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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This report has been conducted by Uta Negre and Luis Montes, Senior Analyst, Global Business Reports
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Taiwan Pharmaceuticals & Biotechnology 2015

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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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.”

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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). A place of 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 alliances with the United States.

Today, Kai-Shek’s legacy is alive and well in Taiwanese politics. The current president, Ma Ying-jeou, who was elected for his first term in 2008 and re-elected in 2012 for another four years. Ma served his first term in 2008 and re-elected in 2012 for another four years. Ma served as President from 2000 to 2008, and is hoping to duplicate the country’s success for Taiwan, and appears to be in fine shape. In recent decades, Taiwan has leveraged the talent of its people, and the vibrancy of its economy, on the other hand, has always been a source of pride and genuine success for Taiwan, and appears to be in fine shape.

Economic Overview

Taiwan faces clear economic and political pressures that 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 alliances with the United States.

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Talented Taiwan

A Brief Political and Economic Overview

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 Taiwan’s 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 was reelected for another four years. Ma served as President Ma Ying-jeou (since 20 May 2008) for the only time in Taiwan’s history that the KMT did not hold the office.

Analysts credit the KMT’s poor results in the general election held in November to widespread voter disappointment in the KMT’s handling of economic growth. Ma’s administration has been criticized for its inability to address economic challenges, many of which are beyond its control, but its past economic success, of which Taiwan is proud, has driven the world economy, and business leaders regard it 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. Today, Taiwan has leveraged the talent of its scientists with the mainland, China, which was the first direct correspondent toward Ma’s government, which they source to the government’s role in encouraging a thaw in Taiwan’s relations with the mainland. In 2008, Ma, as 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 nevertheless 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 scientists with the mainland, China, which was the first direct correspondent toward Ma’s government, which they source to the government’s role in encouraging a thaw in Taiwan’s relations with the mainland. In 2008, Ma, as 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.

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The Ministry of Health and Welfare (MOHW) and Taiwan's Food and Drug Administration (TFDA) are different from other organizations in terms of principle investigator in multi-national drug development projects. The MOHW and TFDA have established a patient-centric strategy for developing pharmaceuticals, food, cosmetics, medical devices, and biotechnologies. The MOHW plays a key role in promoting the biotech industry and also in the development of products.

Today, Taiwan's pharmaceutical industry is promoting the development of products. The MOHW and TFDA have established a patient-centric strategy for developing pharmaceuticals, food, cosmetics, medical devices, and biotechnologies. The MOHW plays a key role in promoting the biotech industry and also in the development of products.

Taiwan is recognized as having one of the world's best public health care systems. The MOHW and TFDA have established a patient-centric strategy for developing pharmaceuticals, food, cosmetics, medical devices, and biotechnologies. The MOHW plays a key role in promoting the biotech industry and also in the development of products.

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 care nationwide. The TFDA was inaugurated in 2010 as a subsidiary of the MOHW.

The biotech industry, as an emphasized mainstream industry, is promoted by the Taiwanese government. The MOHW is the principal government agency for the administration of public health care nationwide. The TFDA was inaugurated in 2010 as a subsidiary of the MOHW.

In order to leverage international relationships between these two agencies? The MOHW and TFDA have established a patient-centric strategy for developing pharmaceuticals, food, cosmetics, medical devices, and biotechnologies. The MOHW plays a key role in promoting the biotech industry and also in the development of products.

Dr. Johnsee Lee
HONORARY CHAIRMAN TAIWAN BIO INDUSTRY ORGANIZATION (TBO)

Dr. Johnsee Lee is the Honorary Chairman of the Taiwan Bio Industry Organization (TBO). He is a leader in the biotech industry and has played a key role in developing the industry in Taiwan. He has served in various capacities at the MOHW and TFDA, and has been a driving force in establishing the biotech industry in Taiwan.

ATTAINING PIC/S COMPLIANCE WAS A MAJOR ACHIEVEMENT FOR THE MOHW AND TFDA.

Attaining PIC/S compliance was a major achievement for the MOHW and TFDA. The Ministry of Health and Welfare promotes public health and in line with industrial development by establishing harmonized regulations and standards. The MOHW and TFDA have established a patient-centric strategy for developing pharmaceuticals, food, cosmetics, medical devices, and biotechnologies. The MOHW plays a key role in promoting the biotech industry and also in the development of products.

The MOHW and TFDA are different from other organizations in terms of principle investigator in multi-national drug development projects. The MOHW and TFDA have established a patient-centric strategy for developing pharmaceuticals, food, cosmetics, medical devices, and biotechnologies. The MOHW plays a key role in promoting the biotech industry and also in the development of products.

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. Through regular meetings, TBIO has fostered international cooperation and has been supportive for the past 26 years.

Dr. Ming-Neng Shiu
VICE MINISTER MINISTRY OF HEALTH AND WELFARE, GOVERNMENT OF TAIWAN

Dr. Ming-Neng Shiu is the Vice Minister of the Ministry of Health and Welfare in Taiwan. He has played a key role in promoting the biotech industry in Taiwan and has been instrumental in establishing the biotech industry in Taiwan.

The Ministry of Health and Welfare (MOHW) plays a key role in promoting the biotech industry 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. The MOHW plays a key role in promoting the biotech industry and also in the development of products.

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 care nationwide. The TFDA was inaugurated in 2010 as a subsidiary of the MOHW.

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The Ministry of Health and Welfare (MOHW) is the principal government agency for the administration of public health affairs nationwide. The TFDA is responsible for the administration of pharmaceuticals, food, cosmetics, medical devices, and biological products.

The MOHW has played an important role in promoting the biotech industry and also attracts overseas manufacturers to outsource their manufacturing activities. It has also fostered international collaborations between these two agencies.

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 health affairs nationwide. The TFDA provides legal, intellectual property, technical, and commercialization services.

Taiwan is recognized as one of the world’s best public health 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.

Attaining PIC/S compliance was a major priority. 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 400 doctors for every 1,000 people, including the dentists and traditional Chinese medical doctors. We also have the State Health Insurance Program to care our National Health Insurance also covers. We have 21,218 clinics and 495 hospitals, of which 92.1% have passed the MOHW’s assessment.

The MOHW and Taiwan’s Food and Drug Administration (TFDA) protect 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.

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 healthcare related products.

Dr. Johnsee Lee
Honorary Chairman
TAIWAN BIO INDUSTRY ORGANIZATION (TIBIO)

TIBIO 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 TIBIO 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 downstream commercialization. The DCB 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 BPPO agency. Taiwan BIO, on the other hand, is a totally independent, private industrial partnership.

Can you talk more about the collaboration 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 opportunities for Taiwan on an international scale and what role will the country play globally? Taiwan has come a long way in the past 25 years and now occupies a position of great importance 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 global trials to Taiwan. One thing that makes Taiwan an attractive option is its capital markets. A second challenge would be the bureaucratic nature of the drug-approval regulations. A final challenge is Taiwan’s culture. One thing that makes Taiwan attractive compared to China is its relatively more open cultural environment for the growth of this industry. The more companies that moms clinical trials of new drugs, 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 the world was suffering? The MOHW 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 BPPO agency. Taiwan BIO, on the other hand, is a totally independent, private industrial partnership.

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 healthcare related products.

Having China so close is certainly another advantage. 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-national companies looking for a springboard into the Asian market. China also has a double-edged sword and political tensions between us is still an issue. This makes Taiwan attractive compared to China.

A second challenge would be the bureaucratic nature of the drug-approval regulations. A final challenge is Taiwan’s culture. One thing that makes Taiwan attractive compared to China is its relatively more open cultural environment for the growth of this industry. The more companies that moms clinical trials of new drugs, the more Asian-prevalent diseases. In this sense, we are already recognized globally for the high standards of our facilities and investigators.
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 1962 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 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 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

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
Taiwan Pharmaceuticals

Entry Point for Asian Markets or Global Hub?

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

Source: PwC Taiwan

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- Dr. Chi-Huey Wong, President, Academia Sinica
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 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 either the pharmaceutical or biotech sectors.

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In 2014, 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 Taiwan 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 other countries such as the United States. Dr. Chi-Huey Wong, president of Academia Sinica, said: “The industry will no doubt continue to grow and develop, 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.

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. The TGPA, 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.

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.

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.

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 manufacturers 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.
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 (PICoS) in 2013, with the agreement that Taiwan would start implementing PICoS 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 Co-operation 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 was not ratified by the US Congress, it 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. PICoS compliance, a high percentage 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 that is being further enriched by the return of many highly skilled and successful Taiwanese citizens 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.

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 industries, particularly related to the pharmaceutical regulations or the guidelines about the National Health Insurance. Also, our members 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 products abroad, membership of the TGPA is probably the most convenient means of achieving this.

How important is innovation to a generic pharmaceutical company? 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.

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Taiwan’s Biotech and Pharma Sectors on the Up

Over the years, Taiwan has created a favorable environment for its biotechnology and pharmaceutical industries, which encompasses the applied biotechnology, pharmaceutical, and medical device sectors. Alone in the region, Taiwan has a strong CRO infrastructure as well as product development, and an institute culture that respects intellectual property rights.

The government has enacted several policies and laws to position biotechnology, pharmaceuticals, and biotech as key priority industries for Taiwan in the 21st century. Its strong policy and financial support has spurred 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 investment. 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. Through relatively small but significant increases, 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 research and infrastructure, and a solid reputation for well-run clinical trials focusing on Asia-prevalent diseases. The government is currently focusing 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 has also signed a medical and healthcare cooperation agreement in 2010, which has led to increased collaboration on drug R&D. With Taiwan in the drug discovery process for certain drugs and enabling Taiwanese players to take advantage of Taiwan’s biotechnology and pharmaceutical industries. This will likely attract more international biopharmaceutical companies to develop in Taiwan.

PwC observations
PwC sees continuing strong growth in Taiwan’s biotechnology and pharmaceutical industries. This will likely attract more international biopharmaceutical companies to develop in Taiwan. PwC is helping 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.

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

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Taiwan is working closely with China on pharmaceutical issues. Their 2010 medical and healthcare cooperation agreement has ushered in a new era of drug development and clinical trial testing. This positive development will further 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 pharmaceutical companies as well as local Taiwanese players to take advantage of their manufacturing and product development capabilities as well as the experience in marketing and distribution in the region—to increase their Asia presence, especially with regard to China.

PwC’s Taiwan’s Health Industries Leader Lily Chiu, the survey’s project director, says Taiwan’s biotech and pharmaceutical industries have always been driven by strong talent pools, but recent trends indicate that these are diminishing and that what is NHRI doing to combat this?

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 with the support of 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.

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**Is the biotech market becoming a bubble?**

In 2013 we raised $2.4 billion and are now the second most active capital market after the United States. A bubble is a natural phenomenon with this sort of growth and whether it bursts 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 mission in Taiwan’s-Chinese trade relations?**

Through 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, much in the way of international interest. The Taiwan’s biotechnology industry?

**What does TRPMA’s mission in promoting research and development (R&D) in Taiwan’s-Chinese trade relations look like?**

TRPMA is 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 YYF along with the National Development Fund (The D Fund) support, was originally successful through biopharmaceutical companies such as TaGen, 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 worked with a private investor and is planning an IPO later this year.

**What are some of the challenges that the biotech sector faces in Taiwan?**

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 50%. What are the main factors behind this meteoric increase?**

According to a ranking of 54 countries by Scientific American, Taiwan is 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 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.

**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 you 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 as 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 constraints, the government ensure that it is able to sustain the single-payer healthcare system evolving over the next five years? 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, work 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.

**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 biotech 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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The DCB’s objective was to create a domestic market for biotechnology products, which is its focus today. One of the DCB’s goals is to create a pre-clinical value as an integrated service center for biopharma. How does the 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 approval, we can share this information with a partner to transfer the product to the industry. This timeline can take four to five years.

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How do you see PwC’s role in Taiwan’s healthcare sector evolving over the next five years? PwC sees significant growth potential in the biotech and healthcare sectors 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 China presence, especially with regard to the Chinese market.
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. Shih-I (Shiow-Ing) Wu, Deputy Director-General, Taiwan Food and Drug Administration (TFDA)
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Taiwan’s Healthcare Regulatory Structure

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Government Backing

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 infringements and low costs have been equated to poor 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 been doing so to the benefit of millions, and even if the industry 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 development.

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 market for Taiwan’s products; and improve the reputation and competitiveness of Taiwan on the global stage. The Vice-Minister of Health and 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 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."

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 extensive, with directives from the above institutions trickling 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 and the National Development Fund, 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
Setting Taiwan on the Path to New Discoveries

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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), the Industrial Technology Research Institute (ITRI) and the Medical and Pharmaceutical Industry Technology and Development Center (PTDC). However, one of the primary agencies operating under the umbrella of the MOEA is the Biotechnology & Pharmaceutical Industries Promotion Office (BPIPO), whose primary objective is to promote the industry and in doing so increase international investment. With an aim to improve the investment environment, it also strives to establish an expansive R&D system, promote industrial development strategy, and frequently revises development regulations. The MOH&FW 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 departmental 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 unrivaled across Asia. Furthermore, while benefiting from a liberal tax regime, international companies can rest assured that there is no compromise in quality as Taiwan is now PCIs compliant and meets the necessary standards for Good Manufacturing Practice (GMP). 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.”

TAINW’S HEALTHCARE REGULATORY STRUCTURE

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The Biotechnology and Pharmaceutical Industries Promotion Office (BPIPO) was established through the National Industrial Development Promotion Office (NIDPO) and the Ministry of Economic Affairs (MOEA). BPIPO holds regular meetings with companies where they have an opportunity to raise any issues that need to be addressed.

Dr. Chien-Hsin Daniel Cheng
Form Director of BPIPO

Since Taiwan has lowered the inheritance tax rate from 40% to 10%, a large amount 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 in investment in start-up companies. As another example, Daia, 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% of this investment.

What is your outlook for the growth of Taiwan’s biotech and pharma sector?

This year we are estimated to reach $50 billion NT in biotech investment, an increase of just $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 0.6% 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 50 companies are focused on biosimilar and innovative antibodies drugs.

The World Economic Forum ranked Taiwan as number one in the world for the cost of its industrial clusters. This is partly because of the investment from Taiwan’s biotech and pharma sector.

Dr. Shiow-Ing Wu
Deputy Director-General of BPIPO

The government had ambitious goals for Taiwan’s biotech and pharma sector. We expect the government to help with product development. This means that many big pharma companies are setting up clinical trial centers in Taiwan. Furthermore, these regulations are harmonized with advanced countries.

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

Since 2013, the Ministry of Economic Affairs (MOEA) has been working to promote the biotechnology industry. The Ministry has established the Center for Drug Evaluation (CDE) to establish the Center for Drug Evaluation (CDE) in 1998 as an independent body. The Center’s mission is to ensure the safety and quality of all pharmaceutical products that are approved in Taiwan. It also plays a major role in helping pharmaceutical companies in Taiwan to export their products internationally.

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 safety and quality of all pharmaceuticals that are approved in Taiwan and exported to other countries. It also plays 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 integrate 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.

Dr. Churn-Shiouh Gau
Executive Director of the TFDA

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 search resources and CRCs for clinical trials. This means that many big pharma companies are setting up clinical trial centers in Taiwan. Furthermore, these 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.

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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 into 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 subsystems 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 startup companies. Previously startup companies were burning cash and doing clinical trials with difficulty 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 startup companies. As another example, Daiva, 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 strength of its industrial clusters. 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.

What is your outlook for the growth of Taiwan’s biotech and pharmaceutical sectors?

This year we are estimated to reach $50 billion NT in biotech investment, an increase of 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, 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.

Could you describe the relationship between the TFDA and various other government agencies?

The Ministry of Health and Welfare established the Center for Drug Evaluation (CDE) in 1998 as an independent body. What was the TFDA’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 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.

Could you talk about the CDE’s relationship with the 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?

In terms of the TFDA, with respect to pharmaceuticals, has always been to protect public health with respect to consumers 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 out of Taiwan. The TFDA plays 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, manufacturing and marketing. It is a rigorous process, which aims to make sure that only safe products will become available to the public.

Dr. Shiow-Ing Wu

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

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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.

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Taiwan has built a reputation for producing quality products. Starting with the information technology (IT) sector, Taiwan had 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 GlaxoSmithKlna (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, vaccine, 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&BC 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 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. Wei-chyun 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 project 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 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. •
A Beacon of Quality
Manufacturing Excellence in Taiwan

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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 high-quality infrastructure, 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 high as a choice for regional clinical trials. The high standard of medical centers will always ensure that there are homogeneous 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 become 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 this 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.
Kevin Liu
Director of PAPAC & 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 is keen on the need to treat the diseases 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 virility 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.

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René Jensen
Vice President and General Manager
GLAXOSMITHKLINE (GSK) TAIWAN

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

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 been 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 first 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 healthcare 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 multi-national 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 hospital reimbursement portfolio, it can take two to three years to get regulatory approval from the Taiwan Food and Drug Administration (TFDA), pricing in reimbursement from the National Health Insurance Administration (NHIA), and listing in hospitals, before new medicines become commercially available.

For example, GSK’s quadrivalent inuenza vaccine (QIV) Fluarix Tetra was launched in Taiwan in 2013, 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 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 access 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?

Our top priorities are to grow our best 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 industries and the current healthcare ecosystem.

GSK has recently completed an agreement with Novartis, which will further expand our vaccine portfolio. Additionally GSK has taken on a number of initiatives to change the way that it promotes its products. From 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 do our sales, by focusing payments to them for speaking about our products on our behalf.
Taiwan Pharmaceuticals & Biotechnology 2015

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

Lotus Pharmaceutical Co. Ltd. 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, Lotus’ partnership with Alvogen will allow us to explore more market potentials and compare 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’ stratic 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.

Can you provide us with a brief introduction to Standard Chem. & Pharm. Co.? What do you foresee over the next ten years for your two companies?

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 multiple stage-controlled release, trans-dermal patches, oral disintegrating tablets, sustained release, and microgranules. In December 2014, OP signed a licensing contract with Beijing Tide Pharmaceuticals Co. Ltd. for dementia patch technology. Furthermore, OP is focusing on a 50:50 (b2b) 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. OEP 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 Methylphenidate Hydrochloride USP 10 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 launch 2-3 products 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.

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

Lotus’ partnership with Alvogen will increase our scale, portfolio and geographic reach. Furthermore, OEP Group will further develop the Asian and U.S. market.

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

We started the company in 1987 with only NT$300,000 and headquarters have a market cap of NT$8.8 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.

A bubble is forming, but with a strong flow of investment. A bubble would like to establish an office in the near-term. We will also be looking to Southeast Asia and the United States, and more specifically to the Asian and U.S. market. Combined with Alvogen’s strong geographic coverage in the United States, Central and Eastern Europe, and Asia, and Alvogen’s 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.

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OEP 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 Methylphenidate hydrochloride 10 mg/30 mg.
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. Our new API plant has a total capacity of 600 mt, with 6,000 to 8,000 liter reactors.

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.

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.

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 daily? 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’ history matters 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 making it more environmentally friendly so that 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.

Some major clients include Sanofi and Novartis; but we have also worked with smaller, new drug development companies. How much of your production is exported? What are your major export markets?

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 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. Where 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 South-East 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.
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Can you please give us an introduction and a brief history of Formosa Laboratories? (R&D)?
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 Selenam for lowering phosphates; both are resistant 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.

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Contact Michele Seah

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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 mark-ets 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 and 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 Taiwan 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 technolo-
gies to contract manufacturers so we decided to buy a plant that Eisai was selling. This plant was one of first ten to be PICoS certified and had lots of expan-
sion possibilities. As part of the contract we also agreed to be a toll manufacturer for Eisai. Our Taiwanese factory currently manufactures our own Bora products, including many that came with our ac-
quision of one of Taiwan’s most well known Generic drug company, Taiwan Chemical and Pharmaceutical Co. in 2014, as well as many other multina-
tional pharmaceutical companies. We export to over 15 countries, which, cov-
ers 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 have a great de-
gree of separation between biotech and pharmaceutical, but I see this converg-
ing in the next five to ten years. Local companies will either need to scale their local legacy business, with con-
solidation 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 manu-
facturing and exporting to many mar-
kets 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. Our goal will then be to have our logo in every pharmacy and hospital around the world.

Can you introduce us to ScinoPharm and its main development 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 file volume in 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 syntheses services to new drug discovery companies, and pro-
viding 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 Tai-
wanese suppliers because of our IP pro-
tection, language and good 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 FDA filing in two to three years. We are the qualified Asian supplier to provide APIs to global market for multiple com-
mercial 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 com-
pliance with U.S., EU and Chinese cGMP standards, and includes an R&D develop-
ment and a multipurpose API man-
ufacturing 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 will be able to leverage more contract research and manufacturing projects there.

Will you also be targeting increased sales in the Chinese market by opening this plant? Our 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 regu-
lated markets. The Changshu plant serves as a launching pad for the rapidly expand-
ing 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 com-
petency of strong R&D and cGMP manuf-
ufacturing 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 cur-
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fered cytotoxic oncology to the market, many customers did not have in-house ca-
pabilities 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 of 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 PICs have on your business? It is a great milestone for Taiwan to be-
come part of the PICs countries. It pro-
vides 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 PICs to control the quality of API or drug products. Once the Taiwanese pharma companies are part of the PICs countries, we will have more specific trade agreements. For instance, we will have a new group of efforts to expand into Japan.

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 into PICs, to build our infra-
structure for growth. While no group can consolidate the resources for help on PICs, Taiwan has a strong base of assis-
tance for companies and a strong future for the industry.
Dr. Yung-Fa Chen
CEO
SCIOPHARM

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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 and a multipurpose API manufacturing plant. As both of our sites, one in China and one in Taiwan, are FDA certified by PIC/S, then we have more market access into PIC/S, as they want to control the quality of API or drug products. Once the Taiwanese pharma companies are able to leverage our own regulations, so in entering these 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.

CEO
SCIOPHARM

Can you tell us what inspired you to establish Bora Pharmaceuticals in 1984? 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 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 innovations 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 endgame 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 undergoing a lot of legacy business importing from global pharmaceutical companies and distributing in Taiwan to support the growth of our R&D division.

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What needs to be done to ensure the growth of the bio-pharmaceutical industry in Taiwan? At the moment you have 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 Taiwan Government backing the whole country on biotech I believe we will start to see more global exposure for Taiwanese companies.

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Chianrman
BORA PHARMACEUTICALS

Bobby Sheng

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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.

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Biotechnology

and Niche Drugs

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 submolecular 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 the 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 TaGen Biotechnology.

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 (BIPPO) 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 private sector. It’s incredibly exciting, but very risky as well," says Dr. Hsu, Founder and CEO, TaGen Biotechnology.

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- Bobby Sheng, CEO, Bora Pharmaceuticals
Biotechnology and Niche Drugs

Mixing the New with the Old and 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 biomolecular 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 of Taigen. According to Dr. Hsu of TaGen, 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 industry 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...”

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The Taiwanese government is banking the whole country on biotech.
Taiwan's biotech sector has quickly trained its focus on the industry's development, the private commitment to biotechnology and high due to the government's strong commitment to 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 industry. 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’s biotech and R&D-oriented 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.

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 TuNiX, an etanercept-biosimilar, is collab- orated with TSH, a strong marketing and sales company especially in chronic disease in Taiwan. This company focuses on cardiovascular and long-time-use drugs, so autologous is in its category. Through our co-development, this project is now in Phase III and will go for a Biologics License Applica- tion (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 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 tech- nology 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 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 biophar- maceutical 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 infrastruc- ture 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, when can we expect to find Mycenax? In five years, TuNiX will be launched as well as its sec- ond-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.
Taiwan’s biotech is seen as a viable, sustainable industry emerging, says Yeh of TLC.

Taiwan Liposome Company (TLC) - George Yeh, CEO,

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As a broad-spectrum antibiotic, what makes it so important that we are able to understand the nature of the cancer. Taigen cannot afford to be our first few drugs fail, so we choose areas with a higher priority of success and potential, such as anti-viral and anti-bacterial drugs.

You have a subsidiary in China and have invested in lipid formulations not only in the diseases that are prevalent in Asia, but also for the diseases that are prevalent around the world. We currently have a product called Lipid-Dox, TLC’s first product that was included in the Taiwan National Health Insurance Program in 2002. Since then we have been working to commercialize this technology to create a tangible business and recruit a solid foundation of scientists. Our main aim is to develop new drugs with innovative technology that can address a gap in the market often approached by reformulating a drug across the strait.

We currently have a product called Lipotocan, 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 II trials in Taiwan and China. Since this drug addresses liver cancer, and China is the largest liver cancer market in the world, it will be our main market for this particular drug. Interestingly this is the first case of China and Taiwan pushing clinical development together. The drug was developed by companies from different countries is that there is a vast difference in the drug development stage. Research conducted by companies from different countries is that there is a vast difference in the drug development stage. Development of new drugs, the competency and expertise to address safety concerns based on pre-clinical (animal testing) data is a major concern that wants companies to perform.

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How much interest is there in investing in Taiwan’s biotechnology industry and what does the future hold? The interest is now large enough for companies to be able to raise substantial amounts of capital. A year following our IPO, TLC was able to raise a secondary offer of $100 million, the largest in Taiwan’s biotechnology 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 pharmaceutical companies are seeing successful partnerships with international players to validate their products, thus attracting foreign investment. Second, the local government is trying to attract foreign investors to Taiwan. This has been a lot of money pouring into biotechnology in Taiwan and it is over a $1 billion a year and the bulk of this money is going to be needed. If a few companies can be successful, a viable, sustainable industry will emerge.

What is TLC’s strategy looking forward? Early on we had not changed. We want to be the strongest in the field of lipid formulations not only in the diseases that are prevalent around the world. We also want to synchronize both our selection and manufacturing processes so that we are able to offer a complete pipeline of products. TLC is the largest and most successful biopharmaceutical company in Taiwan, with a 100% success record in reducing frequencies of commercialization stage. Thus far, we have partnered with major generic companies in China, 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 Lipotocan, 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 II 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 become our main market for this particular drug. Interestingly this is the first case of China and Taiwan pushing clinical development together. The drug was developed by companies from different countries is that there is a vast difference in the drug development stage. Research conducted by companies from different countries is that there is a vast difference in the drug development stage. Development of new drugs, the competency and expertise to address safety concerns based on pre-clinical (animal testing) data is a major concern that wants companies to perform.

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What inspired you to found TaiGen in 2001?

I started a program called the National Research Institutes. Soon after this decision was made, the government felt a moral obligation to conduct R&D in Taiwan. I started the National Health Insurance Program in Taiwan, and TaiGen's strategy has been to place more emphasis on the safety and efficacy to adjust safety constraints and outline what the company is aiming to achieve.

How much interest is there in investing in Taiwanese biotechnology and what does the future hold?

The industry is now large enough for companies selling drugs at around $10 million, the largest in Taiwan's biotechnology and what the industry is starting to plateau, in our IPO, TLC was able to raise a secondary offer of $10 million, which is much more generics-driven, they tend to place more emphasis on the safety and efficacy to adjust safety constraints and outline what the company is aiming to achieve.

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

TaiGen's business model has two engines. The first is in-licensing early stage products and developing them to the proof-of-concept stage, with a view to marketing them globally. This is what we hope to achieve by making it more commercially viable (for example, reducing the frequency of administration for a patient). We form a mutually beneficial partnership with these companies, a virtual incubation program transferring the work and expertise in the field of cancer, and China is the largest liver cancer market.

What is TLC's strategy looking forward?

Early on I identified several advantages in Taiwan, and TaiGen's strategy has always been to utilize these regional resources to the full. In particular, the industry is small and not yet fully understood. We do not have a full understanding of the nature of the cancer. TaiGen cannot afford to have our product that was included in the Taiwan drug law, and out of that eight percent only one in eight will succeed. This is because we do not fully understand the nature of the cancer. TaiGen cannot afford to have our product that was included in the Taiwan drug law.

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 cancer, and China is the largest liver cancer market. Since this drug addresses liver cancer, and China is the largest liver cancer market, it will be our main market for this particular drug.

What is the role of the Chinese government in biotechnology in Taiwan and what is the country's strength in this field?

TaiGen is known globally for its inno-vative drug discovery and development (R&D), developing a new drug for an increasingly widespread disease that is currently treated with a less-than-ideal drug. Our specialization in lipid formulations not only in the diseases that are prevalent in Asia, but also in Taiwan, and TaiGen's strategy has always been to utilize these regional resources to the full. In particular, the industry is small and not yet fully understood. We do not have a full understanding of the nature of the cancer. TaiGen cannot afford to have our product that was included in the Taiwan drug law. That is why we are looking into partnering 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 present to a company looking to develop a drug across the strait?

We currently have a product called Lipotexan, 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 phase three trials in China. Since this drug addresses liver cancer, and China is the largest liver cancer market, it will be our main market for this particular drug. Interestingly, this is the first case of China and Taiwan pushing clinical development together. The drug was first faced by companies from different countries is that there is a vast difference in the drug approval process in China and the United States.

What is the quality of available staff in this country?
Can you please give us a brief introduction to your AIDS research and ilabizumab 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 ilabizumab to initially help those MDR patients. FDA recognizes the importance of our program and granted ilabizumab 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. Ilabizumab 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 of the cell so the virus cannot attach to its intended target. This is a protein drug that needs to be injected subcutaneously, intramuscularly, 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 when we are. We are currently working with local Taiwanese manufacturers for our early stage projects. Even though there is a concern over quality when working with Chinese companies, WuXi is different as it is by far the largest company of its kind in China and cater to Big Pharma companies worldwide. You have to be selective when it comes to incorporate manufacturing in China. The ECFA free trade agreement signed between Taiwan and China covers everything, but general pharmaceuticals make up the majority of volume. Global 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 to Phase III trial and only then 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 also provide these drugs under a special approval by the Taiwan Food and Drug Administration (TFDA). However, in the approval letter, we accept as long as 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.

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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 ibalizumab 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 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 are also doing two more projects in earlier stages. Phase I study will be conducted in Taiwan, and it is better to move to the next phases to the United States as it makes things 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 five years ago, Taiwan did not have this capability.

TaiMed has made significant strides in the last couple of 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 manufacturers for our early stage projects. Even though there is a concern over quality when working with Chinese companies, WuXi is different because they are by far the largest company of its kind in China and cater to Big Pharma companies worldwide. You have to be selective when it comes to choosing a company for manufacturing in China. The ECFA free trade agreement signed between Taiwan and China covers everything, but most of the few government initiatives have been undertaken in the pharmaceutical industry.

What are the main strengths of Taiwan’s biotech and pharmaceutical industry?

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.

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, and a group of prominent Chinese-American scientists who wanted to help expand Taiwan’s biotech industry here in Taiwan began as a group of prominent Chinese-American scientists who wanted to help expand Taiwan’s biotech industry here in Taiwan began. TaiMed Biologics was founded 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 was 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 oligonucleotide manufacturers in the world for orphan drugs, and helped 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 here 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?

As South Korea was the most suitable, not just general pharmaceuticals make up 40% of the funding, while the remainder came from other industry players. The project was called TMB-355 (Ibalizumab), a monoclonal antibody 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 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 are also doing two more projects in earlier stages. Phase I study will be conducted in Taiwan, and it is better to move to the next phases to the United States as it makes things easier to get FDA approval.

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Taiwan Pharmaceutical & Biotechnology 2015

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 need for 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 systems that were some time moved to the current location, acquired the land from an existing bio-chemical technology company, set up the GMP facility and began manufacturing products. In the beginning, the company would import API or finished products from foreign countries like Japan and provide the needs for the CDC and gradually began building up capability to manufacture different needed vaccines.

Taiwan was affected by the SARS epidemic occurred, the government realized that it was important to have its own vaccines produce vaccine. With 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.

Adimmune needed to find a focus on a field of vaccines?

Not as much as I would like to see. If you visit government sponsor lab like National Health Research Institute (NIHR), the research groups are conducting research mostly based on reagents’ scientific interests; there is a lack 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 realize. Vaccines are different from drugs. Drugs are normally for sick people, so as long as there are not so 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 short-sighted, experts have predicted that in the future’s scientific interest, we have to write-off as loss. To maintain a capacity that we built earlier, which is larger than needed for the time being, 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 vaccine. We actually started pouring our own resource into making H7N9 vaccine the first minute 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.

When the SARS epidemic occurred, 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?

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Adimmune, Taiwan’s only EMA certified company in Taiwan’s stock exchange.

In terms of international partnerships, can you discuss last year’s partnership with Valneva to work on the encephali-

tis vaccine?

We entered this partnership because of changing technological standards expected to be demanded by CDC. We are currently making the Japanese encepha-
litis vaccine using live animal produced virus. In this method, the virus is incubated in a live mouse brain. The animals 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 have purchasing JEV vaccine produced in tissue culture cells starting 2017. We do not have a tissue culture cell-based vaccine so we needed to look for an alternative before coming up with our own in the near future.

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 treatment. Can you talk to us about this promising tool that will greatly increase the efficiency of treatment?

Yes there are a number of different areas where we have been involved. One is targeted cancer treatments and is moving into pharmacogenomics.

What is pharmacogenomics?

Personalized medicine, where you match various treatments to a patient’s genetic profile to identify the most suitable choice of treatment.

Vita Genomics is working to provide solutions for what is a particularly good case study of a treatment that has been particu-

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larly successful when combined with pharmacogenomics?

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 business. Gradually we started 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 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 in clinical trials. With this in mind where do you see the company going in the coming years?

We see Vita-Genomics as being the biggest company in Taiwan that is operating in clinical laboratories and gene testing. The company was originally a big biotech company, and we could become the largest company in these fields in all of South Asia.

Eddy Hsieh & Dr. Ellison Chen
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In terms of international partnerships, can you discuss last year’s partnership with Valeva to work on the encapsulation of vaccines?

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

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 very promising 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 matched 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 (EGFR+) non small cell lung cancer (NSCLC). The drug had limited success in Europe as only 10% to 15% of Europeans suffered from this type of lung cancer 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 is the area of hypercholesterolemia affects one in five hundred people. This condition prevents cholesterol being adequately absorbed from our diet, which can have a devastating effect on a person’s life. Another area includes EGFR mutations. About 70% of lung cancer patients suffer from EGFR mutations, whereas about 40% of Asian patients suffered from EGFR mutations, which is the reason we are working on this promising tool that will greatly increase the efficiency of treatment.

Mr. Hsieh, you took over as CEO of Vita Genomics last year and oversee 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 be profitable. We have been working hard to build up our clients. We have taken on a number of investments. We plan to release sixty thousand new patients this year. The future is looking very bright for us.

Eddy Hsieh & Dr.Ellson Chen

Industry Explorations

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 personalized approaches to medicine. With this in mind how do you see the company going in the coming years? Dr. Chen, you have taken on the role of CEO of Vita Genomics as being the biggest company in Taiwan that is operating in clinical laboratories and gene testing. How has this changed the role that the company plays for you? Vita Genomics as being the biggest company in these fields in all of South Asia.
"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."

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Botanicals

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 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.” 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 (PICIS). 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, antroquinol, 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 entity (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 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. Wei-Chu Li, vice general manager of Golden Biotech said, “Unlike in Europe, in Taiwan this is considered a prescribed pharmaceutical and we manufacture this medicine to treat all forms of diseases.” 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 (PICSI). 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 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 from botanical extracts 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 who is focused on the development of the botanically derived SR-T100, which is purportedly able to treat cancer cells whereas SR-T100 does not. Through presenting the results of our clinical trials we hope to raise the profile of botanical medicine. Actinice 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. “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. Actinice keratosis is more prevalent in Caucasians, and it is important to appreciate the benefits of SR-T100 over synthesized Western treatments.”

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What challenges has HEB experienced due to tough local regulations and as a botanical-oriented company? Despite the challenges, HEB continues to prove the safety of its products. This is important for the West to appreciate the benefits of botanical medicines.

Can you please start by giving us a general introduction to Health Ever Bio-Tech (HEB)?

Dr. Kuou-Wha Kuo

President

G&G HERAL BIOTECHNOLOGY CO., LTD.

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 diseases. Patients and the general public today are demanding safety and efficacy in a product before they purchase and use them. We need to get patients’ trust in order to reach a larger market.

President

G&G HERAL BIOTECHNOLOGY CO., LTD.

Can you briefly introduce G&G Herbal Biotechnology and what are you working on?

Fu Feng Kuo

CEO

HEALTH EVER BIOTECH CO., LTD.

In Taiwan this is not a problem. It is in other countries to bring our product to market. We are presenting at Bio International in Philadelphia this year to promote our company and our product.

What other products, aside from pharmaceuticals, does G&E offer?

What other products, aside from pharmaceuticals, does G&E offer?

INTERVIEW

Global Business Reports

Global Business Reports

Can you please start by giving us a general introduction to Health Ever Bio-Tech? What key angle do you think is crucial for the success of your company?

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?

What challenges do you face both domestically and globally from being a botanical company and what are you doing to overcome them?

What needs to be done to ensure that this country is recognized as a global player?

What are your prospects for future products beyond MWS-27?

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?

The local regulations for new drugs are very strict. As a botanical-orientated company, it is very difficult to 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 an extract 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 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 feel that patients’ quality of life will improve significantly when they take our product. The effect is a natural one, where the body repairs itself and where the body makes lifelong changes.

What challenges do you face both domestically and globally from being a botanical company and what are you doing to overcome them?

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Can you please start by giving us a gen-
eral introduction to Health Ever Bio-Tech?

We suggest creating an anti-ageing
established to focus on the development
of botanical new drugs backed with scien-
tific 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 peo-
dle’s quality of life. With in house ISO/IEC
17025 certified laboratory, HEB has been
actively involved in the preclinical and clin-
ical 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 con-
vention and pharmaceutical inspection
cooperation scheme (PIC/S) and current
good manufacturing practices (cGMP)
standards. HEB is headquartered in New
Taipei City and our manufacturing facility
is located in Yilan 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
diabetic, overactive bladder (OAB), chronic
and other diseases. The lead product, MCS-2,
is currently being studied in pivotal mul-
ti-country and multi-center Phase III clin-
ic trials on BPH patients. In a Phase II
clinical trial evaluation, MCS-2 has demon-
strated that treatment with this drug im-
proves patients’ SSS (Simplified Symptom Score) and relieves the symptoms of BPH. The
data also indicated that MCS-2 has a very low
risk of adverse effects. MCS-2 is expected
to have an excellent safety profile com-
pared with chemical drugs.

What are your prospects for future pro-
ducts beyond MCS-2?

HEB is exploring botanical new drug can-
didates including different drug substances.
We are keen to move forward to clinical
trials. In general, most chemical drugs
have certain side effects that many pa-
tients 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 the com-
plex and chronic patients. Botanical drugs
with efficacy and excellent safety will be
come 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 part-
nerships with pharmaceutical companies
specialized in different territories to en-
sure 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-oriented company?

The local regulations for new drugs are
to adapt to the current and modified
regulations. One of the major challenges
is how to adapt to the current and modified
regulations. One of the major challenges
as a botanical-oriented 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 to be
considered. Moving could have impact on the specifica-
tion and stability on the active pharmaceutical
ingredient (API), such as water, etc. These factors make it relatively
difficult to control the batch-to-batch vari-
ce, especially in the clinical trials.

What are some of the strengths of Tai-
wann’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
demand for new products and new treat-
ments to improve the quality of life especially
for chronic disease patients. Botanical drugs
are becoming more beneficial, as they tend
to have fewer side effects. This could
improve the quality of life especially for the
complex and chronic patients. Botanical
research and development 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 com-
pared to other Asian countries. However,
the pharmaceutical market is somewhat
small. Given the aging population, the
opportunities for our products are tremendous.

Given these circumstances, Taiwanese
government funds are putting more
emphasis on the development of the pharma-
caceutical industry. The government is con-
vinced that the high probability of this product
will result in side effects whereas SR-
T100 is over 99 percent pure, some-
disease. In injectable form our product
to treat, many synthetic Western cures
to a global market. We will achieve this
by developing our product for topical
forms. We hope to have this completed
by August this year and next year we
will file for the necessary pharmaceuti-
cal 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?

There are a few things that need to be
kept in mind of which field of
research to pursue is very important.
If we choose to develop Western
medicine we would never be able
to compete with a global
pharmaceutical company. However, for
tropical herbal drugs, this is our specialty as we have
a good understanding of the plants hav-
ing eaten them as health supplements
in the past. The in-depth knowledge of the plants
proves the safety of this compound. This
needs to be done to ensure that the product
is sold domestically as well as abroad.
Proving the safety of the product is
the most important thing to be
and they all recognize that this field is
a good means for Taiwan to progress in
biotechnology. The government re-
cently rated our product SR-T100 as
number one in Taiwan as they recog-
nize the high probability of this product
being launched overseas.

Where would you like to see the com-
pany 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
due to our unique product. Although
we will face many challenges, we will
continue to develop new products and
look for a partner who can assist us in
Our flagship product is SR-T100, which
is extracted from a plant endemic to Tai-
wan, and is the first product ever de-
veloped 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 differ-
ent 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. The 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
due to the over-the-counter gel.

What challenges do you face both
domestically and globally from being a
Western 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 effective-
ness of botanical drugs. With regards to
our product 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 synthetic
Western treatments. Moving forward, we
will need to secure a partner-
ship with pharmaceutical companies
in these countries to bring our product to
the market. We are presenting at Bio Inter-
national in Philadelphia this year to pro-
 mote 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
biotechnology in Taiwan and they all
recognize this is a good means for Taiwan
to progress in biotechnology. The govern-
ment recently rated our product SR-T100 as
number one in Taiwan as they recog-
nize the high probability of this product
being launched overseas.
Taiwan PharmaCeuticals & BiOTEchNOlOgy 2015

Can you please give us a brief introduction to FEBICO and tell us about your research areas, which are microalgae and propolis?

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 propolis, applied in vitro diagnostic use.

Recently we started a new company called Algapharma Biotech. Corp. (Algapharma), and the reason behind that was the corporatization of our 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 products such as microalgae and propolis, and products can be generally categorized into FEBICO® nutritional supplements and FLOGEN® diagnostic 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 it 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 OEM and ODM 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, the beneficial lipid penta- 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 diets—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 helps clean 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 plan?

Far East Bio-Tec. Co., Ltd. is the company focused on research and development of new drugs. Since 1989, we study and put resources into developing new drugs for infectious diseases such as influenza. Our primary product pipeline is to treat influenz 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 phase I 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 (NIH) 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 development of new antiviral drugs, this will be the focus of our R&D for the next five years. We hope to bring new drugs to the market to address these issues and help people around the world.
Taiwan PharmaCeuticals & BiOTEChNOlOgy 2015

**Dr. C.Y. Huang**

President

**NATUREWISE (NBM)**

Can you please give us a brief introduction to FEBICO and tell us about your research areas, which are?

Our company started out as Far East Microalgae Co. Ltd. We have been producing chlorella and spirulina for the past few decades. Our range of microalgae products includes chlorella, spirulina, and other microalgae derived products globally to almost 43 countries.

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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 HDAC6-specific inhibitor called BMX—OS01, which is inexcusably 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 PFL858, which is a group of prenyllavones, which are extracted from specific Taiwanese propolis. Propolis is a resinous mixture that hon- eybees produce for the purpose of sealing cracks of intruding animals or cracks in the bee hive in order to maintain a clean and stable environment in the hives. These prenyllavones, 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 innova- tive products and research and develop- ment is indeed backed up by a large number of patents we have on our major territories such as the United States, China, the European Union, Japan, Australia, South Korea and Tai- wan.

Although the pharmaceutical industry in Taiwan has 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 new careers, now needed to focus on programs for the new Taiwanese pharmaceutical executives who spent their working lives abroad and then came back to Taiwan to start new careers, now needed to focus on programs for the new generation of pharmacists.

What is the role of the biotechnology sector in Taiwan and does it have a number of strengths in comparison to its counterparts.

In terms of the operation of compa- nies, 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 PFL858, which is a group of prenyllavones, which are extracted from specific Taiwanese propolis. Propolis is a resinous mixture that honeybees produce for the purpose of sealing cracks of intruding animals or cracks in the bee hive in order to maintain a clean and stable environment in the hives. These prenyllavones, 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.

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What is the role of the biotechnology sector in Taiwan and does it have a number of strengths in comparison to its counterparts?

In terms of the operation of companies, 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 PFL858, which is a group of prenyllavones, which are extracted from specific Taiwanese propolis. Propolis is a resinous mixture that honeybees produce for the purpose of sealing cracks of intruding animals or cracks in the bee hive in order to maintain a clean and stable environment in the hives. These prenyllavones, 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 on our major territories such as the United States, China, the European Union, Japan, Australia, South Korea and Taiwan.

Although the pharmaceutical industry in Taiwan has a number of strengths in comparison to its counterparts, can you talk to us about these strengths?

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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 our 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? PG2 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. PG2 is a highly purified polysaccharide extracted from a Chinese herb that has been used for over a thousand years called Phellinus linteus. 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.

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 biomaterial 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 naturally grown. Our most successful product to date has been an IV injectable called PG2 being 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 been 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

Dr. Gary Lin

CEO, Chairman Office
PHYTOHEALTH CORP.
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Where would you like to see Be Rich Biotechnology in five years’ time? Be Rich Biotechnology initially started as 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.
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.”

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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 international global clinical trial program for our clinical research associates at all levels. PPD wants 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 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, Tai- wan 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. EirGenix 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 drugs (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 hospi- tals, 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 for fortified infrastructure and supervision. Additionally, the government recently insisted that any company involved in the transporta- tion 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 pharma- ceuticals 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 mar- ket 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 out- side,” said Wayne Hsu, managing di- rector 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 in- ternational pharmaceutical companies. We provide market evaluations to sup- pliers and manufacturers to help them decide if they would like to expand into the market. Chi-Fu then assists in regis- tration, launch, distribution, marketing, and logistics.” DKSH, a global market expansion ser- vices provider with a focus on pharmaceuticals, 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 companies in Taiwan. “In Taiwan, we help, for example, been working with a number of biotech companies focused on rare diseases. 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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 pres- ence on the island.
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DKSH is the leading Market Expansion Services provider with a focus on Asia. Publicly listed in Switzerland, our custom-made offerings for healthcare companies comprise logistics, regulatory service, market entry studies, importation, customs clearance, warehousing, sales, physical distribution, invoicing and cash collection.

Think Asia. Think DKSH.

www.dksh.com

We have been at home in Asia for 150 years and in Taiwan since 1908. Our specialists leverage their strong relationships to get your pharmaceuticals, consumer health and over the counter (OTC) products, and medical devices to more healthcare channels across the island. Our uncompromised commitment to quality and compliance further sets us apart.

So whether you are new to Taiwan or already well-established, DKSH is your growth partner.
Albert Liou

Vice Chairman, Asia Pacific
PAREXEL

INTERVIEW

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. Our 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 in record time and at the lowest 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 in designing their drug development strategy to bring 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 biotechnology 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 this 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 healthcare 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 come with the right approach. With our employees, expertise, and global organizational network, we are a major player in the biotech development community.

Can you outline the circumstances under which EirGenix was formed?

EirGenix was formed when the Development Center for Biotechnology (DCB) decided to spin-off one of the regional pharmaceutical 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 nonprofit organization with the purpose of helping the development of biotech, to be a more efficient and growing private company and still retain its role to serve as a development platform for 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 interna tionally 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 a 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.

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 recent years; this has allowed us 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 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, our 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, who can produce as a subsidiary to Taiwan laws and regulations rather than Chinese.

Dr. Lee-Cheng Liu

President and CEO
EIRGENIX, INC.
Albert Liou
Voice Chairman, Asia Pacific
PAREXEL

Can you please give us a brief introduction to PAREXEL?
PAREXEL was founded 33 years ago by Joseph 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 is clinical research, consulting and development studies including Phase I development, Phase II and Phase III pivotal studies as well as Phase IV and post marketing studies.

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 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 this 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 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 healthcare 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 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 FDA, CFDA, U.S. EMEA, 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 in the biotech industry.

Can you outline the circumstances under which EirGenix was formed?
EirGenix was formed when the Development Center for Biotechnology (DCB) decided to spin-off one of the pharmaceutical pilot plant facility (BPPF) that we now find ourselves in, which was first established in 2003. The aim behind this was to change the plant’s original specific role within the DCB, a nonprofit organization with the purpose of helping the development of biotech, to be 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 to treat diabetes (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 for these projects and we hope to continue to operate in the global markets, and eventually 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.

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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, which can provide us with a subsidiary subject to Taiwan laws and regulations rather than Chinese.

Dr. Lee-Cheng Liu
President and CEO
EIRGENIX, INC.
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 would like 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. I want to see more of these innovative products to NDA. With this, investors will be more encouraged to look to the biotechnology industry and fund further projects.

Your office in Taiwan opened in 1998. What was behind this decision and what strategic advantages did Taiwan offer at the time? J.J.: 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. J.L.: 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? J.L.: 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. J.J.: 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? J.L.: Quintiles is consistently maintaining our key focus of productivity, delivery and quality. From an operational level this is what we can guarantee. It has been at the heart of what we do for the past ten years now.

J.J.: 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. If ever 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 biotech companies in the region? J.L.: Our CROs operating in Greater China, VCRO in Taiwan and Quintiles Shanghai. Our customers appreciate the fact that we have a single leadership office in Shanghai, which will help them in an integrated fashion under the direction of our Greater China region headquarters, which will help them more easily reap the benefits of the Cross-Strait agreement on clinical research.

J.J.: 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 for companies wanting to run clinical trials here? J.L.: What is most important for companies is to find the right partners. 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 the advantages that Quintiles can offer is rich, local expertise. J.J.: 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? J.L.: Many local Taiwanese companies approach us about taking their clinical trial programs to a global level, and Quintiles can offer sound advice on how to go about it and always ensure that they have the right partners. Taiwan has a lot of work in this area at the moment.
You founded VCRO in 1997, two years after finishing your Ph.D. in the United States. How did this spark your interest in setting up a clinical trial company in Taiwan?

Dr. Chun-Chun Li

General Manager
VCRO

Having trained as a clinical pharmacol- ogist 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 trial activities in the country, with a family background in business, I decided to set up my own company providing 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 highlight the services that you now offer?

Dr. Chun-Chun Li

General Manager
VCRO

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. At 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?

Vivian Liao & Jay Johnson

VL: General Manager
JJ: Senior Director
Corporate Communication
QUINTILES

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

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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 growth in the biopharmaceutical 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. ‘Vibrant and active’ market, how easy is it for these biotech companies to raise the funding that they need for new projects?

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

How has the recent progress in mutual recognition of data between China and Taiwan affected Quintiles’ operations in these two countries?

JJ: The company recently placed its first Phase III study in Greater China, which includes China, Hong Kong and Taiwan, under one leader, who is based in Shanghai. Our customers appreciate having their studies brought to them in an integrated fashion under the direction of our Taiwan 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.
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.

What are some major challenges that the pharmaceutical industry faces in Taiwan in the development of new drugs?
YC: Taiwan is an advanced regulatory 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 TFDA. The Taiwanese government is looking to help speed up the process and has been initiating and participating in discussions with all interested parties, as well as neighboring countries. For example, we have 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 near future?
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.

Can you give a brief introduction of DKSH and tell us about some of your recent developments in Taiwan’s healthcare sector?
Dr. Ronald Linke
Vice President Healthcare
DKSH TAIWAN

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 tailored services along the entire value chain, offering any combination of sourcing, marketing, sales, distribution and after-sales support services.

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 highly trained medical personnel, 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.

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 Unit. 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 work with more than 13,000 customers in the healthcare sector, including hospitals, pharmacies, clinics and other outlets.

According to the latest report published by Roland Berger Strategy Consultants, the market expansion services segment for healthcare products in Taiwan is expected to expand to NT$9.3 billion in 2019. We continue to focus on offering a range of market expansion services across the entire value chain to companies in Taiwan. We help clients with integrated and tailor-made service providers, from sourcing to local knowledge and experience.

Another focus area of our growth strategy is healthcare products in Taiwan is expected to expand to NT$9.3 billion in 2019. We continue to focus on offering a range of market expansion services across the entire value chain to companies in Taiwan. We help clients with integrated and tailor-made service providers, from sourcing to local knowledge and experience.

What is the outlook for DKSH in Taiwan over next five years?
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Dr. Yasmine Chiu
Joyce Lee & PJ Chen

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

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 meeting 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 3.

What are some major challenges that the industry faces in Taiwan in the development of new drugs? YC: Taiwan is an advanced, regulated 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 FDA. The Taiwanese government is looking to help speed up the process and has been initiating and participating in discussions with all interested parties, as well as neighboring countries. For example, we have 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. Our 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 near future? 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. •

Can you give a brief introduction of DKSH and tell us about some of your recent developments in Taiwan’s healthcare sector? DR: 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 33 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 capital 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 other counter products, medical devices and pharmaceuticals. We have particularly invested in our commercial capabilities to offer marketing and sales promotion services. We now truly provide our clients with integrated and tailored 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. 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 are among the 13,000 customers in the healthcare sector, including hospitals, pharmacies, clinics and other outlets.

How does the strength of Taiwan’s healthcare sector compares 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 own personal doctor. This adds up 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 physical 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-funded presence, yet they want to tap into the Taiwanese market. In such cases, we can provide administrative work for them, including working with the Food and Drug Administration (FDA) to acquire the import license and other regulatory requirements. We then leverage our network of hospitals to import this product and deliver on a ‘named patient’ basis. This helps us partner with the local hospitals and clinics and with providers to educate them about the products.

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 at a steady rate. We continue to focus on offering a range of market expansion services across the entire value chain to companies in Taiwan. We are helping companies 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 that is allowed to acquire all PIC/GMP licenses even before it was mandatory.

Our other 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.
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 or 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 and accelerate 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 developed?

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 rebranded 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 will continue to grow with a goal 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 PIVS, the majority of logistics operators were not too 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 we 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 low cost, so we are now the largest distributor of low cost generics from India. Multinational companies such as Novartis, which are branded generics, are not doing as well because in Taiwan they are still simply branded. 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 market will be bigger, but 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 aspiring to when patients can copay for their healthcare.
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 or 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 accelerate 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.

Can you talk about the circumstances under which T-join Logistics merged with Hong Kong’s Kerry group and how the company has evolved from there?

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

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

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What do you foresee for the Taiwanese pharmaceutical market?

Generics will continue to expand and the life of ‘new 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.

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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)
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Taiwan’s Pharma Future

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 sector. 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 the market itself is fairly small. With biotechnology bringing in revenues of $2,027 million and pharmaceuticals bringing in $2,768 million in 2013, the market is still a work in progress, 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 encouragements 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 and development of their pharmaceutical and biotechnology industries, Taiwan aims to make Taiwan themselves a perfect entry point to the Chinese market, vast talent pool, and English being a primary language, explained: “One of the big challenges is that the country has not had much experience in biotech that either the Western Europe or the US have.”

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, but then we use our capabilities to put it into practice. We therefore work with the NHI due to restricted regulations. 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 have the best regulatory support in the industry. Tiegexyn, a new chemical entity, broad spectrum, non-fluorinated quinolone antibiotic was the first regulatory body to approve it in Taiwan and we are the first to have reached the global market. However, our relationship with these biotech companies is limited to only 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 a number of joint programs with local and international universities. Can you talk to us about your model and the universities with which you collaborate? One of our main local programs is with National Taiwan University (NTU). They have a world-class biology department and their MDs or PhDs can come to our laboratory to do their research. We have the best facilities in all of Taiwan and an excellent faculty; we have the best regulatory support in the industry. 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.

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 law in 2003 to facilitate biotech development in Taiwan. I was involved in writing the articles and helped to get the by-law passed. This act was finally enacted four years later as the Biotech and New Pharmaceutical Act (2007). This act encouraged new drug discovery and high-end medicinal devices and helped promote investment in 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. What is your thought on this industry as well as the future of Academia Sinica? The coming years, the biotechnology industry is going to become one of Taiwan’s major industries. As biotechnology is an environmentally friendly industry, it is a great choice for Taiwan. I am very optimistic about Academia Sinica’s future. We will continue to build on our strengths, especially in the life sciences, and will take a leading role in the new wave of biotechnology in Taiwan. We will expand and expand, due to the creativity of the Taiwanese scientists as well as the universities. The TIGP and a number of joint programs here that are interdisciplinaries, such as chemical-biology and biophysics, nanoscience and technology et al. We will continue to build a biocentre park, as this will 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? Although the NIH 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.

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Taiwan’s Pharma Future

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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 aging population has put pressure on these medical centers and with domestic market demand for pharmaceuticals rising from $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 develop 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, which is the world’s most successful health care system, 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 needlessly a number of challenges that stand in the way of Taiwan growing into a major hub for 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 Tafgev, a new chemical entity, broad spectrum, non-fluorinated quinoline antibiotic that is available in both oral and intravenous formulations.

Dr. Chi-Huey Wong

Academia Sinica is considered the premier research institute in Taiwan. What role does Academia Sinica play in the research for new drug discoveries? 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 tell us about the cooperation between the universities with which you collaborate? One of our main local programs is with National Taiwan University (NTU) in the area of translational medical research. 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 inter-disciplinary, such as chemical-biology and biophysics, nanoscience and technology et al. We market rather than the genetic 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.

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

“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 phase of 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.

“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

“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.

“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 II 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.

"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.

“OBI’s most advanced candidate drug, OBI-822, Globo H HKLH, 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-848, a cancer diagnosis technology from Academia Sinica.”

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

“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
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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.

"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

"OBI's most advanced candidate drug, OBI-822, Globo H KLYH, is an active cancer immunotherapy targeting Globo H, a glycan found highly expressed in breast cancer patient's tumors, 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-848, a cancer diagnosis technology from Academia Sinica."

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

"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
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THANK YOU

We would also like to sincerely thank all the governmental bodies and associations that took time to share their insights into the market as well as their experience and knowledge.

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mohw.gov.tw/EN/Ministry

BIOTECHNOLOGY AND PHARMACEUTICAL INDUSTRIES PROMOTION OFFICE (BPIPO)
bpiopo.org.tw

TAIWAN GENERIC PHARMACEUTICAL ASSOCIATION (TGPA)
tgpa.org.tw

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

TAIWAN BIO INDUSTRY ORGANIZATION (TBIO)
taiwanbio.org.tw

TAIWAN RESEARCH-BASED BIOPHARMACEUTICAL MANUFACTURERS ASSOCIATION (TRPMA)
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- **PwC TAIWAN**

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