

# Will Biotech be the Next Trillion NT Dollar Industry?

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***Taiwan is making great strides in developing its biotech sector, but reaching the NT\$ trillion mark in annual production value by 2025 won't be easy.***

When the Biotech Innovation Organization (BIO), the world's leading industry association for biotechnology, chose to hold its annual regional conference this summer in Taipei, it was a big boost for the local affiliate, BIO Taiwan, and for Taiwan's entire biotech sector. The event was recognition of how the sector has evolved over the years from producing only food additives and generic drugs to developing cutting edge solutions in precision drugs, advanced diagnostics and drug delivery systems.

Another recent accolade came from the industry website GEN: Genetic Engineering & Biotechnology News, which last fall ranked Taiwan sixth on its Top 10 Asia Biopharma Clusters 2018, just behind Australia and ahead of Singapore. The website commended Taiwan's commitment to R&D and its high number of listed companies.

Further, as biopharma increasingly looks to information technology for help in devising better diagnostic solutions and treatments, Taiwan is strategically positioned to benefit from its well-established IT manufacturing sector. Precision medicine, for example, deploys advanced diagnostic tools powered by artificial intelligence, coupled with genetic data analysis, to provide more accurate treatment options.

“Taiwan is already a global powerhouse in technology, IT, and computing systems, and as biotech evolves, we are creating new products that marry breakthroughs like artificial intelligence with Big Data, derived from the human genome,” says BIO Global’s CEO, Jim Greenwood, in a video recording on the BIO Global website. “That’s why Taiwan is uniquely situated to play an integral role in the future of our industry.”

Taiwan’s biotech sector is now a NT\$500 billion (almost US\$16 billion) industry with a number of companies at the forefront of breakthrough medications, delivery systems, and diagnostics. In particular, Taiwan has carved out a niche in oncology, with several companies – including OBI Pharma and PharmaEngine – developing new cancer drugs.

Among other prominent players, ACT Genomics and Pharmagene specialize in advanced genetic sequencing to enable precision medicine tailored for individual patients, and TLC Biopharmaceuticals focuses on drug delivery systems. Industry stalwarts TaiGen Biotech and TaiMed Biologics have taken on the challenge of developing treatments for some of the world’s most frightening infectious diseases, including HIV.

“Twenty years ago there was no new drug development – we were only making generics – but now we’re moving to a stage where we have a whole bunch of companies that are really producing or doing research and development for discovery of new drugs, and are collaborating with big pharma,” says Johnsee Lee, chairman of BIO Taiwan and former head of Taiwan’s leading research organization, the Industrial Technology Research Institute (ITRI).

The administration of President Tsai Ing-wen has shined a spotlight on biotech by including it within the 5+2 Innovative Industries program. The program is aimed at upgrading Taiwan’s industrial base to reduce reliance on contract manufacturing and encourage innovation in high-value, high-growth industries. Among them is “biomedicine,” a loosely defined category that includes everything from conventional pharmaceuticals to “large-molecule” protein-based biologic medications, as well as medical devices and innovative diagnostic tools and drug delivery systems.

Under the Biomedical Industry Innovation Program within the 5+2 scheme, the government has stated goals of “developing 20 new medicines, bringing 80 high-value medical devices to market, and building biomedicine in Taiwan into a NT-trillion-dollar industry by 2025.”

The Tsai administration has a keen focus on the sector as many prominently placed officials have had careers in related fields, including Vice President Chen Chien-jen, an epidemiologist trained at Johns Hopkins University. Tsai herself sat on the board of directors of TaiMed Biologics before being elected president.

According to a report by PwC Taiwan, government financial support for the biomedical sector had reached NT\$109 billion (US\$3.4 billion) by 2016. The investment seems to be paying off, as the production value of Taiwan’s biomedical industry reached an estimated NT\$514.1 billion in 2018, more than halfway to the NT\$1 trillion goal.

But growth will have to ramp up considerably for Taiwan to achieve its 2025 target. What would be necessary are sustained compound annual growth rates of over 11% for the next six years, roughly doubling the recent pace.

“Yes, these goals are audacious, but that’s the point of setting goals – to exceed the organic growth that would get there without any push,” says David Silver, president of BiotechEast, an industry consultancy based in Taipei. “But what’s different is that a lot more infrastructure has come online in the last couple of years. The target numbers reflect the anticipation that this infrastructure will start to pay off.”

One of those infrastructure projects is the NT\$20 billion (US\$648 million) National Biotechnology Research Park in Taipei’s Nangang district that opened in October last year. The park spans some 25 hectares and includes a bioinformatics facility, incubation hub, and translational medicine research center. It also serves as headquarters for the Taiwan Food and Drug Administration, National Laboratory Animal Center, and Development Center for Biotechnology.

Meanwhile, construction is underway on major expansion of the Hsinchu Biomedical Science Park, which has been in operation since 2011, on a 38.1-hectare site near the Hsinchu High Speed Rail Station.

These two parks are key links in Taiwan’s comprehensive biomedical value chain that includes the Central Taiwan Science Park in Taichung, Pingtung Agricultural Biotechnology Park in Pingtung County, and the two campuses – in Tainan and Kaohsiung – of the Southern Taiwan Science Park. Taiwan also has a number of leading academic and research institutes, including ITRI as well as National Chiao Tung and National Tsing Hua Universities, Academia Sinica, National Taiwan University, and Chang Gung University and its associated hospital network. Taiwan’s “biotech corridor” stretches from Taipei to Pingtung, enabling synergies across disciplines and among businesses and research institutes.

The investment in biotech infrastructure is “enormous, with huge amounts of potential,” says BiotechEast’s Silver. He notes the “focus on high-end stuff, such as precision medicine, artificial intelligence, and Big Data.”

## **Human resources**

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Besides the impressive infrastructure, Taiwan’s biotech sector has the advantage of a large pool of experienced professionals. “The talent here in Taiwan is amazing – in terms of the physicians, in terms of the researchers, and in terms of how hard we work,” says TLC Biopharmaceuticals President George Yeh.

Su-jen Chen, Chief Scientific Officer and co-founder of ACT Genomics, concurs. ACT Genomics works in the field of oncology, providing genetic sequencing of tumors to find specific mutations that can be matched to the most effective treatments. “Knowledge is

especially important in this field, because oncology is very complex and is advancing very quickly,” she says. “For a company like us, you need the right people to make sense of the data, to design better tests for patients, and to know future trends for oncology drugs.”

Since many students in Taiwan prefer to become biomedical scientists instead of physicians, “Taiwan actually has an advantage in its talent pool,” she says.

Another positive factor is Taiwan’s National Health Insurance (NHI) program and well-run hospitals, enabling biopharmaceutical companies to efficiently conduct clinical trials on new drugs.

There are also significant challenges. For example, Taiwan lags in eighth place in the number of biopharma patents in the Asian region, with only 853 patents listing at least one Taiwan inventor, according to World Intellectual Property Organization.

TLC’s Yeh attributes this phenomenon to Taiwan’s general inexperience in turning research discoveries into breakthrough products. “What we lack is experience in terms of product development capability,” he says.

A key factor contributing to this dearth of experience in commercialization, including the small scale of Taiwan’s domestic market. The logical remedy is to work with larger markets, particularly the United States, whose Food and Drug Administration serves as the model for similar regulatory bodies around the world, including Taiwan and China.

Taiwan has made strides in adopting standard international practices, aligning its industry with key global benchmarks such as those of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use. Taiwan is also participating in the U.S. National Cancer Institute’s Cancer Moonshot program, an initiative aimed at eradicating cancer, in line with Taiwan’s goal to develop niche and precision medicines.

The most commonly heard complaint about the industry is the continued existence of certain “Taiwan-specific” regulations that inhibit international marketing and development, as well as restrictions on financing that curtail venture capital investment.

“The regulatory environment – not only in terms of drugs, but in terms of IP, investment, and IPOs – all that has to be internationally harmonized with other countries,” says BIO Taiwan’s Lee. “Otherwise, there’s a big gap.”

Yet Lee and his fellow industry professionals are optimistic that Taiwan is working through these issues. “It takes time for investors to learn what’s the risk and what’s the return, and for government officials to learn the best way to regulate,” he says. “It’s all part of the growing pain.”