

BioJapan 2021 Special Report

Asia's largest bio business event, BioJapan, gathered delegations from 26 countries. The 3-day event was an opportunity for diverse players, including Shonan iPark, to gather and discuss various perspectives on the challenges and way forward for the Japanese life science innovation ecosystem. This special report highlights key topics of discussion at the two sessions.

Key Takeaways

How can Japan build a Biotech-Ecosystem that is open to the world?

- Launching a biotech company requires three key fundamentals—technologies, funds, and talents. Unfortunately, the stumbling blocks commonly encountered in Japan are the shortage of funds and talent.
- Japan's basic level of science is among the highest in the world. Perhaps the way forward is to procure funds overseas leveraging Japanese science, secure talents overseas, and commence business operations.
- For Japanese biotech companies, where success stories are still scarce, securing US investor funding is challenging. CEO Hiroshi Miyake of Chordia Therapeutics* shares, "Regardless of the results from our ongoing efforts to secure funds in the US, we want to share our experience with the Japanese life science community to help foster future startup generations."

*The company is in preparation for IND application for CTX-712, a selective CLK inhibitor.

What can Shonan iPark offer for health innovation and building an ecosystem?

- Various players, including academia, pharma, biotech, and the food science industry, have made decisions to co-locate at Shonan iPark with the ambition to unleash the full potential of scientists for their research.
- They are seeking collaborative opportunities and eyeing impactful outcomes within a 5-year-period. One outcome example that has already been announced is the first-in-industry collaboration between Mitsubishi Tanabe Pharma and Takeda on sharing partial ADMETox data to accelerate drug discovery.
- Still, many challenges lie ahead for startups in Japan. Underlying this situation is a domestic biotech market viewed as less attractive for investors. Also, policies need review to improve the entrepreneurship environment and ecosystems.
- Shonan iPark can play a leadership role to address such challenges, driving a vibrant ecosystem, and eventually leading to successful biotech business creations.

Session: Building a Biotech-Ecosystem, Open to the World

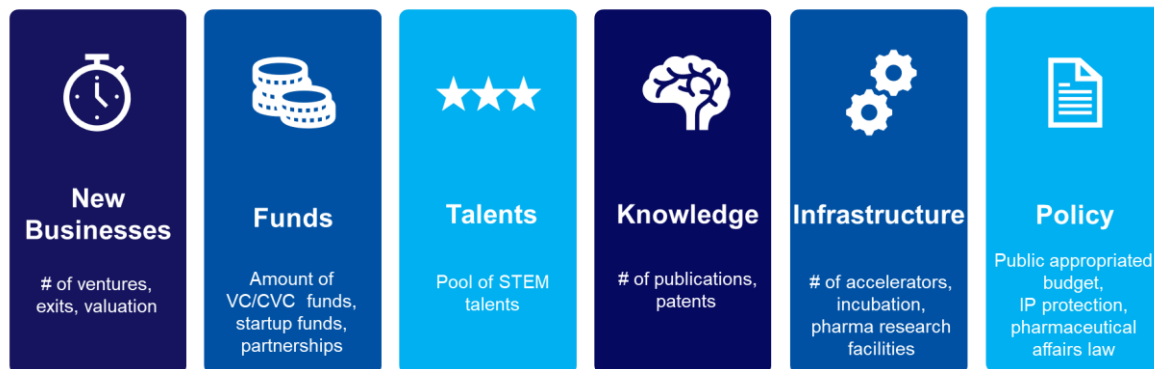
Challenges of Japan's Life science Ecosystem

Dr. Toshio Fujimoto (General Manager, Shonan Health Innovation Park)

Japan has lagged behind other countries in creating ecosystems. Despite its scientific strength, Japan's efforts have yet to yield fruitful results that lead to innovation. **Developing a healthy ecosystem requires six fundamentals. One such element, our topic of discussion today, is how to secure global funding for investment in Japanese biotech.**



“Six Fundamentals of the Growth of Ecosystem” that Must Interplay Dynamically



Let's Go Fly, Japanese Biotech!—Views From an Overseas Investor

Mr. Sheen Komoto (Partner, Eight Roads Ventures Japan)

We are actively investing in startups in biotech and healthcare, with our scope of operation spanning the US, China, India, and Japan.

We practice rigorous due diligence for each investment around the globe, supported by multiple global teams working simultaneously. Generally, scientific data is the critical component underlying our investment decisions.

However, **the most crucial element is whether there is an experienced management team. Japan's basic level of science is among the highest in the world. Two out of our three investments this year are overseas business operations based on Japanese science.**



Perhaps the way forward can be: procure funds overseas leveraging Japanese science, secure talents overseas, and commence business operations. In this way, greater returns are generated, ultimately contributing to Japan's national interests.

Globalizing the Business Environment for Japan's Bio Ventures

Dr. BT Slingsby (Founder & Managing Partner, Catalys Pacific, LLC)

We are a VC firm specializing in creating companies and operating both in Japan and the US. Our business projects are divided into two types: 1) projects undertaken for overseas clinical development based on seeds originating in Japan, and 2) domestic clinical development based on seeds originating overseas. Today, I would like to talk about the current situation and issues surrounding the second point. **Generally speaking, launching a biotech business requires three elements—technologies, funds, and talents. Unfortunately, the stumbling blocks commonly encountered in Japan are a shortage of funds and talents.**



One solution is to give incentives to pharmaceutical companies for limited partnership investments, which is a form of investment in which investments are made in startups through VCs, not directly. Introducing this step would likely lead to a dramatic increase in the number of VCs in Japan. Another possible step includes revising the current taxation system on investment to spur investment from overseas players. For example, maintaining prices of pharmaceutical products developed by biotech firms at certain levels for a fixed period could expedite M&A. Additionally, public offering (PO) is a fund procurement option for biotech firms. However, conducting POs is close to impossible for them, given that **in Japan, POs are not allowed unless there are sales, and most biotech firms have yet to produce sales. Therefore, such a rule should be reassessed.**

Our Approach to the Global Market

Dr. Hiroshi Miyake (President and CEO, Chordia Therapeutics Inc.)

Our company, established as a spin-out from Takeda Pharmaceutical Co. Ltd., focuses on the R&D of small-molecular compounds in oncology. We own five assets—four licensed from Takeda and one developed through our research activities. The lead asset, CTX-712, is currently in Phase-1 trials in Japan, and the second asset in the pipeline, CTX-177, was licensed out to Ono Pharmaceutical Co. Ltd. **To launch CTX-712, a selective pan-CDC-like kinase ("CLK") inhibitor, worldwide, we are willing to start a Phase-1 study in the US on our own, and preparation is currently underway for an IND application. Our company has many pharmaceutical drug development experts, so these tasks are not a very big hurdle. However, we find it challenging to secure local talents and procure the funds necessary for clinical**



development in the US. In June this year, we initiated our approach to 72 prospective investors in the US with a teaser campaign. As a result, 16 companies contacted us immediately, including nine companies with which we have signed non-disclosure agreements. Discussion is still underway with the remaining companies. As for tackling the challenge of securing local talents for clinical development, we believe we will be able to accelerate the search and acquisition of excellent local talents while receiving support through US investors.

Regardless of the results from our ongoing efforts to secure funds in the US, we want to share our experience with the Japanese life science community to help foster future startup generations.

METI's Strategy for Accelerating Growth of Biotech Startup Ecosystems

Mr. Kozo Saiki (Director, Bio-Industry Division, Commerce and Service Industry Policy Group, Ministry of Economy, Trade, and Industry)

The METI regards bio ventures as vital for Japan's future. However, given that it can take significant time for developing pharmaceutical products to be launched on the market, METI has revised company delisting rules to prevent companies from being delisted before their products have launched.



METI has further introduced a new tax system aimed at promoting open innovation. In response to corporate demand for the active use of stock options to secure quality external talents, METI has expanded the eligibility criteria for the stock option taxation system. The system, which previously covered only directors and employees at startup companies, now includes competitive talents from outside the companies, such as supporters, programmers, engineers, and lawyers.

In June, the Japanese government developed a strategy to facilitate the development and production of vaccines. One key goal of the strategy is to foster drug discovery ventures. Projects at phase 1 and 2 stages of clinical trials face especially significant financial risk, requiring large amounts of funding. METI is considering the possibility of providing subsidies to such ventures in addition to the use of government-linked funds to help alleviate the burden of funding shortages. **Furthermore, for university researchers to be able to focus on research activities, it is essential to build an ecosystem that supports the recruitment of external talents and hands-on functions.** METI is currently considering a support scheme for drug discovery ventures to help realize such an ecosystem.

Session: Cultivating a Collaborative Space for Health Innovation Practices at the Life Science Ecosystem – Shonan Health Innovation Park



Breaking Free From Conventional Thinking – Fostering Open-mindedness in Researchers

Dr. Aruto Yoshida (General Manager, Kirin Central Research Institute, Kirin Holdings Co., Ltd.)

Joined Shonan iPark in 2019 as the first resident of the food industry



Initially, we moved to Shonan iPark on a trial basis. Eventually, a consensus was formed among our employees that Shonan iPark is the most suitable place for engaging in research activities. Therefore, at the end of 2020, we moved our activities to iPark at full scale.

We plan to expand our business into the research and development of functional food ingredients in the health and healthcare products field. We also plan to conduct basic studies toward the development of next-generation pharmaceuticals.

Shonan iPark houses various shared facilities for tenants, which have been well-received, especially by active and ambitious researchers. iPark also hosts special events throughout the year that provide the ideal environment for our researchers to find inspiration by engaging researchers from other companies. Unsurprisingly, thanks to the open and collaborative culture, inspiration abounds at Shonan iPark, a steadfast proponent of creativity and innovation. **By leveraging new collaborations at Shonan iPark, we are committed to reaching our goal of realizing the social implementation of research outcomes within five years.**

Data Sharing Across Noncompetitive Fields – Pharma Forges New Paths Forward

Dr. Rikako Yamauchi (Head of Research Unit / Frontier Sohyaku, Innovative Research Division,
Mitsubishi Tanabe Pharma Corporation)

Stimulate researchers by relocating research unit to the place of co-creation



We joined Shonan iPark in 2019. **Open innovation is essential for drug discovery in the future, and open-mindedness is a key ingredient in achieving open innovation.** The genuinely open, collaborative environment at Shonan iPark facilitates frank exchange among tenants. I believe it is the kind of environment where open innovation is possible.

Drug discovery requires massive data, and this data must be collected efficiently and effectively. However, pharmaceutical data are corporate assets and, based on this understanding, we have refrained from providing such data to third parties. We then realized **that by redefining some elements of competitive fields as "noncompetitive fields," we could collect data more efficiently and effectively.**

Together with Takeda Pharmaceutical Co., Ltd., we studied the feasibility of this idea. As a result, **it was confirmed that the two companies can mutually deepen their knowledge through data sharing. In January 2021, we shared partial ADMETox (pharmacokinetics/toxicology) data on publicly known compounds and early-stage pharmacological activity data, most of which had been used exclusively within each company. In five years' time, we aim to implement new technologies in fields including precision medicine while making the best use of the many benefits of Shonan iPark's ecosystem.**

On the Path to Developing a New Method to Treat Phenylketonuria Through Crowdfunding

Dr. Nobuhiko Kojima (Associate Professor, Regenerative Biology Laboratory,
Graduate School of Nanobioscience, Yokohama City University)

Received development funds through crowdfunding led by Shonan iPark

Our laboratory has studied ways to treat phenylketonuria, a designated intractable disease, using spheroids (3D cell colonies). In the process, we came up with the idea of "liquid liver." The technique involves enclosing metabolic enzymes in red blood cells to



enable them to perform a function similar to that of the liver. The "liquid liver" is then transplanted into the patient's blood to treat the disease. However, it was hard for us to obtain a competitive grant, such as the Grant-in-Aid for Scientific Research, based only on an idea because grants are usually awarded to concretized projects that have already produced specific results. Under these circumstances, **Shonan iPark proposed the idea of crowdfunding, and we decided to take part.**

In five years, we aim to solidify our development team further to build a laboratory system under which all members can devote themselves to the daily challenge of establishing the method with smiles on their faces.

Regenerative Medicine – Working Toward Social Implementation Utilizing Japan-based Research

Dr. Kenji Nonaka (President, Representative Director, and CEO, Orizuru Therapeutics Inc.)

Leveraging ecosystems to overcome obstacles to commercialization



Before joining Orizuru Therapeutics, I was in charge of devising R&D strategies at a global pharmaceutical company from clinical development post-marketing. At that time, **two technologies developed under the T-CiRA program, treatment of severe type-1 diabetes using pancreatic islet cells and treatment of severe heart failure using cardiomyocytes, were reaching development. Orizuru Therapeutics was established to deliver the outcomes of these two technologies into medical practice.**

We must consider how to make this happen using a real, comprehensive approach, not only as science but also as a business. For example, when we face price issues such as when the price exceeds one hundred million JPY per person, patients cannot access the drug. Such a comprehensive approach has thus far only worked with the mega pharmaceutical company model, but **I believe that ecosystems can also use this approach if they are fully functioning. In five years, I imagine that our company will be recognized by society as a major player in regenerative medicine.**

Challenge of Overseas Business Deployment Using Japanese Seeds

Dr. BT Slingsby (Founder and Managing Partner, Catalys Pacific, LLC)

The expectation for Shonan iPark's leadership

We operate a VC called Catalys Pacific in the US and Japan at Shonan iPark.

We have two business strategies: 1) fostering seeds originating in Japan for clinical development overseas, and 2) bringing pharmaceutical products originating overseas into Japan for clinical development.



Specifically, in collaboration with Mitsubishi Tanabe Pharma Corp., we promote clinical development in the US of compounds developed by Mitsubishi Tanabe Pharma. For that purpose, we have founded Mineralys Therapeutics, Inc. in the US. Meanwhile, **many challenges lie ahead for startups in Japan. Underlying this situation is a domestic biotech market viewed as less attractive for investors.** Especially problematic is the difficulty of raising funds from overseas investors. It is, therefore, **necessary to review policies on domestic entrepreneurship environment and ecosystems. We believe this is where Shonan iPark can serve in a leadership role. We expect robust ecosystems to be created across Japan in five years' time, eventually leading to successful biotech business creation.**