's Republic of China and is historically known as a center for low cost, quality driven manufacturing. An ever-adapting nation that has always overcome the economic downturns of the past few decades, Taiwan succeeded as an IT powerhouse through a concerted effort on the part of the government and its talented workforce. At the moment, we are turning our attention to a new, if not the principal, driving force of the country's economic growth and scientific innovation: pharmaceuticals and biotechnology.

For the past three decades the government has invested over NT $13 billion (USD 400 million) through the National Development Fund into the development and promotion of the pharmaceutical and biotechnology industry, leading to an abundance of research clusters throughout the country, as well as players of various sizes working hard to compete internationally. This is all backed by a strong oversight and institutional framework, with the establishment of the Taiwan Food and Drug Administration in 2010, and the enforcement of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) earlier this year. On the research front, the industry is waiting with bated breath to see who will have a breakthrough in new drug development that could help improve the health of people in all corners of the globe.

All in all, the island is poised for success on the global biopharma arena thanks to its strategic geographical position, favorable governmental initiatives, competitive manufacturing capabilities, and, crucial to it all, the remarkably gifted and hard working population.

We would like to heartily thank the Ministry of Health and Welfare, the Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO), and the Taiwan Generic Pharmaceutical Association (TGPA) for working alongside us, as well as the Taiwan Food and Drug Administration (TFDA), Taiwan Research-based Biopharmaceutical Manufacturers Association (TRPMA), Academia Sinica, and other key institutions and companies for their support and insights, without which this book would not have been possible.

We hope you enjoy reading it as much as we have enjoyed putting it together and encourage you to discover the advancements and delights that this beautiful island has to offer.

Sincerely,

Project Director: **Irina Negoita**
Journalist: **Lubo Novak**
Journalist: **James Hogan**
Journalist: **Karl Reilly**


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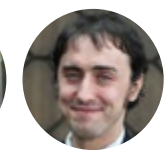
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This research has been conducted by Irina Negoita, Lubo Novak, James Hogan, and Karl Reilly.

Edited by John V. Bowlus
Graphic design by Gonzalo Da Cunha

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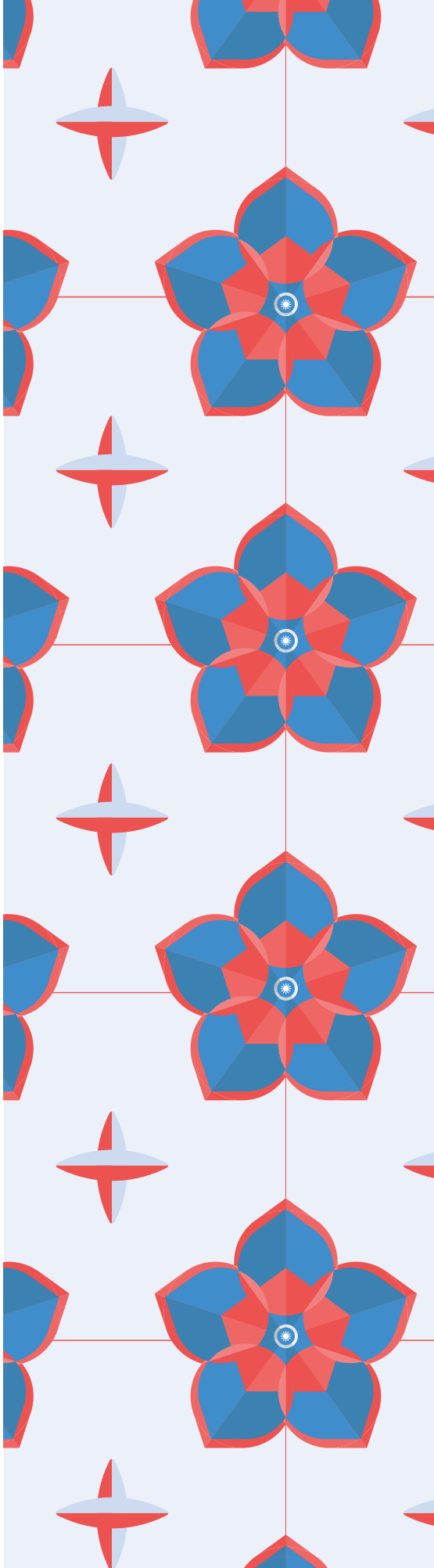

Exclusive Interviews

Leading industry and government figures from Taiwan's pharmaceuticals industry discuss market trends and opportunities, as well as pitfalls and current business strategies.

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Editorial Content

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Introducing Taiwan and its Pharmaceuticals Industry

"One strength is our capital markets, which have been supportive for the past eight years. Additionally, our existing strengths in electronic and information technologies can be leveraged to develop medical devices and health care related products. Having China so close is certainly another strength. Since we are legally and financially more transparent and able to offer better protection for IP than in China, it makes Taiwan a perfect development site for anything new."

- Dr. Johnsee Lee, Honorary Chairman, Taiwan Bio Industry Organization (TBIO)

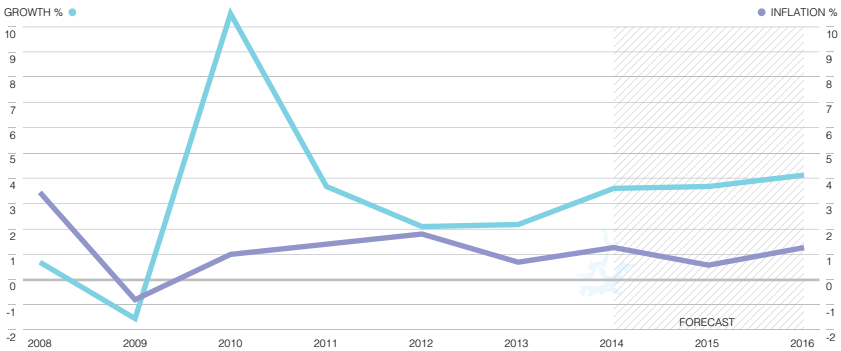
Image: G&E Herbal Biotechnology Co.

Talented Taiwan

A Brief Political and Economic Overview

TAIWAN GROWTH VS. INFLATION (2008 TO 2013)

Source: International Monetary Fund



TOTAL HEALTH EXPENDITURE FOR ASIA-PACIFIC ECONOMIES

	(% of GDP)
Australia	9
China	5.1
Indonesia	2.9
Japan	10
Malaysia	3.8
New Zealand	10.3
OECD	9.3
Philippines	4.4
Sigapore	4.2
South Korea	7.4
Taiwan	**6.5**
Vietnam	6.8

HOSPITAL BEDS

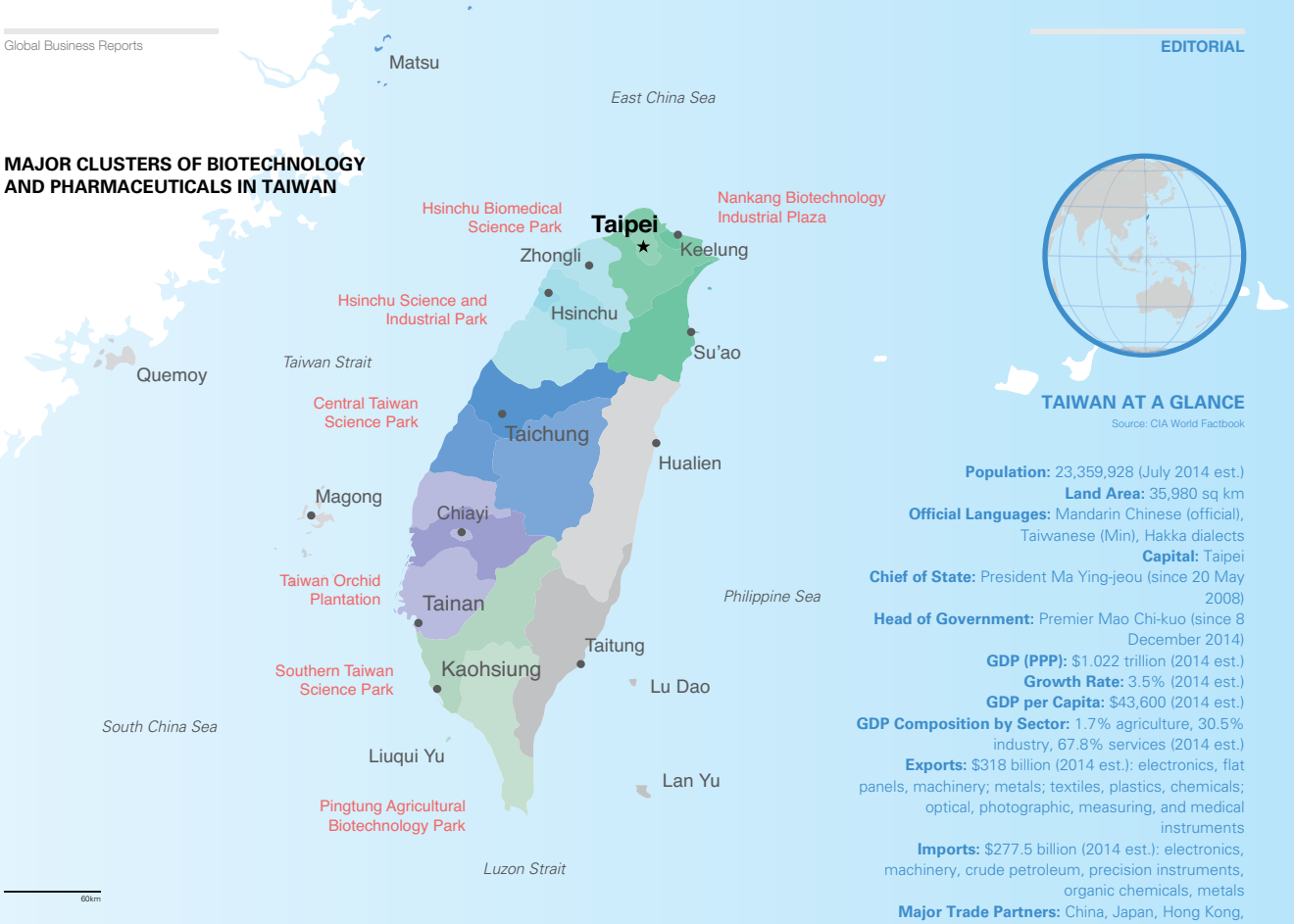
	PER 1,000 PEOPLE
Australia	3.9
China	3.8
Indonesia	0.9
Japan	13.7
Malaysia	1.9
New Zealand	2.3
OECD	4.8
Philippines	5
Sigapore	2
South Korea	10.3
Taiwan	**5.7**
Vietnam	2

The Republic of China (ROC), commonly known as Taiwan, was built out of and in relation to its much larger brother on the mainland, the Peoples Republic of China (PRC), or China. The difference in name can be traced to the civil war fought 65 years ago, which resulted in Chiang Kai-shek and his Chinese Nationalist Party, the KMT, retreating to the island of Formosa and establishing an independent nation. Despite political independence, the Taiwan's relations with Mainland China, with whom it shares a common language and culture, have always been the largest factor shaping Taiwan's domestic politics, economy, and foreign policy, including its diplomatic alliance with the United States.

Today, Kai-Shek's legacy is alive and well in Taiwanese politics. The current KMT administration is led by President Ma Ying-jeou, who was elected for his first term in 2008 and reelected in 2012 for another four years. Ma served as Party Chairman from 2005 to 2007 and again from 2009 to December 2014, until local elections in November 2014 presented the KMT a resounding defeat, losing nine of the municipality mayor and country magistrate positions that it held and finishing with six out of 22 total positions. The main opposition party, the Democratic Progressive Party (DPP), on the other hand, gained seven new positions, pushing their total to 13 and vastly improving their chances to win the presidency in 2016. The DPP held the presidency from 2000 to 2008, the only time in Taiwan's history that the KMT did not hold the office.

Analysts credit the KMT's poor results in November to widespread voter discontent towards Ma's government, which they source to the government's role in encouraging a thaw in Taiwan's relations with the mainland. In 2009, Ma, as a representative of his own party, exchanged direct messages with party leaders in China, which was the first direct correspondence, albeit at a party level, since the civil war between the two countries. One year later, China and Taiwan signed a trade pact that eventually produced the Cross-Strait Service Trade Agreement in 2013, which liberalizes trade in services industries, including the banking, tourism, and healthcare. In the spring of 2014, a student uprising swept the country, capturing a great deal of the popular opposition to the trade pact. While some Taiwanese regard any thaw in relations with China as anathema, others with softer stances on the issue nonetheless characterize the government's approach to China as clumsy and indicative of its general weakness and other foibles, namely corruption.

The economy, on the other hand, has always been a source of pride and genuine success for Taiwan, and appears to be in fine shape. In recent decades, Taiwan has leveraged the talent of its people to realize incredible levels of economic growth, most notably through the developing of an information technology (IT) sector. The Taiwanese government is hoping to duplicate the country's success in IT in the pharmaceuticals and biotechnology sectors, as this book discusses in great detail. Past economic success has given Taiwan freedom and dynamism but is no guarantee of future performance. The International Monetary Fund (IMF) forecasts tepid growth for the domestic economy, 2.8% per year until 2019. Though export demand has strengthened in recent months,



TAIWAN AT A GLANCE

Source: CIA World Factbook

Population: 23,359,928 (July 2014 est.)
Land Area: 35,980 sq km
Official Languages: Mandarin Chinese (official), Taiwanese (Min), Hakka dialects
Capital: Taipei
Chief of State: President Ma Ying-jeou (since 20 May 2008)
Head of Government: Premier Mao Chi-kuo (since 8 December 2014)
GDP (PPP): $1.022 trillion (2014 est.)
Growth Rate: 3.5% (2014 est.)
GDP per Capita: $43,600 (2014 est.)
GDP Composition by Sector: 1.7% agriculture, 30.5% industry, 67.8% services (2014 est.)
Exports: $318 billion (2014 est.): electronics, flat panels, machinery; metals; textiles, plastics, chemicals; optical, photographic, measuring, and medical instruments
Imports: $277.5 billion (2014 est.): electronics, machinery, crude petroleum, precision instruments, organic chemicals, metals
Major Trade Partners: China, Japan, Hong Kong, United States, Singapore

but at the same time, the currency has weakened. Today, there is little political will for further liberalization of the economy, as income inequality has risen.

Taiwan's economic resurgence, of course, has coincided with the equally spectacular rise of China itself, particularly since it joined the World Trade Organization in 2001. China's growth has driven the world economy, and businesses seeking to grow simply cannot afford to be absent from the Chinese market. In fact, one of Taiwan's largest assets for foreign investors is that it serves as a gateway to the massive market on the mainland. China and Taiwan began harmonizing regulatory standards for pharmaceuticals in 2010, which will eventually make the path from the Taiwanese market into the Chinese market smoother than ever before. Taiwan's potential in biotech, therefore, presents real potential for growth in the Chinese market, and, for that matter, in all corners of the globe. However, the Chinese economy is slowing down, which will create head winds for Taiwan's economy. According to an April report from the International Monetary Fund, Chinese economic growth fell to 7.4% in 2014 and is forecast to go to 6.8% in 2015 and 6.3% in 2016. (From 2006 to 2011, growth never dipped below 9% and averaged 9.2% from 1996 to 2005.)

China is actually creating far more geopolitical uncertainty. Taiwan is caught between a rising China and a host of Asia-Pacific nations that are in alliance with the United States and concerned about Chinese encroachment on their national sovereignty. Rather than relenting in its rhetoric about reuniting Taiwan with the mainland, China has amplified it in recent years, and its actions are even more troubling than its words. China has constructed numerous man-made islands in the South China Sea that can be used for military expansion, among other things. China shares competing claims with its neighbors to waters in the South China Sea. Vietnam, Japan, the Philippines, and Taiwan, among others, view Chinese actions as menacing, not least because these waters have hydrocarbons and are essential for these countries' respective fishing industries.

Meanwhile, the United States has shifted some of its military forces from the Middle East to the Asia-Pacific region to contain Chinese expansion and support its allies. In May 2014, U.S. Vice President Joe Biden criticized China's island building. The U.S. navy already controls the sea lines of communication for China's oil and gas imports from the Middle East and can project substantial power in the region to block China's oil or other imports. It is worth recalling that the U.S. embargo of Japan's oil imports in 1941, as well as steel and iron in 1940, were proximate causes of the outbreak of hostilities in the Pacific. Analysts have been warning for years of the possibility of war between China and the United States and its Asian allies, the likelihood of which only seems to grow every year. Obviously, Taiwan would fall squarely in the middle of such a calamity.

Taiwan faces clear economic and political challenges, many of which are beyond its control, but its past economic success, built on the proactivity of its government, the talent and hard work of its people, and the vibrancy of its democracy, suggests that Taiwan is worth betting on again. •

Dr. Ming-Neng Shiu

Vice-Minister
MINISTRY OF HEALTH AND WELFARE, GOVERNMENT OF TAIWAN

The Ministry of Health and Welfare (MOHW) plays a key role in promoting pharmaceuticals and biotechnology in Taiwan, which has become particularly evident with the Taiwan Biotech Industrialization Take-off Plan. Can you comment on your agency's activities?

The biotech industry, as an emphasized mainstream industry, is promoted by the Taiwanese government and benefits from government initiatives. Through collaborative efforts between government agencies, biotech has established a strong foundation with a comprehensive health care system and an advantageous research and development (R&D) and production environment.

The MOHW and Taiwan's Food and Drug Administration (TFDA) protect and promote public health in line with industrial development by establishing harmonized regulations and standards. These agencies also integrate review processes for food, medicinal products, medical devices and cosmetics.

The Ministry of Economic Affairs (MOEA) assists in developing the pharmaceutical industry, while the Ministry of Science and Technology (MOST) facilitates stronger links between academic research and industrial development.

The Executive Yuan introduced the Taiwan Biotech Industrialization Take-off Plan in 2013. Pharmaceuticals, medical devices, and health care management services are all central pillars of this plan. It aims to build on upstream R&D and establish venture capital to attract private funding in addition to the National Development Fund. It also fosters international harmonization, establishes incubation centers and industrial clusters, and provides legal, intellectual property, technical and commercialization services.

Based on your current MOHW role and your former post as TFDA acting director-general, can you discuss the relationship between these two agencies?

The MOHW is the principal government agency for the administration of public health affairs nationwide. The TFDA was inaugurated in 2010 as a subsidiary agency to centralize administration of pharmaceuticals, food, cosmetics, medical devices and biological products.

In order to leverage international resources to protect public health, becoming a PIC/S member was a top TFDA priority. The MOHW has played important roles in supporting the TFDA to attain PIC/S compliance and to implement PIC/S GMP. For instance, I led a group of TFDA staff to participate in the 2011 PIC/S Committee of Officials Meeting in Cape Town, South Africa, to assist the TFDA with the PIC/S accession process.

Attaining PIC/S compliance was a major achievement for the MOHW and TFDA. How has this compliance changed the pharmaceutical industry?

Our regulatory framework for medicinal products has been accredited by the PIC/S as meeting international standards, which has already helped to expand our pharmaceutical industry's global market access and increase exports of both generic drugs and APIs. It also attracts overseas manufacturers to outsource their manufacturing activities to Taiwan's local pharmaceutical industry.

Taiwan signed the Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs with the People's Republic of China in 2010. How has this evolving relationship influenced R&D?

The agreement specified that TFDA and China's FDA begin a Clinical Trial Cooperation Project, which we did so in 2014. We have a working group to promote development in medicine and public health through regular meetings. Concerning clinical trials, both parties agree to cooperate on relevant regulations, management of implementing institutes, and the executing teams responsible for research. By reducing repetition of clinical trials, both sides benefit from accelerated development of products.

Taiwan is recognized as having one of the world's best public health care systems. What are the system's strengths?

Our public health care system has gained global recognition. 14 Taiwanese hospitals rank among the world's top 200. Only the United States and Germany ranked higher. Our high-quality care is due largely to our health facilities' highly trained staff and advanced medical equipment, but we are also a global leader in innovative surgical procedures, cardiovascular and liver transplant surgery, artificial reproductive technologies, and joint replacement.

This excellence is no accident: Taiwan's health resources have been carefully planned. In 2013, the system had 3.11 general acute-care beds per 1000 population, and 1.54 special-care beds; the former figure exceeds the OECD countries' median of 3.0 acute-care beds per 1000 population. We have 2.6 physicians for every 1,000 people, including the dentists and traditional Chinese medicine practitioners whose care our National Health Insurance also covers. We have 21,218 clinics and 495 hospitals, of which 92.1% have passed a rigorous accreditation process. 93% of health care facilities are National Health Insurance contractors, and 99.9% of Taiwanese residents have coverage.

Even better is the system's efficiency. Adjusted for purchasing power parity, Taiwan's annual health expenditure per capita is $2,499, or about one-third of the amount spent in the United States. Health care spending as a percentage of the total economy is just 6.6% of Taiwan's GDP, which is lower than most developed nations. •

Dr. Johnsee Lee

Honorary Chairman
TAIWAN BIO INDUSTRY ORGANIZATION (TBIO)

TBIO was founded in 1989. Can you discuss the role of the organization over the last 26 years?

Our main goal has always been to accelerate the growth of the biotech and pharmaceutical industry. Although a lot of our focus is on companies in the new drug development spheres, we also represent companies in fields such as agriculture biotechnology and in fact have an entire sub division devoted to molecular diagnostics called the Taiwan Molecular Diagnostics Alliance. In this sense, we are different from other organizations in that we cover a broad swathe of the industry. To achieve our goal, there are four components to what we do. The first two, and the most important, are to promote the biotech industry and also act as a regulatory advocate. The third component is our work with the international community for companies looking for global connections. Finally, we act as an internal networking platform, linking companies in the industry with the government and also academic and research institutes.

You were at one point chairman of both TBIO and the DCB. What is the relationship between the two organizations and how do they differ?

The DCB is a non-profit research and development (R&D) organization that was initially formed in 1984, whose focus was to connect upstream basic research to commercialization. Though the government had the budget for this field, it had neither the manpower nor the expertise to address it and so contracted the DCB to effectively run the BPIPO agency. Taiwan BIO, on the other hand, is a totally independent, private industrial partnership.

Can you talk more about the collaboration efforts between Taiwan and China?

In the past, everything imported to Taiwan was subjected to Taiwan's testing processes and everything exported to China had to be tested in China. We now have mutually recognized labs, and the Chinese authorities will now accept some test data in a recognized facility in Taiwan. At the moment this is just for foods and cosmetics. There is currently no so-called bi-lateral mutual recognition of the approval process for pharmaceuticals. However, there have been exceptions, most notably a new drug developed by TaiGen, which underwent Phase I and II trials in Taiwan, had its Phase III clinical trials in China. An official agreement is forthcoming, but there are still obstacles to be overcome. For speedier approval of new drugs, it would only be mutually beneficial to both sides.

Where aside from China do you see Taiwan focusing on an international scale and what role will the country play globally?

Taiwan has come a long way in the past 20 years. Hospitals did not have experience in conducting clinical trials, but now clinical trials are being held with a high level of quality and cost effectiveness that are hard to find elsewhere in the world. Even Quintiles, one of the largest CROs in the world, plans to send more cases to Taiwan. In addition, Taiwanese investigators are taking the role of principle investigator in multi-national Phase I clinical trials of new drugs for the more Asian-prevalent diseases. In this sense, we are already recognized globally for the high standards of our facilities and investigators.

During the global financial crisis, Taiwan's biotech capital markets grew by 520%. Why do you think that growth was so high when the rest of world was going in a completely different direction?

A major contributing factor was the improved relationships between China and Taiwan. President Ma was inaugurated in 2008 and established new measures that softened tensions between Taiwan and China and somewhat freed up trade. Taiwanese companies suddenly could enter a huge market and benefitted. This drove the market forward. A second factor was the New Drug Development Act, which was passed in 2007 and encouraged investment and R&D into new drugs by offering tax incentives. In addition, the government offered schemes for which, if a company qualified, it would receive financial support of up to 50% R&D expenses.

What are the fundamental strengths of the biotech market in Taiwan and what challenges does it face?

One strength is our capital markets, which have been supportive for the past eight years. Additionally, our existing strengths in electronic and information technologies can be leveraged to develop medical devices and health care related products.

Having China so close is certainly another strength. Since we are legally and financially more transparent and able to offer better protection for IP than in China, it makes Taiwan a perfect development site for anything new. It has made us attractive to many multi-nationals looking for a springboard into the Chinese markets. However, China is also a double-edged sword and political tensions between us are still presenting challenges to our drug approval market. A second challenge would be the bureaucratic nature of the drug-approval regulations. A final challenge is Taiwan's lack of international collaboration, a crucial ingredient for the growth of this industry. The more companies that you work with globally, the more people that you will be benefiting and ultimately the more value that you will be generating. •

Image: Sheng Chang Pharmaceutical

Taiwan Pharmaceuticals

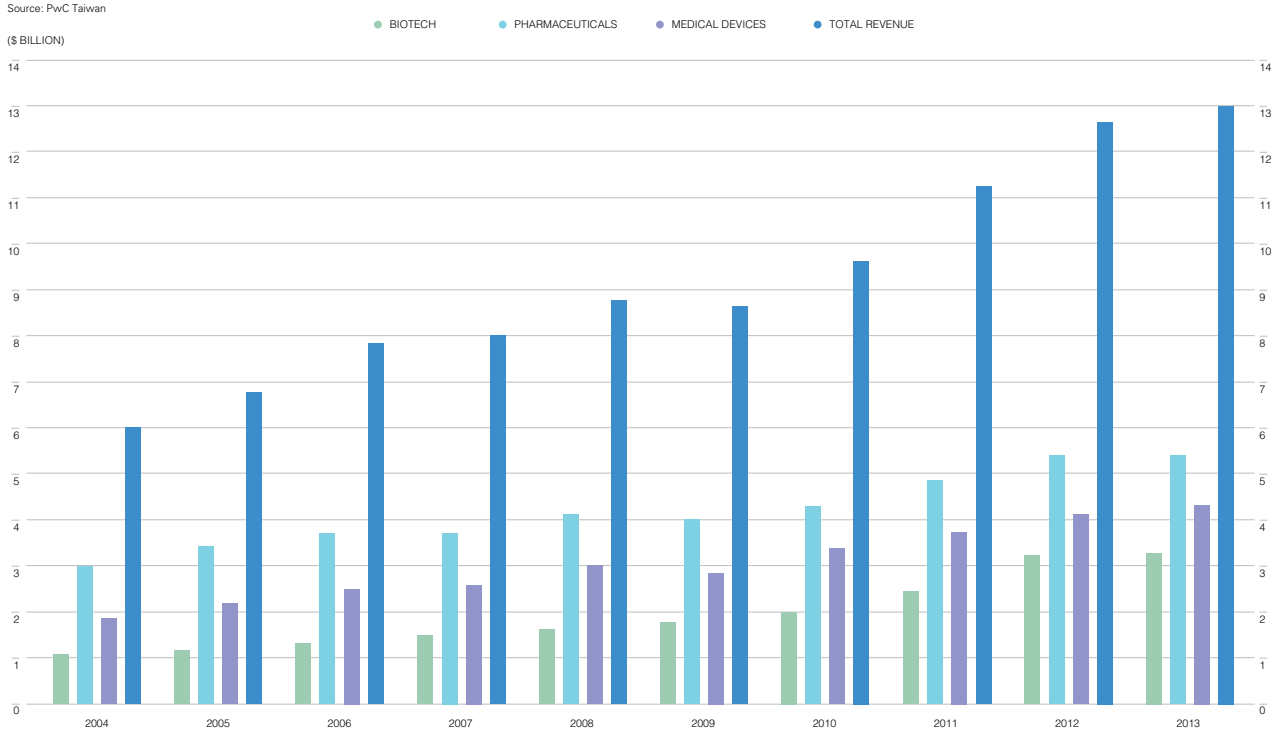
Entry Point for Asian Markets or Global Hub?

In the latter half of the twentieth century, Taiwan experienced an economic revolution that witnessed an average annual economic growth rate of 8.7% between 1952 and 1982, with the gross national product growing by 360% between 1965 and 1986. This period of growth transformed Taiwan from poverty to prosperity and helped to close the social gap that previously existed between the rich and poor strata of society. While there is no consensus on a single cause for what became known as the Taiwan Economic Miracle, it does seem clear that the transition was heavily influenced by government policy. Measures taken by the governments during that time included

> The industry will no doubt continue to grow and expand, due to the creativity of the Taiwanese scientists as well as the unwavering support that we have received from our government.
>
> - Dr. Chi-Huey Wong,
> President,
> Academia Sinica

MARKET SIZE BY REVENUE OF TAIWAN BIOTECH, PHARMACEUTICALS, AND MEDICAL DEVICES INDUSTRIES (2004-2013)

Source: PwC Taiwan



foreign exchange reform, the Nineteen-Point Economic and Fiscal Reform Program, and the Statute for the Encouragement of Investment.

Central to Taiwan's success in recent decades has been the government's commitment to developing Taiwan as a hub for the information technology (IT) industry. In the 1970s, the government began a campaign of promoting IT with the establishment of the Industrial Technology Research Institute (ITRI), which has been credited with helping to transform Taiwan's economy from one that was reliant on labor-intensive industries to one reliant on the high-tech industry. Crucial to Taiwan's success has been the unique talent pool that consists of a highly educated and entrepreneurial workforce.

If government support is considered to be fundamental to an industry's success, as could be argued in the case of the IT industry, then Taiwan's pharmaceutical and biotechnology industry is well positioned, as the government's support cannot be questioned over the course of the last three decades. From 1984 to 2013, the National Development Fund, Taiwan's government backed investment fund, has invested NT$12.4 billion into the pharmaceutical and biotechnology sector, including direct investments of NT$4.7 billion into thirteen pharmaceutical and biotechnology companies and a further NT$7.7 billion into twenty-four biotech-focused venture capital firms.

Apart from investing heavily into the industry, the government is keen to show its support through policies such as the Biotech and New Pharmaceutical Act (2007), which have resulted in Taiwan becoming an epicenter of research and development (R&D) in the biotechnology and pharmaceutical sectors. The extent of how far Taiwan has come in terms of its contribution can be clearly demonstrated by its industrial clusters that are scattered throughout Taiwan, for example the Hsinchu Biomedical Science Park and the National Biotech Park that is being promoted by Academia Sinica and

is due to open in 2016. These biotech parks, which offer considerable tax benefits, have been so successful that the WEF Global Competitiveness Report ranked Taiwan first in the world for its cluster development in 2014. Furthermore the government has established a system of incubation centers in order to strengthen the innovative environment for small and medium-sized enterprises (SMEs). There are currently in excess of 130 such incubation centers, more than half of which are exclusively focused on either the pharmaceutical or biotech sectors.

In addition to heavily investing in the industry, there have been a number of milestones that have been achieved by the government in recent years. The establishment of the Taiwan Food and Drug Administration (TFDA) in 2010 by the Organization Act for the Food and Drug Administration helped to consolidate the Bureau of Food and Health, Bureau of Pharmaceutical Affairs, Bureau of Food and Drugs Analysis and the Bureau of Drug Control and Administration into a single department.

Another major milestone, which secured Taiwan's status as a pharmaceutical manufacturer that met international standards, was the country's acceptance as a member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) in 2013, with the agreement that Taiwan would start implementing PIC/S Good Manufacturing Practices (GMP) in January of 2015.

Taiwan's relationship with the People's Republic of China (PRC) has also seen a significant thaw in recent years with the establishment of the Economic Cooperation Framework Agreement (ECFA), which was signed in 2010 with the goal of boosting bilateral trade on both sides of the Formosa Strait. Although the ECFA continues to be a work in progress, today four hospitals in Taiwan are directly collaborating with four hospitals in the PRC in areas of research and development.

Aside from a supportive government that is keen to promote the country's research capabilities, Taiwan offers a host of benefits that make it very attractive for future investors. Taiwan's geographic location at the center of the emerging markets of Asia and close to China make it an effective entry point for foreign companies that are interested in these markets. PIC/S compliance, a high number of English speakers and research excellence have resulted in an extensive pipeline of potential breakthrough drugs that could revolutionize the pharmaceutical and biotechnology sectors in the coming years. Taiwan's most important strength may be the Taiwanese people themselves, who provide an extensive talent pool which is being further enriched by the return of many highly skilled and successful Taiwanese from countries such as the United States. Dr. Chi-Huey Wong, president of Academia Sinica, said: "The industry will no doubt continue to grow and expand, due to the creativity of the Taiwanese scientists as well as the unwavering support that we have received from our government."

While Taiwan's pharmaceutical and biotechnology industries remain a work in progress with a substantial pipeline of potential blockbuster treatments, only time will tell if it will become a global hub of research excellence. •

Samuel Wang

President
TAIWAN GENERIC PHARMACEUTICAL ASSOCIATION (TGPA)

The TGPA was established in April 2007. Can you describe the primary role of the TGPA in Taiwan's pharmaceutical industry over the last eight years?

The TGPA was founded in 2007 and is now in its third term of leadership. This is the second term for which I have been elected President. The organization is a legally established, non-profit social organization. The TGPA started to contact with the International Generic Pharmaceutical Alliance (IGPA) since 2007, which was the same year that TGPA was established. The TGPA has also been an associate member of the International Generic Pharmaceutical Alliance (IGPA) since 2009 and has already become the full member this year. The IGPA was born as an international organization of generic medicines associations, committed to promoting generic medicines and exchanging information worldwide. As a member of IGPA, the TGPA has access to the most updated information related to the generic drugs in other countries and has dialogues with the international organizations. Also because the quality of the Taiwan's pharmaceutical industry has already reached international standards, promoting the Taiwan's pharmaceutical industry to the world is the primary role of TGPA.

Can you talk to us about your relationship with the government here in Taiwan?

The TGPA works closely with the government to implement various policy decisions. As the Taiwanese government is eager to reduce the cost burden of the National Health Insurance system, it makes sense that they would want to work with high-quality, local generic companies that seek to provide the same quality medication at a fraction of the cost. Based on having international information and data and by understanding the situations of the local pharmaceutical industry, the TGPA works with the government and acts as a mediator between the government and industry, from time to time. This is particularly true when the government is seeking to bring new regulations to bear on the industry and wants help in deciding which policies may be practical and which policies may not.

How do generic pharmaceutical companies benefit from being a member of the TGPA?

The immediate benefit that all of our members quickly notice is the communication between government and industry related to the pharmaceutical regulations or the guidelines about the National Health Insurance. Also, our members can gain access to the large amount of information that we have for companies who are seeking to export internationally. The TGPA could be the platform that allows our members swift access to potential international customers. If any local generic manufacturer wants to export their products abroad, membership of the TGPA is probably the most convenient means of achieving this.

How important is innovation to a generic pharmaceutical association like the TGPA?

While many people may believe that innovation does not play a big role in a generic pharmaceutical association like the TGPA, this is most certainly not the case. Our members remain committed towards developing new drug delivery systems, new formulations and biosimilars. So, the TGPA always has to keep following the most updated information and does all it can to respond it timely.

As the government tries to reduce the costs associated with its healthcare, it makes sense that generic medication would be the way to go, as you mentioned earlier. What impact have generic medications made on the Taiwanese market as a result?

In Taiwan, more than 70% of the amount of drug usage is now prescribed generic medications. The National Health Insurance pays almost the entire sales in Taiwan, but only 20% to 30% of the spending is for generic drugs, not including the patent-expired branded drugs. After the exclusive sales period for the patent drugs, the cost of manufacturing is actually lower in multi-national corporations (MNCs), most are the patent-expired branded drugs, than in local generic manufactory. This means that the MNCs have more advantageous prices to compete in the market.

Looking at the pharmaceutical industry as a whole, can you give us a brief analysis of the various sectors that the industry is involved with?

The most popular sector of the pharmaceutical industry in Taiwan is the formulations or finished products. Almost half of the industry is manufactories of the finished products. The second most popular is active pharmaceutical ingredients (APIs). These two areas compose most of the industry in Taiwan, with the remaining small percentage being devoted to other niche manufacturers. The percentage of Chinese medicines is 10% of the industry.

Finally, with regards to the pharmaceutical companies that operate out of Taiwan, what is the breakdown of local domestic companies versus the larger MNCs with regards to size?

There are a number of large local pharmaceutical companies that have enjoyed recent success, but, when it comes to size, all of the largest pharmaceutical companies are MNCs. A look at our list of the top ten pharmaceutical companies in Taiwan will reveal that all of the largest pharmaceutical companies are MNCs. •

Dr. Chuan Shih & Dr. Chiung-Tong Chen

CS: Director
CTC: Associate Director
NATIONAL HEALTH RESEARCH INSTITUTES (NHRI)


CS


CTC

Can you please give a brief introduction to NHRI and tell us about its recent developments?

CS: NHRI is one of the major biomedical research centers in Taiwan. It was established by the government in 1996 and modeled after National Institutes of Health (NIH) in the United States and the Medical Research Council in the UK. We are focusing on biomedical research with the directive to benefit and improve the healthcare for the people of Taiwan. Most of the research groups are now located in our Zhunan main campus, north of Miaoli County. In total we have seven research institutes, one research division, and three research centers. All of these operations are supported by around 1,500 research scientists and physicians. While we are supervised by the Ministry of Health and Welfare (MOHW), we have a fair degree of freedom in the drug discovery projects we select. At the Institute of Biotechnology and Pharmaceutical Research (IBPR), we decide what projects are important to the field and for Taiwan. Of course we work in line with government in determining the projects that are most relevant to local health care needs and emerging healthcare crises.

What are the main criteria you consider when choosing your target areas of research?

CS: At the IBPR, some of our therapeutic area expertise and focus include oncology, metabolic disease, infection disease and stem cell research. We want to work on projects that are innovative and competitive. Additionally, they must address some of our local unmet medical needs. Looking to the future, we can transfer these projects to the local pharmaceutical and biotech industry. Whatever project we choose should provide Taiwan biotech industry with a competitive edge in innovation.

Recently there has been progress in the level of collaboration between China and Taiwan on late-stage clinical trials; can the same be said for the earlier stages?

CS: On the early drug discovery area, we have not had any collaboration with Mainland China groups, with either government-sponsored institutions or private companies. However, we do work with a number of Mainland China based contract research organizations (CRO) to help us conduct various preclinical CM&C and toxicology studies. Although Taiwan has a strong CRO infrastructure and network, in certain areas China presents more options as potential partners for collaboration. Before joining IBPR, I was working for a U.S.-based biotech company in Shanghai area. It was at that time that I became aware of the spectrum of pricing and the capabilities of various Chinese CROs. We have also collaborated with some U.S.-based biotech companies as well as CROs, which can offer higher quality, better performance, and a greater attention to detail in managing various projects moving into the preclinical development stage.

Taiwan's biotech and pharmaceutical industries have always been known for their deep talent pools, but recent trends indicate that these are diminishing; what is your view on this subject, and what is NHRI doing to combat this?

CS: NHRI does not see this as a critical issue at the moment. Admittedly, the overall higher education talent pool in Taiwan appears to be diminishing in recent years, especially in the biomedical research area. It is becoming more challenging to find qualified scientists in chemistry, biology, and pharmacology across the country. Although we are competing with other private industry and universities in areas like Taipei, NHRI has a solid reputation and can still attract excellent scientists and researchers to join various research initiatives and activities.

CTC: In terms of the talent pool, we have observed a troubling trend in the last three to five years of fewer students pursuing higher education and degrees, especially in doctoral programs. This is a future concern, but not currently affecting us. To avoid this becoming a future crisis, students must be encouraged to enter scientific and medical programs (doctoral programs) as well as extended post-doc training (either in Taiwan or abroad). This issue may require resolutions at the higher government policy level so that Taiwan does not lose its competitive standing in the biomedical, biotech, and pharmaceutical industries.

What are your thoughts on the industry in the coming years, as well as the future of NHRI?

CS: The biotech industry in Taiwan will continue to grow rapidly, and we will see more successful companies, whether they are working in small-molecule drugs, protein-based therapeutics, or medical instruments arena. The country possesses a great deal of talent, innovative power, resources and business opportunities in biomedical research in general, which will lead to excellent opportunities for the growth of the biotech and pharmaceutical industry. NHRI will continue to play its mission-oriented role in supporting various new drug discovery efforts and then transfer/license some of our development candidates to the local industry for successful drug development into the local and global markets. For example, we are actively considering the possibility to spin off several of our new drug discovery and development assets to local biotech companies as an effective way to channel more of NHRI's innovation into the local biotech sector. •

Taiwan's Biotech and Pharma Sectors on the Up

Contributed by PwC Taiwan's Health Industries Practice

This article, drawn from the PwC publication, "Taiwan health industries outlook," provides an overview of Taiwan's biotech and pharma sectors, including key issues and prospects.

Over the years, Taiwan has created a favorable environment for its biotechnology and pharmaceutical industries, which encompass the applied biotechnology, pharmaceutical and medical device sectors.

Already in place is a highly-regarded clinical research infrastructure, a high-quality, low-cost research and development (R&D) and manufacturing environment, a large talent pool with capabilities in both fundamental and applied research as well as product development, and an industry culture that respects intellectual property rights.

The government has enacted several policies and laws to position biotechnology and pharmaceuticals as key priority industries for Taiwan in the 21st century. Its strong policy and financial support has helped spur the domestic biotech and pharma market to double in size from $5.9 billion in 2004 to $13 billion in 2013.

Biotechnology overview

Taiwan's biotech industry is expanding steadily, supported by strong government commitment and private sector interest. A 2009 national plan for biotechnology development helped kick-start the domestic market, which almost doubled in size over the next five years to $3.3 billion. Although relatively small in size, the market's growth momentum is seen as strong, due to continued government support, closer collaboration with China on new drug development, and the maturation of biotech drug pipelines and service offerings.

Taiwan's key biotech strengths include the availability of a large talent pool, good medical and research infrastructures, and a solid reputation for well-run clinical trials focusing on Asia-prevalent diseases. The government is currently focused on building the capability of the biotech value chain in Taiwan. The completion of a National Biotechnology Research Park, due in 2016, will facilitate translation of drug discovery results to clinical trials, and is expected to accelerate further development of the biotech industry.

Taiwan's strategic location on the Pacific Rim and its strengthening ties with China also make it an ideal gateway for international partners to enter the Asia region, as well as a springboard for multinational companies looking to enter the large Chinese pharma market. Taiwan and China signed a medical and healthcare cooperation agreement in 2010, which has led to increased collaboration on drug R&D.

With Taiwan's biotech sector in the late incubation stage and attracting strong investor interest, there has been a marked jump in the number of companies going public through IPOs to raise funds for R&D and growth opportunities. The number of biotech firms listed in Taiwan grew from 37 in 2007 to 83 at end-2013, and their combined market capitalization grew from $3.5 billion to $21.1 billion over the same period.

Pharmaceuticals overview

Pharmaceutical demand in Taiwan totaled about $5.4 billion in 2013, having grown by a CAGR of 5.8% between 2008 and 2013, due to high volume consumption of prescription drugs per capita. (Prescription drugs for both outpatient and inpatient care account for over 90% of the domestic market). Taiwan's fast ageing population and subsequent increased consumption of advanced and high-treatment for long-term chronic illnesses are expected to result in higher demand for prescription drugs in the coming years.

Most new and patented drugs (which represent about 70% of total prescription spending) are imported by pharma multinationals, but their market share is under pressure from government policies promoting the use of cheaper locally-made generic drugs, as well as pending patent expirations. Domestic firms mostly focus on generic drugs, but are increasingly engaging in original R&D to move up the pharma value chain.

Taiwan's government is also actively assisting domestic pharmaceutical producers to upgrade their manufacturing facilities in line with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) standards. Taiwan became a member of PIC/S in 2013, and this will undoubtedly help boost Taiwan's standing as a pharmaceutical manufacturing hub in the Asia region.

In addition, Taiwan is working closely with China on pharmaceutical issues. Their 2010 medical and healthcare cooperation agreement has ushered in a new era of regulatory cooperation in the areas of new drug development and clinical trial testing. This positive development will help accelerate the market clearance process for certain drugs and enable Taiwanese drug makers to gain faster entry into China.

PwC observations

PwC sees continuing strong growth in Taiwan's biotechnology and pharmaceutical industries. This will likely attract more international biopharmaceutical companies to team up with, or acquire, Taiwanese players to take advantage of their manufacturing and product development capabilities—as well as their experience in marketing and distribution in the region—to increase their Asia presence, especially with regard to China. •

PwC Taiwan's Health Industries Leader Lily Wong is the contact person for this article, which has been written with the support of Damian Gilhawley.

Dr. Hongjen Chang

Vice Chairman
TRPMA

What is the TRPMA's mission in promoting research and development (R&D) in Taiwan's biotechnology industry?
Though the R&D subsection of this industry has been developing for quite some time, historically it has never had much in the way of international interest. The TRPMA's main efforts have been to expose globally what has now become, despite the size of the population, a vibrant and active part of the pharmaceutical industry in Taiwan.

Is the biotech market becoming a bubble?
In 2013 we raised $2.4 billion and are now the second most active biotech capital market after the United States. A bubble is a natural phenomenon with this sort of growth and whether it will burst or not depends on events. Good outcomes will cause the bubble to grow and bad news will obviously cause it to burst. At moment, there is a mixture of exciting news and disappointments.

What is TRPMA's involvement in Taiwanese-Chinese trade relations?
With TRPMA being the only association representing R&D-based companies in Taiwan and the fact that China has no counterpart, we could be the window through which other nations will be able to access the Chinese market.

As president/CEO can you highlight a few of the success stories of the Taiwan Global Biofund over the past decade?
Taiwan Global Biofund, established by YFY along with the National Development Fund (The D Fund) support, was originally successful through biopharmaceutical companies such as TaiGen, the company behind the stem cell mobilizer and hepatitis C novel treatments, and Taiwan Liposome Company. In 2008, we became the only fund to shift focus exclusively to Taiwan. More recently our biggest story has been an innovative medical devices company called Medeon Biomedical, which we co-incubated with a private investor and is planning an IPO later this year.

What strengths does Taiwan have to make it an international hub for biopharmaceuticals?
Taiwan's local market is small but it has branched out and is working at the highest levels of quality. TFDA approval is one of the strictest and most difficult approvals, and many South East Asian countries will now excuse companies that already have TFDA approval from their own equivalent. This coupled with a strong capital market will continue to secure Taiwan's position. •

Dr. Tsu-Hwie Annie Liu

Program Director,
Division of
Industry
Promotion
DCB

The Development Center for Biotechnology (DCB) was established in 1984. What was the government's objective in establishing the center?
The DCB's mission is to promote the development of the biotechnology industry. At the time that it was founded, the United States biotech sector was already booming. The government saw the potential importance of the sector to Taiwan and established the DCB. Most of the group leaders or department heads were recruited from the United States, where many Taiwanese students went to study and then worked in the biotech sector. Initially, agricultural biotech was an important area, but Taiwan has grown more competitive in biotech pharmaceutical products, which is our focus today.

One of the DCB's goals is to create pre-clinical value as an integrated service center for biopharma. How does DCB add value through research and development (R&D)?
Taiwan has strong fundamental research capability, but most of this strength is in universities and research centers where their main focus is to publish research. Taiwanese biotech companies, on the other hand, are small and cannot afford to translate this research into product development. DCB helps to facilitate this transition from academia to industry.
We have close relationships with the major research institutions. We transfer research projects from these research institutions to the DCB and then carry out R&D to move the project toward commercialization. We then apply for Investigational New Drug (IND) approval. Before or after we receive the IND is when we look for a partner to transfer the product to the industry. This timeline can take four to five years.

In the past four years, we have seen Taiwan's biotech sector market capitalization shoot up by 520%. What are the main factors behind this meteoric increase?
According to a ranking of 54 countries by Scientific American, Taiwan ranks third in the world for capital markets after the United States and Australia. The capital market in Taiwan is attracting a lot of foreign attention. Even though a lot of biotech companies do not have products on the market right now, they are still valued highly. This indicates that people believe these companies have potential to make great profits in the next five to 10 years. Right now we have an abundant pipeline of pharmaceutical products, with over 150 potential drugs in the pre-clinical and clinical stages. •

Lily Wong

Advisory Partner and
Health Industries Leader
PwC TAIWAN

Can you give us a brief introduction to PwC Taiwan and tell us how your local health industries practice has evolved over recent years?

PwC Taiwan has over 2,700 people who deliver assurance, tax and legal, and advisory services. Overlaying these lines of service are several industry practices, which include the healthcare, pharmaceutical and life science sectors. Besides our traditional accounting services, we provide a range of other value-added services for biopharmaceutical companies in all stages of growth, from start-up to IPO and beyond. We can help clients to grow through M&A, working alongside them on all aspects of the deals process, including strategy, due diligence, valuation analysis and negotiation with transaction parties.

PwC has been actively involved in Taiwan's biotechnology industry since its beginnings. Our firm served as an accounting and tax advisor to the government on the 2007 Biotech and New Pharmaceutical Development Act and related policy initiatives, which have helped spur industry development. We continue to play a prominent advisory role in various biotech industry bodies.

What has PwC's experience been with the boom in the number of biotech companies wanting to carry out an IPO?

The government's earlier relaxation of IPO rules has made it easier for biotech companies to raise funds through listing on Taiwan's stock exchanges, leading to the biotech IPO boom. PwC has been engaged to work on many of the 80-plus listings so far of biotech companies in Taiwan. PwC primarily provides accounting, auditing and capital market services to emerging and early stage companies as they prepare for IPOs, as well as various tax, legal and advisory services. We are also seeing an increasing number of international companies looking to enter Taiwan's IPO market.

Taiwan's single-payer healthcare system is one that has been very successful, but is a difficult model to sustain. How can the government ensure that it is able to continue?

The implementation of a second-generation national health insurance system in 2013 has helped put the scheme's finances on a sounder footing. Even so, uncertainty remains due to the added pressures of an ageing population and rising healthcare costs. The government has aggressively sought to cut reimbursement rates as well as adopt various other reimbursement methods. To cope with the projected demand and financial impact of a fast ageing population, it plans to establish a more comprehensive care and support system as well as a new long-term care insurance scheme.

How do you see PwC's role in Taiwan's healthcare sector evolving over the next five years?

PwC sees significant growth potential in Taiwan's health industries and is well positioned to help domestic and international companies across the health continuum to resolve complex issues and identify opportunities. Besides IPOs, we expect to see more international companies and investors looking to acquire, or team up with, Taiwanese biopharmaceutical players to take advantage of their manufacturing and product development capabilities—as well as their experience in marketing and distribution in the region—to increase their Asia presence, especially with regard to the Chinese market. •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Island Rules: Governance and Regulations in Taiwan

"There are a number of government agencies that have a close relationship with the TFDA, including the Ministry of Economic Affairs and the Ministry of Health and Welfare. Both of these ministries play an important role in the operation of the pharmaceutical industry. As the TFDA sets the required regulations that are required for consumer health and safety, there is a regular dialogue among ministries to ensure transparency and efficiency."

- Dr. Shiow-Ing Wu,
Deputy Director-General,
Taiwan Food and Drug Administration
(TFDA)

Image: Sheng Chang Pharmaceutical

Government Backing

Setting Taiwan on the Path to New Discoveries

While the number of initiatives that the government has undertaken to promote the industry is vast, they all aim at one sole primary objective: to establish Taiwan as a center of research excellence.

This facet of Taiwan's pharmaceutical industry is what sets it apart from a number of its major Asian counterparts. The story of the Asian pharmaceutical industry has been dogged for decades with stories regarding patent infringement and low costs have been equated to low quality. While their methods may have been questionable, the Asian pharmaceutical industry has played a major role in increasing the accessibility of life saving medicines on a global scale. It has become clear, however, that Taiwan is not going to follow this model, instead choosing to be one of the select Asian countries that will carve out its own sustainable niche through intensive research and high-quality production.

The government's dedication to its objective of becoming a center of global innovation in the pharmaceutical and biotechnology sphere is clearly expressed through the numerous policies that have been implemented to promote this. In March of 2009, the Executive Yuan (executive branch of the Taiwanese government) put forward the Taiwan Diamond Action Plan for Biotech Take-off, which cemented the country's intention of becoming a major player in the biotech arena. This policy aims to strengthen Taiwan's technology acquisition capabilities, establish venture capital for the industry, promote the country's incubation system, as well as set up the Taiwan Food and Drug Administration (TFDA).

Following this policy, the Taiwan Biotech Industrialization Take-off Action Plan was approved in 2013, which is expected to have a profound effect on the industry in the coming years. Its primary objectives include further promoting Taiwan's incubation system to link Taiwan with global regulatory practices to improve local infrastructure in order to attract more private investment; assist in the promotion of the pharmaceutical, biotechnology, medical device and medical management industries; expand the international mar-

> "Pharmaceuticals, medical devices, and healthcare management services are all central pillars of [the Taiwan Biotech Industrialization Take-off Action Plan, which was approved in 2013]. The aim is to build on upstream research and development, establish venture capital to attract private funding in addition to the National Development Fund, foster international harmonization, support the establishment of incubation centers and industrial clusters and provides legal, intellectual property, technical, and commercialization services."
>
> - Dr. Ming-Neng Shiu, Vice-Minister, Ministry of Health and Welfare, Government of Taiwan

ket for Taiwan's products; and improve the reputation and competiveness of Taiwan on the global stage. The Vice-Minister of Health & Welfare, Dr. Ming-Neng Shiu was keen to stress the importance and scope of this plan going forward: "Pharmaceuticals, medical devices, and healthcare management services are all central pillars of this plan. The aim is to build on upstream research and development (R&D), establish venture capital to attract private funding in addition to the National Development Fund, foster international harmonization, support the establishment of incubation centers and industrial clusters and provides legal, intellectual property (IP), technical, and commercialization services."

The task of raising Taiwan's R&D facilities to a world-class standard and promoting it as such is primarily shared by the Executive Yuan and the four ministries: the Ministry of Economic Affairs (MOEA), the Ministry of Health and Welfare (MOHW), the Ministry of Education (MOE), and the Ministry of Science and Technology (MOST). However, the reality of the situation is somewhat more expansive, in that the directives from the above institutions trickle down to a vast network of agencies, each with their own clear agenda.

The Executive Yuan set up the One-Stop-Service Office for Biotechnology Industry in 2001. The aim of this office was to reduce the bureaucratic red tape that can sometimes be seen as counter-productive for companies that are operating in a highly regulated industry. Working across both the pharmaceutical and biotech markets, the office is specialized in providing assistance to resolve matters with regards to drug approval and regulatory affairs, R&D, technology transfer, personnel training, recruitment, investment promotion as well as to provide market and services information related to the industry.

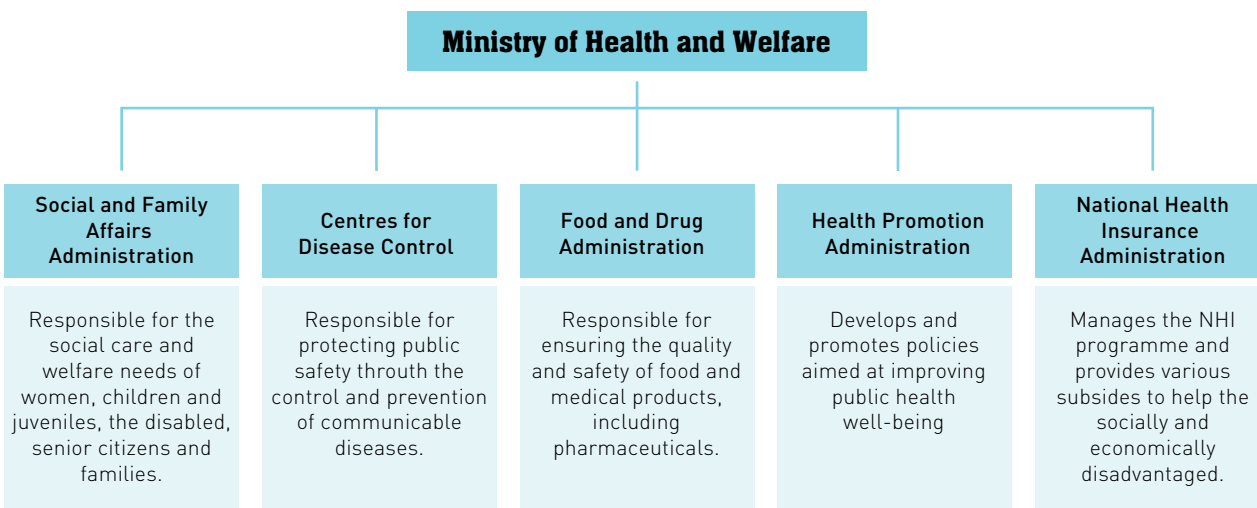
The MOEA has a number of agencies that focus on biotechnology application research and product development, sourcing private investment and product commercialization and industrialization. These agencies include the Development Center for Biotechnology (DCB), Industrial Technology Research Institute (ITRI) and the Medical and Pharmaceutical Industry Technology and Development Center (PITDC). However, one of the primary agencies operating under the umbrella of the MOEA is the Biotechnology & Pharmaceutical Industries Promotion Office (BPIPO), whose primary goals are to promote the industry and in doing so increase international investment. Apart from working to improve the investment environment, it also strives to establish an extensive R&D system, promote industrial development strategy and frequently revises development regulations.

The MOHW also have a number of agencies that work to formulate and implement policies and regulations that govern clinical trials, public health and drug approval. These agencies include the Taiwan Food and Drug Administration (TFDA), Centers for Disease Control and Center for Drug Evaluation (CDE). The role of these agencies cannot be overstated, as their standards are a reflection of the Taiwanese healthcare system as a whole. Finally the MOE and MOST collectively work towards the same objective of implementing fundamental and innovative research, which is achieved through a number of university departments as well as the world renowned Academia Sinica.

With a plethora of tax-incentive schemes as well as a range of subsidized programs (primarily administered by the Industrial Development Bureau and the Department of Industrial Technology) aimed at promoting research and development, Taiwan's business environment in this sector is unrivalled across Asia. Furthermore, while benefitting from a liberal tax regime, international companies can rest assured that there is no compromise in quality as Taiwan is now PIC/S compliant and meets the necessary standards for current Good Manufacturing Practices (cGMP). Most importantly, Taiwan has a rigid patent system in place that respects IP. Overall, Taiwan's pharmaceutical and biotechnology industry is poised to benefit from its government's strong support, and Taiwan has great potential to become a major center of research and innovation. •

TAIWAN'S HEALTHCARE REGULATORY STRUCTURE

Source: Ministry of Health and Welfare, Taiwan.



Dr. Chien-Hsin Daniel Cheng

Former Director
BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES PROMOTION OFFICE (BPIPO), MOEA

The Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO) was set up by the Executive Yuan 20 years ago. Can you introduce us to the office and your mandate?

BPIPO covers the pharmaceutical and medical devices industries, as well as the biotech industry and its subsectors in agriculture, food, environment and biofuel. Since the value chain from research to commercialization for these industries is long, the government set up BPIPO to help with product development. BPIPO was established through the Ministry of Economic Affairs' Industrial Development Bureau as a one-stop service office to integrate all the governmental agencies.

Can you give us an example of one of BPIPO's initiatives aimed at helping biotech and pharmaceutical companies to achieve growth?

BPIPO holds regular meetings with companies where they have an opportunity to raise any issues that need to be resolved. For example, if a company needs assistance with regulations, BPIPO will introduce the company to the Taiwan FDA to help them solve the problem. We also help with obtaining land, recruiting talent and obtaining tax benefits. If the issue is not resolved by this working group we bring it to a higher level in the ministries.

As of 2013 the government had invested up to NT $12.4 billion in the biotech sector. Can you explain how the government chooses their projects?

Through the National Development Fund (NDF), the government funds either venture capital or individual start-up companies. Previously start-up companies were burning cash and doing clinical trials with difficultly accessing the financial markets. Over the last three years, however, the capital market has become very interested in investing in biotech, so it is now easier for biotech companies to hold IPOs with higher share prices.

What role does the BPIPO play in assisting private and foreign investment in Taiwan's biotech and pharmaceutical sectors?

Since Taiwan has lowered the inheritance tax rate from 40% to 10%, large amounts of overseas money has returned to Taiwan. We are working to guide this money into industrial investment, and biotech has become a hot target. We have set up private venture capital firms, such as Diamond Venture Capital, which has raised $300 million to invest in start-up companies. As another example, Daiwa, a Japanese security firm, has collaborated with the NDF to set up a joint-venture capital fund, named Taiwan-Japan Biotech Fund. NDF has agreed to commit 30% to the total fund.

The World Economic Forum ranked Taiwan as number one in the world for the state of its industrial clusters. Why do you think the industrial clusters in Taiwan have been so successful?

Within Hsinchu Science Park we have the world-leading semiconductor industry. The biotech sector has a cluster in Nankang where, within a 10 km radius, one can find the best hospitals in Asia and a large supply of CROs. Within a short distance, companies can find all the help they need developing their products throughout the supply chain. Taiwan's biotech sector is not just focusing on manufacturing; we have research resources and CROs for clinical trials. This means that many big pharma companies are setting up clinical trial centers in Taiwan. Furthermore, our regulations are harmonized with advanced countries.

Industry members have said that the Taiwan FDA is even tougher than the US FDA. How easy would it be for a company to go through the approval process in Taiwan?

In China you wait a long time for approval because they are short on manpower, whereas in Taiwan we are more transparent and efficient. Even though the Taiwanese market is small, it can be used as a clinical trial center for many countries. The US FDA is more advanced, so they are more experienced reviewers and can go through the approval process faster. At the end of the day, the Taiwan FDA is the gatekeeper to protect our people from harmful products.

What is your outlook for the growth of Taiwan's biotech and pharma sectors?

This year we are estimated to reach $50 billion NT in biotech investment, an increase from $45 million in 2014. In terms of new drug development, Taiwan does not have the same capabilities as big pharma. In the past ten years, only 26.8% of new chemical entities (NCEs) have been approved by the U.S. FDA, while 73.2% of improved products (such as new dosage forms, new indications, new delivery systems and etc.) have been approved by statistics. These products have shorter times and lower costs in development, which make them a focused area for our sector. Our sector also has strong potential in biosimilars for protein drugs. Protein drugs are effective but also expensive. With biosimilars, we can treat patients at a lower cost. Currently, more than 30 companies are focused on biosimilar and innovative antibodies drugs. •

Dr. Shiow-Ing Wu

Deputy Director-General
TAIWAN FOOD AND DRUG ADMINISTRATION (TFDA)

In 2010, the Bureau of Food Safety, Bureau of Pharmaceutical Affairs, Bureau of Food and Drug Analysis and Bureau of Controlled Drugs came together to form the Taiwan Food and Drug Administration (TFDA). What is the role of the TFDA in the pharmaceutical industry today?

The mission of the TFDA, with respect to pharmaceuticals, has always been to protect public health with regards to consumer products and to promote the pharmaceutical industry here in Taiwan. The primary role of the TFDA is to ensure the quality and safety of all pharmaceuticals that are imported into Taiwan and exported internationally. We also play a major role in helping pharmaceutical companies in Taiwan to export their products internationally.

How does the TFDA protect the national health in Taiwan with regards to the pharmaceutical industry?

The TFDA is committed to strengthening programs and policies that enable it to carry out its mission to protect and promote public health with harmonized regulations and standards as well as efficiently integrated review processes. These processes take place at every stage of a drug's lifecycle from the early stages of basic research and preclinical testing, all the way to clinical testing, approval, manufacture and marketing. It is a rigorous process, which aims to make sure that only safe products will become available to the public.

Could you describe the relationship between the TFDA and various other government ministries, as well as the non-governmental organizations in the sector?

There are a number of government agencies that have a close relationship with the TFDA, including the Ministry of Economic Affairs and the Ministry of Health and Welfare. Both of these ministries play an important role in the operation of the pharmaceutical industry. As the TFDA sets the required regulations that are required for consumer health and safety, there is a regular dialogue among ministries to ensure transparency and efficiency.

To ensure that the government's objectives are balanced with the industry's objectives, we also ensure that we have a regular dialogue with the industry as well as with healthcare professionals, international organizations and the consumer. This is achieved through various channels including quarterly meetings, press releases and regional or international conferences. •

Dr. Churn-Shiouh Gau

Executive Director
CENTER FOR DRUG EVALUATION (CDE)

The Ministry of Health and Welfare established the Center for Drug Evaluation (CDE) in 1998 as an independent body. What was the CDE's mission when it was established?

The government had ambitious goals for biotechnology and medicinal products but had to increase its capacity to review new drugs. Foreign regulatory bodies have already approved a large number of drugs that are approved in Taiwan. If Taiwan is to develop its own new chemical entities and be the first to approve them, it needed an additional body to evaluate these new drugs and determine whether they could be approved.

Can you talk about the CDE's relationship with the TFDA?

We work closely with the TFDA in providing assistance with the review process. Whenever the TFDA receives an application, our professional review team goes through the technical aspects of the dossier and reports back to the TFDA with final recommendations. In addition, we provide assistance in drafting new regulations and guidelines.

Can you also talk about your relationship with the National Health Insurance Administration (NHIA)?

This relationship has evolved from our success working with the TFDA. In order to determine whether a drug should be considered for the reimbursement scheme, the NHIA needs to perform a health technology assessment (HTA) of the new drugs and high-priced medical devices. We do the clinical effectiveness comparison, cost effectiveness comparison, budget impact, and determine the applicability in Taiwan. The reports from the HTA team are used to support the NHIA's decision on reimbursement.

What consultation services do you provide to the private industry?

Our consultation services fall into two different categories. The first is our general consultation service, which is normally regarding administrative procedures. The second is our index consultation service, which is provided on a case-by-case basis and is primarily focused on technical issues with regards to R&D, namely how to reduce R&D costs and shorten the R&D process.

How do you promote the Taiwanese pharmaceutical and biotechnology industry in Mainland China?

The situation in Mainland China is somewhat complex as it is heavily regulated, which can act as a barrier to entry for Taiwanese companies. Our focus is therefore on increasing dialogue. •

Market Composition: Overview of Taiwan's Major Players

"Taiwan has a very good research base, which is something that the country must exploit if it is to succeed as a global player. Taiwan must now seek to translate this into something that is commercially viable and move innovation and discovery forward into clinical development. Government support will be key in ensuring that these small local companies and ultimately the country are able to look beyond Taiwan's borders, which is something that is crucial for success."

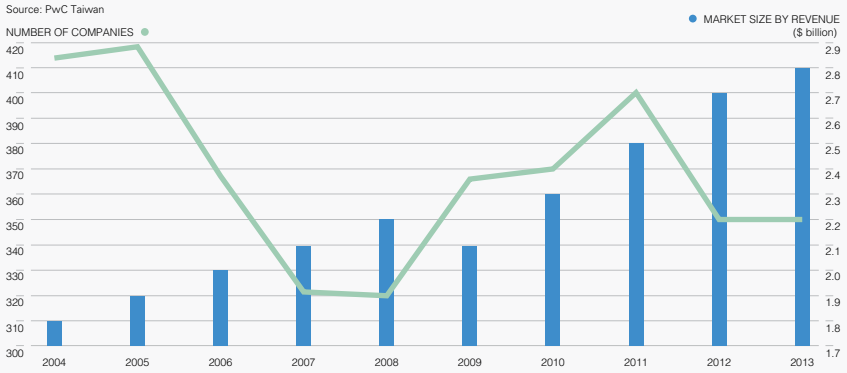
- Kevin Liu,
Director of PAP&C and Market Access,
Pfizer Taiwan

Image: Sean Pavone / Shutterstock.com

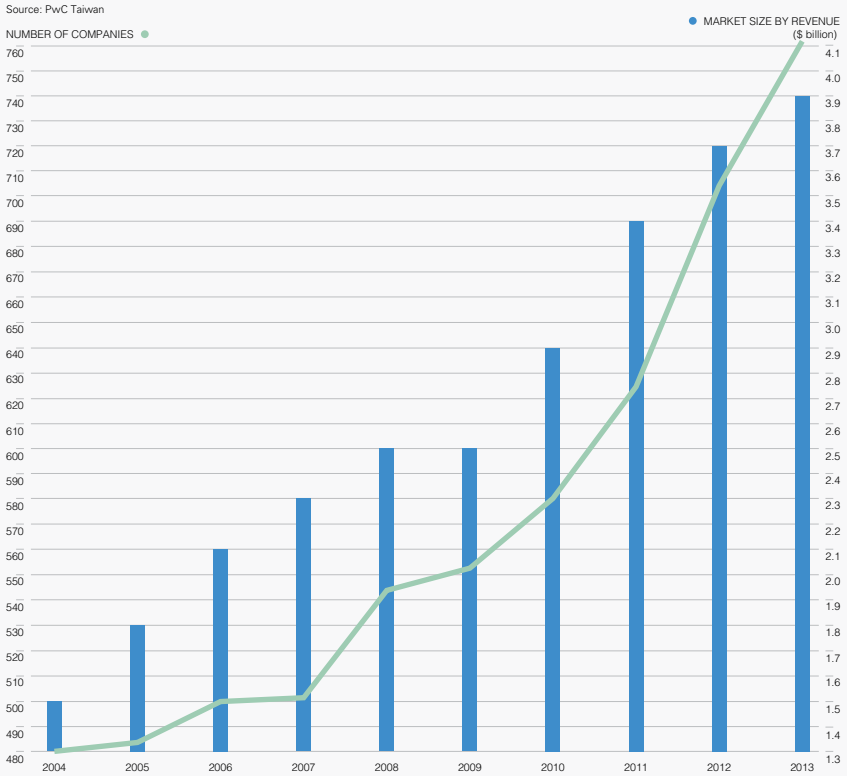
A Beacon of Quality

Manufacturing Excellence in Taiwan

TAIWAN'S PHARMACEUTICALS INDUSTRY (2004-2013)



TAIWAN'S MEDICAL DEVICES INDUSTRY (2004-2013)



Taiwan has built a reputation for producing quality products. Starting with the information technology (IT) sector, Taiwan has produced some of the most advanced electronics products in the world. With the government now identifying pharma and biotech as vital to Taiwan's economic future, the Taiwanese penchant for innovation and creativity has come in handy. Not to be outdone by other generics and active pharmaceutical ingredient (API) manufacturing countries, Taiwan has established itself as a hub for manufacturing excellence. As Taiwan itself is a small market of only 23 million people, most of the produced generics and APIs are for export, especially to Europe, United States, and Japan. Some of the biggest players in this market in Taiwan are Yung Shin, CCSB, ScinoPharm, Standard Chem & Pharm and SCI Pharmtech.

Besides well-established local API manufacturers, there is also a presence of Big Pharmaceuticals, with companies like GlaxoSmithKline (GSK), Pfizer, Bayer, Roche and others having a foothold in Taiwan. "Since 2007, GSK has invested over NT$1 billion in drug research and have over 50 large-scale international clinical studies in Taiwan. Taiwan is represented in the majority of our studies in new drug development. GSK is currently one of the leading multinational pharmaceutical companies in Taiwan, and our portfolio spans multiple disease areas. Our presence is particularly strong in respiratory, HIV, vaccines, CNS, and urology, as well as consumer health care," said René Jensen, vice president and general manager of GSK's Taiwan branch.

Pfizer is the only multinational pharmaceutical company to have its own manufacturing plant in Taiwan. "This plant actually produces some of Pfizer's antibiotics and supplies not only Taiwan, but also other countries. The plant is also used for the manufacturing of consumer products and nutritional supplements and the efficiency of this plant is very high. Pfizer very much wants to be seen to have a tangible investment in Taiwan and having this site very much is in line with Pfizer's policy of centralizing manufacturing operations," said Kevin Liu, director of PAP&C and market access of Pfizer Taiwan.

As the API market becomes increasingly competitive in Taiwan, some API manufacturers have also chosen to venture into new drug discoveries to differentiate themselves and because the margins on generics and API products are becoming smaller. "Last year we produced a total of two billion tablets. Though our volume is high, generics are sold for far less than the originals. In Taiwan, 80% of the volume produced is generics, but this only actually accounts for about 20% of the market value," said Roy Fan, CEO of Standard Chem & Pharm. "Our first goal is to have 50% of our revenue generated from overseas business. Secondly, we hope to have a new drug that will be in either in phase I or phase II. We hope to do much more Paragraph IV in the United States and have more of our own products launched in Japan," added Fan.

Others, like ScinoPharm, have had to also differentiate their service offerings to keep up with the competition. "Today we are still focused on APIs, with a specialty in high-potency and oncology injectables. Our top three products are oncology cytotoxic injectables. Seventeen years ago there were very few suppliers in this high-potency area, however today we are seeing much more competition from Chinese and Indian companies, especially on price. We have adjusted our company strategy to target different areas, such as providing custom synthesis services to new drug discovery companies, and providing process development for NCEs. About 25% of our business comes from CRO/CMO accounts, while 75% comes from generic APIs," said Dr. Yung-Fa Chen, CEO of ScinoPharm.

Although not as large as India's and China's market for APIs, Taiwan's API market does have a number of competitive advantages over its huge competitors. "Taiwan's API market is not that large on a global scale, as we have only around 15 active companies. However, the quality of all these companies is very high. They are all U.S. FDA-inspected and have strong records. Others countries may have a larger market but do not have as consistently as high of standards as can be found in Taiwan. Previously, pharmaceutical companies from developed countries turned to India or China where products and services were cheaper, but after encountering difficulties they realized that cost is not the only factor and that quality must be first considered in the equation. Thus, focus has shifted to Taiwan. In the past ten years, the value of this market in Taiwan has more than doubled. Taiwan's image for high quality, coupled with its reputation for respecting IP, has been attracting more and more companies here," explained Dr. Weichyun Wong, president of SCI Pharmtech.

Some Taiwanese API manufacturers are choosing to expand to China to face the competition there head on. "To stay ahead of competitors, Formosa has taken advantage of the developing API industry in China. We continue to source our intermediate/starting material from China who will take on any new drug in the market as they are behind in GMP compliance. Raw material costs are similar to competitors; labor costs and profit margins are variable; and companies in China benefit from government subsidies. Formosa's company practice will gain advantage from the increased emphasis on environmental control. We are setting up a 300-acre site factory in China for an API joint venture with Yung Shin Pharm and the third partner is, HueiXin, a local long-term supplier for Formosa," explained Dr. C. Y. Cheng, president of Formosa Laboratories.

Taiwan continues to strive for manufacturing excellence in IT, pharmaceuticals, and biotech. The country's advanced engineering experience coupled with world-class universities and research centers will surely be used to their full extent in the hopes of establishing Taiwan as a dominant global force. •

Kevin Liu

Director of PAP&C and Market Access
PFIZER TAIWAN

Can you give us a brief introduction to Pfizer's operations in Taiwan and outline the company's main area of focus in this country?

Pfizer Taiwan covers many disease areas including even rare diseases, which is one of the reasons why Pfizer has such a strong presence in this country. The company not only has a rich history of introducing innovative drugs to Taiwan, but also cooperates with the local experts to ensure that Taiwanese patients have access to the treatment that they need as early as possible. When introducing a new drug, Pfizer will work closely with Taiwanese investigators and bring their own ideas to our research and development (R&D) department, especially when addressing diseases that are more prevalent in Taiwan. Additionally, Pfizer has recently been working alongside the government in the field of vaccines, not only for treatment, but also for prevention.

What efforts is Pfizer currently making to combat the increasing threat of drug resistance?

Drug resistance is a very real and ever increasing problem, and Pfizer works with HCP and with the society in Taiwan to promote clinical practices that reduce drug resistance. One solution is to promote the virality of antibiotics. Pfizer's strengths lie in its broad range of antibiotics, and studies have shown that if hospitals, rather than using one type of antibiotic as treatment, use a number of drugs, there is a higher chance of overcoming any threat of drug resistance. Pfizer has several educational programs in place within the society to educate and promote this concept.

Pfizer is the only multi-national pharmaceutical company to own its own manufacturing plant in Taiwan. Why was this decision taken instead of utilizing Taiwan's contract manufacturing services?

This plant actually produces some of Pfizer's antibiotics and supplies not only Taiwan, but also other countries. The plant is also used for the manufacturing of consumer products and nutritional supplements and its efficiency is very high. Pfizer very much wants to be seen to have a tangible investment in Taiwan and having this site is in line with its policy of centralizing manufacturing operations.

It has been said that Taiwan wants to be seen as a regional hub for clinical trials. Is this an achievable goal and what strengths does Taiwan offer for companies wanting to develop drugs in the region?

An important strength of Taiwan is its tight regulations, especially with regards to the protection of intellectual property. This is why Taiwan tends to be the initial site for the introduction of a wave of new drugs. A strong infrastructure regulation coupled with a high quality of personnel involved, not only the investigators, but also the support teams of nurses, has meant that Taiwan ranks very highly as a choice for regional clinical trials. The high standard of medical centers will always ensure homogenous and reliable results.

There has been recent progress in mutually shared clinical trial data between China and Taiwan. Has Pfizer seen its operations in these two countries becoming more integrated?

Current barriers that exist between China and Taiwan and the differences in drug regulations and health care between the two countries has meant that Pfizer Taiwan is very much independent from Pfizer's operations in China in terms of drugs. There has been more in the way of alignment with Hong Kong and Singapore. China is still very much a stand-alone country in this aspect. The political environment has, in the past, made it very difficult to overcome these regulatory differences.

Pfizer has been in Taiwan for over half a century and has seen the birth of the country's own pharmaceutical industry. What does the future hold for this growing industry?

Taiwan has a very good research base, which is something that the country must exploit if it is to succeed as a global player. Taiwan must now seek to translate this into something that is commercially viable and move innovation and discovery forward into clinical development. Government support will be key in ensuring that these small local companies and ultimately the country are able to look beyond Taiwan's borders, which is something that is crucial for success. •

René Jensen

Vice President and General Manager
GLAXOSMITHKLINE (GSK) TAIWAN

GSK has been in Taiwan for over a decade. Can you give us a brief introduction to its role in this country?

GSK has been in Taiwan since 2001, and our work here is focused mainly on ensuring access to our medicines for appropriate patients by working closely with health care professionals (HCP) and government authorities. Furthermore, Taiwan is also an important country for GSK's clinical programs, as the country has high quality infrastructure and talent. GSK has invested heavily in important clinical research in Taiwan in close collaboration with HCPs and hospitals. This is part of our long-term commitment to partnering with key Taiwanese stakeholders on the basis of trust and mutual respect and helping to improve health care in Taiwan.

Since 2007, GSK has invested over NT$1 billion in drug research and has over 50 large-scale international clinical studies in Taiwan. Taiwan is represented in the majority of our studies in new drug development. GSK's portfolio spans multiple disease areas, but it is particularly strong in respiratory, HIV, vaccines, CNS, and urology, as well as in consumer health care.

Does GSK undertake any work in diseases that are less common?

GSK is committed to discovering new medicines and helping patients with rare diseases. In fact we have a dedicated Rare Diseases Unit, which was created in 2010 to help bring medical solutions to patients with serious unmet medical needs. We have recently introduced a number of new medicines in this area. For example, Benlysta (belimumab) is the first new treatment in 50 years for the treatment of systemic lupus erythematosus (SLE), commonly known as Lupus. We are one of the few companies researching treatments and vaccines for all three of the World Health Organization's (WHO) priority infectious diseases: malaria, tuberculosis and HIV. In the world's least developed countries, we are reinvesting 20% of our profits to improve health care infrastructure, which will contribute to our wider goal of improving access to health care for 20 million under-served people by 2020. GSK looks at where it can add value and make a difference to people's lives.

How does the government's reimbursement scheme affect multinationals such as GSK?

The government has taken many great initiatives over the last decade and created what is recognized as a good health care system. However, it does take significantly longer for new medicines to enter the market, and the approval rate is lower than in other countries. Access in Taiwan is slower due to the lengthy regulatory and reimbursement process. Then afterwards the listing into hospitals takes additional time. It can take up to two years to get regulatory approval from the Taiwan Food and Drug Administration (TFDA), pricing reimbursement from the National Health Insurance Administration (NHIA), and listing in hospitals, before new medicines become available for patients.

For example, GSK's quadrivalent influenza vaccine (QIV) Fluarix Tetra was launched in 2013 in Taiwan, and Taiwan was the first market in Asia Pacific to receive TFDA approval. However, two years later, the government has not funded QIV in its national influenza vaccination program, even though the WHO recommended it in 2012 as the world's future flu vaccine.

What strengths can Taiwan offer to the global pharmaceutical and biotechnology markets?

Firstly, research and development (R&D) is critical, both for Taiwan and the industry, and the level of quality and expertise in clinical trials is very high. It will be important for biotech companies to learn from the success of the country's hi-tech industry.

Taiwan is also an attractive R&D location for the Asia Pacific region, despite its relatively small market size. The government launched a plan in 2013 to attract R&D funding on top of its ongoing initiatives. R&D in Taiwan is fast, high quality and most of all, reliable. In addition to being a good research platform, Taiwan is also the perfect epidemiological environment for proof of concept or early-phase trials for products destined for the Chinese market.

How are we going to see GSK evolve over the next five years?

GSK has one of the most promising pipelines in the pharmaceutical industry and is looking to launch at least five new products in the next two years. We will achieve this through close partnerships with key stakeholders in government, academia, and industry not only in regards to our medicines, but also through working with the authorities to address key challenges in industry policies and the current healthcare system.

GSK has recently completed an agreement with Novartis, which will further strengthen its vaccines portfolio. Additionally GSK has taken on a number of initiatives to change the way that it promotes its products. From January 2015, the company no longer has a system in place whereby our medical representatives are incentivized by their own sales, but based on their technical knowledge and customer relations. By 2016 we will also change the way that we interact with HCPs by stopping payments to them for speaking about our products on our behalf. •

Roy Fan

CEO
STANDARD CHEM. & PHARM. CO.

Can you provide us with a brief introduction to Standard Chem. & Pharm. Co. and tell us about some of your recent achievements?

We started our company in 1967 with only NT$500,000 and have grown to a market cap of NT$6.8 billion today. Like other companies in Taiwan, we started in generics. Only in the last 10 years has biotech taken off. In addition to generics, we work with APIs, vertical integration, and are now carrying out our own studies in new drug discovery. We started to export to Southeast Asia some 20 years ago, and in the past six to seven years we have expanded to China, Japan and the United States.

Can you give us a general overview of your manufacturing facilities?

Right now we have two pharmaceutical plants in Taiwan, Plant 1 and Plant 2, including a dedicated cepha plant, as well as a patch-manufacturing site in China. We are capable of manufacturing of a variety of dosage forms including solid, semi-solid (syrup/cream/ointment), and sterile injectables (e.g. lyophilized dosage form). Last year, we produced a total of two billion tablets. Though our volume is high, generics are sold for far less than the originals. In Taiwan, the ratio between generics and originals is about eight to two, meaning 80% of the volume produced is generics, but this only accounts for about 20% of the market value.

After having your IPO in 1995, has it been easier to attract capital?

As a private company, the accounting, balance sheet, and income statements are not made public. However, as a public company with a strong track-record, people will be able to see that you are a stable company and ultimately that the profit is growing. When we carry out a stock floatation, we can attract more public funds or offer convertible bonds later on.

Biotech has been attracting a great deal of of investment, roughly $2.5 billion in 2013 and 2014. Could this be a bubble?

Similar to venture capital, there are always successes and failures. For venture capital, normally a 20% success rate is needed, which is similar to the success rate of new drugs. For Phase I there is a certain percentage failure, as there is for Phase II and Phase III. This investment is essential though, because despite not having any revenue, funding is still needed for the development process. New drug companies are a popular focus for the public at the moment and the market is seeing a strong flow of investment. A bubble could be said to be forming, but with some of these companies at late-stage clinical development and even license application, there is bound to be a huge return soon. The fate of the industry lies on these successes.

With eight subsidiaries, how does the parent company benefit from them in terms of research and development (R&D)?

Each subsidiary has its own function, though we are all involved in R&D. Two companies are API manufacturers, Syngen Biotech and Syn-Tech Chem & Pharm, which sell their products on their own, though we do have an element of vertical integration. The other companies range from running drug stores to importing baby powder milk. One company is solely involved in marketing over-the-counter drugs. Therefore, there is vertical integration from API to pharmaceuticals and finished pharmaceuticals are sold in drug stores.

Having established the Fan Dow Nan Foundation in 1995, can you tell us about Standard Chem's commitment to the community?

My father set up the foundation in memory of my grandfather. Our family used to be poor, so my father wanted to help children and give something back to the community. The foundation's sole purpose is to help the children with their education and their happiness. Mostly, this takes the form of scholarships that we offer from elementary school through college. Standard Chem gives 3% of profits to the foundation, which translates to about 10 million NT for scholarships each year. We do not ask that the children be academically excellent; as long as their teacher says that he or she deserves it, we will award them the scholarship. As for happiness, besides Ping-Pong tournaments, there is a graduation trip at the end of the year that some cannot afford.

Where can we expect to find Standard Chem in five years?

Our first goal is to have 50% of our revenue generated from overseas business. Secondly, we hope to have a new drug that will be in either in phase I or phase II. We hope to do much more Paragraph IV in the United States and have more of our products launched in Japan. We are currently carrying out R&D for Japanese companies, but would like to establish an office in the country. Manufacturing in Japan may be possible at some point, but today this is not something we see happening in the near-term. We will also be looking to China, a huge market in which we hope to see more of our products. We eventually want to see Standard Chem not just exporting generics, but also having drugs of its own. •

Renaat Janssen

CEO
LOTUS PHARMACEUTICAL CO.

Can you provide us with a brief introduction to Lotus and tell us about some of your recent developments?

Headquartered in Taiwan, Lotus is a research-based company focused on development of difficult-to-make generic pharmaceuticals. Our chairman and founder, Charles Lin, took an approach to differentiate ourselves and thus decided to invest heavily in a plant that would have two main areas of focus: a cytotoxic capability for oncology products and high-potency products. Not many local manufacturers have these capabilities, and now, with U.S. FDA, EMA, and Japan PMDA approval, we are in a better position to explore more market potentials and compete with bigger companies that cannot match our capabilities. Alvogen, an international pharmaceutical company with presence in more than 30 countries, has seen the growth momentum in Asia and decided to partner with Lotus by acquiring 63% of Lotus shares via private placement in August 2014. The combination of Alvogen's strong geographic coverage in the United States, Central and Eastern Europe, and Asia and Lotus' foothold in Taiwan and growing U.S. product pipeline is expected to generate significant opportunities to drive revenue growth and margin enhancement and create further value for both companies.

We focus on difficult-to-make generics in oncology, cardiology, nephrology and central nervous system disease and have a robust pipeline in oral oncology and high potency, soft gel drugs. We have strong research and development (R&D) and manufacturing capabilities, more than 100 strategically selected projects in development and registrations across Asia and the United States, and more than 250 products in the market.

How has Lotus been able to expand its manufacturing capabilities internationally?

Lotus' partnership with Alvogen will increase our scale, portfolio and geographic reach. Combined with Alvogen's October 2012 purchase of the South Korean company, Kunwha Pharmaceuticals, the partnership will significantly strengthen our operations in the Asia Pacific region. We then acquired another South Korean company, Dream Pharma, which has a manufacturing plant and an exceptional R&D team, which won Korea's New Drug Development Technical Award in 2014 and is very strong with modified drugs and fixed-dose combinations. These acquisitions brought Lotus additional revenue of about $180 million, which allows us to invest more and provides a solid platform for access to a big pharma market in Korea. •

Calvin Tsai & Dr. Chi-Tai Chang

CT: CEO
CTC: RA & CRO Division Director
ORIENT PHARMA

Orient Pharma (OP) was founded in 2008 as a subsidiary of Orient Euro Pharma (OEP). What is the relationship between the two companies?

Orient Euro Pharma (OEP) is the parent company and we are distinguished based on our roles, position and strength. OEP focuses on the marketing and commercialization of Pharmaceutical, nutrition and healthcare supplement and dermo-cosmetic products through subsidiaries across China, Hong Kong, Malaysia, Singapore and the Philippines. Orient Pharma (OP) focus on new drug development, clinical research and manufacturing with a pharmaceutical plant in Taiwan and has U.S. FDA GMP and Taiwan FDA PIC/s certificates. Overall, OEP Group is one of the few companies that can vertically integrate drug research and development, clinical trial, manufacturing and marketing.

What is primary strength of Orient Pharma?

Orient Pharma owns strong R&D and manufacture capabilities, including five technology platforms, including multi-stage controlled-release, trans-dermal patches, oral disintegrating tablets, sustained release, and microgranules. In December 2014, OP signed a licensing contract with Beijing Tide Pharmaceutical Co. Ltd for dementia patch technology.

Furthermore, OP is focusing on a 505 (b)(2) new drug R&D and clinical trials, which include new dosage form, formulation, indication, and combination. Currently, we are very excited about our new anti-attention deficit hyperactivity disorder drug, which is currently in phase III clinical trials. The other important drug is anti-sialorrhea for Parkinson's disease, which is in phase II clinical trials.

OP is also committed generic drug development and has won two generic licenses issued by U.S. FDA, which are Carisoprodol tablet USP 350 mg and Miglitol table 25, 50 and 100 mg.

What do you foresee over the next ten years for your two companies?

OEP Group's goal is to build up the capability and model of developing, manufacturing and marketing our own products in global market. We will continue to develop new drugs and expect to have concrete results in the next decade. Furthermore, OEP Group will further develop the Asian and U.S. market. Finally, our success is entirely due to our excellent team, so we will continue to hire talented people. •

Dr. C. Y. Cheng

President
FORMOSA LABORATORIES

Can you please give us an introduction and a brief history of Formosa Laboratories since its founding in 1995?

Formosa draws an advantage from its strong research base. We started in 1995 as a contract research laboratory and accumulated experience in GMP production over the years. Formosa also maintains a complete and comprehensive GMP track record, and has been inspected by all the major authorities. We have two lines of products, APIs and UV filters. We have recently become a major supplier of polymer APIs, including Colesevelam for lowering cholesterol and Sevelamer for lowering phosphate; both are resins in nature and require different equipment than other products. Formosa is currently expanding its existing facilities for high potency APIs. We are building on our earlier success with vitamin D derivatives and are looking to grow other areas of our business, such as custom synthesis. Some major clients include Sanofi and Novartis, but we have also worked with smaller, new drug development companies.

Can you give us an overview of your manufacturing facilities and your expansion plans?

We have a kilo laboratory on site for both regular and high potency APIs. The equipment for production is scaled up in roughly a ten-time scale. Formosa has plants for pilot scale production, with 600 to 1,000 liter reactors; the total capacity being from 20 metric tons (mt) to 30 mt. Our new API plant has a total capacity of 600 mt, with 6,000 to 8,000 liter reactors. Formosa can handle production of different APIs with varying quantity requirements and can work with a brand or new drug development company up to any commercial scale. We also have a product line in UV filters: an active ingredient for sun screen and some cosmetics. Over the last two years, this sector of our business has suffered with competition from China and India, and inclement weather in Europe. However, we are confident that this lull in sales is temporary, and our cost structure will maintain our competitive position. Our growth in API has nullified the affect of our drop in UV filter sales.

How much of your production is exported? What are your major export markets?

Historically, our UV filter sales have been bigger than API. In 2013, it was 60% UV filter and 40% API. There are higher margins on API sales, and, in 2014, API sales increased to over 60%. Our drug production is mainly exported; only 5% is consumed domestically. In 2014, 50% to 60% of production was for the United States, with 20% for Europe. Japan is an evolving market, and the remaining exports are for Latin America, Korea, Turkey and Eastern Europe.

Where would you like to see Formosa Laboratories in five years?

Formosa will still be growing its business, especially in China. The company's recent acquisitions of land adjacent to its current site will double the size of its facility. We will be bigger and arguably more vertically integrated, which will enable us to offer new drug development with formulation capabilities. •

Dr. Weichyun Wong & Michele Seah

WW: President
MS: Senior VP
SCI PHARMTECH, INC.

WW

You were established in 1987 and have since been primarily involved in APIs, intermediates and custom products. Can you tell us a little more about your role in research and development (R&D)?

Compared with India and China, Taiwan is not the cheapest destination in terms of production cost. We need to offer something other than cost effectiveness. The chemistry involved in the development of drugs is crucial and products' quality can make a huge difference. Therefore, our main goal is to be always developing our core technology and scaling up our capabilities. We are constantly seeking new ways to improve our technology as well as make it more environmentally friendly so that year after year we are able to meet every demand of our customers, especially in our role as a contract manufacturing organization (CMO) for both big pharmaceutical companies and start-ups.

What was behind your decision to liquidate your Nanjing plant in China?

The turnover rate for personnel in China is very high. Unlike in Taiwan, where people stay in the same job for a considerable amount of time, our staff in China was constantly moving on. We felt as if we were training people for our rival companies, and this was a drain on our resources. Another reason is that many of our customers were uncomfortable having their products developed in China, where intellectual property (IP) is not nearly as safe as it is in Taiwan.

What do you think are the primary strengths of Taiwan's pharmaceutical industry, specifically API?

Taiwan's API market is not that large on a global scale, as we have only around 15 active companies. However, the quality of all these companies is very high. They are all U.S. FDA-inspected and have strong records. Few other countries, though they may have a larger market, have as consistently high of standards as can be found in Taiwan. Previously, pharmaceutical companies from developed countries turned to India or China where products and services were cheaper, but after encountering difficulties they realized that cost is not the only factor and that quality must be first considered in the equation. Thus, focus has shifted to Taiwan. In the past ten years, the value of this market in Taiwan has more than doubled. Taiwan's image of high quality, coupled with its reputation for respecting IP, has been attracting more and more companies.

What are the plans for SCI Pharmtech over the next five years?

While keeping our current markets in Europe and the United States, we are now looking towards the so-called pharmerging markets, such as Southeast Asia and North Africa. We are doing more in the way of generics and believe that it is in these countries that our future in this field will be. Ultimately, our continuous goal is to keep up the daily practice of building and developing our core technology strength. •

Bobby Sheng

Chairman
BORA PHARMACEUTICALS

Can you tell us what inspired you to establish Bora Pharmaceuticals in 2007?

My family has been in pharmaceuticals for forty years and I would consider myself second generation to the business. Traditionally our business has been in the distribution and marketing, but around 2004 to 2005 profitability was hindered because of the NHI's squeeze on drug prices so we decided to expand the business up the supply chain, into manufacturing and research and development (R&D). Rather than try and develop a new chemical entity (NCE) from pre-clinical all the way to FDA approval, which is very high risk and requires hundreds of millions of dollars, we decided to focus on new formulations and indications for current molecules; a field that was not of much interest to the big pharmaceutical companies who had invested billions into new drugs. We also found a substantial talent pool of formulation scholars and engineers, which were being underutilized or spread out through different industries. This is where Bora came from and since then we have been growing our R&D arm.

For a company to cover the chain end to end is quite an undertaking. Why did you choose to adopt this model?

Biotech companies focused on R&D will tend to want to only take a drug to phase II. With no knowledge of the markets or experience in distribution they are happy to sell the drug on or license it out. However, at the end of the day they will only be able to receive a small percentage in royalties and would have spent a large amount of money in the process of developing the drug, while the larger pharmaceutical companies handling the end game get the bulk of the margins. Our core expertise comes from marketing and distribution and, as such, we're not afraid of the market, so when we expanded into R&D we adopted a model similar to the ones of North European companies such as Lundbeck. Right now you are seeing us at an inflection point where we are still undertaking a lot of legacy business (importing from global pharmaceutical companies and distributing in Taiwan) to support the growth of our R&D division.

We see that you recently bought a manufacturing plant in Tainan from the Japanese pharmaceutical company Eisai. What plans do you have for this facility?

Around the time Bora was established, the manufacturing quality in Taiwan was varied in quality and we also did not want to give away our technologies to contract manufacturers so we decided to buy a plant that Eisai were selling. This plant was one of first ten to be PIC/S certified and had lots of expansion possibilities. As part of the contract we also agreed to be a toll manufacturer for Eisai. Our Tainan factory currently manufactures our own Bora products, including many that came with our acquisition of one of Taiwan's most well known Generic drug company, Union Chemical and Pharmaceutical Co. in 2014, as well as many other multinational pharmaceutical companies. We export to over 15 countries, which, covers Southeast Asia, the Middle East, and Central America.

What needs to be done to ensure the growth of the bio-pharmaceutical industry in Taiwan?

At the moment you there is a great degree of separation between biotech and pharmaceutical, but I see this converging in the next five to ten years. Local companies will either need to scale their local legacy business, with consolidation or expansion, or venture into value chain of new drugs. Additionally, and I think crucially, companies need to export and get into other countries in order to expand this market, which currently is worth only a fraction of the global market. There is vast room for growth and with the Taiwanese Government banking the whole country on biotech I believe we will start to see more global exposure for Taiwanese companies.

What does the future hold for Bora Pharmaceuticals?

We are expanding fast and aggressively into global markets and we are looking for partners for both the local and export business. We are currently toll manufacturing and exporting to many markets already, within three to five years, you will start seeing our own Bora products in South East Asian countries and soon after the US, EU, and Japan markets. Our goal will then be to have our logo in every pharmacy and hospital around the world. •

Dr. Yung-Fa Chen

CEO
SCINOPHARM

Can you introduce us to ScinoPharm and its main developmenta; milestones?
ScinoPharm was established as an API exporter in Taiwan, initially with support from the Taiwanese government. Our first target market was regular markets including the United States and European countries. We enjoy a leading position in terms of U.S. drug master files volume of oncological APIs, among stand-alone API suppliers. Combining cost-effective resources and productivity of Asia along with extensive regulatory know-how, ScinoPharm is uniquely positioned to serve global pharmaceutical research and development (R&D) and manufacturing needs at any level and for any company in this sector.

How have you developed your product areas over time in reaction to market trends?
Today, we are still focused on APIs, with a specialty in high-potency and oncology injectables. Our top three products are oncology cytotoxic injectables. Seventeen years ago, there were very few suppliers in this high-potency area, but today we are seeing much more competition from Chinese and Indian companies, especially on price. We have adjusted our company strategy to target different areas, such as providing custom synthesis services to new drug discovery companies, and providing process development for NCEs. About 25% of our business comes from CRO/CMO accounts, while 75% comes from generic APIs.

What are the advantages of a Taiwanese CRO/CMO in the global marketplace?
Big pharma is more comfortable with Taiwanese suppliers because of our IP protection, language, and GMP standards. Since we received FDA approval in 2001, we have conducted more than 80 NCE CRAM projects, with 5 launched and 9 in phase III for
NDA filing in two to three years. We are the qualified Asian supplier to provide APIs to global market for multiple commercial NCEs.

What is the strategic role that your Changshu plant in China will play in your operations?
We established our presence in China via our Changshu plant, which is in compliance with U.S., EU and Chinese cGMP standards, and includes an R&D development center and a multipurpose API manufacturing plant. As we have both sites, one in China and one in Taiwan, we can leverage our generic API production chain by carrying out early steps in China and later steps in Taiwan for cost saving. Once our site in China gets FDA-approval, we can conduct more contract research and manufacturing projects there.

Will you also be targeting increased sales in the Chinese market by opening this plant?
The new site is part of ScinoPharm's long-term strategy to bolster its presence in China. Additional manufacturing and R&D facilities will complement our existing experience in selling quality APIs in regulated markets. The Changshu plant serves as a launching pad for the rapidly expanding Chinese market as well as a backup site.

Can you provide us with more detail on ScinoPharm's "Double A" plan to expand your services?
ScinoPharm is migrating into a full-scope specialty pharma based on our core competency of strong R&D and cGMP manufacturing in hard-to-make APIs. We are further developing several APIs in our product pipeline into generic formulations. Our "Double-A" strategy of offering APIs and ANDAs is focused on high-potency and oncology as an extension to our current portfolio. In the past, when we offered cytotoxic oncology to the market, many customers did not have in-house capabilities for formulation and had to work with CMO third parties. Customers prefer to have a one-stop shop provided by us, so we have invested into a new segment for in-house formulation. This gives us an advantage for new markets like Japan and China.

What role does ScinoPharm play within the region as an API provider?
The pharmaceutical industry in the region is very fragmented. Japan and China have their own regulations, so in entering these markets we have spent a lot of effort studying the regulation in these countries. Now we have APIs approved by Japan, and in China we are looking to get our first product approved this year.

What impact will Taiwan's membership in PIC/S have on your business?
It is a great milestone for Taiwan to become part of the PIC/S countries. It provides the advantage for us to export our product to Europe, but not to the United States or Japan, because at this time they are not yet members. The EU put a lot of effort into PIC/S, as they want to control the quality of API or drug products. Once the Taiwanese pharma companies are certified by PIC/S, then we have more business opportunities for export. For ScinoPharm, since we already have US and EU approval, it will not significantly change our business.

What are the main strengths of Taiwan's pharmaceutical industry?
We have a strong talent pool and many returnees from the U.S. pharmaceutical industry. The government has spent a lot of effort in putting together the necessary infrastructure for growth. While no group can consolidate the resources for help on the island, there is a strong base of assistance for companies and a strong future for the industry. •

Booming Biotech: Taiwan's R&D Advancements

"In general, most chemical drugs have certain side effects that many patients cannot tolerate. Botanical drugs are becoming more beneficial, as they tend to have fewer side effects. This could improve the quality of life especially for chronic disease patients. Botanical drugs with efficacy and excellent safety will become important to the aging Taiwanese population and other aging societies worldwide."

- Fu Feng Kuo, CEO,
Health Ever Bio-Tech Co., Ltd.

Image: Formosa Laboratories

Biotechnology and Niche Drugs

Mixing the New with the Old and the Old with the New

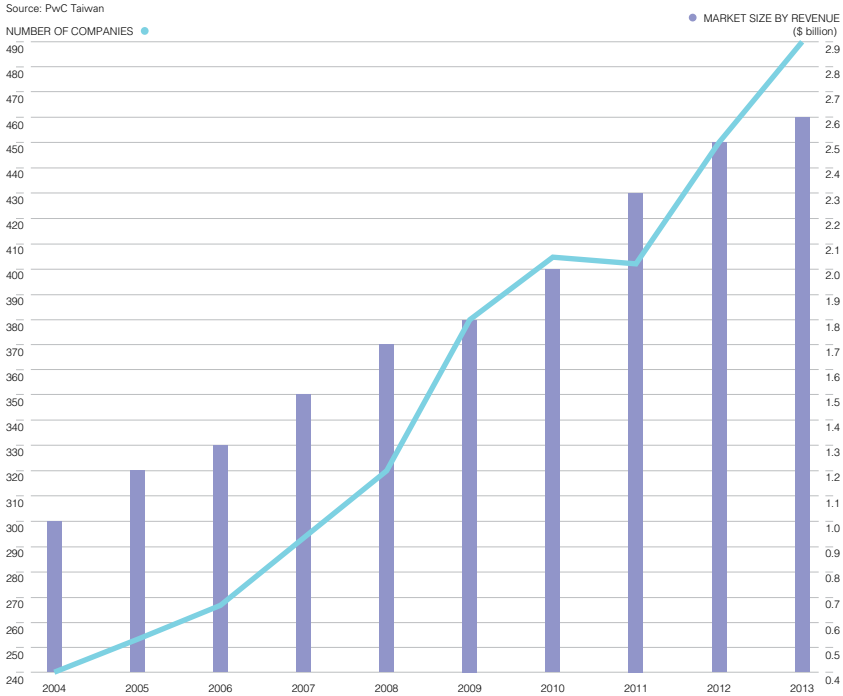
In Taiwan, biotechnology is a new term that can be generally defined as technology based on biology. Globally, biotechnology is used to harness cellular and bimolecular processes, which is providing breakthrough products and technologies to combat debilitating and rare diseases. Moreover, it has become an important sector for scientific research, technology and industrial development in most developed countries, including Taiwan, where it has been regarded as one of the most important industries since 1995.

With clusters such as the Hsinchu Biomedical Science Park and the Nangkang Biotechnology Plaza in Taipei, Taiwan is seeing the birth of a plethora of small biotech companies. These companies are seeking to develop new and innovative products that can address medical needs, which have often been overlooked by large multinational companies. Taiwan can already claim the title of leader in biotech in the Asia-Pacific region and has many of the elements for a winning strategy.

Taiwan's reputation historically has been built on its strong high-tech industries, and the country has long been regarded as a leader in the development of information technology. This ability is now being leveraged to achieve the same success in biotechnology. "The quality of available staff in this country, especially in the area of chemical synthesis, is something to be envied by other nations," says Dr. Hsu, founder and CEO of Taigen. According to Dr. Hsu of TaiGen, a Taiwanese company that is set to bring its first successful product to market very soon, Taiwan owes its success to the quality of its human talent. The biotechnology indus-

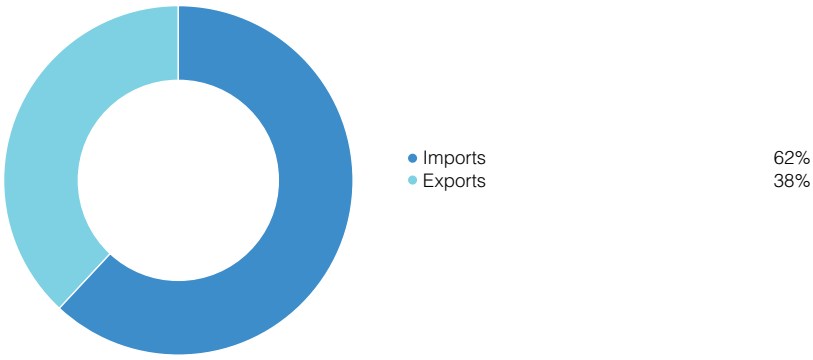
TAIWAN'S BIOTECHNOLOGY INDUSTRY (2004-2013)

Source: PwC Taiwan



Import-Export Ratio of Taiwan's Biotechnology Industry (2013)

Source: PwC Taiwan



MARKET CAPITALIZATION OF TAIWAN'S BIOTECHNOLOGY INDUSTRY (2007-2013)

Source: PwC Taiwan

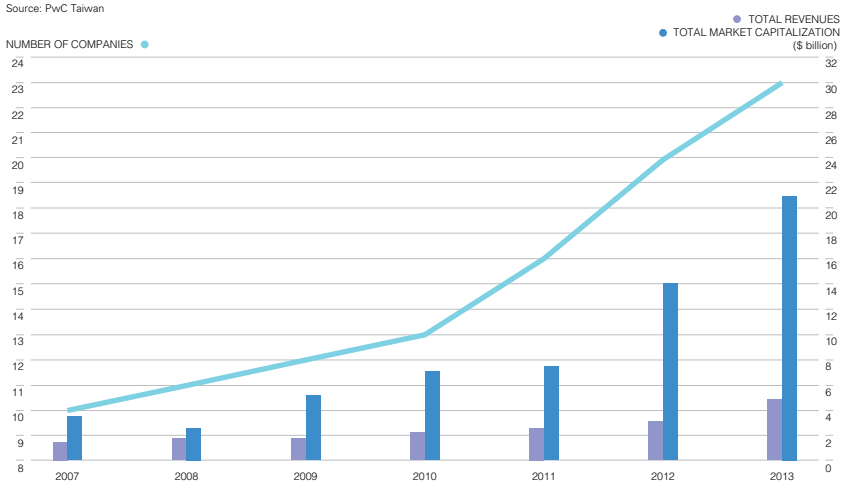


Image: Health Ever Bio-Tech Co., Ltd.

> The quality of available staff in this country, especially in the area of chemical synthesis, is something to be envied by other nations.
>
> - Dr. Hsu, Founder and CEO, TaiGen Biotechnology

try is knowledge-intensive and relies on professional experts to operate the industry value chain smoothly and drive its sustainable development.

The government is also making huge investments that will support this blossoming industry. According to Bobby Sheng, CEO of Bora Pharmaceuticals: "The Taiwanese government is banking the whole country on biotech." The National Development fund, Taiwan's government-backed and managed investment fund, has invested NT$12.4 billion in pharmaceuticals and biotech through the end of 2013, including an additional NT$7.7 billion into 24 biotech-focused, venture capital firms. "Our government will offer support for up to 50% of the cost of a program in non-diluted grants and without any ownership of the company," says George Yeh, CEO of Taiwan Liposome Company (TLC). "Unlike government grants in other countries, in Taiwan companies are supported all the way to clinical trials."

Taiwan's government also has several initiatives and organizations to promote growth in biotechnology. The Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO) was established in 1996 with a view to coordinating relevant ministries in establishing and improving R&D.

In addition to government funding, the private sector has also directly invested in the sector, with NT$142 billion invested in 2013 alone. Large-scale investments in biotechnology, including productivity expansion, high value-added product investment, and innovation upgrading, are a new trend in Taiwan. This reflects how discoveries, after going through years of development, are beginning to reach the commercialization stage. This requires vast amounts of investment with no return. "Over the last few years, there has been a lot of money pouring into

> The Taiwanese government is banking the whole country on biotech.
>
> - Bobby Sheng, CEO, Bora Pharmaceuticals

Image: Sheng Chang Pharmaceutical

> Our government will offer support for up to 50% of the cost of a program in non-diluted grants and without any ownership of the company. Unlike government grants in other countries, in Taiwan companies are supported all the way to clinical trials.
>
> - George Yeh, CEO,
> Taiwan Liposome Company (TLC)

biotechnology in Taiwan, and it is over the next two to three years that results are going to be needed. If just a few companies are successful, you will see a viable, sustainable industry emerging," says Yeh of TLC.

Due to the government's strong commitment to biotechnology and high levels of global investment supporting the industry's development, the private sector has quickly trained its focus on biotechnology. Taiwan's biotech industry increased from 1,505 firms and 69,470 employees in 2012 to 1,601 firms and 71,580 employees in 2013.

Taiwan is also strongly focused on its hidden niches. These include drugs for rare diseases that are not economically viable to be developed by mainstream pharmaceutical firms and are, therefore, being developed by smaller players with the support of government grants and subsidies. The idea of an orphan drug is a relatively new concept. A drug that is intended to treat diseases so rare that sponsors are reluctant to develop it under usual market conditions is not something one would expect to be a strategic business model to pursue. However, with recent economic pressures and heavy competition from generic drugs, large pharmaceutical companies are deciding to shift their focus to these so-called "niche busters," in order to help reduce the impact of revenue loss caused by patent expiries of block-buster drugs.

The rare disease and orphan drug act was implemented in Taiwan in 2000 and by the end of April 2006 the government had classified 159 diseases to be under the rare disease category. Most drugs aimed at the treatment of these diseases have been through the Taiwan Food and Drug Administration (TFDA) approval process and are imported, and as such must have a local partner for distribution. One company offering such services is Giddi Pharma. "My father started this company back in 1995 more as a moral crusade to help patients with rare diseases and we have increased access to drugs that were not commonly available," said Kelly Lin, executive vice president of Giddi Pharma. "At the time, there were no other companies that were interested in putting in the necessary time and effort to supply these orphan drugs as there were a very limited number of patients and the process was too complicated for such a niche market," explained Lin.

As the importance of the research and development (R&D) side of orphan drugs increases, Taiwan will expect to see some of its own biotech companies follow the example of big pharma and branch into these more niche fields.

To take a bird's eye view, the pieces are very much on the board, and it is now a simple case of putting them together. Once this happens, Taiwan's potential is vast. In the meantime, an important next step is for companies to start being more outward looking. There is a concern that when the time comes, many of these biotech and R&D-orientated companies will not have the expertise or knowledge to take a product from the development stage to market. Therefore, Taiwan must seek ways to ensure that inexperienced companies are able to access the partnerships that they will need to market their products, along with promoting its biotechnology industry globally. •

Dr. Karen Wen

General Manager
MYCENAX BIOTECH, INC.

Can you give us a general introduction to Mycenax and tell us about your recent developments?

The chemistry, manufacturing and control (CMC) of biologics is our core. We use CMC to establish an in-house pipeline, creating the biosimilars first and providing manufacturing services thereafter. The CMC service that we provide is up to 2000 L scale process development and cGMP production for mammalian origin and up to a 50 L process development and cGMP production for E.coli. For our biosimilar pipelines, we cooperate with regional partners because of our highly similar CMC, low cost, and good results for Phase I data. For example, our TuNEX, an etanercept-biosimilar, is collaborated with TSH, a strong marketing and sales company especially in chronic disease in Taiwan. This company focuses on cardiovascular and longtime-use drugs, so autoimmune is in its category. Through our co-development, this project is now in Phase III and will go for a Biologics License Application (BLA) in these two years. TSH gets the marketing and sales rights in Taiwan. We will provide the finished drug and also conduct co-promotion and co-marketing to TSH.

Can you give an overview of your manufacturing facilities and technology?

As mentioned above, our facility offers up to 2000 L scale for mammalian origin and up to 50 L scale for E.coli. The facility applies 100% disposable technology and is a pioneer in Asia and in the world. From 2004, the facility was built with 100% disposable technology line. A new production line was accomplished in 2014, and disposable technology is applied as well. At the time, many people did not understand this kind of system, but now it is popular. For the technology, we are familiar with fed-batch, perfusion and high cell density cultivation and now work on continuous processing. Speed and low cost are our goals; therefore, we use platform technology for monoclonal antibody, peptide product, and DNA product in both the manufacturing and analytical phases.

Despite governmental support for biotech, what else could be done to help this industry?

The government has already helped significantly with funding, but a more friendly and reasonable authority is also important. For the biopharmaceutical industry, it is still difficult to get a Taiwanese approval before an approval from other major countries. The industry is still young and inexperienced, and we have limited reviewers. The barrier to entry is high.

Is there any indication that the market could be a bubble?

Biotech is not like IT, where you can see the result within three years, as many products are launched and there are short product lifecycles. The development stage for biopharmaceutical industry is long, and authority's approval is the critical factor. Everybody is working hard, but we need to better educate investors. There was a bubble here in 2000 in the biotech industry, and the remaining companies are all pharmaceutical companies.

How does Taiwan's biotech sector attract investment from foreign companies?

In Taiwan, the people are highly educated, quality-oriented, honest, and full of integrity. Moreover, labor and infrastructure are low in cost compared to other places in Asia. More than 90% of our regulations are translated directly from U.S. regulations. People would like to use Taiwan as a gateway to enter China, but it is not there yet.

In five years, where can we expect to find Mycenax?

In five years, TuNEX will be launched as well as its second-generation version. LuciNEX, another biosimilar, is in Phase III with collaborator participation. For the CDMO part, we want to maintain revenues, our clients, and explore new drug areas. •

Dr. Ming-Chu Hsu

Chairman and CEO
TAIGEN BIOTECHNOLOGY

What inspired you to found TaiGen in 2001?

Having spent a lot of my early life in the United States both in academia and industry, I was invited back to Taiwan in 1998 to organize a division called the Biotechnology and Pharmaceutical Research Division in the National Health Research Institutes. Soon after this division was founded, the government started a program called the National Research Program for Biopharmaceuticals, for which they asked me to be the program leader. Through collaborations with academia and the public and private sectors, I realized that the government was sincere about pushing biotechnology forward and, having witnessed the country's strength in this field, I started TaiGen.

As a broad-spectrum antibiotic, what is giving your product, Nemonoxacin, a competitive advantage over similar existing products?

TaiGen's business model has two prongs. The first is in-house research and development (R&D), developing a product from drug discovery. The second is in-licensing early stage products and developing them to the proof-of-concept stage, with a view to marketing them globally. We did this with Nemonoxacin, which we in-licensed from P&G in 2005 when the product was in Phase Ia trials in the United States. Through TaiGen's development, the drug has been structurally designed and strengthened to be quite potent against resistant bacteria. In terms of activity profile, it is different from any other similar class of drugs and has a unique structure. The drug has been approved for marketing in Taiwan, and we are in the process of applying for reimbursement price from the National Health Insurance Administration. We are also fully confident that the product will soon receive drug and manufacturing licenses in China.

What efforts is TaiGen making to address different areas of the disease spectrum and what influences these choices?

The criteria for selecting which diseases to address were mainly based on a few considerations. The first is prevalence. The medical needs of developing countries are different than those of developed countries, and multi-national companies have tended to ignore such needs. Since I came to Taiwan, I have felt a moral obligation to conduct R&D in diseases that are prevalent in Asia. The second consideration is risk management. On average, only eight percent of exploratory programs for oncology will make it to the development stage and out of that eight percent only one in eight will succeed. This is because we still do not fully understand the nature of cancer. TaiGen cannot afford to have our first few drugs fail, so we choose areas with a higher probability of success and market potential, such as anti-viral and anti-bacterial drugs.

You have a subsidiary in China and have filed several INDs there, which is lengthy and difficult process. What advice would you have for companies wanting to follow suit?

Ultimately, there is no shortcut. Any company that wants to bring a new drug into China must be patient and persistent. Our product, Nemonoxacin, has gone through the approval process and everyone has been asking us what our secret was. To a certain extent, it helped being Taiwanese, especially since the Economic Cooperation Framework Agreement (ECFA) was established in 2011. However, there is still very little knowledge among Taiwanese companies about the new drug application and approval process in China. We began a clinical trial program in China for Nemonoxacin in 2005 and have since gained the trust of CFDA. For any company wanting to follow suit, it must display credibility to gain the trust of the agency.

You have recently submitted your application for reimbursement for Taigexyn. Is this system of drug reimbursement fair or will it inhibit the growth of Taiwan's pharmaceutical industry?

This system has been in place since the NHI was founded 20 years ago and is primarily intended to support the huge costs of universal healthcare. It is a difficult system and many say it could be managed better. However, the Taiwanese government is taking measures to ensure that drugs and original compounds that are developed in Taiwan by local companies are given special consideration when applying for reimbursement. China has recently announced that it will be setting a totally new pricing policy. At present there are multi-national companies selling drugs at around ten times the price of a generic counterpart. The Chinese government claims that this is unfair and that the price should be the same for the same active chemical ingredient.

Taiwan is known globally for its innovation. What other strengths can the country offer?

Early on I identified several advantages in Taiwan, and TaiGen's strategy has always been to utilize these regional resources fully. The most important thing in this industry is people, and certainly TaiGen's biggest asset is its personnel. The quality of available staff in this country, especially in the area of chemical synthesis, is something to be envied by other nations. This is the primary strength that I witnessed before starting TaiGen and is still very much the case today. •

George Yeh

President
TAIWAN LIPOSOME COMPANY (TLC)

Can you give us a brief history of TLC and outline what the company is aiming to achieve?

Dr. Keelung Hong founded TLC in 1997 with a view to bringing back to Taiwan the work and expertise in the field of liposomes that he had collected from the United States. Before I joined in 2002, the company was essentially in a virtual incubation period transferring and utilizing Dr. Hong's technology in developing Lipo-Dox, TLC's first product that was included in the Taiwan National Health Insurance Program in 2002. Since then I have been working to commercialize this technology to create a tangible business and recruiting a solid foundation of scientists. Our main aim has been to reformulate existing drugs that are already off patent with a view to reducing the toxicity, increasing the efficacy and broadening indications. Having first started in the field of oncology, we are now looking to expand into different diseases. Our specialization in lipid formulations has meant that companies wanting to address a gap in the market often approach us looking to reformulate a drug to make it more commercially viable (for example, reducing the frequency of administration for a patient). We form a mutually beneficial partnership with these pharmaceutical companies as they are strong in distribution and market intelligence, while we are strong in Research and Development. We now have ten products in our pipeline and are successfully moving forward with all of these and looking to partner with global pharmaceutical companies to launch these products onto the commercialization stage. Thus far, we have partnered with major generic players such as Teva and Sandoz, as well as giants in Japan, Taiwan and Korea.

As a company looking at going into phase three trials in China, what challenges are presented to a company looking to develop a drug across the strait?

We currently have a product called Lipotecan, which was granted Orphan Drug Designation by the U.S. FDA and EMA, conducted Phase I trial in both Taiwan and the United States, and is now in phase two trials in Taiwan and China. Since this drug addresses liver cancer, and China is the largest liver cancer market in the world, it'll thus be our main market for this particular drug. Interestingly this is the first case of China and Taiwan pushing clinical development together. The problem faced by companies from different countries is that there is a vast difference between how the food and drug agencies in China and the United States review a package. The U.S. FDA, an agency used to dealing with new drugs, has the competency and expertise to adjust safety constraints based on pre-clinical (animal testing) data. In China, where the industry is much more generics-driven, they tend to place more emphasis on the safety and CMC data, which are generally not as robust at the IND stage for new chemical entitites (NCEs) as they are for generics. This is where a lot of companies get bogged down.

You have received substantial grants from the Taiwanese government. To what extent is the government supporting the biotech industry?

Our government will offer support for up to 50% of the cost of a program in non-diluted grants and without any ownership of the company. Unlike government grants in other countries, in Taiwan companies are supported all the way to clinical trials. These grants are given out in installments of increasing sizes depending on the company's success. Currently, TLC has a 100% success record, which makes it easier to secure these grants. This system reflects the strong government support for the industry and encourages companies to perform.

How much interest is there in investing in Taiwan's biotechnology and what does the future hold?

The industry is now large enough for companies to be able to raise substantial amounts of capital. A year following our IPO, TLC was able raise a secondary offer of $100 million, the largest in Taiwanese biotech to date. There are two reasons why it is attracting so much capital. First, up until now, Taiwan has been heavily focused on IT, but as that industry is starting to plateau, investors are looking elsewhere. Slowly the focus is shifting towards biotech. Second, more and more companies are securing successful partnerships with international players to validate their products, thus attracting foreign interest. Over the last few years there has been a lot of money pouring into biotechnology in Taiwan and it is over the next two to three years that results are going to be needed. If a few companies can be successful, a viable, sustainable industry will emerge.

What is TLC's strategy looking forward?

Our goal has not changed. We want to be the strongest in the field of lipid formulations not only in the diseases that we currently treat, but across the whole spectrum. We also want to systemize both our selection and manufacturing processes so that we are able to push at least one to two TFDA and U.S. FDA IND approved drugs every year. This is what we hope to achieve over the next ten years. •

Dr. James N. Chang

President and CEO
TAIMED BIOLOGICS

Can you please give us an introduction and a brief history of TaiMed since its founding in 2007?

The Taiwanese Congress passed a law that encouraged investment in the biotech industry here in Taiwan. TaiMed began as a group of prominent Chinese-American scientists who wanted to help Taiwan expand its biotech industry. They decided to license a high-profile project that is proven with Phase II data and are looking for U.S. approval. The Taiwanese government provided 40% of the funding, while the remainder came from other industry players. The project was called TMB-355 (Ibalizumab), a monoclonal antibody for the treatment of HIV/AIDS. The Phase IIA study was already complete and they were looking to do a large scale Phase III study to get approval in the United States and get the product to the market within three years. However, shortly after the in-licensing, the U.S. FDA (FDA) followed World Health Organization's lead and adopted a new AIDS treatment guideline, which slowed down the development and approval process for TMB-355. In 2008, the company had to look for new investors. The original concept of getting a product on the market quickly to help Taiwan's visibility without regard for profit had to be shelved. For the last few years, our new investors were, in fact, interested in profit and we had to rethink our strategy. We are now trying to get our drugs approved economically and at the lowest cost possible.

Can you tell us more about your AIDS research and Ibalizumab in particular?

As a lot of AIDS patients are now resistant to certain drugs, new drugs are always needed, especially for those who are resistant to multiple AIDS drugs (MDR). We are developing Ibalizumab initially to help those MDR patients. FDA recognizes the importance of our program and granted ibalizuamb IV the breakthrough designation. The FDA recently established a new "breakthrough" status to help speed up the drug approval process and has been more engaged once this status was granted. Following our last meeting with the FDA, we feel that we will be able to start the Biologics License Application by the end of 2015 and launch the product next year. Ibalizumab is a monoclonal antibody drug that attaches itself to the CD4 receptors on T cells. T cells are the primary target of HIV. Our drug binds to the primary receptor on the T cell so the virus cannot attach to its intended target. This is a protein drug that needs to be injected subcutaneously, intramuscularly or intravenously (IV) and cannot be taken orally. There have been about 30 HIV drugs approved by the FDA in the last 25 years. There are now about four or five classes of AIDS drugs and our drug would be the first in a new class. We also have two more projects in earlier stages. Phase I can be done in Taiwan, but it is better to move the next phases to the United States as it makes it easier to get FDA approval.

Can you tell us about your collaboration with WuXi PharmaTech and your engagement with other Chinese companies?

First of all, WuXi hired a few key employees who once worked for Tanox and Genentech and were directly involved in Ibalizumab manufacturing. This was a major consideration for us when we selected WuXi as our manufacturing partner. In addition, our Ibalizumab project is in advanced stages and we are collaborating with WuXi as they have much bigger facilities and, to be cost-effective, we currently need our drug to be manufactured at a scale of at least 2,000 liters for our Phase III trial and upcoming commercialization. Their facilities can handle up to 2,000 liters because these reactors are disposable and made of plastic. We teamed up with WuXi because three years ago, Taiwan did not have this capability.

Taiwan has made significant strides in the last couple years and has promise for the future. However, as a profit oriented company, we cannot wait for local companies to build up this capacity. We have to work with the ones that are ready when we are. We are currently working with local Taiwanese manufactures for our early stage projects. Even though there is a concern over quality when working with Chinese companies, WuXi is different as they are by far the largest company of its kind in China and cater to Big Pharma companies worldwide. You have to be highly selective when it comes to biotech manufacturing in China. The ECFA free trade agreement signed between Taiwan and China covers everything, but few government initiatives have been undertaken in the pharmaceutical industry.

What are the main strengths of Taiwan's biotech industry that would encourage foreign companies to invest here?

The main thing that investors look for is what products you have in development, in other words, your pipeline. This represents about 80% of a company's strength. The other 20% would be represented by good management. The government's involvement such as currency restrictions and tax policies also plays a role, but because this is an industry that they are supporting, outside investors find it encouraging. •

Keya Chiang & Kelly Lin

KC

KC: Business Operation Director
KL: Executive Vice President
GIDDI PHARMA CO., LTD.

Giddi Pharma was established in 1995 to supply orphan drugs to patients with rare diseases. Why do you get into this niche area of the pharmaceutical industry?

My father started this company back in 1995 more as a moral crusade to increase the access of patients with rare diseases to drugs that were not commonly available. At the time, no other company was investing the time and effort to supply these drugs, as there were a limited number of patients and the process was complicated.

Can you talk to us about the importance of your partnership with Genzyme?

In 1998, we secured a partnership with Genzyme, which is one of the largest manufacturers in the world for orphan drugs, and helped us expand our operations. We have recently terminated this partnership on good terms. Our current major partner is BioMarin, which is another major orphan drug manufacturer. We have been partners for ten years and were their first partner in the APAC region.

Can you give us a breakdown of the main areas in which you work?

In the beginning, we focused primarily on orphan drugs, but over the years we have taken on various other areas such as transplantation medication, hematology and oncology. Orphan drugs still account for about 70% of our sales revenue.

You recently opened up a branch office in South Korea. What was the motivation behind this decision?

Australia, Japan, Taiwan and South Korea are the only four countries in the APAC region that support orphan drugs and have a national health service to reimburse their cost, which can be quite high. Japan can be quite difficult to enter, while Australia is more attractive to American and European companies. South Korea was the most suitable, not least because we had an experienced country manager available there.

What are your views on Taiwan's Orphan Drug Act that was passed in 2000?

Taiwan's Orphan Drug Act considers fewer conditions as rare diseases and would qualify for payment reimbursement. In the United States, any condition that has less than 200,000 patients is considered a rare disease. Still, the act has allowed for some treatments to be fast-tracked through the regulatory system. •

Dr. Joseph Chen

President
EXCELSIOR BIOPHARMA

Can you please give us a brief introduction to Excelsior?

Excelsior Biopharma Inc., a Taiwan-based pharmaceutical company, was founded in 1986. When the government implemented national health insurance in 1995, the market expanded, and the government promoted the biotech industry, alongside information technology (IT). Taiwan's Industry Technology Research Institute (ITRI) was assigned to help the biotech and pharmaceutical industries, and there is now one incubation center for IT and one for biotech and pharmaceuticals. In 1996, Excelsior Biopharma established a research and development (R&D) Lab in ITRI and started to develop new drugs. Our areas of focus are rare diseases, antidotes for poison, specific anti-cancer drugs, and human vaccines. We now have six product lines. In 2014, we built a PIC/S plant in the Hsinchu Biomedical Science Park to initiate local production, so we can supply other Asian countries with our product. We have several key investors and hope to IPO in the Taiwan Stock Market by the end of this year.

What are your major product lines?

We have six product lines: prescription drugs or general pharmaceuticals; orphan drugs for rare disorders; antidotes for poisons; anti-cancer drugs for specific cancers; monoclonal antibodies for specific infectious diseases and high risk pregnancy; and finally, over-the-counter products, such as oral care, Omega-3s, probiotics, and activated charcoal. Orphan drugs account for 70% of revenue, but general pharmaceuticals make up the majority of volume. General pharmaceuticals account for 20% of revenue, anti-cancer drugs 5%, and the others a small percentage.

Do you receive any support from the government in the form of funding or grants?

Fifteen years ago, there was no policy or funding supporting us, and rather stringent regulations. Every country insisted that if you wanted to launch a new product, you had to develop it from preclinical trials onward before you could receive the license to sell to the market. With so few patients, this was impossible, but Taiwan passed the Rare Disease Prevention Act in 2000, which allowed us to import orphan drugs without a license and a clinical trial. We could then provide these drugs under a special approval by the Taiwan Food and Drug Administration (TFDA). However, in the approval letter, we accept all responsibility should there be any adverse effects or other negative consequences. •

Dr. Liu Chung-Cheng

President
ADIMMUNE CORP.

Can you please give us a brief introduction to Adimmune?

Adimmune was founded in 1965 in the northern part of Taiwan. It was initially founded by a group of people familiar with the needs of the Centers for Disease Control and Prevention (CDC) of the central government; it was a mutually-dependent relationship but difficult to become a growing business. After the government began promoting the good manufacturing practices (GMP) manufacturing system, the company moved to the current location, acquired the land from an existing bio-chemical company, set up the GMP facility and systems, and began producing vaccine products. In the beginning, the company would import API or finished products from foreign countries like Japan and provide the needs for the CDC but gradually began building up capability to manufacture different needed vaccines. When the SARS epidemic occurred, the government realized that it was important to have its own vaccines production facility and established partnerships with foreign companies like GSK or Baxter, hoping that they would contribute some technology and capital. However, this never happened. Adimmune made a proposal and lined up technology collaborators to build such a facility to produce seasonal flu vaccine. During the H1N1 pandemic scare in 2009, Adimmune turned its entire efforts to meet the challenge to fulfill government demand for over 15 million doses of H1N1 vaccines. Such a successful experience also helped Adimmune obtain the 50% flu market share in Taiwan and provide enough antigens for a few million doses of flu vaccine to our partner in Europe. Our facility received EMA certification in 2010 and currently is the only EMA certified one in Asia. In 2012, Adimmune's stock had a successful IPO in Taiwan's stock exchange.

In terms of international partnerships, can you discuss last year's partnership with Valneva to work on the encephalitis vaccine?

We entered this partnership because of changing technological standards expected to be demanded by CDC. We are currently making the Japanese encephalitis vaccine using live animal produced virus. In this method, the virus is incubated in a live mouse brain. The animal is used to propagate the virus then the virus is isolated and chemically deactivated to make a vaccine. As an effort to reduce the use of live animals, the Taiwanese government may start purchasing JEV vaccine produced in tissue culture cells starting 2017. We do not have our own cell-based vaccine, so we needed to look for an alternative before coming up with our own in the near future.

Looking at this year's avian flu outbreak, how do you work with the government in times of pandemic to ensure the population's safety?

I assume you are talking about H7N9 virus. We actually started pouring our own resource into making H7N9 vaccine the first moment that we heard of its outbreak in China almost two years ago. We finished the phase II trial recently and are getting ready for the phase III trial in humans of our H7N9 vaccine. Budgetary issues prevented the government from following through with what they intended to do initially; we had to provide our own resource to make it happen quickly.

There have been many government initiatives to drive forward research and development (R&D) in biotech fields like oncology and pharmaceuticals. Have you seen the same focus in the field of vaccines?

Not as much as I would like to see. If you visit government sponsor lab like National Health Research Institute (NHRI), the research groups are conducting research mostly based on researchers' scientific interest instead of urgently needed vaccine products. It is time for people to understand the need for R&D in the field of vaccines as we all agree that emerging infectious disease is becoming a larger problem. Few were paying attention to Ebola research, but the disease's spread made people nervous. Vaccines are different from drugs. Drugs are normally for sick people, so as long as there are not many side effects, the regulators are sometimes not so concerned. However, vaccines are given to healthy people, so safety is paramount. This lack of emphasis on vaccine R&D is shortsighted; experts have predicted that in 10 years or 20 years from now, the emerging diseases will be important and preventative medicine is the trend for the future.

Where do you hope to see Adimmune in five years?

Firstly, we will be in the black. We are in the red currently because of the huge capacity that we built earlier, which we have to write-off as loss. To maintain a GMP system means to maintain the size of our trained workforce, even though it is larger than needed for the time being so we can continue to explore opportunities outside Taiwan. We aim to broaden Adimmune, but we must go about making choices carefully. When working with vaccines, you are making infectious material. For this reason, regulation requirements from the FDA and other regulatory bodies have very stringent requirement in separation. This issue will take time to work through. Currently, the more pressing matter is how to make use of the excess capacity and capabilities that we have. •

Eddy Hsieh & Dr. Ellson Chen

EH: CEO
EC: Chairman
VITA GENOMICS, INC.

EH

Dr. Chen, one of the most fascinating areas you work on is in the area of pharmacogenomics or personalized medicine, where you match various treatments to a patient's genetic profile to identify the most suitable choice of therapy. Can you talk to us about this promising tool that will greatly increase the efficiency of treatment?
There had been a lot of research into the idea of personalized medicine and in 2000 I began thinking about how I could use this research to benefit society. Most U.S. FDA-approved drugs are effective in 60% to 70% of patients, with 20% to 30% having no response to the treatment. However what is most worrying though, is that about 5% to 10% are negatively affected. In the past there was no way of knowing which people would react positively to such drugs, but now with the advanced technology of pharmacogenomics, we can predict what treatments will be the most effective based on the patient's DNA. This technology is now quite prevalent for cancer treatments and is moving into a number of new areas including psychiatric treatment. This is an important area for us as 1% of the world's population suffers from schizophrenia and 10% from depression.

What is a particularly good case study of a treatment that has been particularly successful when combined with pharmacogenomics?
One very good example is a drug that was developed by AstraZeneca called Iressa that we were also involved with. The drug was developed for patients with advanced or metastatic epidermal growth factor receptor mutation positive (EGFRm) non small cell ling cancer (NSCLC). The drug had limited success in Europe as only 10% to 15% of Europeans suffered from EGFR mutations, but in Asia 30% to 40% of people suffer from these types of mutations. By testing to see if a patient has an EGFR mutation beforehand, we can see if this treatment will be successful for them.

Apart from providing personalized medicine, are there any other areas that Vita Genomics is working to provide solutions for?
Yes there are a number of different areas. One condition known as hypercholesterolemia affects one in every five hundred people. This condition prevents cholesterol being adequately absorbed from the blood and can have a devastating effect on a person's life with most victims dying before they are thirty years of age. We have been collaborating with a hospital in Taiwan and Affymetrix to create a diagnostic tool that will be able to identify patients who are suffering from this condition at an early stage, so that it can be treated before it is too late.

Mr. Hsieh, you took over as CEO of Vita Genomics last year and oversaw the company making its first year of profits. Can you talk to us about your experience so far?
When I became CEO of Vita Genomics last year, I saw that the company was making a net loss of $3 million. We would have to do a lot of work to become profitable. We started by selling the Shanghai laboratory, as it facility was outdated but still costing a lot of money to operate. We also decided to shift the direction of the company from research and academia to a more commercial field. Gradually we started to build up more commercial clients with a very large contract coming from world-famous pharmaceuticals, which greatly helped us enter into financial recovery. Today, due to the financial restructuring of the company, we are now in a much healthier financial situation.

You recently stated that you hope to double the company's profit this year. What is the company's strategy to achieve this goal?
One of the company's strategies to achieve this goal is through mergers and acquisitions as we have recently acquired five clinical laboratories. Through these acquisitions we have vertically integrated a number of high price and mid price testing systems. These laboratories have been an excellent investment, as they are connected to over two thousand clinics and hospitals and have helped us to rebuild our sales channel. Obviously in order to make such acquisitions, we needed to raise a large amount of capital and have taken on a number of investors. We plan to release sixty thousand shares this June.

How easy is it to raise capital in this market here in Taiwan?
I find that it can be difficult to raise capital in this market. Usually investors are more interested in niche companies that have a story to tell. Vita-Genomics has been in successful in this field because we fit this bill.

The FDA has recently recommended the use of pharmacogenomics. With this in mind where do you see the company going in the coming years?
In the next three years I want to see Vita Genomics as being the biggest company in Taiwan that is operating in clinical laboratories and gene testing. The future is looking very bright for us, and we could become the largest company in these fields in all of South Asia. •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Bottling Up a Tradition: Botanical Medicine in Taiwan

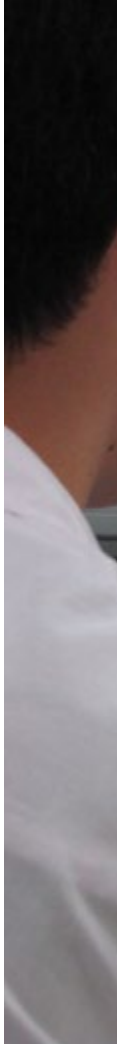
"Our most successful product to date has been an IV injectable called PG2 that is a highly purified polysaccharide extracted from a Chinese herb that has been used for over a thousand years called astragalus membranaceus. The NDA for PG2 was approved by the TFDA for the treatment of cancer-related fatigue that may result from chemotherapy and radiotherapy, thus improving the quality of life of patients who are suffering from cancer. The treatment is now available in over thirty hospitals and medical centers in Taiwan and sales are growing each month."

- Dr. Gary Lin,
CEO, Chairman Office,
PhytoHealth Corp.

Image: Sheng Chang Pharmaceutical

Botanicals

The Healing Powers of Nature



Traditional Chinese medicine (TCM), a range of practices dating back over 2,000 years, is something that is very much alive and considered by most in the region as equal to Western medicine. Few people in Taiwan would share the skepticism that many Westerners would display when told of treatment for all ailments involving modalities such as acupuncture, herbs, moxibustion and dietary therapy. TCM doctors exist and operate in Taiwan in the same way as Western doctors and most botanical based medicines are only accessible with a prescription. Despite the established presence of Western medicine, many in Taiwan and Mainland China still prefer to use medicine derived from botanical extracts.

However, Taiwan is now witnessing a convergence of these two practices and the twenty-first century has given rise to a number of companies taking a Western approach to the development and production of botanical drugs. Sheng Chang Pharmaceutical, a company established in 1946, is a major producer of concentrated medicine, derived from a range of raw materials such as herbs and fungi. "Our main focus now is on the concentrated medicine, which is extracted from raw materials, put through a process of concentration and then granulated to form a powder," said Dr. Wei-Chu Li, vice general manager of Sheng Chang. "Unlike in Europe, in Taiwan this is considered a prescribed pharmaceutical and we manufacture this medicine to treat all forms of diseases."

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>
> - Dr. Wei-Chu Li, Vice General Manager, Sheng Chang Pharmaceutical

In 2003, Sheng Chang invested NT$3 billion in a new laboratory and manufacturing plant, which, to the untrained eye, looks no different to the facilities of a Western synthesized medicine producer. The company's goal now is to be operating at the same standards as a conventional pharmaceutical company. "In 2014, the government announced that all pharmaceutical companies must comply with the pharmaceutical inspection cooperation scheme (PIC/S). As a traditional Chinese medicine company we are exempt from this. However, we intend to be the first company of our kind to pass this standard. We hope to achieve this by 2018," said Dr. Li, whose vision is shared by many in this field.

The challenge for companies involved in botanical based drug discovery is to expand the body of scientific evidence that show botanical products do work. Golden Biotech is a botanical company, focused solely on the development of their proprietary compound, antroquinonol, a compound discovered in the mycelia of the fungus Antrodia Camphorata. This compound is now going through the same rigorous clinical trial program that any Western new chemical element (NCE) would. "For the Taiwanese biotech industry, this has been seen as a huge achievement. For us it is the result of much hard work, and a lot of time and money spent," said Alex Liu, chairman and CEO of Golden Biotech. "It was four years in the running from the discovery of this compound to receiving its IND status from the U.S. FDA and their recognition of completion of the phase I clinical trials. We are now looking forward to phase II clinical trials."

Recognition from the U.S. FDA is very much proof that there is hope for these botanical products, although some consider that there is more work that

> "It does not make sense to me that if a medicine can be derived naturally and offer minimal side effects, why it is not seen as being a more favorable alternative to a chemical drug that can inflict a series of side effects. This is an issue that the Taiwanese government really needs to address in order to find a way in which traditional and natural medicines can be integrated with pharmaceutical medicines."
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> - Dr. C. Y. Huang, President, NatureWise (NBM)

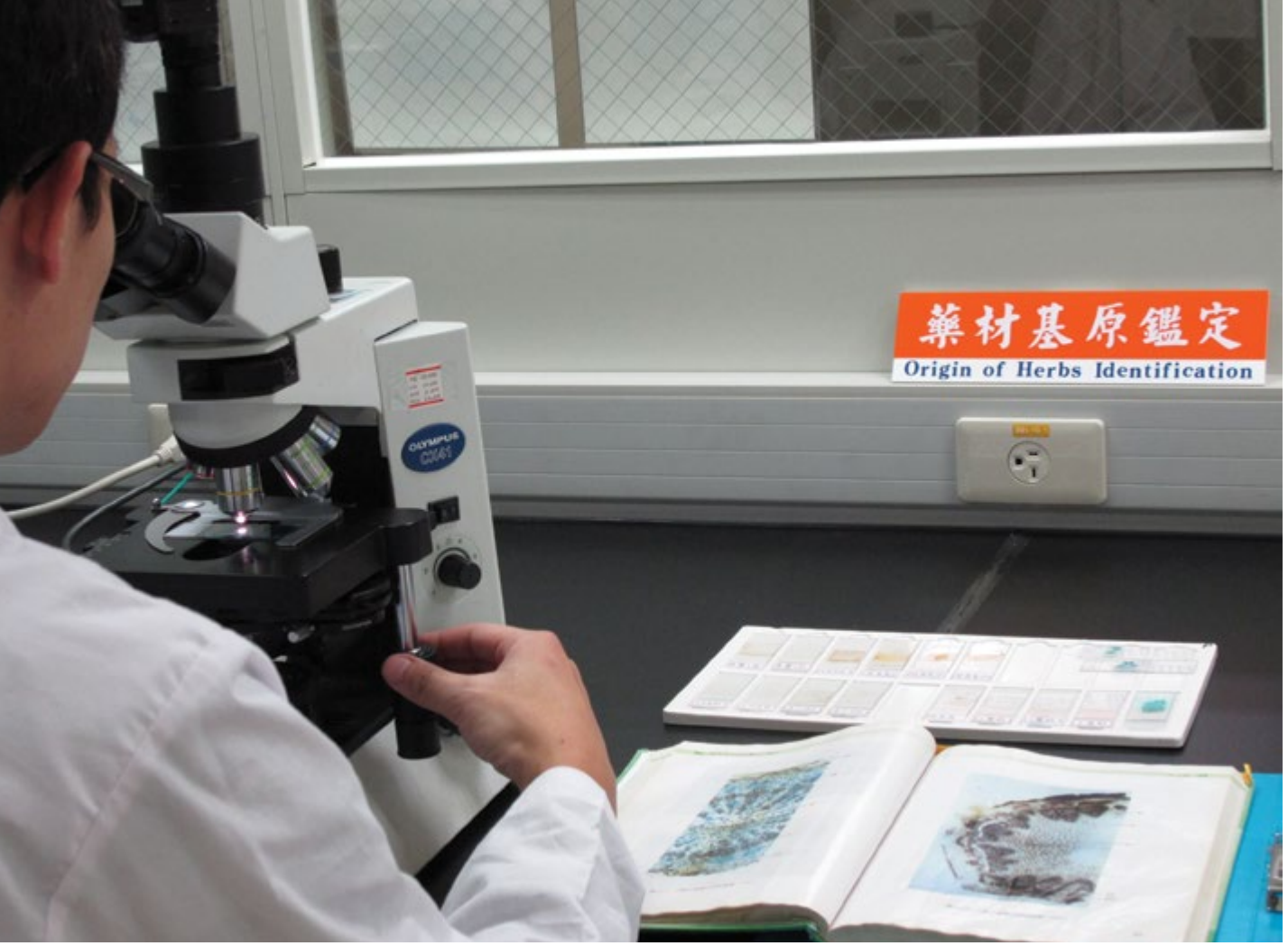

Image: Sheng Chang Pharmaceutical

needs to be done, both domestically and abroad. "It is absolutely true that the traditional medicine field and indeed all drugs that are extracted naturally from botanical extracts are not given the same amount of support that chemical drugs receive," said Dr. C. Y. Huang, president of NatureWise (NBM). "It does not make sense to me that if a medicine can be derived naturally and offer minimal side effects, why it is not seen as being a more favorable alternative to a chemical drug that can inflict a series of side effects. This is an issue that the Taiwanese government really needs to address in order to find a way in which traditional and natural medicines can be integrated with pharmaceutical medicines."

Other development-stage companies believe that the key to their success will be the promotion of their product overseas, but for this to become a reality, the profile of botanical drugs must be raised. "It is in Western countries where we need to raise awareness. We need to show to the world the evidence of the effectiveness of botanical drugs," said Dr. Kou-Wha Kuo, president of G&E Herbal Biotechnology, a company focused on the development of the botanically derived SR-T100, which is purportedly able to treat cancer cells without damaging the healthy ones. "With regards to our product and the afflictions it aims to treat, many synthetic western cures will result in side effects, whereas SR-T100 does not. Through presenting the results of our clinical trials we hope to raise the profile of botanical medicine. Actinic keratosis is more prevalent in Caucasians and for this reason we feel it is important for the West to appreciate the benefits of SR-T100 over synthesized Western treatments."

G&E Herbal Biotech and the growing number of similar companies must now strive to secure foreign partnerships to both fund their development and ensure successful commercialization of these products. Globally recognized clinical trials and solid, reliable scientific data, proving the effectiveness of botanical drugs will be the only means of achieving this, thus safeguarding the future of this small industry. •

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>
> - Dr. Kou-Wha Kuo, President, G&E Herbal Biotechnology

Fu Feng Kuo

CEO
HEALTH EVER BIO-TECH CO., LTD.

Can you please start by giving us a general introduction to Health Ever Bio-Tech?
Health Ever Bio-Tech (HEB) was established to focus on the development of botanical new drugs backed with scientific and medical evidence. Over the past 20 years, HEB has been committed to the research and development (R&D) of innovative botanical drugs to help with unmet medical needs and improve people's quality of life. With in-house ISO/IEC 17025 certified laboratory, HEB has been actively involved in the preclinical and clinical developments of botanical new drugs that have been verified to be effective and safe on animal, cellular and human studies. In 2006, HEB completed a Phase II clinical trial in Taiwan on MCS-2, our most promising product, and the results were encouraging. In 2009, HEB initiated large-scale, Phase III clinical trials both in the United States and Taiwan. In order to satisfy the market demand, HEB set up a manufacturing facility in 2013 designed to meet the pharmaceutical inspection convention and pharmaceutical inspection co-operation scheme (PIC/S) and current good manufacturing practices (cGMP) standards. HEB is headquartered in New Taipei City and our manufacturing facility is located in Yi-Lan County.

Can you give us a more specific overview of your products and what they treat?
HEB has a pipeline of botanical new drugs under development to treat and prevent benign prostatic hyperplasia (BPH) and other diseases. The lead product, MCS-2, is currently being studied in pivotal multi-country and multi-center Phase III clinical trials on BPH patients. In a Phase II clinical trial evaluation, MCS-2 has demonstrated that treatment with this drug improves patients' I-PSS score and relieves the symptoms of BPH. The clinical data also indicated that MCS-2 has a very low risk of adverse effects. MCS-2 is expected to have an excellent safety profile compared with chemical drugs.

What are your prospects for future products beyond MCS-2?
HEB is exploring botanical new drug candidates including different drug substances. We are keen to move forward to clinical trials. In general, most chemical drugs have certain side effects that many patients cannot tolerate. Botanical drugs are becoming more beneficial, as they tend to have fewer side effects. This could improve the quality of life especially for chronic disease patients. Botanical drugs with efficacy and excellent safety will become important to the aging Taiwanese population and other aging societies worldwide.

Partnering with the government and other international companies nurtures future success. Can you tell us about your strategies in this regard and how HEB is planning to secure future investments?
HEB has received clinical research grants from several Taiwanese Government Development Programs, especially the Ministry of Economic development, in the R&D of our MCS-2 drug. On a more international front, HEB is negotiating partnerships with pharmaceutical companies specialized in different territories to ensure the product can be safe and efficient once approved and put on the market. As for future investments, HEB is planning its IPO on the Taiwanese Stock Exchange in 2016. Further fundraising rounds will occur for the continuation of HEB's R&D pipelines and clinical trials. In addition, we expect to receive the licensing amounts from international partners.

What challenges has HEB experienced due to tough local regulations and as a botanical-orientated company?
The local regulations for new drugs are complex and mutable. The challenge is how to adapt to the current and modified regulations. One of the major challenges as a botanical orientated company is the chemistry, manufacturing, and control (CMC) set of regulations. Botanical drug products are mostly derived directly from plants and there are many factors that could have impact on the specification and stability on the active pharmaceutical ingredient (API), such as weather, soil, water, etc. These factors make it relatively hard to control the batch-to-batch variance, especially in the clinical trials.

What are some of the strengths of Taiwan's pharmaceutical and biotechnology industries and do you think that Taiwan can become a global player in this field?
Due to the aging population, the recent biotechnology boom in Taiwan has made a huge positive impact on this industry, especially in fund-raising. As the market in generic drugs is becoming more crowded and competitive, many pharmaceutical and biotech companies start to turn their focus to the R&D of new drugs to create higher value-added products. Taiwan has a relatively mature health care system compared to other Asian countries. However, the pharma market is somewhat small. Given these circumstances, Taiwanese pharmaceutical and biotech industries strategically collaborate and partner with global pharmaceuticals through the R&D of new drugs including out-licensing and in-licensing.

Where would HEB like to see itself in five years?
HEB has been fully dedicated to the R&D of MCS-2 over the past 20 years. HEB hopes to obtain approval to deliver our products all over the world. Our goal is to be the first Taiwanese biotech company that obtains Botanical New Drug approval from the U.S. Food and Drug Administration (FDA) and continue to move forward with more potential drug products and to collaborate with international partners to develop more botanical new drugs. •

Dr. Kou-Wha Kuo

President
G&E HERBAL BIOTECHNOLOGY CO., LTD.

Founded in 2002, can you give us a brief introduction to G&E Herbal Biotechnology?
We are a company focused on developing new compounds that are extracted from plants. Our mission is to create and develop botanical pharmaceuticals to the same standard and level of quality control that you would find in any Western pharmaceutical company. Our flagship product is SR-T100, which is extracted from a plant endemic to Taiwan, and is the first product ever developed that is able to target and treat cancerous cells without any damage caused to healthy cells. This product is currently in clinical trials both in Taiwan and the United States for three different indications: actinic keratosis, genital warts and verrucae. An injectable form of this drug is currently in pre-clinical development, but once in human trials, this will be able to treat solid tumors in the body.

What other products, aside from pharmaceuticals, does G&E offer?
We offer health supplements and derma cosmetics that are all derived from SR-T100. Due to the fact that this compound is able to treat cancer without damaging the healthy cells, we were approached by dermatologists who suggested we create an anti-aging cosmetic. With a product derived from SR-T100 already on the market as an over-the-counter gel, we are able to prove the safety of this compound. This is sold domestically as well as abroad and the revenue generated from this cosmetic is supporting our clinical trials for the development of the pharmaceutical.

Last year the government insisted that all pharmaceutical companies comply with PIC/S. Have you reached this standard despite being a botanical company?
We are currently constructing our manufacturing plant. It will meet all PIC/S standards in the same that any Western pharmaceutical manufacturing facility would. We hope to have this completed by August this year and next year we will file for the necessary pharmaceutical certifications.

Although growing, the Taiwanese biotech market is still quite small. What needs to be done to ensure that this country is recognized as a global player?
In Taiwan the choice of which field of research to pursue is very important. If we choose to develop Western medicine we would never be able to be a competitor to a global pharmaceutical company. However, for botanical drugs, this is our specialty as we have in-depth knowledge of the plants having eaten them as health supplements for centuries. The crucial thing is being able to make and develop a botanical drug to the same standard as a Western pharmaceutical. The origin is irrelevant to the patient as long as it cures the disease. In injectable form our product SR-T100 is over 99 percent pure, something found in Western medicine, but it is purified from botanical substances.

What challenges do you face both domestically and globally from being a botanical company and what are you doing to overcome them?
In Taiwan this is not a problem. It is in Western countries where we need to raise awareness. We need to show to the world the evidence of the effectiveness of botanical drugs. With regards to our product and the afflictions it aims to treat, many synthetic Western cures will result in side effects whereas SR-T100 does not. Through presenting the results of our clinical trials we hope to raise the profile of botanical medicine. Actinic keratosis is more prevalent in Caucasians and for this reason we feel it important for the West to appreciate the benefits of SR-T100 over synthesized Western treatments. Moving forward, we need to secure a partnership with pharmaceutical companies in these countries to bring our product to market. We are presenting at Bio International in Philadelphia this year to promote our company and our product.

The government is considered to be very supportive of biotechnology in Taiwan. Can the same be said for the botanical aspect of this industry?
I recently attended a meeting regarding botanical drug development in Taiwan and they all recognize that this field is a good means for Taiwan to progress in biotechnology. The government recently rated our product SR-T100 as number one in Taiwan as they recognize the high probability of this product being launched overseas.

Where would you like to see the company in five years?
We hope to complete all our current clinical trials and will endeavor to find a good partner with whom we will be able to collaborate in getting these products to a global market. We will achieve this by developing our product for topical use within five years and the injectable form of the drug will take eight to 10 years. •

C. C. Chiuh

President
FEBICO

Can you please give us a brief introduction to FEBICO and tell us about your recent developments?

Our company started out as Far East Microalgae Co. Ltd. We have been producing chlorella, spirulina, and other kinds of microalgae for about 20 to 30 years until the present. About 10 years ago we started Far East Bio-Tec Co. Ltd. to focus on sales and marketing of nutritional supplements. We also put resources into developing special proteins extracted from microalgae, applied in in vitro diagnostic use.

Recently we started a new company called Algapharma Biotech. Corp. (Algapharma), and the reason behind that was that the corporation had four departments, including nutritional supplements, diagnostic tools, green energy, and new drug development, which often appeared to be too diverse.

Therefore, we split these four departments into two companies. Now Algapharma is the supplier of nutritional supplements and diagnostic reagents, as well as marketing and sales of those products. FEBICO will focus solely on new drugs development and hold the core technology for green energy with microalgae. We wanted to clearly position these two companies.

Can you provide us with some background on your products?

We specialize in microorganism production such as microalgae and probiotics and products can be generally categorized into FEBICO® nutritional supplements and FLOGEN® diagnostics reagents.

For nutritional supplements, we started to produce chlorella and our major market was Japan in the 1980s. In the early 1990s, we started to expand sales to the United States and to Europe within the following five years. We now sell our chlorella, spirulina, and other microalgae derived products globally to almost 43 countries.

About five years ago, domestic sales used to account for about 70%, but now the Taiwanese government has changed its policies on how we can advertise, so domestic sales have decreased to approximately 40%. Europe is now our fastest-growing export market. In Japan we started with chlorella, but spirulina is what took off in the United States and Europe.

For diagnostic reagents, we extract fluorescent proteins from microalgae and apply them to the use of molecular staining. Our clients include world-renowned biotechnology and clinical diagnostic companies. Business-to-business customers from the United States and Europe account for 90% of our market. In addition, we also provide ODM and OEM services to meet customers' specific demands.

What is the difference between chlorella and spirulina?

Chlorella grows in fresh water with a spherical shape, and spirulina grows in salt water with a spring like shape. In terms of their origins, chlorella is more evolutionarily advanced with a thick cell wall. Nutrition-wise, they are both considered as whole food because they contain carbohydrates, proteins, amino acids, fatty acids, and trace minerals that no other food can match.

Interestingly, chlorella and spirulina are different in vitamins composition and health function. We advise taking spirulina in the morning and chlorella at night. Spirulina contains vitamin B and fatty acid GLA—which is often missing in vegetarian diet—so it increases energy, something you would want in the morning. It also has a lot of antioxidants to strengthen your immune system, so you have better immune support against the various pollutants you might face during the day. Chlorella contains chlorophyll, which is known as a heavy metal cleanser, so it can help your body remove the toxic substances from the food you eat. If you take chlorella in the evening, it promotes bowel movement overnight so you can go to the bathroom in the morning and avoid constipation problems.

You mentioned that one of your companies will focus strictly on R&D. Can you please tell us about your drug development plans?

Far East Bio-Tec. Co., Ltd. is the company focused on research and development of new drugs. Since 1999, we study and put resources into developing new drugs for infectious diseases such as influenza. Our primary product pipeline is to prevent or treat influenza A and influenza B. We have already finished all the in vitro and in vivo experiments prior to human clinical trials. Our applications for Investigational New Drug (IND) in the United States and Taiwan have both been approved. This is an indicative achievement for us because it means that we can start Phase II human clinical trials. We currently have two other products in the pipeline in place and both are still in the early lead compound development stage.

What are your plans for the next five years?

We want Far East Bio-Tec. Co., Ltd. to be focused solely on the development of new drugs. Recently we have sent our product to National Institutes of Health (NHI) as virus drug screening including Ebola and many other life threatening viruses. Our material has been tested to be very effective and NIH thought it could be a promising drug candidate. We now need to focus on programs for the development of new antiviral drugs; this will be the focus of our R&D going forward. We hope to bring new drugs on the market to address these issues and help people around the world. •

Dr. C.Y. Huang

President
NATUREWISE (NBM)

NatureWise Biotech & Medicals Corporation (NBM) was established in 2000. Can you talk to us about the foundation of your company?
I started this company in 2000 with the sole aim of developing new drugs from natural sources. Such sources have been heavily influenced by Chinese traditional medicine as well as herbal extracts. I am a big believer in the power of nature to cure illness so setting up this company was a very natural choice for me.

Can you tell us about some of your product offerings?
We are currently working on a number of different therapies that are sourced from nature. In recent years there has been a lot of talk regarding HDAC inhibitors as a form of cancer therapy. Here at NBM we have developed an HDAC8-specific inhibitor called BMX – OS01, which is inexpensively extracted from herbs with a very high extraction rate and structurally modified by three simple chemical synthetic processes. Both in vitro and in vivo studies have shown BMX – OS01 to be more effective than the FDA approved HDAC inhibitor called SAHA, whilst being less toxic. Another product that we have is called PPLs®, which are a group of prenylflavanones, which are extracted from specific Taiwanese propolis. Propolis is a resinous mixture that honeybees produce for the purposes of sealing carcass of intruding animals or cracks in the beehive in order to maintain a clean and stable environment in the hives. These prenylflavanones, only present in Taiwan, were discovered by NBM scientists to have neurotropic properties, which can increase the survival of neural stem cells and induce them to differentiate into neurons. They also help the growth of neurites.

NBM has a large number of patents and has discovered a large number of natural therapies. How important is research and development at NBM?
NatureWise is committed to researching and developing new drugs from natural sources. We are constantly looking at new and innovative ways to develop new drugs to ensure our pipeline does not dry up. Our commitment to innovative products and research and development is indeed backed up by a large number of patents we have that cover major territories such as the United States, China, the European Union, Japan, Australia, South Korea and Taiwan.

Although the pharmaceutical industry is currently quite small in Taiwan, it does have a number of strengths in comparison to its counterparts. Can you talk to us about these strengths?
Taiwan has a number of advantages in the pharmaceutical industry. For a start, a lot of Taiwanese students go abroad and study at top-tier universities and bring their knowledge home with them. Furthermore, the talent pool is further enriched by a large number of retired Taiwanese pharmaceutical executives who spent their working lives abroad and then came back to Taiwan to start up their own companies. The talent pool here in Taiwan is particularly strong for the biotechnology sector. On a separate issue the local small and medium sized companies that work in the Taiwanese pharmaceutical industry have a great degree of flexibility in managing their operations.

As a company that also operates in the traditional medicine field, can you talk to us about the challenges that you face in an industry that does not always receive the same level of support as its mainstream pharmaceutical counterparts?
It is absolutely true that the traditional medicine field and, indeed, all drugs that are extracted naturally from botanical extracts are not given the same amount of support that chemical drugs receive. It does not make sense to me that if a medicine can be derived naturally and offer minimal side effects, why it would not be seen as being a more favorable alternative to a chemical drug that can inflict a series of side effects. This is an issue that the Taiwanese government really needs to address in order to find a way in which traditional and natural medicines can be integrated with pharmaceutical medicines.
In terms of the operation of companies in the traditional fields of medicine and in the pharmaceutical industry as a whole, there has been an ongoing issue with a lack of capital available for investment. However, the situation is improving. The capital market has been much friendlier toward this area than before because there are fewer investing alternatives where large returns can be generated. •

Dr. Gary Lin

CEO, Chairman Office
PHYTOHEALTH CORP.

PhytoHealth Corporation was established in 1998 as a member of the Maywufa Biopharma Group. What is the relationship between PhytoHealth and the Maywufa Group today?

The Maywufa Group was originally focused on consumer cosmetics such as shampoo and skincare products before opening up a pharmaceutical business division of which PhytoHealth is a member. In 2002, the company held its initial public offering (IPO) and in doing so became the first new drug development company to be listed on the Taiwan Stock Exchange (TWSE). Today, PhytoHealth continues to be a member of the Maywufa Group, while also being a public company. Presently, there are pharmaceutical and medical device companies in the Maywufa Group, but PhytoHealth operates independently from the other companies.

We see that PhytoHealth is focused in the area of new drug development of botanical drugs. Can you talk to us about the major role that research and development (R&D) must play in a company that is concentrating in this field?

R&D is at the heart of what we do here at PhytoHealth and as a result we have a number of patents that protect the intellectual property that we are currently working on. Our patents cover all of the major regions including the United States, the European Union, Canada, Australia, China, Japan and Korea.

Our commitment to R&D is further emphasized by our modern research and manufacturing plant, which was built in compliance with PIC/S CGMP and opened in 2010. The plant covers an area of 3,000 square meters with a potential capacity of producing 200,000 vials per year.

As a result of its commitment to R&D, PhytoHealth has a steady stream of drugs in its pipeline that are currently undergoing clinical trials. Which drug do you believe shows the most potential?

PH3 is a drug that is currently at phase II of our clinical trials with U.S. FDA and Taiwan Food and Drug Administration (TFDA) for two separate treatments. PH3 is a small molecular fraction that is extracted from a traditional Chinese medicine. It is showing potential as a preventative treatment for osteoporosis as it is believed to increase bone mass through enhancing osteoblast proliferation and maturation. It is also showing promise as a diabetic nephropathy treatment, as it is believed to enhance the hepatic clearance of the AGEs as well as repair and prevent tissue damage.

From your historic pipeline of clinical trials, what has been the most successful drug to make it to market?

Our most successful product to date has been an IV injectable called PG2 that is a highly purified polysaccharide extracted from a Chinese herb that has been used for over a thousand years called astragalus membranaceus. The NDA for PG2 was approved by the TFDA for the treatment of cancer-related fatigue that may result from chemotherapy and radiotherapy, thus improving the quality of life of patients who are suffering from cancer. The treatment is now available in over thirty hospitals and medical centers in Taiwan and sales are growing each month.

PG2 is also considered to be a potential treatment for idiopathic thrombocytopenic purpura (ITP), which is a rare disease. We have currently progressed to phase II clinical trials with the U.S. FDA for PG2 being a potential treatment for ITP patients. PG2 has also being granted orphan drug designation by the U.S. FDA for the treatment of ITP. While we have been quite successful with this drug so far, the true potential has yet to be realized.

With so many drugs in your pipeline awaiting the results of clinical trials, the next few years are going to be very important for PhytoHealth. What do you see for the future of the company?

We are very much focused on becoming one of the global leaders in the botanical new drugs industry. It is a huge challenge but one that we feel we can achieve due to our solid foundation in this area and the pending pipeline of drugs that are currently in clinical trials. We are actively looking to cooperate with international partners who are interested in working with us to develop and market new drugs on the global market. •

Ken Lin

CEO
CHEN FU/BE RICH BIOTECHNOLOGY

Could you give a brief history of Be Rich Biotechnology and tell us about the mission that has driven the company over the past decade?

Initially, Be Rich Biotechnology started as an enzyme factory and the key products of our company are enzyme-based. In addition to producing enzymes, Be Rich Biotechnology also acts as an original equipment manufacturer (OEM), offering a wide variety of biotech and biopharmaceutical products to the market. As we developed good marketing capabilities, we began to offer our services as a marketing platform to other companies around the globe. After the establishment of the "Three Links" trade agreement between China and Taiwan, our main market focus shifted from Southeast Asia to China.

Can you tell us about the application of these enzymes as well as about the production processes involved and some of the advantages that Taiwan possesses in this field?

Enzymes are greatly beneficial for the human body; if the 20th century was the century of vitamins, the 21st century will be the century of enzymes. Taken as a health supplement, enzymes are most commonly known to assist in digestion. However, Taiwan has discovered many more that are helpful in the treatment of allergies and even diabetes or hypertension. It was the Japanese who initially introduced the fermentation technique of producing enzymes in Taiwan. Probiotics are essential for the production of enzymes, and our company uses Japanese produced probiotics, which are better for our manufacturing processes. However, Taiwan has been strongly committed to the research and development (R&D) of probiotics over the past twenty years. This, coupled with the geography of the island, which gives Taiwan four different climate zones in which a vast variety of plants can be cultivated, has greatly improved the countries production of enzymes. Additionally, in terms of biotechnology, Taiwan's academic institutes such as Academia Sinica and National Taiwan University are world-renowned for their research and work in this field.

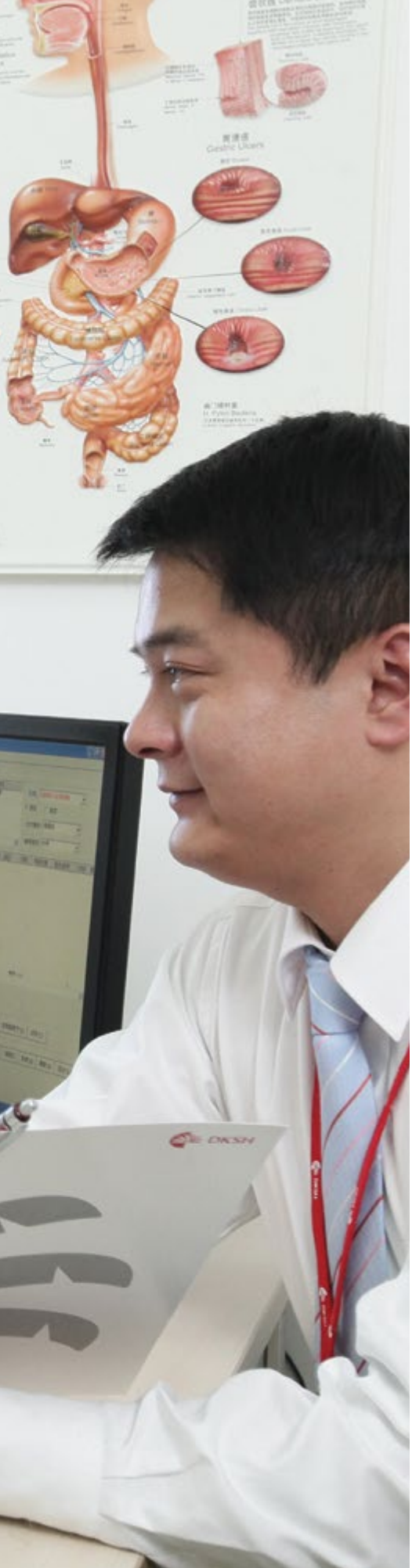
Taiwan is often considered as a gateway into China. With the Cross-Straits Economic Cooperation Framework Agreement (ECFA) in 2010 slowly taking effect, what are your views on collaboration between the two countries?

Taiwan's relationship with China can be described as very delicate and unique. The effect of ECFA is not yet being felt in small businesses like this one. However, there are more and more special connections being emplaced, which are slowly freeing up trade. As we become closer with China in terms of trade, companies will seize the opportunity of operating in this large and complicated market and attract interest from businesses wanting to enter the Chinese market.

Where would you like to see Be Rich Biotechnology in five years' time?

In the future we plan to establish an enzyme factory in China in order to reduce our costs as well as transportation fees. We are also now focusing on the development and promotion of our cross border e-commerce platform. We want to use our expertise on what is a very complicated system and become an agency for companies wishing to enter the Chinese market. •


Nexium
DELL



From Discovery to Distribution: Servicing Taiwan's Pharmaceuticals Industry

"In Taiwan, we have been working with a number of biotech companies focused on rare diseases. Because of the rareness of the disease, it is not viable for these companies to establish a fully-fledged presence, yet they want to tap into the Taiwanese market. In such a case, we do all the administrative work for them, including working with the Food and Drug Administration (FDA) to acquire the import license and other registration requirements. We then leverage our network of hospitals to import this product and deliver on a 'named patient' basis. Our marketing and sales teams work closely with prescribers to educate them about the products."

- Dr. Ronald Linke,
Vice President Healthcare,
DKSH Taiwan

Image: DKSH Taiwan

CROs, Distribution, and Logistics

More Than Just Good Roads

As Taiwan's pharmaceutical and biotech sectors continue to develop, services that the industry needs will continue to establish their presence in the country. One of the main service offerings that any country with a large pharmaceutical industry needs are contract research organizations (CROs). Taiwan happens to already have a solid presence of international CRO providers, some of which include VCRO, Parexel, Quintiles, PPD and EirGenix. CROs can provide services such as biopharmaceutical development, commercialization, preclinical research, clinical research, clinical trials management, and pharmacovigilance.

"PPD started operations in Taiwan in 2000, and has grown in this country in an organic way by maintaining high-quality standards over the years. We continue to work closely with the Taiwanese regulatory authorities and keep introducing new technologies to support our clients. In 2005, we started using electronic data capture technology in Taiwan, and in 2007 we began to employ electronic trial master file technology. We also have an outstanding intensive global training program for our clinical research associates at all levels. PPD wants its clients to have highly qualified staff working on monitoring their trials. PPD also cooperates with 40 medical centers and hospitals in Taiwan," explained Joyce Lee, associate director, clinical management of PPD.

The reasons behind global companies seeking the services of CROs and contract development and manufacturing organizations (CDMOs) in Taiwan can be varied. They range from an established local industry to Taiwan's proximity to China. Dr. Lee-Cheng Liu, president and CEO of EirGenix, said: "One factor is that Taiwan is more cost competitive than other countries, but crucially Taiwan offers high quality. Other countries may offer cost-effectiveness, but without quality this means nothing. A third reason, for EirGenix in particular, is that we offer companies a window into the huge market that is China. EirGenix is planning the construction of a plant in China that will directly mirror our new plant in Hsinchu. For any company working with us, the development stage of their product will be carried out in Taiwan, where IP is better protected than in China, and then, once the product reaches the manufacturing stage, the work can be transferred to the mirror image plant in China. This plant will be seen as a subsidiary therefore subject to Taiwan laws and regulations rather than Chinese."

In addition to CROs and CDMOs, Taiwan also had to develop a good distribution and logistics network for the pharmaceutical and biotech sectors. These services are specialized and require special equipment and high safety standards to transport the necessary products to and from Taiwanese clinics, hospitals and research centers. Taiwan boasts a convenient transportation infrastructure and, with a high-speed railway running north to south and a number of major domestic airports, the efficiency of the freight logistics industry is high. Effective distribution means getting the right products to the right places at the right times. This may seem simple enough on an island that is slightly smaller than the states of Maryland and Delaware combined, but with pharmaceuticals and biotech, it is a more complicated process.

Different from consumer goods, the source and distribution of medicinal goods (including active pharmaceutical ingredients) has to be highly regulated. To ensure that the predetermined quality of drugs is maintained after they leave a GMP plant and are transported to distributors, pharmacies, or hospitals, various countries have determined Good Distribution Practice (GDP), which prescribes guidelines to be followed by the pharmaceutical transport industry. Today, GDP issues are increasingly important. The Taiwan Food and Drug Administration (TFDA) promotes GDP guidelines to encompass the quality management of the whole supply chain with fortified infrastructure and supervision. Additionally, the government recently insisted that any company involved in the transportation and distribution of pharmaceutical products must comply with the globally recognized Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

One company that has been eager to capitalize on these requirements is Kerry TJ Logistics, Taiwan's leading logistics services provider. "Before the Taiwan government insisted that any company dealing with pharmaceuticals comply with PIC/S, the majority of logistics operators involved in pharmaceuticals were not as concerned with the quality of their operations," said Richard Shen, chairman of Kerry TJ Logistics. "Kerry TJ wanted to offer a global standard of pharmaceutical logistics services, as set by our KLN head office in Hong Kong. We endeavored to build up our branding in line with the quality of the service we offered. The quality assurance is now what is sup-

porting the company branding, not the other way round. With our technologies and equipment we are now able to offer a fully integrated, total solution service to the pharmaceutical industry."

In addition to having good internal logistics, Taiwan also enjoys a strategic geographical location in the region. Being close to Japan, Hong Kong and, most importantly, Mainland China has made it an attractive expansion base for foreign companies looking to gain a foothold in South-East Asia. Many companies see Taiwan as a gateway into the vast and lucrative market that is China, but although it may be easier to establish operations on the island than on the mainland, there still exist hurdles to be overcome. "To set up a local task force as an outsider in a market in which you are not integrated is extremely difficult. The market is ever changing due to regulations and market trends so that it is nearly impossible to be sufficiently informed from the outside," said Wayne Hsu, managing director of Chi-Fu Trading Co., a company offering a range of services to foreign pharmaceutical companies wishing to expand their business to Taiwan. "Chi-Fu provides turnkey solutions for international pharmaceutical companies. We provide market evaluation to suppliers and manufacturers to help them decide if they would like to expand into the market. Chi-Fu then assists in registration, launch, distribution, marketing, and logistics."

DKSH, a global market expansion service provider that originally dealt only with pharmaceutical distribution, now provides their clients in the healthcare sector a vast range of services along the entire value chain. Despite Taiwan being a strategic location for outside companies to establish operations in, many smaller companies simply do not have the resources to do so, thus preventing certain products from reaching the patient in need. DKSH is now able to resolve that by acting not only as their distributor in the country, but also as a representative of their operations. "In Taiwan, we have, for example, been working with a number of biotech companies focused on rare diseases. Because of the rareness of the disease, it is not viable for these companies to establish a fully-fledged presence, yet they want to tap into the Taiwanese market," said Dr. Ronald Linke, vice president of Healthcare for DKSH Taiwan. "In such a case, we do all administrative work for them, including working with the Food and Drug Administration to acquire the import license and other registration requirements. We then leverage our network of hospitals to import this product and deliver on a 'named patient' basis. Our marketing and sales teams work closely with prescribers to educate them about the products," added Linke.

With an already well-established and efficient logistics framework, distribution companies in Taiwan must now look to expand their range of services outside of simply transporting a product from A to B. Foreign companies are constantly in search of local partners to help navigate Taiwan's regulatory structure and assist in overcoming the barriers to entry in establishing a presence on the island. •

Albert Liou

Vice Chairman, Asia Pacific
PAREXEL

Can you please give us a brief introduction to PAREXEL?

PAREXEL was founded 33 years ago by Josef von Rickenbach, who still serves as CEO and Chairman. He has grown PAREXEL from a two-person operation to what is now a company with more than 17,000 employees and $2 billion in revenue. Presently our major business units are clinical research, consulting and medical communications, and PAREXEL informatics. Our clinical research unit conducts early phase and early product development studies including Phase I and Phase IIa, Phase II-III pivotal studies as well as Phase IV and post marketing surveillance studies. Our Consulting unit assists pharma and biotech companies in bringing their products to the global market. This includes strategic planning for drug development, clinical development, regulatory compliance and risk management as well as guiding them through all regulatory issues related to the Taiwan Food and Drug Administration (TFDA) or any of the global regulatory bodies. Medical Communications works with the client after the development stages to design and execute the drug launch, publicizing the product in order to better penetrate the existing market. Our experts utilize their medical expertise to provide information to doctors so they can better understand the drug and more confidently prescribe it to patients. Finally, our PAREXEL Informatics unit has a complete technological suite for clinical trials, including randomized systems, data management systems, and imaging services. Regardless of the size of the company, our focus is to provide everything the client needs from designing their drug development strategy to bringing a drug to market through post-marketing services.

Why did PAREXEL enter Taiwan in 1999?

At the time, we saw the need for clinical research in Taiwan, but there were not many companies entering the market. We chose Taiwan for a number of reasons. In terms of geography, Taiwan is in the center of everything; in two hours, you can fly to Korea, China, and Japan. Taiwan has a lot of talent returning to the country after receiving training and education overseas. Many people speak English proficiently, making it easier to reach out internationally. The government realized in the 1990s that the technology industry would eventually move to countries like China or Malaysia, so they began targeting the biotech industry as an important growth sector and have since invested a great deal of resources into it. The doctors and hospitals are aligned with American and/or European medical practices which also facilitate transitioning to international markets more efficiently. For all of these reasons, we identified Taiwan as the most advantageous site in the region.

What is PAREXEL's strategy to maintain its competitive edge in Taiwan?

Soon after entering Taiwan, we became the largest contract research organization (CRO) here. Our goal has been to be the best CRO in Taiwan, and our size gives us an advantage over our smaller competitors. The regulations are harmonized in the United States and Europe; if you gain approval in one state, you have approval in all states. This is not the case in Asia, where approval in one country does not qualify as approval in another. We are able to utilize our greater resources to establish offices as legal entities in these different countries. We hire local experts who are familiar with international standards and are able to apply these to local practices and regulations. As a result, if our clients need data from Asia, we are able to provide it holistically for the region while meeting the required standards in each country.

After the Taiwanese government instituted a price ceiling on pharmaceuticals, have you noticed a change in the attitude of big companies towards conducting clinical trials here?

The impact has not been significant. Taiwan's NDA regulation requires registration studies or quite a lot of local bridging data. The cost of clinical study needs to be justified before entering Taiwan market. However, the price ceiling may contribute to some companies' decision not to enter Taiwan. Nevertheless, Taiwan continues to provide quality data, excellent clinical research infrastructure, and industry-friendly regulations. Furthermore, if China recognizes Taiwan's sites, it would have a huge, positive effect for the data generated in the region and help leverage the advantages that the Taiwanese health care landscape offers.

How much work does PAREXEL do to support small local companies from initial drug development to production?

Small companies have restrictions in terms of the resources and expertise they can access, so a CRO partner like PAREXEL will be a partner of right choice for them to bring their product to the global market. They approach us because PAREXEL is a global company that can deliver the best return on investment for them. The process begins with PAREXEL's Consulting unit, where many of our employees come from regulatory bodies like the TFDA, CFDA, U.S. FDA and EMEA. This kind of expertise ensures that any regulatory challenges will not present hurdles and can be overcome with the right approach. With our employees, expertise, and global organizational network, we are a major player who can provide the necessary support to help a smaller company accomplish their desire to go global. •

Dr. Lee-Cheng Liu

President and CEO
EIRGENIX, INC.

Can you outline the circumstances under which EirGenix was formed?

EirGenix was formed when the Development Center for Biotechnology (DCB) decided to spin-off this unit of the biopharmaceutical pilot plant facility (BPPF) that we now find ourselves in, which was first established in 2005. The aim behind this was to change the plant's original specific role within the DCB, a non-profit organization with the purpose of helping the development of biotech, to be a more efficient and growing private company and still retains its role to serve the development of domestic biotech companies. Having spent 35 years in the United States, I was brought in to run EirGenix, which only finalized the acquisition of the facility in March 2013 and has been operating under the name since.

Taiwan is becoming known internationally as a contract development and manufacturing organization (CDMO) player. What is EirGenix's role in this sense and what other services does it offer?

Our focus is in two areas. The first is as a CDMO, which will be our main focus in the short-term. The other is our product pipeline. We currently have four products in development: two are biosimilars focused on cancer, one is an anti-body drug conjugate (ADC), and the last is a special carrier protein used in vaccine products. We hope to have this last product on the market in the reagent business soon. We will start to construct our new facility in Zhubei Biomedical Science Park, Hsinchu this year and complete it by 2017, thus expanding our production capacity. Our clients are mainly domestic ones, but we have now set up marketing teams in the United States, Europe (Germany) and Japan. By 2017, we will have 50% to 60% of our projects from overseas clients.

What has been your experience in biotech and what is your current relationship with Formosa Laboratories?

We have been very fortunate in raising funds in record time and are happy to be a part of the vibrant and savvy investment community for biotech. Formosa is our key investor, holding 18% of the company, but our alliance is also strategic. We work closely in the field of ADCs, with Formosa Laboratories being one of the largest high-potency chemical manufacturers in Asia, and present ourselves as two companies providing an integrated service in ADC development, which few companies in the world can match.

What do global companies look to Taiwan for CDMO services and for biopharma in particular?

Taiwan is more cost competitive than other countries, but also offers high quality. EirGenix also offers companies a window into China, as it is planning to construct a plant in China that will directly mirror our new plant in Hsinchu. For any company working with us, product development will be carried out in Taiwan, where IP is better protected than in China, but manufacturing can be transferred to the plant in China. This plant will be seen as a subsidiary subject to Taiwan laws and regulations rather than Chinese. •

Dr. Chun-Chun Li

General Manager
VCRO

You founded VCRO in 1997, two years after finishing your Ph.D. in the United States. Can you tell us what inspired you to set up the company?

Having trained as a clinical pharmacokineticist and pharmacodynamics scientist, I wanted to pursue this field and bring something back to Taiwan. At the time, there was not much in the way of clinical activities in the country so, with a family background in business, I decided to set up my own company offering clinical trial research services. I wanted to offer a contribution to drug development in Asia and do something that had no limits.

Can you expand on how the company has evolved since its beginnings and about the services that you now offer?

There was little in the way of new drug initiatives in Taiwan twenty years ago, so we started working with multi-national pharmaceutical companies for their local clinical trials, which were a necessity for any company wanting to register a new drug in this country. As a contract research organization (CRO), we were the first one to conform to the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) standard, despite it not being obligatory, thus making us more attractive to potential clients. These collaborations with foreign companies on local and regional trials were our main focus for the first five to 10 years. After 10 years, I wanted to shift the focus towards helping local companies in Asia that were looking to file for investigational new drug (IND) status in the United States, but had little or no knowledge on how the process worked. We wanted to become a bridge for companies that sought to bring their new initiatives to the world and in 2009 we filed our first successful IND for a new chemical entity (NCE), which was the first to be completely developed in Taiwan. This product is now in phase II clinical trials and VCRO has since filed a further seven successful IND applications for local companies. As of now, VCRO has 4 on-going IND projects, and continues to be the market leader in ICH CTD IND writing, consulting and filing services in Taiwan.

With our own internationally GLP-compliant bioanalytical lab and our proprietary electronic data capture (EDC) and interactive voice response system (IVRS) technology, VCRO is now able to act as a total-solution provider for a client and collaborate on a project from its beginnings, through all clinical trial phases, to a successful new drug application (NDA).

How are service companies like VCRO ensuring that Taiwan maintains its blossoming reputation as a leader in innovation in the field of biotechnology?

Despite the innovative products that we are emerging in Taiwan, the companies that have discovered them know little about taking their products on to clinical trials, let-alone NDA filing, and are very naïve in terms of the international regulatory requirements. VCRO shares the vision of these companies and looks to be the means by which they can move their innovative products from the discovery stage and into clinical trials and also support them right through to NDA filing. Working with these companies is exciting and rewarding, but obstacles still lie ahead, and we continually have to evolve to overcome them.

In what is now being described as a 'vibrant and active' market, how easy is it for these biotech companies to raise the funding that they need for new projects?

It is certainly not as hard as it used to be, but investors are still hesitant to make the leap into what they deem a risky industry. Generally this is because they have little knowledge of biotechnology, which is in itself a very complicated field, and it is hard for them to foresee a return on their money. To combat this, we need to see more success stories emerging from Taiwan and strive to move these innovative products to NDA. With this, investors will be more encouraged to look to the biotechnology industry and fund further projects.

Where would you like to see VCRO in five years?

I want to see the projects in which we have successfully filed for IND move towards NDA, and help our clients through the difficulties that lie ahead for them. Secondly, I want to expand the experience that the company has accumulated here in Taiwan into China. There are many good initiatives in China that need to be helped and encouraged in the same way that we have supported Taiwanese companies. •

Vivian Liao & Jay Johnson

VL: General Manager
JJ: Senior Director, Corporate Communication
QUINTILES

VL

JJ

Your office in Taiwan opened in 1998. What was behind this decision and what strategic advantages did Taiwan offer at the time?

JJ: Our founder Dennis Gillings recognized the potential in Asia sooner than other companies in the CRO field. He looked at the concentrated populations, the growing economies, and the Asian cultures, where relationships are very important, and realized that being there early and showing a commitment would ensure future growth. Quintiles has been in Asia longer than any CRO, since 1993, and Taiwan was part of this growth.

VL: About 20 years ago, Taiwan's government started to appreciate the importance of having early phase trials carried out in the country. At the time, the country had some initiatives in place in terms of clinical trial regulations that would later on lead to the harmonization of clinical trials based on the ICH standards. It was then that Quintiles really saw the potential opportunity for the company to grow in Taiwan.

How important is Taiwan to Quintiles' corporate strategy?

VL: Taiwan has always been part of Quintiles' global clinical trial development strategy. We have continuously seen a lot of multi-national pharmaceutical companies interested in early stage clinical trials in this country. Taiwan is also one of the few countries in Asia that has strong research and development (R&D) capabilities in drug development.

JJ: Taiwan very much wants to become a regional hub for clinical research in Asia and is making progress toward that goal.

How are service companies like Quintiles ensuring that Taiwan is maintaining its reputation as a leader in innovation in the field of biotech?

VL: Quintiles is consistently maintaining our key focus of productivity, delivery and quality. From an operational level this is what we can guarantee. This has been at the heart of what we do for the past ten years now.

JJ: We recently released a handbook, "Investigator Initiated Trials Made Easy," as part of our efforts to improve the quality of clinical trials and give investigators direction in how they can conduct their own clinical trials. Whatever country we work in, we work with the local stakeholders to raise the level of professionalism in clinical trials.

What is Quintiles strategy in maintaining a competitive advantage over other CROs operating in the region?

VL: Aside from our history in the region, we also we have several key strategies for ensuring partnerships with both local and multi-national companies. Firstly, Quintiles has an in-depth knowledge in the therapeutic field and a wide experience in different functionalities in clinical developments. With this we are able to provide many local biotech companies with answers to any questions they may have regarding their own development programs. Our second strength is the quality of our staff. Thirdly, Quintiles boasts a strong partnership direction with all of the company's customers. We share their goals and success and always ensure that we are compatible to their development needs. We currently have two prime sites, sites with extensive ongoing studies in about 20 or so projects, in Taiwan with a further four partner sites, which are sites with a fewer number of projects per year.

How has the recent progress in mutually recognized data between China and Taiwan affected Quintiles' operations in these two countries?

JJ: The company recently placed its operations in Greater China, which includes China, Hong Kong and Taiwan, under one leader, who is based in Shanghai. Our customers appreciate having their services brought to them in an integrated fashion under the direction of our Greater China regional headquarters, which will help them more easily reap the benefits of the Cross-Strait agreement on clinical research.

VL: Our two prime sites in Taiwan are two of the four hospitals that are used for mutually recognized clinical data between China and Taiwan.

What challenges does Taiwan present to companies wanting to run clinical trials here?

VL: What is most important for companies is that they find the right partner. For either a local company wanting to expand globally or for a multi-national company wanting to enter Taiwan, a thorough understanding of the regulatory environment is essential, as companies will often get bogged down with this. One the advantages that Quintiles can offer is rich, local expertise.

JJ: Compared to a lot of other countries in the Asia-Pacific region, Taiwan takes much more of an entrepreneurial approach to the biotech industry. There is strong government support and a large number of research institutes focusing on this field.

What efforts is Quintiles making to help smaller, local companies succeed?

VL: Many local Taiwanese companies approach us about taking their clinical trial programs to a global level, and Quintiles can offer sound advice on which market to target and what strategy to take. We are doing a lot of work in this area at the moment. •

Dr. Yasmine Chiu, Joyce Lee & PJ Chen

YC: Senior Medical Director, Pharmacovigilance
JL: Associate Director, Clinical Management
PJC: Executive Director, Clinical Management
PPD


YC


JL


PJC

PPD was founded in 1985 in Maryland in the United States. Can you please give us a brief introduction and tell us about some of your recent milestones?

JL: PPD started operations in Taiwan in 2000, and has grown in an organic way by maintaining high-quality standards over the years. We work closely with the Taiwanese regulatory authorities and keep introducing new technologies to support our clients. In 2005, we started using electronic data capture technology and in 2007, we began to employ electronic trial master file technology. We also have an outstanding intensive global training program for our clinical research associates at all levels. PPD wants its clients to have highly qualified staff working on monitoring their trials. PPD cooperates with 40 medical centers and hospitals in Taiwan.

YC: PPD has undertaken some developments to expand its presence in Asia Pacific. In April, we launched a joint venture with Shin Nippon Biomedical Laboratories Ltd. (SNBL) that will provide a full range of clinical development services in Japan. In addition, we have opened a central laboratory in Shanghai, China, to deliver global scientific and technical laboratory expertise to meet growing client demand for these services in China.

How important is Taiwan to PPD on a global scale?

YC: Asia Pacific has been a big focus for PPD. Within the region, Taiwan is very important as it is a mature clinical development environment when it comes to clinical trials. In fact, Taiwan was one of the first Asia Pacific countries where we established a local office with clinical operations in the region. As such, we have established a phenomenal professional relationship with a large number of experienced clinical research experts and investigators with both global and local knowledge and experience.

PJC: PPD has the capability to provide excellent service to clients of all sizes across all sectors, including large pharma, small and medium-sized clients, and biotech companies. PPD not only provides clinical trial services, but also delivers comprehensive, integrated drug discovery services spanning target identification through Phase 0.

What are some major challenges that CROs face in Taiwan in the development of new drugs?

YC: Taiwan is an advanced, regulatory-friendly country, but as other countries like South Korea have continued to develop and improve their infrastructure for clinical trials, Taiwan has started to trail somewhat. There is a parallel approval process before a clinical trial can be executed in Taiwan. One is the review and approval process by the Taiwan Food and Drug Administration (TFDA) and the other is the review and approval process by the individual Institutional Review Board (IRB). This parallel process sometimes may lengthen the approval time before a clinical trial can actually start. In terms of NDA approval, in some countries in Southeast Asia, once a drug has U.S. Food and Drug Administration (FDA) approval, the process in these countries is almost automatic. In Taiwan, FDA approval certainly helps, but almost always an NDA must start here from scratch, at least to the extent of getting additional data from the local population. The Taiwanese government is looking to help speed up the process and has been initiating and participating in continuous discussions with all interested parties, as well as neighboring countries. For instance, the government here has talked to Korea and Japan about the idea of holding Asian consortium studies to conduct tri-party clinical trials in all three countries and share data in order to support new drug development. In the past 10 years, the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan has conducted several inspections of some clinical trials executed in Taiwan to support part of the data required for the NDA in Japan, and the results of inspection were all very satisfactory. We look forward to an increasingly sound and friendly infrastructure and regulatory environment for clinical trials and new drug development in Taiwan, based on the historically good quality of clinical trial execution here.

What are PPD's plans in Taiwan for the next five years?

YC: PPD can support companies of all sizes, including the local affiliates of global pharmaceutical companies, as well as biotech companies that may possess just a handful of assets in their pipeline, but do not have the resources to run a global clinical trial or plan for an NDA outside of Taiwan, by FDA or EMEA. •

Dr. Ronald Linke

Vice President Healthcare
DKSH TAIWAN

Can you give a brief introduction of DKSH and tell us about some of your recent developments in Taiwan's healthcare sector?

DKSH is the leading market expansion services provider with a focus on Asia. We help other companies and brands to grow their business in new or existing markets. Publicly listed on the SIX Swiss Exchange since March 2012, DKSH is a global company headquartered in Zurich, Switzerland. With 750 business locations in 35 countries – 720 of them in Asia – and 27,600 specialized staff, DKSH generated net sales of CHF 9.8 billion in 2014.

This year we are celebrating our 150th anniversary. DKSH has been in Taiwan since 1958 and is the country's leading provider of market expansion services. We offer our business partners deep industry knowledge, experience and have a capillary distribution network of unique scope and depth. Out of our almost 300 clients that we serve nationwide, more than 60 are from the healthcare sector.

Can you outline some of the principle services DKSH can offer to Taiwanese pharmaceutical companies?

The healthcare part of our business came into life in 2002 and initially only offered pharmaceutical distribution services. Over the course of the past 13 years, we have steadily expanded our business into over-the-counter products, medical devices and pharmaceuticals. We have particularly invested in our commercial capabilities to offer marketing and sales promotion service activities. We now truly provide our clients with integrated and tailor-made services along the entire value chain, offering any combination of sourcing, marketing, sales, distribution and after-sales support services.

Our supply chain capabilities are essential to our success. For example, we are the only company in Taiwan that can deliver any medical device to operating facilities within two hours of requesting it, 24 hours per day.

How important is the healthcare sector to your operations both in Taiwan and globally?

With 46.2% of total net sales, Business Unit Healthcare nowadays is DKSH biggest business. With 150 locations in 14 countries and around 9,200 specialized staff, Business Unit Healthcare serves over 150,000 customers Group-wide. In Taiwan, we have more than 13,000 customers in the healthcare sector, including hospitals, pharmacies, clinics and other outlets.

How does the strength of Taiwan's healthcare sector compare to that of the countries in which DKSH operates?

Taiwan has an extremely comprehensive health insurance system, which is both an opportunity and a challenge. The universal coverage is unique for the island. Taiwanese people have access to any treatment they may require, provided by their preferred specialist and with a minimal waiting time. This system is costly, though.

To what extent is DKSH taking initiatives to help the products of smaller foreign companies, who may not wish to have a presence here, reach those patients in Taiwan in need of them?

DKSH provides market expansion services to companies of any size, whether they are new in Asia, expanding within the region or already well established.

In Taiwan for example, we have been working with a number of biotech companies focused on rare diseases. Because of the rareness of the disease, it is not viable for these companies to establish a fully-fledged presence, yet they want to tap into the Taiwanese market. In such a case, we do all the administrative work for them, including working with the Food and Drug Administration (FDA) to acquire the import license and other registration requirements. We then leverage our network of hospitals to import this product and deliver on a 'named patient' basis. Our marketing and sales teams work closely with prescribers to educate them about the products.

This service allows us to represent companies that do not wish to have physical operations in Taiwan.

What is the outlook for DKSH in Taiwan over next five years?

According to the latest report published by Roland Berger Strategy Consultants, the market expansion services segment for healthcare products in Taiwan is expected to grow by 5.7% per year until 2019.

We continue to focus on offering a range of market expansion services across the entire value chain to companies in Taiwan. This includes continuous investments in our commercial capabilities as well as distribution and logistics.

With regard to the latter, transporting a product from A to B may sound like a simple task, but as the product (like biologicals) becomes more complicated and its storage conditions are narrowed, we must adapt and evolve accordingly.

One of our biggest competitive advantages is quality. We are at the forefront of quality development, which has been high on our agenda since we entered Taiwan. We recently became the first company in Taiwan of our type to acquire all PIC/S GMP licenses even before it was mandatory.

Another focus area of our growth strategy in healthcare is value added services like regulatory services, consignment inventory management, hospital inventory management and market data insights. These services supplement our core services (logistics, distribution, marketing and sales) and provide additional value and growth opportunities for our clients and customers. •

Terry Lin & Freia Wei

TL: General Manager
FW: Director of International Business
UNIPHARMA CO., LTD.


TL


FW

UniPharma was established in 1998 by a team of professional pharmaceutical managers who were focused on a very niche market. Can you tell us more about UniPharma's establishment and growth?

UniPharma was set up to address the unmet medical needs of patients with rare diseases, predominantly in the area of neurology and disease diagnosis. The company's main focus from the beginning was the distribution of international pharmaceutical products, medical devices and diagnostic tests, both domestically and abroad. Distribution rights, however, can be easily lost. To offset these risks and add value to the company, we transformed UniPharma into a research and development (R&D)-driven company and expanded our regional distribution channels.

Developing drugs is a completely different challenge than distributing, is time consuming, and requires large amounts of investment. How did UniPharma overcome these challenges?

Instead of developing drugs from scratch, we got involved with drugs that were at an advanced stage of the process, usually in Phase II of the clinical trials or later stage. We entered into such a partnership was Raptor Pharmaceuticals, a company actively involved in developing orphan drugs, and acquired the licensing rights to be the manufacturer and distributor.

Why has UniPharma chosen to focus more on the self-pay market than on the National Health Insurance's (NHI) reimbursement market?

The NHI's reimbursement scheme has been difficult for us to work with. Although it is a great system for patients, it can be less favorable for the industry due to government control of prices, which restricts profits. UniPharma has decided to focus more on the self-pay market, which accounts for about 70% of our revenue.

One of our major, recent strategies was the decision to expand into the medical device and in vitro diagnostic test market. In 2013, we were awarded the manufacturing rights of DR-70 diagnostic test, which is a minimally invasive, FDA 510(k) cleared test for colorectal cancer follow-up and monitoring. It can also screen for thirteen different types of cancers at an early stage. While we currently hold the licensing agreement to manufacture and distribute this product in Taiwan and a number of Asian countries, we are aiming to use our GMP certified manufacturing facility to produce DR-70 for other global markets.

UniPharma plans on becoming a public company next year. Why did you decide to go public and how does this fit into your goals for the future?

In order to become a publicly listed company there is a strict set of standards that must be met. We are currently in the process of ensuring that we are compliant with these standards and intend to successfully file for an IPO in 2016. UniPharma is distinguished and unique in that we have a number of products in the market, while we continue to strengthen our capability in R&D to increase our product pipeline. By building trust in our brand and company image, we are hoping to further our collaboration efforts with global partners and maintain steady growth. •

Richard Shen

Chairman
KERRY TJ LOGISTICS CO., LTD.

Can you talk about the circumstances under which T-Join Logistics merged with Hong Kong's Kerry group and how the company has moved forward?

In 2008 Kerry logistics Network (KLN), an international logistics group, started gradually acquiring T-Join's shares from the public market to become the majority shareholder. As the main shareholder, KLN restructured the organization and re-branded the name to Kerry TJ logistics. T-Join Logistics was established 60 years ago and under its new name Kerry TJ, the company bought the building we are currently in, thus moving the headquarters from the center of Taiwan to Taipei, the capital city and also the home of the majority of our international clients. With all of KLN's affiliates now based in this office, Kerry TJ has greatly improved its efficiency and with a growth of 25% CAGR on core net profit in 2014 compared to 2008.

What is the strategic role of the pharmaceutical industry to Kerry TJ?

Before the Taiwan government insisted that any company dealing with pharmaceuticals comply with PIC/S, the majority of logistics operators were not as concerned with the quality of their operations. Kerry TJ wanted to offer a global standard of pharmaceutical logistics services, as set by KLN head office in Hong Kong. We endeavored to build up our branding in line with the quality of the service we offered; quality assurance now supports the company branding, not the other way round. We can now offer a fully integrated, total solution service and hope to expand our operations to pharmaceutical distribution, in addition to logistics.

Can you give us an example of a recent project that demonstrates your services?

Recently, we worked with Lotus Pharmaceutical on good distribution practices (GDP) for both their facilities and product transportation. We also worked with the delivery of Baxter Healthcare's products to patients' homes in Hong Kong.

What outlook do you have for the pharmaceutical side of your business?

We initially needed an area to maintain KLN's operations in pharmaceuticals, which Taiwan offered, but now are looking to expand to Asia and globally by providing a total-solution service in line with international standards. We want to be recognized as an internationally qualified, GMP/GDP compliant operator and to be able to assure our clients that their products are safely and securely transferred to medical centers and, ultimately, to patients. •

Wayne Hsu

Managing Director
CHI-FU TRADING CO., LTD.

Chi-Fu was started eighty-five years ago under the Japanese occupation. How has the business evolved into its operations today?

My grandfather started the business while he was an apprentice at a pharmacy. He opened his first pharmacy in 1930, when he was 18 years old. Back then it was a local neighborhood pharmacy, but he started importing British and European products through the Shanghai branch. He did not work directly with Japanese manufacturers until after the war. As the Republic of China started to impose more stringent rules on imported products, it reduced our inventory. So he moved the focus to helping multinationals distribute products in Taiwan.

What are some of the services that Chi-Fu provides for pharmaceutical companies?

Chi-Fu provides turnkey solutions for international pharmaceutical companies. We provide market evaluation to suppliers and manufacturers to help them decide if they would like to expand into the market. Chi-Fu then assists in registration, launch, distribution, marketing, and logistics.

What are some of the barriers to trade for international companies to come into Taiwan?

To set up a local task force as an outsider is extremely difficult. The market is ever changing due to regulations and market trends. Also, unless you are operating on an economy of scale you simply cannot acquire enough market traction to make it profitable. The market is set up to eliminate corruption and prevent fraud but the vast amount of hurdles and restrictions become counter productive and push manufacturers towards questionable activities at times.

The current universal health care system was launched in Taiwan two decades ago. How has this affected the business environment for Chi-Fu?

In the beginning, we moved towards high-end generics, but the market value of generics was their low cost, so we are now the largest distributor of low cost generics from India. Multinational companies such as Novartis, which are branded as 'high-end generics', are not doing as well because in Taiwan they are still simply generics. Chi-Fu also has a wide product offering, which protects us from price cuts in the market.

What do you foresee for the Taiwanese pharmaceutical market?

Generics will continue to expand and the smaller players will disappear. Certain products will also disappear due to a lack of demand. The Taiwanese healthcare system will only reach the level of quality that it presently aspires to when patients can co-pay for their healthcare. •

Into the Future: Final Thoughts, Company Index, and Credits

"The biotech industry in Taiwan will continue to grow rapidly, and we will see more successful companies, whether they are working in small-molecule drugs, protein-based therapeutics, or medical instruments arena. The country possesses a great deal of talent, innovative power, resources and business opportunities in biomedical research in general, which will lead to excellent opportunities for the growth of the biotech and pharmaceutical industry."

- Dr. Chuan Shih, Director, National Health Research Institutes (NHRI)

Image: NH / Shutterstock.com

A Diamond in the Rough

Taiwan's Pharma Future

“Although the NHI is a great system for patients, it can be less favorable for the health care industry, as the government controls the prices. As a result, profit margins can be somewhat strained. Due to this predicament, UniPharma has decided to focus more on the self-pay market, which accounts for about 70% of our revenue.”

- Terry Lin, General Manager, UniPharma Co., Ltd.

Throughout the past few decades, Taiwan has been seen as a Mecca for Western industries wishing to enter the Asian market. Its geographical positioning, vast talent pool, and English being a primary secondary language made it the perfect entry point to the Chinese market. While such benefits could apply to all industries, it is clear that the pharmaceutical and biotechnology sectors have been the focus of the Taiwanese government's efforts from the abundance of industrial clusters and the support of four major ministries to the fact that over half of Taiwan's business incubations are involved in either the pharmaceuticals or biotechnology.

Taiwan enjoys a world-renowned health care system with 495 hospitals and 21,218 clinics across the country as of 2013, as well as a large number of drug stores and outlets for both Western and traditional Chinese medicines. However, a rapidly ageing population has put pressure on these medical centers and with domestic market demand for pharmaceuticals rising from $5,366 million in 2012 to $5,442 million in 2013, companies are now seeking to find more cost-efficient ways.

There is little doubt that Taiwan has the capabilities to fully exploit an industry and position itself as a global hub, as evidenced by the Taiwan Economic Miracle. Some may question if a policy that worked for information technology can easily be replicated in pharmaceuticals and biotechnology, but it is important to remember that Taiwan has one of the world's most successful health care systems. Taiwan's National Health Insurance (NHI) was established in 1995, currently provides healthcare to 99% of Taiwanese citizens, and has been highly praised internationally for its accessibility and efficiency. However, it has proved difficult for some companies to work with the NHI due to constrained profit margins. Terry Lin, general manager of UniPharma commented: "Although the NHI is a great system for patients, it can be less favorable for the health care industry, as the government controls the prices. As a result, profit margins can be somewhat strained. Due to this predicament, UniPharma has decided to focus more on the self-pay market, which accounts for about 70% of our revenue."

There are needless to say a number of challenges that stand in the way of Taiwan growing into a major hub for the pharmaceutical and biotechnology industry. To start with, the market itself is fairly small, with biotechnology bringing in revenues of $2,627 million and pharmaceuticals bringing in $2,768 million in 2013. In light of these figures, Taiwan must develop its role as an entry market for Mainland China and other major Asian markets.

Another challenge is its regulatory bodies, which many believe are reluctant to make bold moves and be the first to approve new drugs. While this trend looks set to continue, there is some room for optimism, with the TFDA's decision to be the first regulatory body to approve Taigexyn, a new chemical entity, broad spectrum, non-fluorinated quinolone antibiotic that is available in both oral and intravenous formulations.

Dr. Carl Firth, CEO of Aslan Pharmaceuticals, explained: "One of the big challenges is that the country has not had the experience in biotech that either the United States or Europe have. There is not as much understanding of the level of risk involved. In biotech, perhaps nine in every ten companies fail and to date, a lot of the companies in Taiwan that have progressed have not fully shared the right balance of risks with their stakeholders. As a result, the expectations are very high. The problem is that if a company cannot deliver on its expectations, suddenly people start panicking, which can damage the industry."

Since the Taiwanese government first earmarked the pharmaceutical and biotechnology sectors as a key focus for national development in the 1980s, the industry has exploded onto the business scene with numerous industrial clusters dotted throughout this small island of innovation. Yet the Taiwanese pharmaceutical and biotechnology industry is still a work in progress, with numerous agencies and policies only being established in the last ten years. It has a healthy pipeline of potential products, but only time will tell if any of these will reach blockbuster status. For now, we can contend that the government's encouragement of the industry is working, as investments and revenues increased by 6.3% and 5.3% in 2012 and 2013, respectively. As one of a few countries in Asia that chose to focus on the research market rather than the generic market, it could be argued that policies such as the aptly named Take-Off Diamond Action Plan have truly made Taiwan's pharmaceutical and biotechnology industry a diamond in the rough. •

Dr. Chi-Huey Wong

President
ACADEMIA SINICA

Academia Sinica is considered the premier research institute in Taiwan. What role does Academia Sinica play in the research for new drug discoveries?
The academy is the highest-ranking research institution in Taiwan and is involved in cutting edge research in the fields of sciences and humanities. Our role is focused on fundamental research so in the case of biotechnology, we would conduct the basic research and then use any important discoveries as a foundation for further collaboration within the institute or with other research entities to the stage for tech transfer. We decided to build a bioscience park, as this would enable us to bring together the basic research of Academia Sinica and the translational research of the various research departments of the Ministry of Economic Affairs, Ministry of Science and the Ministry of Health and Welfare. This initiative has allowed us to move efficiently from the basic research stages to translational research, which will help to bridge the gap between discovery research and innovation.

Academia Sinica is a crucially important resource for many major research companies here in Taiwan. What is the institution's relationship with these companies?
Academia Sinica currently works with a number of major research organizations and biotech companies here in Taiwan, including NHRI, ITRI, DCB, NTU, OBI, CHO Pharma and TaiGen. However, our relationship with these biotech companies is limited only to tech transfer, whereas Academia Sinica will do the basic research and then transfer our discoveries over to these companies. After this transfer, our scientists may act as advisors to these companies or collaborate with the company on the project related to the transferred IP and funded by the company, but they are primarily in charge of bringing the research forward.

Academia Sinica has some of the best talent in this industry. Why do graduates choose to come to Academia Sinica?
Academia Sinica is world-renowned for its work in the area of academic research. We have the best facilities in all of Taiwan and an excellent faculty; we take our role in training the next generation of talent seriously. For graduates who are very focused on furthering their careers in research, Academia Sinica is the clear choice for them.

Academia Sinica has a number of joint programs with local and international universities. Can you talk to us about these programs and the universities with which you collaborate?
One of our main local programs is with National Taiwan University (NTU) in the area of translational medicine. The purpose is to train physicians to become physician-scientists, so after receiving their MD from NTU, they will come here to complete their Ph.D. We also have an international graduate program called TIGP and a number of joint programs here that are interdisciplinary, such as chemical-biology and biophysics, nanoscience and technology et al. We do not have the same boundaries as universities, where one can usually only specialize in one field. These programs are carried out in collaboration with local universities and the students receive their degree from that university. The TIGP program is also open to students from foreign universities.

As the president of Academia Sinica, you also act as a chief science advisor to the government. How do you feel about Taiwan's evolving regulation with regards to research in this field and what role did you play in helping to change it?
I first started to take a role in trying to enact a new by-law in 2003 to facilitate biotech development in Taiwan. I was involved in writing the articles and helped to get the by-law approved by Congress, which was finally enacted four years later as the Biotech and New Pharmaceutical Act (2007). This act encouraged new drug discovery and high-end medical devices and helped promote investment to this high-risk area by providing tax deductions. It also allowed inventors to own technical stocks and serve as founding scientists, board directors, and scientific advisors, and universities and research institutions like Academia Sinica to own their IP, whereas in the past the state would have owned it. This law helped Taiwan grow into a center of research excellence and biotech development.

The coming decade is going to be an exciting time for the biotechnology industry. Can you talk to us about your thoughts on this industry as well as the future of Academia Sinica?
In the coming years, the biotechnology industry will become one of Taiwan's major industries. As biotechnology is an environmentally friendly industry, it is a great choice for Taiwan to focus on, especially in the Taipei area where there is a concentration of excellent academic institutions and medical centers. The industry will continue to grow and expand, due to the creativity of the Taiwanese scientists as well as the unwavering support from our government. I am equally optimistic about Academia Sinica's future. We will continue to build on our strengths, especially in the life science area. With the completion of our bioscience park next year, our activity will be greatly increased. This is not only a great step forward for the institution, but also for the industry and the academic environment as a whole. •

"This is an exciting time in terms of research as China and Taiwan have, in recent years, entered into a free trade agreement that is helping to make research findings in both countries interchangeable. This will be a crucial step forward for both countries, as both China and Taiwan can learn from each other."

- Dr. Mei-June Liao, President,
United BioPharma Inc.

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"GWOXI will continue to expand on applications and integrations for stem cell research, tissue regeneration, and genetic engineering. GWOXI's deposit bank for autologous, adipose-derived stem cells is officially open to the public since September 2013. And the first time stem cell clinical trial for liver cirrhosis in Taiwan will kick off in 2015. These make GWOXI a leader in stem cell-regenerative medicine in Taiwan and we hope to maintain that leadership going forward."

- Mercy Chuang, Chairman/CEO & Dr. Po-Cheng Lin, Vice President,
Gwo Xi Stem Cell Applied Technology Co., Ltd.

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"We want to be focused solely on the development of new drugs. Recently, we have sent our product to the National Institutes of Health (NIH) as virus drug screening, including Ebola and other life threatening viruses. Our material has been tested to be very effective and NIH thought it could be a promising candidate. The focus of our R&D going forward will be to develop new antiviral drugs, which we hope to bring on the market to address these issues and help people around the world."

- C. C. Chiuh, President,
FEBICO

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"HEB has received clinical research grants from several Taiwanese governmental development programs, especially the Ministry of Economic Development, in the R&D of our MCS-2 drug. On a more international front, HEB is negotiating partnerships with companies specialized in different territories to ensure the product will be safe and efficient once approved and put on the market."

- Fu Feng Kuo, CEO,
Health Ever Bio-Tech Co., Ltd.

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"For biotech companies in Taiwan, most are coming from the United States, so they are already in global expansion. For local companies, they understand that they must extend their reach beyond Taiwan because the domestic market is small. For example, last year we entered into an agreement with a Canadian company because it had done the research and development (R&D) through Phase IIB for P113, a new drug. This drug was in R&D for about seven years, and it has now been in development for two or three years, with $5 million to $6 million invested in contract research organization clinical trials."

- Frank Lin, Vice President, Marketing,
General Biologicals Corp.

"As a company wanting to develop an NCE, we started by screening many thousands of fungi and developing the technology behind the fermentation processes used to extract a compound. Out of the many fungi screened, we singled out Antrodia camphorata, which is endemic to Taiwan. There have already been several compounds isolated from this fungus, but it was in our labs that we discovered, in the mycelia, new compounds."

- Alex Liu, Chairman and CEO,
Golden Biotech

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"Our flagship product is SR-T100, which is extracted from a plant endemic to Taiwan, and is the first product ever developed that is able to target and treat cancerous cells without any damage caused to healthy cells. This product is currently in clinical trials both in Taiwan and the United States for three different indications: actinic keratosis, genital warts and verrucae. An injectable form of this drug is currently in pre-clinical development, but once in human trials, this will be able to treat solid tumors in the body."

- Dr. Kou-Wha Kuo, President,
G&E Herbal Biotechnology Co., Ltd.

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"In 2014 the government announced that all pharmaceutical companies must comply with the pharmaceutical inspection cooperation scheme (PIC/S). As a traditional Chinese medicine company, we are exempt from this but we intend to be the first company of our kind to pass this standard, by 2018. We hope to achieve this by 2018. Additionally, we are looking to expand abroad. Currently 80% of our market is domestic, but we would like to increase our export market to 50%. To do this, we need to expose the benefits of Chinese traditional medicine to the rest of the world."

- Dr. Wei-Chu Li, Vice General Manager,
Sheng Chang Pharmaceutical

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"OBI's most advanced candidate drug, OBI-822, Globo H-KLH, is an active cancer immunotherapy targeting Globo H, a glycan found highly expressed in breast cancer patients, and also other 13 types of cancers. To further strengthen our pipeline, OBI licensed exclusive global rights to develop OBI-833, another Globo H-targeting cancer immunotherapy drug with a preferred antibody profile, and OBI-868, a cancer diagnosis technology from Academia Sinica."

- Dr. Youe-Kong Shue, Vice Chairman,
OBI Pharma

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"There has been strong government support in Taiwan for biotechnology. For a country the size of Taiwan it is difficult to have a truly self-sustaining ecosystem and certainly the government has succeeded in building a strong portfolio of local companies and local capabilities. The next step is to ensure that Taiwan remains open to foreign investments and foreign companies that want to work here."

- Dr. Carl Firth, CEO,
ASLAN Pharmaceuticals

This list contains those companies interviewed during the course of research for this publication and as such represents only a limited selection of the companies operating in the pharmaceutical industry of Taiwan. It should not be considered a comprehensive guide. GBR holds an exclusive and extensive pharmaceutical database for Taiwan and the wider region. For further information on database access packages, please contact info@gbreports.com or call +44 20 7812 4511.

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Additional copies of this book can be ordered through Elif Ozturk (elif@gbreports.com).

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mohw.gov.tw/EN/Ministry

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bpipo.org.tw

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tgpa.org.tw

TAIWAN FOOD AND DRUG ADMINISTRATION (TFDA)
fda.gov.tw/EN

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