

## Flourishing or languishing ?

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An overview of Taiwan's life sciences industry.

When it comes to Taiwan's life sciences, there is much debate within the island over whether the sector is succeeding or languishing.

Some question the rate at which progress is being made, including journalists who also cover Taiwan's computer and IT industries with their breakneck development speed and make the inevitable comparisons. On the other hand, there are policy makers and industry promoters who cheer at the slightest milestone obtained, however early-stage. As such, it's hard to gauge the true state of the industry.

It is not helped by the fact that in Taiwan the very definition of the industry incites confusion. The so-called "biotechnology industry" is defined by the government as including the pharmaceutical sector, the medical devices sector, as well as the "emerging" biotechnology sector. Chinese herbal medicine, nutraceuticals, and cosmetics are considered biotech as well.

Another difficulty, at least from an overseas perspective, are the many (and overlapping) industry contact windows, industry promotion bodies, government and quasi-governmental agencies, many with seemingly similar roles and responsibilities. For local companies, it is difficult enough to understand who is responsible for what, but for overseas companies looking for information, collaboration advice or assistance, it can truly be daunting.

But despite these hurdles, it appears the industry is making steady progress.

## **Pharma**

Taiwan's pharmaceutical sector can be divided into three sub-sectors: generic drug makers, API manufacturers and contract biopharmaceutical manufacturers.

Unfortunately, the generic drug companies are firmly stuck in "sunset industry" mode. Too small and inefficient to compete on an international level with global generics giants like Teva or Dr Reddy's, and with their profits squeezed by powerful hospital purchasing departments, the many hundreds of generics manufacturers operating in Taiwan don't have much of a future. As it is, nine of the top 10 pharmaceutical firms by revenue in Taiwan last year were foreign. Even in a market dominated by generics, local companies find it hard to compete with Big Pharma and their well-drilled sales teams. Exports remain both small in real and total percentage terms; figures that would be smaller still if it weren't for Wyeth skewing the numbers with exports from its Taiwan-based logistics center to Southeast Asia and Australia.

To remain competitive, some of the larger generics companies are diversifying: China Chemical and Pharmaceutical Corporation (CCPC) with its API subsidiary China Chemical Synthesis Biotech Company; Yung Shin Pharmaceutical with its subsidiary Yung Zip, also an API maker; and the drugmakers Standard Chemical and Sinphar Pharmaceutical, both making inroads into consumer health and nutraceuticals markets.

For API manufacturers, the flagship for the sector and a model for government investment and support of local start-ups, is ScinoPharm Taiwan. According to its CEO, Dr Jo Shen, the company supplies API to many top 10 Big Pharma, and even manages to supply its product to Indian generic drugs giants-quite a feat considering the competitiveness and cost pressure of the industry in India.

The emerging contract manufacturing sector, particularly in biopharmaceuticals, is dominated by the government-funded research institute and industry promotion unit, the Development Center for Biotechnology (DCB). With its new cGMP and FDA-approved facility boasting of bioreactors in its manufacturing plant of 100, 300 and 500 liters, the facility complements the DCB's existing biotech and pharmaceutical industry services, including a contract laboratory facility and ALAAC-certified toxicology center.

Along with the DCB in this industry space is Mycenax Biotech, also boasting of FDA-approved biopharmaceutical manufacturing facilities, as well as UBI Asia, and Advanced Gene Technology, to name a few.

## **Medtech**

In medical devices and technology, Taiwan believes it has all the pieces in place to be a major global player in the sector. It is easy to understand when one looks at what first made Taiwan a global powerhouse in the IT sector-its expertise in precision manufacturing, miniaturization, electronic circuitry design and engineering, and efficiency and innovation in the manufacturing process itself-all are transferable to the medical technology industry, be it in innovation, design or manufacturing.

The local medical devices industry has been growing in double-digits in recent years; \$1.6 billion in revenues were posted in 2004, with revenues expected to reach \$6 billion by 2011. In fact, the medical devices sector is already the best performing of Taiwan's life sciences sectors, far exceeding pharma and emerging biotech.

For local venture capital firms used to quick returns from investment in the IT sector, the idea of investing in medical devices companies with their relatively short lab-to-market timelines makes more sense than a similar investment into drug discovery companies. And with the latest devices offering health solutions that in the past only surgery or pharmaceuticals could deliver, medical devices-particularly implantables-are changing the very landscape of medicine. And this isn't limited to cardiovascular disease, where drug-eluting stents are being almost mainstream; there are now devices solutions for strokes, diabetes, and epilepsy. While such high-end devices are still mainly being developed and manufactured in western countries,

Taiwan (and to a growing extent, China) is playing an increasing role in the global supply chain for the industry.

For the world hospital consumables market, there are a host of Taiwanese companies succeeding in the safety syringe, IV set, and protective gear product sectors. With the home diagnostics market booming worldwide due to the rising cost of hospital care, companies in this space are growing along with it. Such companies include Rossmax International, a leading provider of OEM blood pressure monitors; Apex Biotechnology, a blood glucose monitor manufacturer; and Microlife, producing digital thermometers. In addition, a new class of companies are developing novel products with cutting-edge technologies. These include DailyCare BioMedical with its pocket-sized ECG machine, and Formosa Biomedical, with a device to measure arterial hardness, a marker for cardiovascular health.

With Taiwan's LCD display industry leading the world in sales and innovations, it was only a matter of time before medtech and display technologies got together. The first success from this convergence has been New Medical Co., with its Digital Direct Radiography (DDR)-in other words, film-less X-ray imaging systems for the detection of lung and breast cancers, systems that are both cost effective and efficient from a hospital management perspective.

The driving force behind medical technologies in Taiwan is the Industrial Technology Research Institute (ITRI). ITRI is the island's premier applied research facility, with over 7,000 scientists stationed at its impressive facilities an hour south of Taipei. With its Biomedical Engineering Center (BMEC) split into two at the beginning of the year, ITRI now holds the Biomedical Engineering Research Laboratories (BEL), and the Medical Electronics and Device Technology Center (MED). BEL is a multidisciplinary R&D and commercialization unit drawing from fields such as biology, chemistry, optics and micromachining. MED on the other hand focuses solely on the development of homecare medical devices. Being pioneers in the company spin-off process (the world's largest contract computer chip manufacturer, Taiwan Semiconductor Manufacturing Company, or TSMC, was an early ITRI spin-off), ITRI spinoffs in the life sciences include Phalanx Biotechnology, a biochip manufacturer; and DailyCare BioMedical. ITRI also has a very successful business incubation center, where many companies not only in medical technology but high-tech as a whole have been nurtured from start-up into successful ventures.

## **Biotech**

So-called "emerging biotechnology" has been making steady progress, albeit slower than original government and industry expectations. With the amount of money already spent on infrastructure development-including biotech science parks, genomics research centers, so-called "National Research Programs" in biotechnology and pharmaceuticals, genomic medicine, and agricultural biotechnology, Taiwan is now expecting to begin to reap the benefits.

Once again the pieces are all in place: around 8,000 graduates in biological sciences every year, the recent return in large numbers of previously overseas-based renowned scientists and successful biotech entrepreneurs, generous incentive programs including tax holidays, interest-free loans, and matching grants, an impressive range of world-class research facilities and university biotech laboratories, a vibrant venture capital community, and so on.

However, be it in innovation or in license deals, the extent of success in drug discovery and development has been a little disappointing. Reasons: Most companies are too small, and have subsequent funding issues; management inexperience, with many companies still run by their founding scientists; language and cultural barriers; technology transfer and technology valuation inexperience, meaning innovations tend to stall rather than be taken up by a licensee; and immature and inexperienced local regulatory bodies, leading to bottlenecks in the development process. It could also be argued that the innovation that biotechnology success depends upon is not being nurtured or encouraged to the same extent as it would be in the West. Or it could just be a perception problem; the long development times, typical in biotechnology test the patience of a population (and the investment community) used to fast change and quick results.

Subsequently, there has been a new focus on behalf of the government for Taiwan to develop its biotech service sector, pushing its advantages as a drug development center for Western biotech firms, a cost-effective bioproduct manufacturing location, and a clinical trials center for the Asian region.

In the meantime, companies in the drug discovery industry space are quietly making progress, and in the last few years at least the efforts are increasingly bearing fruit. For example, last year AbGenomics licensed its AB168 antibody (for autoimmune diseases, MS, psoriasis, and rheumatoid arthritis) to German drugmaker Boehringer Ingelheim; and Panion & BF Biotech, licensed its drug Zerenex (end-stage renal disease treatment) to US-based Keryx Biopharmaceuticals. US FDA IND approval was given to Medigreen for its asthma drug 1217B, while the DCB had several drugs in early-stage clinical trials

overseas.

The challenge for drug discovery and development companies worldwide is solving inevitable cash flow problems, and in Taiwan many such companies have branched into the health food market as a solution. For example, cancer-drug developer PharmaEssentia has turned to manufacturing CoQ10, a food and cosmetics additive, becoming in the process the world's fourth largest manufacturer and the biggest outside Japan. As many of Taiwan's drug discovery companies use herbal medicine as the source of their drug candidates, naturally the health food and consumer-level herbal medicine business is an effective means to bring in cash in the short term. Such companies using this approach include SunTen Phytotech, Sagittarius Life Science, Golden Biotechnology, and Medigreen.

Taiwan has a large number of biotech companies working outside drug development and discovery as well; for example, in agricultural biotechnology in areas such as animal cloning and genetic modification being world-class. Innovations have also been made in new drug delivery technologies, novel DNA applications, stem cell research and applications, and biomaterials.

While biotechnology in Taiwan gotten off to a slow start, achievements are now coming and at a faster pace than ever before. With the exception of a languishing pharmaceutical sector, there are encouraging signs for the future.

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