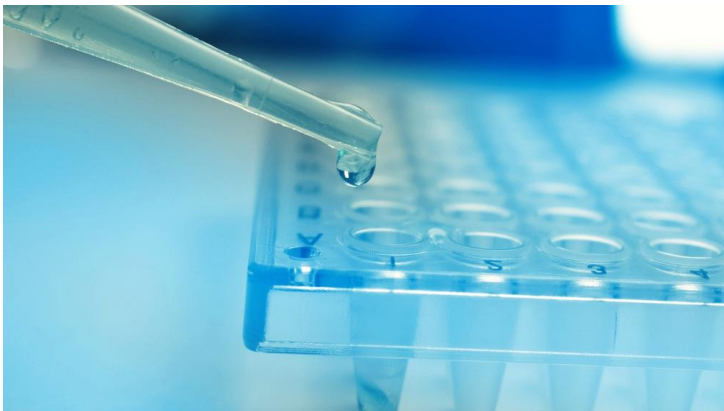


The Lure of USA for BioStartups

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Asian biotech startups are increasingly expanding their global footprint and making a mark in the global healthcare industry. We examine the challenges they faced while doing so and strategies for successful international expansion.



Global expansion is a natural trajectory for any startup. Asian biotech startups, even those with large domestic markets, need to expand globally at some point to fuel their growth.

Depending on the stage of a biotech startup and where it hails from in Asia, there are several considerations for their expansion internationally – to tap on global resources such as financing, talent, experienced contract development and manufacturing organisations (CDMOs), and to access the wider market.

Expansion to other markets also reap financial benefits. Approximately two-thirds of US (United States) biotech launches are followed by launches in other countries, generating around 35 per cent of total revenues from drugs launched internationally. It's clear that the global reach of biotech startups contributes to their success and impact on global health, a report by McKinsey highlights.

Recognising this, several Asian biotech companies are expanding globally, with the US and EU being top destinations due to advanced healthcare systems, innovative ecosystems, talent availability, and broader markets.

Several Asian startups have also shifted their base overseas. One such example is Biofourmis, which originated in Singapore but is now headquartered in Boston, USA. They offer care-at-home solutions utilising FDA-cleared AI-guided algorithms, clinical-grade wearable devices, in-home services orchestration technology, and nursing services. Another example is BeiGene, a global oncology firm that originated in China and now has a major presence in the US and Europe.

Startups going global

Here are a list of the few startups who have expanded to the international space in the recent times:

Founded in Singapore, Lucence is a precision oncology company that has developed ultra-sensitive liquid biopsy tests. These tests make it possible to profile cancer accurately, rapidly, and affordably with a single blood draw. In early 2023, Lucence secured coveted Medicare approval for its cancer tests, granting access to millions of patients in the US under the

reimbursement scheme. This approval establishes Lucence as the first and only Asian-headquartered healthcare services company to secure United States national insurance coverage.

Lunit, a South Korean medical AI company, develops AI-powered tools for accurate cancer screening, diagnosis, and personalised treatment guidance, with the aim of improving patient outcomes. The firm is aggressively pursuing global expansion and has announced several deals in Europe and the Middle East. It has now set its sights on the US market and sealed a deal to acquire a breast and lung imaging AI software firm Volpara Health Technologies for approximately \$193 million. This acquisition positions Lunit as a leading force in the American market, leveraging Volpara's mammography solutions operational in over 2,000 US medical sites.

Telix, an Australian-headquartered commercial-stage radiopharmaceutical company, pioneers targeted radiation imaging and therapy technologies with the potential to revolutionise cancer management and address critical rare diseases globally. In 2022, Telix launched its first commercial product, Illuccix, for prostate cancer imaging in Australia and the United States. Further expanding its presence, Telix acquired Iso Therapeutics in 2024 to bolster its US development and manufacturing infrastructure.

Toku Eyes, a New Zealand-based startup develops tools using AI and retinal photography to enable accessible healthcare for early and accurate diagnosis of health conditions. In 2022, Toku Eyes made its mark in the US market with the launch of ORAiCLE, an AI platform that assesses heart risk through a retinal scan.

FELIQS is a Japanese startup company funded with a seed round of \$2.5 million to develop a portfolio of two patent-protected drug product candidates targeting two attractive multi-billion-dollar markets in ophthalmology and neonatology: Retinopathy of prematurity (ROP) – FLQ-101, a lipid peroxidation inhibitor repurposed to prevent ROP. FLQ-101 will be in Phase I/II dosing planned in the US for 2024. Age-related macular degeneration (AMD) – FLQ-104, proprietary lipid peroxidation and ferroptosis inhibitor for earlier intervention to treat AMD. FLQ-104 is currently in the discovery stage in the US. Each of these developmental candidates is identified through FELIQS's proprietary screening platform targeting lipid peroxidation/ ferroptosis with proven efficacy from past prospective clinical trials. In 2023, FELIQS opened the US office in JLABS@NYC.

The path to global leadership

Expanding into international markets is not easy; biotech startups face numerous challenges worldwide, including policy, regulatory, talent, technology, and cash flow obstacles.

“Asian biotech startups face valuable growth opportunities when expanding internationally, especially into US and European markets such as complex regulatory environments, establishing secondary operational bases, securing funding, and understanding local ecosystems. Additionally, recruiting suitable talent and managing dispersed organisations are significant areas for strategic development,” said **Dr Grace Lau, Head of the Institute for Translational Research at Hong Kong Science and Technology Park (HKSTP)**.

With a vibrant community of over 250 biotech companies, HKSTP has developed an extensive network of world-leading scientists and industry and academic partnerships to support the translation of biotech breakthroughs for global impact. In particular, HKSTP provides a prime ecosystem to leverage Hong Kong's status as a gateway between Asian and global markets.

Healthcare is a highly regulated space worldwide. To access market opportunities, biotech startups need to understand and adhere to rigorous clinical trial standards and secure regulatory approvals. However, that just does not end there.

“Beyond having to navigate regulatory hurdles, biotech startups with approved therapeutics will still need to secure reimbursement from payors and insurers for scaled adoption of their therapeutic solutions,” said **Dr Clarice Chen, Director, Healthcare & Biomedical, Enterprise Singapore (EnterpriseSG)**. EnterpriseSG is cognisant of these challenges and has put in place partnerships and programmes that will enable these startups to overcome them.

To navigate regulatory hurdles, one important strategy is forming partnerships. Partnerships with large pharmaceutical companies are valuable as they have the necessary experience and expertise to bring potential treatments through validation and into clinics around the world.

“By prioritising flexibility, innovation, and collaboration, startups can overcome obstacles and establish a strong foothold in global markets, showcasing the potential of Asian biotech innovation,” said **Vishal Doshi, CEO of AUM**. AUM, a Singapore biotech company, focuses on developing cancer therapies. To navigate potential regulatory hurdles, AUM forms strategic partnerships with local pharmaceutical companies, such as Newsoara in China, to leverage their expertise to gain market

access.

Licensing is another strategy that startups can utilise to springboard into the international markets. “With a significant increase in licensing deals between Asian biotech companies and US/European biopharmaceutical companies, Asia is playing an important role in global innovation, especially in licence-out deals. Global CDMOs can help biotech companies go to market from the pre-clinical to commercial manufacturing stages, leading to a win-win situation, which will be a major trend in the next decade,” said Michelle Pan, Head of Marketing, Chime Biologics, China. Chime received \$190 million in Series A+ financing in 2021 and built the world's first GE Kubio modular bio-manufacturing facility in China's Wuhan Bio-Lake Biotech Industry Development Zone (China Optics Valley).

And of course building local expertise is crucial for successful international expansion, as it enables startups to navigate cultural nuances and regulatory environments effectively.

“Investing in human resources is crucial. If you want to effectively navigate the intricacies of the new market, it requires to build a team of local experts who possess a profound understanding of the cultural landscape, consumer preferences, and business dynamics that shape the market environment and are beneficial to the company moves,” said **Steven Truong – Founder and CEO VinBrain, Vietnam**. VinBrain which has successfully expanded to the US, is developing AI solutions for healthcare and has developed more than 300 AI models specifically designed for processing medical images.

Countries in the region are implementing various programmes to assist startups in establishing international expansion. Singapore launched the Global Innovation Alliance (GIA) acceleration programme in San Francisco, specifically aimed at helping Singaporean small and medium-sized enterprises (SMEs) and startups seize opportunities in the US market. Over 60 Singaporean tech SMEs and startups have participated in the programme to date.

CSSi LifeSciences, a prominent international provider of regulatory affairs and access to the US healthcare market, has entered into partnerships with the governments of New South Wales, Queensland, and Victoria, three key Australian states. This strategic collaboration is designed to provide support to Australian life science enterprises aiming to penetrate the US healthcare market.

Japan has also taken initiatives in this regard. The government launched the Beyond JAPAN programme. Launched by the Japanese government's Ministry of Economy, Trade and Industry (METI) and the Japan External Trade Organization (JETRO), this five-year endeavour aims to cultivate entrepreneurial talent capable of driving the expansion of global businesses. As part of this initiative, 1,000 participants are slated to participate in overseas training programmes over the duration of five years.

For biotech companies, scaling up is essential to fulfil their commitment of delivering innovative medicines to patients. By cultivating local expertise and navigating regulatory landscapes adeptly, these companies can effectively address unmet medical needs and make significant contributions to healthcare globally.

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