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ASIA EDITION

Rebooting Japan's biotech growth engine

01 September 2024 | Analysis | By Ayesha Siddiqui

Japan was once a global leader in life sciences innovation, responsible for nearly 30 per cent of all new drugs. However, its share has since dropped to less than 10 per cent. Between 1995 and 2018, Japan's contribution to the global pharmaceutical industry's value-added declined by 70 per cent, from 18.5 to 5.5 per cent. Factors such as strict price controls, reduced government investment in basic research, weak collaboration between industry and universities, and a slow regulatory process have significantly contributed to the decline in Japan's biopharmaceutical competitiveness, as noted in a 2022 paper by the Centre for Life Sciences Innovation, part of the Information Technology and Innovation Foundation, US. Japanese companies' share of clinical trials also declined from 11 per cent in 2013 to 4 per cent in 2023. An IQVIA report found that the number of trials initiated by Japanese companies dropped from 501 in 2013 to 244 a decade later. Additionally, Japan launched only 20 new medicines in 2023, the lowest total since 2014, trailing behind the US and other major markets. Recognising this, the Japanese government has announced several initiatives designed to reshape the country's biopharma ecosystem. These efforts include substantial increases in capital for venture funds, targeted subsidies for therapeutic drug development, and a suite of tax incentives aimed at empowering investors, entrepreneurs, and startup employees.

On July 30 2024, Japanese Prime Minister Fumio Kishida unveiled a roadmap to establish Japan as a 'drug discovery land,' marking it as a top government priority. The plan includes creating international-level clinical trial systems, attracting global pharmaceutical companies and venture capital, and doubling private investments in drug discovery startups by 2028. The aim is to foster an environment that supports both academia and startups, accelerates innovation, and enhances Japan's role in the global pharmaceutical industry.

Drug lag is a serious concern in Japan. As of March 2023, 143 drugs approved in Europe or the US had yet to be approved in Japan, with 86 of these having no plans to seek approval in Japan. To address this issue, Japan has introduced measures to support innovative drugs. Under the 2024 drug pricing reform, the Ministry of Health, Labour and Welfare (MHLW) has maintained and, in some cases, increased the Price Maintenance Premium (PMP) and initiated an early launch programme. This programme encourages the introduction of drugs in Japan either first or shortly after their global launch. Additionally, Japan plans to speed up regulatory approvals for pharmaceuticals starting 2025, with a new deadline of approximately three weeks from when a drug or indication clears the review of its key advisory panel.

Moreover, MHLW promotes the development of drugs through tax deductions, drug-price incentives, as well as subsidies to offset R&D and application fees. The Ministry of Economy, Trade and Industry (METI) launched an initiative worth 300 billion

yen in fiscal 2022 to support biopharmaceutical manufacturing, specifically vaccines.

Creating innovation ecosystem

Japan was ranked comparatively low in innovation, startups, and entrepreneurship. The United Nations' 2022 Global Innovation Index placed Japan 13th globally, a significant drop from its 7th place in the 1970s and in 2007. In response to this decline, the Japanese government is significantly strengthening the startup ecosystem. At the 2023 BIO International Convention in Boston, METI organised the 'Japan Innovation Night,' where Prime Minister Kishida announced a $7 billion budget to support Japanese startups, with 30 per cent of the funds specifically designated for drug discovery.

The Japanese government launched the Startup Development Five-Year Plan in 2022. The plan, spearheaded by METI, aims to increase startup investment tenfold by 2027 through public-private partnerships. The ambitious goals of the plan include creating 100 unicorns, establishing 100,000 startups, and transforming Japan into the largest startup hub in Asia and one of the world's leading clusters of startups. Over the past five years, investment in startups has already grown by 2.3 times, from 360 billion yen in 2017 to 820 billion yen in 2021. However, METI's five-year plan seeks to further increase investment to 10 trillion yen by 2027. Japan also unveiled plans for a 10 trillion yen national endowment fund to boost the research capabilities of the universities.

METI's other efforts include the creation of the Japan Agency for Medical Research and Development (AMED) to accelerate medical research into treatments. The agency's key initiative, the Strengthening Program for the Pharmaceutical Startup Ecosystem, with a budget of 350 billion yen in subsidies to support pharmaceutical startups.

“AMED operates the Strengthening Program for Pharmaceutical Startup Ecosystem Project, offering substantial subsidies of up to $60 million per project. This programme specifically supports therapeutic drug development by pharmaceutical startups, with more than one-third of the subsidised costs covered by AMED-registered venture capitalists who provide specialised commercialisation support. Saisei Ventures, one of these registered Venture Capitalists (VCs), has successfully leveraged this programme, significantly enhancing the value of its portfolio companies,” said **Dr Jonathan Yeh, Co-founder and Managing Partner at Saisei Ventures**.

In January 2024, METI launched the Japan Innovation Campus in Silicon Valley, an innovation hub that connects Japanese startups with international partners. This campus supports startups aiming to expand globally by working with local VCs, accelerators, and top universities.

“Japan's biotech ecosystem has seen several notable initiatives and collaborations in recent years to drive innovation and growth in the sector. One critical development has been the government's efforts to promote public-private partnerships and encourage greater collaboration between industry, academia, and research institutions,” said a spokesperson from Chugai Pharmaceuticals.

Ecoching similar views, **Dr Hide Goto, Head of Open Innovation Management, Astellas** says, “The presence of academia and startups in drug discovery research is increasing, and Japanese pharmaceutical companies are now in an era where they imagine value not only through their research but also through collaboration with external stakeholders like academia, small startups/biotech and other pharma companies. Japan lags behind the West in terms of the maturity of the biotech ecosystem. Hence industry, government, and academia need to work together to foster a culture of innovation. Some efforts to promote the development of the biotech ecosystem in Japan have begun in various places.”

Pharmaceutical companies are increasingly establishing incubation facilities to support startups. For example, Takeda Pharmaceutical Co. Ltd. launched Shonan iPark in 2018. As of April 2023, Shonan iPark hosts approximately 150 companies and over 2,000 individuals, spanning not only pharmaceutical firms but also sectors such as next-generation medicine, cell agriculture, AI, government, and others, creating a vibrant ecosystem. In 2023, Astellas also launched SakuLab-Tsukuba, an open innovation hub in Astellas' Tsukuba Research Center, to help nurture and support new startups, small businesses and academic institutions to pursue their cutting-edge science. Leveraging presence in Tsukuba and Kashiwa-no-ha, leading life science hubs in Japan, the firm also aims to activate Japanese innovation through various initiatives such as hosting pitch events and strategic partnerships with academia.

“Not only in the Japanese market but globally, more and more of the drugs and therapies approved in recent years have originated from academia or startups, making open innovation essential for the creation of new medicines,” says Dr Hide Goto.

In April 2024, Takeda, Astellas and Sumitomo Mitsui Banking Corporation announced a master agreement to establish a joint venture company for the incubation of early drug discovery programmes primarily originating from Japan and toward the

creation of innovative therapeutics.

Lack of funding has been a major roadblock for Japanese startups, as historically big pharma companies and VC firms have invested more outside Japan. However, recent government actions—including initiatives to establish a global startup ecosystem and relaxed regulations—have spurred many venture capital firms to announce funds specifically for Japan. Notable examples include American VC firm Arch launching a $3 billion biomedical fund with a focus on Japan, Kyoto University's VC fund investing $140 million in AI and biotech, and Otsuka Pharmaceutical investing $30 million with AN Venture Partners to support global biotech companies leveraging Japanese science.

Evolving trends

Japan is a frontrunner in conducting induced pluripotent stem cell (iPSC) therapeutic trials. Out of the 19 iPSC clinical trials worldwide, 10 were conducted in Japan, followed by 4 in the US and the rest in Australia, China, Iran and Germany, according to AE Research Management. Apart from regenerative medicines, the country is now prioritising cell and gene therapies, antibody-drug conjugates, etc.

“Japan is increasingly prioritising next-generation therapies, including monoclonal antibodies, gene therapies, and stem cell research. Significant investments are being funnelled into these areas, with a strong emphasis on developing treatments for conditions that were once considered untreatable. The rise of personalised medicine is also gaining momentum, aligning with global trends toward more precise and individualised healthcare solutions,” said Dr Yeh.

Japan's rapidly ageing population presents significant challenges, including an increased risk of degenerative diseases. Therefore, many Japanese pharmaceutical companies are focusing on treating neurological disorders like Alzheimer's, epilepsy, Parkinson's, and depression.

The government has also made extending healthy life expectancy to 100 years one of the 10 goals of Japan's national moonshot research and development policy, which supports challenging R&D projects that aim to resolve difficult societal issues by drawing on the wisdom of researchers around the world.

“The Japanese pharmaceutical market is undergoing various changes, including addressing an ageing society, promoting generic drugs, pioneering efforts in regenerative medicine, focusing on rare diseases, and the rise of digital health. Opportunities may arise for domestic and international companies to develop innovative therapies, address the healthcare needs of the elderly, enter the generic drug market, and expand into new fields like regenerative medicine and remote/telemedicine,” said a spokesperson from Chugai Pharmaceuticals.

This ageing landscape is driving the need for scalable, efficient healthcare solutions. Digital health technologies, including AI-powered diagnostic tools and digital therapeutics (DTx) offer vital solutions. CureApp, a startup company pioneering digital therapeutics in Japan, received Japan's first regulatory approval in 2020 for its ‘CureApp SC’ nicotine addiction treatment app, followed by the world’s first regulatory approval for hypertension in 2022 for its ‘CureApp HT’ high-blood-pressure-management app. Big pharma firm Shionogi is actively engaged in the DTx space. The company is collaborating with US medical tech specialist Akili to commercialise mobile games aimed at helping children with attention deficit hyperactivity disorder (ADHD). Additionally, Shionogi has partnered with NTT DATA KANSAI Corporation and QUNIE CORPORATION to develop a distribution platform for digital therapeutic services.

The biotechnology sector in Japan has grown steadily, reaching 5.2 trillion yen in 2020, a 70 per cent increase over the last five years. According to the National Institute of Technology and Evaluation, this market is expected to continue its growth, reaching 15 trillion yen by 2030. With such a large market size, an ageing population, high-quality fundamental research and government initiatives, Japan is perfectly positioned to reclaim the top spot and become a global leader in biotech.

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