

Stanford

SILICON VALLEY NEW JAPAN
PROJECT



STANFORD SV-NJ CASE STUDY SERIES:
JAPANESE FIRMS IN SILICON VALLEY (STARTUP-UPS)



Company Name: SanBio, Inc.
Arrival to Silicon Valley: 2001
Business Location: Mountain View, CA
Interviewee: Keita Mori
Interview Date: 7.20.2016
Website: <http://www.san-bio.com/>
US Entity Type: California Corporation
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Company Overview:¹ What is the company's business purpose?

SanBio was founded in 2001 in order to develop products for brain cell regeneration therapy. SanBio is focused on cell therapy for neurological disorders such as stroke, traumatic brain injuries, diseases of the eye, and Parkinson's disease. Previously, patients in the chronic phase of cerebral stroke had little to no hope of recovery, and would become completely paralyzed in the 3-6 months following a stroke. SanBio aims to give hope to these kinds of patients by developing regenerative therapies for neurological disorders.

Company Story: What are the company's origins and connections to Silicon Valley?

Keita Mori and Toru Kawanishi founded SanBio in 2001. Mori graduated from the University of Tokyo Agricultural Studies Department, specializing in bioscience. He worked for Kirin Beer,

¹ Company overview information is collected from the company's website and marketing materials. Any merits of the company's abilities and technologies expressed herein do not reflect the opinions of Stanford nor SV-NJ.

and got an MBA from the UC Berkeley, Haas School of Business. Mori had always wanted to develop new businesses, and was previously involved in developing new products in an IT startup called Xuma. Kawanishi was a friend of Mori's from the University of Tokyo. He had a previous career with a major international consulting firm, and had started a healthcare information startup, CareNet (TSE: 2150).

Neither Mori nor Kawanishi were initially set on starting a firm in Silicon Valley. However, the lack of opportunity in Japan due to strict regulations that made it seem impossible to take their product into clinical trial stages, made them look to other potential hubs. They chose Silicon Valley as it seemed like the easiest place to obtain high quality personnel, and the Food and Drug Administration (FDA) of U.S. was moving forward with medical approving systems for novel treatments.

Unlike many startup stories in which founders will grapple with different ideas and business directions until they finally land on that million-dollar idea, SanBio is one of the rare examples in which the founders Mori and Kawanishi had a very clear idea from the beginning, and have stuck with this vision for 15 years. There are two approaches in regenerative therapy; one is autologous cellular therapy, which is a process in which a patient's own cells are extracted, reproduced and then reintroduced to the patient for specific cosmetic and medical applications; the other is allogeneic cellular therapy, which is a process in which a healthy donor's cells are extracted, reproduced and then reintroduced to a patient who is not the same person as the donor. SanBio is focused on the latter, as it is more suitable to mass-production at a relatively low cost. One of SanBio's core values from the very beginning was the hope that they would be able to affect as many people as they could; rather than work with patient one by one, mass production is much more conducive to this goal. Allogeneic cellular therapy has made it possible to produce regenerative medicines for thousands of patients per production. Although, in general, allogeneic cellular therapy does run the risk of immune rejection, research has demonstrated that this risk is little to none when the method is applied to the brain, and spinal cord.

In the beginning, SanBio conducted phase 1/2a clinical trials with Stanford University and the University of Pittsburgh. Currently, clinical testing for SanBio's regenerative medicine for cell therapy, SB623, is underway. SanBio started conducting a Phase 2b clinical trial study in 2015 to evaluate the safety and efficacy of SB623 cell therapy for stroke, and a Phase 2 clinical trial to evaluate the safety and efficacy of SB623 for traumatic brain injuries in the U.S. Collaborating with neurosurgery expert Professor Gary Steinberg of the Stanford University School of Medicine, SanBio has conducted clinical trials with 18 patients, at the University. The patients who received SB623 two years after stroke have shown significant steps towards recovery. In a

CBS segment that covered this story, a patient who had been paralyzed post stroke, raises her arm triumphantly above her head after surgery. Similarly, another patient who could not move her leg before, is shown taking steps forward.² SanBio is one of two companies in the world, to reach this trial phase. SanBio's positive trial results have attracted the attention of large pharmaceutical companies. In 2010, SanBio began collaboration with Teijin and Dainippon Sumitomo Pharma. These collaborations have been mutually beneficial – while SanBio provides the know-how about producing regenerative medicines, they have also been able to take advantage of the large companies' development and sales resources in order to expand the business. In particular, they are able to continue development without having to use its own resources, and do not have to overly concern themselves with fundraising.

2014 was a turning point for SanBio. In November 2014, the amended Pharmaceutical Affairs Act was enforced. The amendment significantly shortened the clinical trial period, and as a result, regenerative medical products can be used on a conditional authorization basis in a much timelier manner – from 10 years to 2~3 years on average. Now, when it comes to cell regeneration therapy, the Pharmaceuticals and Medical Devices Agency (PMDA) in Japan can complete an examination and approval process much faster than FDA. This enforcement proved to be a historical break for companies related to regenerative therapy. In 2014, in anticipation of the forthcoming amendment, SanBio moved its headquarters from the U.S. to Japan, and made its U.S. office a subsidiary. In addition, in order to gain more visibility in Japan, SanBio decided to go public on Tokyo Stock Exchange MOTHERS in April 2015.

SanBio has started joint development with large companies in the U.S. and Canada, and has conducted stroke treatment experiments in 60 hospitals. Upon approval, Sunovion, a subsidiary of Dainippon Sumitomo Pharma, will be in charge of the sales of its regenerative medicines in the U.S. Similarly, in Japan, Teijin, which obtained a sales license of the stroke medicines in Japan from SanBio, is going to be responsible for the sales.

Human Capital: Who are the key leaders and employees of the company, and what plans exist for personnel expansion?

The founders used personal networks as well as headhunters to put together a management team. For the business team, they assessed people through resumes, and an interview process. The engineers were assembled through the management team through networks and advertisements. In the early stages, Mori and Kawanishi were involved in engineer hiring, however, now they leave this to the managers. SanBio hires employees locally. The Japanese headquarters is

² CBS picked up the story (<https://youtu.be/E4WXwhTp7Ow>)

focused on clinical development, while its U.S. subsidiary is focused on product development, as there is a lab only in the U.S. SanBio keeps its cross-national offices connected through frequent conference calls and business trips between the Japan and U.S. offices.

Currently there are around 30 employees – 10 employees in Japan and 20 employees in the U.S. About half of the employees are women, however, like a lot of other Silicon-Valley companies, senior management is still male dominated. At other levels, there are many female managers and directors

Funding: What are the sources of funding for the company?

- In 2002 SanBio received \$3 million from three Japanese bio-related VCs (Biotech-Healthcare Partners, NIF ventures, and another bio-related public VC) in series A financing. The company also received \$1 million in series B financing. It took 1.5 years to complete the initial fundraising, and concluded with an MOU with the Japan Science and Technology Agency.
- In 2004, the company received \$20 million from 10+ Japanese VCs in series C financing.
- In 2009, the company received \$5 million by entering into an alliance with Fujifilm in series D financing, and received \$5 million by entering into an alliance with Teijin in series E financing.
- In 2010, the company received \$30+ million by entering into an option agreement to co-develop a new cell therapy for stroke recovery with Dainihon Sumitomo Seiyaku; the companies concluded their joint development and license agreement for exclusive marketing rights in the U.S. and Canada for SB623 in 2014.
- In April 2015, the company went public on MOTHERS and successfully fundraised 7 billion Yen.

Business Challenges: What challenges does the company face?

Within a year of starting the company, the founders shifted from their initial product to another one. The initial product required fetal stem cells – a political gray area for many Americans. The implications this had for the potential to mass-produce the final product in the U.S. led SanBio to adopt a product using bone marrow.

Although, as we have previously mentioned, SanBio has steadfastly stuck to its original vision, at the very beginning, there were two separate avenues that SanBio wanted to explore – regenerative therapy and also drug screening technology. However, they realized that it was

much easier to brand themselves for venture capitalists with just one or the other, leading them to focus solely on regenerative therapy. However, other than the slight abridgment of their original business idea, this has been the only pivot that SanBio has experienced.

In the medical market, the best business strategy is quite simple; it is first come first serve. This is mainly due to patents for medicines. In addition, with regenerative medicines, unlike other medicines, a company has to get approval from authorities of not only medicines, but also their production process. This means that it is difficult for competitors to produce generic regenerative medicines unless the front-runner company discloses the know-how to produce them. Therefore, the first company with a patent is able to solidify its position as front-runner, and take leadership of the market. This was the case for SanBio.

What professional service providers do you use? (Attorney, accountant, etc.)

During the team building, recommendations from George Martin, former head of the National Institute of Health (NIH), proved to be critical. The founders also visited Mario Rosati, of the international law firm, Wilson Sonsini Goodrich and Rosati, who had lectured on startup financing at Berkeley, who provided major know-how and schemes for multiple investment contract negotiations. The law firm's strategy of getting performance pay (2% of shock warrants) ex post rather than hourly rates has been instrumental. He became legal advisor to SanBio.

Advice for Japanese Entrepreneurs?

Mori's advice is to establish yourself as a Silicon-Valley company and work on standing out. A lot of Japanese companies that come to Silicon Valley are staffed with Japanese employees and rely heavily on Japanese networks in the Bay Area – as a result, the Japanese business community in Silicon Valley can be very insular, and companies can miss out on making other valuable connections in the bay area. SanBio has operated as a completely U.S. company from the get go – finding people best suited for its company locally, and building networks through local connections and a lot of cold calls. SanBio's team and network is completely ingrained in Silicon Valley – workers, managers, and advisors are all experts based in Silicon Valley. For example, advisors of SanBio include former president of Stanford University, and the former scientific director of National Institute on Aging. SanBio's identity as a Silicon-Valley company has been one of its core strengths.



About the SV-NJ Case Studies Series: Japanese Silicon Valley Firms (Start-Ups)

The Stanford Silicon Valley – New Japan Project case study series investigates Japanese firms in Silicon Valley. The purpose is to understand each firm’s business purpose, its journey from Japan to Silicon Valley, human capital issues, business challenges and best practices, funding, and resources utilized. Information was compiled by interviewing leaders of start-ups based in Silicon Valley with one or more Japanese nationals as founders. The subject companies range from bootstrapped to fully funded companies with or without a presence in Japan, but all of which contain a technology element such that they are scalable enterprises. For more information or to refer a case study interviewee, please email: stanford.svnj@stanford.edu