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Advancing Japan's Biotech Ecosystem: Current Initiatives and Future Outlook

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Japan has a robust drug discovery capability, having developed an interleukin-6 inhibitor, a programmed cell death protein 1 inhibitor, and, in earlier years, an acetylcholinesterase inhibitor for Alzheimer's disease. Additionally, in stem cell research, Professor Shinya Yamanaka's discovery of induced pluripotent stem cells (iPSCs) has placed Japan at the forefront of regenerative medicine (RM). Despite its strong basic research capabilities, Japan has fallen behind in building its biotech ecosystem due to the lack of venture financing and lower labour mobility to startups. To address this and make drug development a growing industry in Japan, the Japanese government has been implementing measures to enhance the biotech ecosystem.

Initiative to Enhance the Ecosystem

Most importantly, the Japanese government introduced the "Strengthening Drug Discovery Venture Ecosystem Project" with a budget of 300 billion yen starting in 2022. This initiative provides subsidies of up to twice the investments from multiple certified Venture Capitalists (VCs) through the completion of Phase II clinical trials, as long as the biotech does not go public. This subsidy enhances VC returns and provides more funding for biotech than would otherwise be available. The project requires that the investment amount from a lead certified VC, including already executed investments, be 1 billion yen or more, to reinforce commitments from the VC. Since the subsidies do not apply to investments made before the project period,

this system primarily targets early to mid-stage startups that are yet to receive new VC investmentsÃ£â?¬â?¬

Challenges in Late-Stage Funding

However, financial challenges remain for later-stage biotechs. While advancing pivotal trials would significantly increase corporate value, many companies are forced to go public or be acquired before reaching such value inflection points due to insufficient private funding. Because the development stages are too early for investors specialising in biotech, relatively small funds are raised at biotech IPOs in Japan. Consequently, post-IPO growth has been limited, and Japanese biotechs have yet to produce globally successful drugs. Since the risk of drug development is dramatically reduced after confirming early clinical data, activation of late-stage financing, including from public market investors, is crucial to strengthen the ecosystem in Japan.

Anticipated Success Stories

For late-stage investors to turn their attention to Japan, successful examples are indispensable. Japan has the potential for breakthroughs in the field of RM, supported by favourable regulatory policies and world-leading technologies. To accelerate the practical application of RM, the Japanese government introduced a conditional approval scheme, allowing companies to initiate commercialisation based on Phase II trial data, demonstrating efficacy through post-marketing surveillance as an alternative to Phase III trials. This scheme is vital for keeping Japan an attractive market for RM development. In fact, public companies that have clinical pipelines in RM are valued relatively highly on the Tokyo Stock Exchange. Among them, Heartseed, a leading biotech in cardiac RM, went public in July 2024. Heartseed has established a global partnership with Novo Nordisk, aiming to accelerate global development, manufacturing, and commercialisation. This partnership combines the agility of biotech with the quality and scale of a mega pharma, and could serve as a model for global expansion.

Biotech growth as National Priority

The Japanese government positions startup support as a key priority and is actively developing truly effective measures to produce home-run success stories. As a result of these efforts, the ecosystem has been strengthened, as seen in the influx of experienced talent from pharmaceutical companies and the emergence of venture capital firms capable of supporting new company creation. As signs of success cases are beginning to emerge, it is expected that groundbreaking medicines from Japan will have a significant impact globally in the near future, presenting compelling investment opportunities in Japan’s biotech sector.

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