

Is Japan on the Verge of a BIOTECH BOOM?

A GROWING NUMBER OF BIOPHARMA START-UP COMPANIES ARE LOOKING BEYOND THE UNITED STATES AND EUROPE FOR BUSINESS OPPORTUNITIES. AND ONE MARKET THAT IS GENERATING A LOT OF BUZZ IN BIOTECH TODAY IS JAPAN.

One of the more under-reported business stories of the past year has been the steady emergence of Japan from its decade-long economic doldrums. And while biotechnology may not be credited as a driver of the initial recovery, the Japanese government views the industry as a key component in broadening the recovery and sustaining Japan's re-emergence as a key player on the world economic stage.

Gene Networks International (GNI) is a global pharmaceutical development company based in Japan with operations in the United States and the United Kingdom. GNI uses gene regulatory and systems pharmacology to develop improved drugs for the treatment of infectious disease, cardiovascular disease, inflammation, and cancer.

GNI's Japan location takes advantage of start-up opportunities created through a series of landmark legal and regulatory changes. The company's founders credit the Japanese government for transforming the country from a second-tier biotech player into a country that is now churning out new "bioventures" and biotechnology start-up companies such as GNI at an impressive pace.

GNI's gene regulatory networks technology was developed by renowned scientists at Kyushu University and the University of Tokyo.

"Before all the legal changes in Japan, we could never have taken the technology out of the academic setting and applied it to the development of better medicines," says Christopher Savoie, M.D., Ph.D., GNI's CEO and one of its founders. "Until deregulation began in 1998, restrictions on technology transfers and the ability of academics to participate in commercializing biotech advances hampered the

biotech industry's development in Japan. But all that is changing."

It may be too early to declare that Japan is on the verge of becoming a world biotech powerhouse, since, on many counts, the United States and Europe retain a significant lead. But the growth in biotech start ups and a growing number of initial public offerings, has fueled interest and excitement both in Japan and around the world.

"Despite Japan's generally 'risk averse' culture, GNI's investors have been very supportive," Dr. Savoie says. "They are forward-thinking and enthusiastic about our entrepreneurial biotech opportunity and, of course, looking forward to our successful IPO. Their willingness to support a company based on technology and one from the United Kingdom attests to their global outlook."

JAPAN'S BIOTECH SECTOR AT A GLANCE

There are an estimated 334 "bioventures" (biotech-related start ups) in Japan, with an average of 20 employees (9 of which are in R&D), 314 million yen in sales, and R&D costs of 153 million yen. Japan now leads the world in biotech research and development spending as a percentage of GDP at 3.18%. The United States is second at 2.59%. In 1971, Japan spent just 1.86% of GDP, compared with 2.32% in the United States. Nomura Securities estimates that Japan's biotech industry will reach 5 trillion yen in 2005, up from an estimated 1.5 trillion yen in 2002.

Sources: Japan Technology Group, Japan Bioindustry Association, Nomura Securities Co. Ltd. For more information, visit nomuraholdings.com.

for alcohol production, discovered that its processes had biotech applications. It has since ventured into modern biotech.

The explosion of small biotech start ups and subsequent IPOs is a recent phenomenon, spurred by a series of legislative and regulatory



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UNIQUE BIOTECH ROOTS

Japan's take on biotechnology has a number of unique aspects. One of these is that many of the innovations in Japanese biotech have their roots in the nation's sizable expertise in fermentation from the production of beer, soy sauce, and amino acids.

In Japan, unlike in the United States and Europe, large companies in traditional industries have been the key players in biotech. Companies such as Kirin Brewery, for example, which had been using fermentation processes

measures aimed at spurring innovation in general, with biotech identified as one area of emphasis.

A number of signs suggest the government's efforts are paying off. There were an estimated 387 bioventures similar to GNI operating in Japan in 2003, according to estimates by Shinko Securities, compared with 167 in 1998.

Under Prime Minister Junichiro Koizumi, the focus on biotech has intensified. In December 2002, the government issued the Biotechnology Strategy Guidelines, which analyzed the current state of Japan's biotech industry and established a set of objectives for transforming biotech into a key economic driver. The strategy brought with it a significant increase in Japanese government investment in bio-related research.

The United States experienced a biotech boom in the 1980s following passage of the Bayh-Dole Act, which removed many of the barriers preventing government sponsored research from being patented by the private sector.

Almost two decades later, Japan has followed the U.S. roadmap and instituted its own

set of reforms, primarily aimed at allowing innovation within Japan's academic research community to transfer efficiently to the private sector.

FULL-COURT PRESS TO FOSTER ENTREPRENEURSHIP

Japan has been actively engaged in promoting entrepreneurship, which indirectly has helped foster Japanese biotech development. It has also more recently set its sights specifically on encouraging biotechnology entrepreneurship.

Japan's first Biotechnology Strategy document was drafted in mid-2002. Its key provisions include doubling the national budget for biotech research and development programs, providing incentives to drive industrialization efforts and maximize private sector participation, and promoting awareness of biotech in schools and among the general public.

Until deregulation in 1998, the number of start-up biotech companies spun out of universities was negligible. That year the Japanese government, as part of its industrial promotion policy, enforced the so-called TLO (technology licensing organization) law, which allows universities and research institutes to transfer the fruits of basic research to private companies.

In 2000, the government gave approval for instructors at public universities to serve simultaneously as directors of companies.

"Five years ago, researchers in Japan were not interested in transferring their technologies to industry because there were so many restrictions," says Taro Yaguchi, a patent and trademark attorney and president of the Japan Technology Group, a firm that facilitates technology transfers between the United States and Japan, another key driver in the development of Japan's biotech field.

Mr. Yaguchi points to one key measure of the result of the recent governmental reform; an explosion in the number of "spinout" companies formed to commercialize innovations created within Japan's state-run universities. In 1997, there were roughly 100 such firms created. By 2004, the number had risen to almost 800, according to Mr. Yaguchi.

Experts in the biotech industry and those operating in the Japanese biotech sector agree there is potential, but they also acknowledge there is a steep hill to climb before Japan catches up with its Western competitors in the biotech field.

"There is a lot of interest, and I think the Japanese government is pushing biotech and thinks it is an area where Japan can make a lot of contributions going forward," says Eric Sedlak, a Tokyo-based partner with the international law firm Squire Sanders. "The government is trying pretty hard, but the infrastructure probably isn't quite as good as in the United States."

It is, however, fair to say the gap between Japan and the West is narrowing, and the

focused efforts of the Japanese government play a large role, both in removing structural barriers and in funding the development of the industry through supporting basic research and funding start-up ventures, often indirectly through investments in venture capital funds.

FOSTERING GLOBAL PARTNERSHIPS

A key element of promoting Japan's biotech industry is fostering the formation of partnerships between Japanese biopharma companies and those in other geographies. The Japan External Trade Organization (JETRO), for example, has made this one of its key initiatives.

Changes in the legal and business environments have led to a different dynamic in the partnerships forming between Japanese and Western biopharma firms.

One such example is San Diego-based Anadys Pharmaceuticals' recent partnership with Tokyo-based start-up Aphoenix. In the past, the typical scenario was for small U.S. or European biotech companies to establish partnerships with large, well-established pharma companies in Japan. While not a major pharmaceutical company, U.S.-based Anadys is the more mature company compared with Aphoenix.

Mike Kamdar, Anadys Pharmaceuticals' senior VP for corporate development and finance, points to a number of developments that led to this shift.

One is consolidation among large pharmaceutical companies, which has led to a restriction in the number of therapeutic areas that the large companies focus on, creating demand for new innovation. Consolidation also has unleashed a talent pool of people once guaranteed lifetime employment that now available to smaller start-up firms.

"There is a confluence of several different things; talented individuals who have some money and therapeutic areas that are not being addressed," Mr. Kamdar says. "The other key thing is really a strong academic presence in the various universities in Japan. There is a great foundation for biotechnology start ups."

Mr. Kamdar points to Aphoenix as a clear example of what he means.

"Aphoenix's leadership is comprised of individuals who came from Nomura Securities, a large securities firm in Japan, and Tanabe, which is a long-standing pharmaceutical company," he says.

As in other geographies, the convergence of biotech, nanotechnology (the Japanese government also is driving growth in this area), and engineering will play a major role in expanding Japan's biotech industry. Japan's biotech industry also will benefit from outsourcing to nearby China where labor costs are much lower.

The success of several recent biotech IPOs in Japan bodes well for more such offerings, as well as increasing numbers of Japanese VCs that will invest in Japanese biotech start ups,

KEY REFORMS IN THE JAPANESE BIOTECH MARKET

A series of governmental reforms, not all of which target biotech exclusively, have created a much better environment for biotech startups to thrive in Japan.

1998

Law Promoting Technology Transfers from Universities to Industry. This act created the institution of Technology Licensing Organizations.

1999

Law on Special Measures for Industrial Revitalization. This is modeled after the U.S. Bayh-Dole Act, which removed restrictions on the granting of licenses and patents for inventions emanating from publicly funded research.

Small- and Medium-Size Enterprise Technology Reform Act. This law establishes the Small Business Innovation Research program, which provides government subsidies and loans, and ensures credit security for technology development and innovation conducted by SMEs.

2000

Law to Strengthen Industrial Technology. This act removes restrictions on the ability of academics at public universities to moonlight as officers or directors of private companies.

2001

The Hiranuma Plan. Named for Minister of Economy, Trade and Industry Takeo Hiranuma, this policy initiative includes 15 points, one of which set an objective of creating 1,000 spinout companies from public universities by 2004.

2003

Basic Law on Intellectual Property. This law was designed to promote the development of new intellectual property in Japan.

2004

National University Incorporation Law. This act transforms national universities into national administrative agencies, which enables university researchers to own their inventions, rather than granting patents to the universities, which had suppressed disclosure of inventions by academics.

and overall, the growth of Japan's biotech industry.

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