POC Clinical Research Inc.

Providing comprehensive clinical research and development services to bioscience and biotechnology innovators

www.poccr.com

POC Clinical Research Inc.
Carrot Tower 6F
4-1-1 Taishidou
Setagaya-ku, Tokyo 154-0004
JAPAN

Founded in	2005
No. of employees	13
State of Ownership	private
Primary stock exchange	N/A

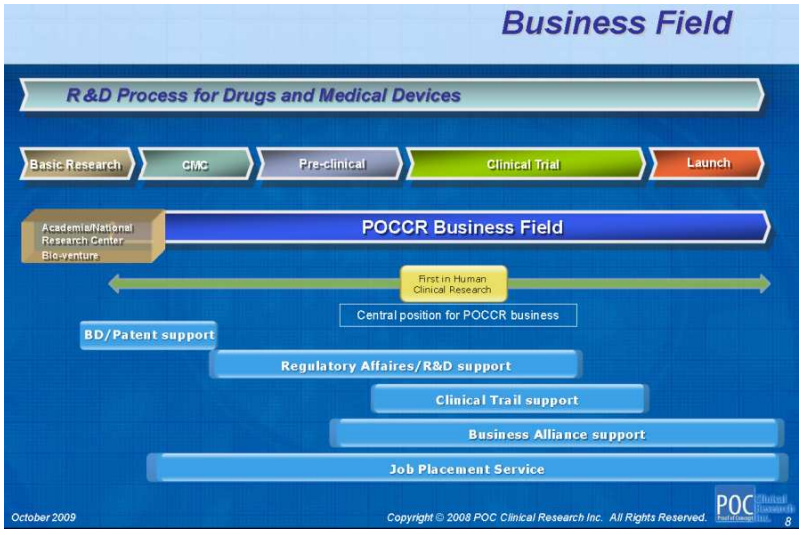
December 2009: As the company name "POC" (Proof Of Concept) demonstrates, POC Clinical Research offers services to accelerate clinical research and development, to establish proof of concept efficiently, and to commercialize technologies.
Venture Valuation (VV) interviewed Mr. Takeo Ozawa, President and CEO.

VV: **Would you please describe your business?**

Ozawa: We specialize in clinical research and development services, particularly, at the very early stage. Most of our customers are developing advanced medical technologies such as gene therapy medicines, nucleic acid medicines, tissue engineering medicines/devices, cell therapy, preventive/treatment vaccine and so on.

They are frequently young biotech ventures that lack experience and knowledge of strategic planning, patent filing, drug development planning, regulatory affairs, clinical trials, alliance management, manufacturing, and commercialization.

We support them from basic research through launching products. We also recruit and provide qualified professionals to our client companies by using our network of experts in the industry. Our selection criteria are not always based on experience in life science but motivation to contribute to the industry. (See Figure "Business Field")



VV: **What are your strenghts?**

Ozawa: We believe in face-to-face communication. In consequence, we have successfully built trust-based relationship with our clients. This allows us to offer thoroughly customized services that fulfill their goals and needs.

Furthermore, by leveraging our in-depth knowledge and know-how in the life science industry, we are able to help scientists in academic institutions and public research organizations formulate research and development project plans for highly advanced research fields such as DNA vaccine and next generation therapies. We also assist them in submitting grant proposals.

VV: **What are your objectives in the future?**

Ozawa: We intend to increase contract research and development projects on a large scale. Our strategic goal is to go public in four to five years. Depending on our company's development, merger or acquisition is also our option.

VV: **What opportunities are you exploring?**

Ozawa: We are planning to expand our business abroad in collaboration with our partners in the U.S., Europe, and Asia. In the immediate future, there are huge opportunities in the Asia-Pacific region.

Supposing the clinical equivalence between Asian and Japanese populations is scientifically proved, Asian countries will provide valuable data to support new drug applications in Japan. This means that Japanese patients will have access to new therapies at the same time as patients in North America and Europe.

Specifically, in case of orphan drugs and unmet medical needs for which the number of Japanese patients is very limited, the participation of patients from Asian countries to clinical studies will be a great advantage to speed up drug development.

In this context, we are beginning to work with ITRI(Industrial Technology Research Institute) and PITDC(Pharmaceutical Industry Technology Development Center) in Taiwan in order to conduct clinical studies in East Asia.

VV: **How do you differentiate from your competitors and position your company?**

Ozawa: Our competitors are Japanese CROs (Contract Research Organizations)[1]. Most of them provide mainly monitoring and data management services in the late phase clinical trials. We differentiate ourselves by focusing on planning, management and conducting clinical trials. We also play a representative role for our client companies.

[1] There are over 40 companies registered at the Japan CRO Association. The CRO market in Japan is estimated to JPY110 billion (approximately USD1.1 billion) in 2009.

One of our strengths is our negotiation skills with the Japanese health authorities, especially for novel drugs/medical devices development. Our company is selected to be on the ICH GTDG (International Conference on Harmonization Gene Therapy Discussion Group) as one of the delegate of JPMA (Japanese Pharmaceutical manufacturers Association).

VV Comments after the Interview:

The Japanese pharmaceutical industry has been characterized in various ways: "Gray Maze"[2] for the bureaucratic drug regulatory system; "hollowization" for the phenomenon that Japanese pharmaceutical companies develop their drugs outside Japan because of the lengthy time required for approval in the country and lack of GCP (Good Clinical Pracitice) certified infrastructures[3]; and "drug lag" for average 3.5 years[4] longer time to launch a medicine in Japan than in the U.S. and Europe.

In September 2007, the PMDA (Pharmaceuticals and Medical Devices Agency) released a new guideline on trial data entitled "Basic Concept for International Joint Clinical Trials". The guideline broadened the criteria for accepting clinical data from non-Japanese patients. It encourages Japanese companies to join multinational clinical trials as well as global companies to conduct clinical studies in Japan. The regulatory changes open the door to make new therapies available to Japanese patients at the same time as patients in North America and Europe.

Taking advantage of the current circumstances, POC Clinical Research is energetically participating in improving the drug development environment in Japan. Focusing on the specific segment, that is, offering support to early-stage technologies, the company is well positioned in the industry.

Contact

Mariko Hirano, m.hirano (at) venturevaluation.com

Venture Valuation specializes in independent assessment and valuation of technology-driven companies in growth industries, such as the Life Sciences (Biotech, Pharma, Medtech), ICT, high-tech, Nanotech, Cleantech and Renewable energy. In addition to valuation products, Venture Valuation offers high-quality, focused information services like the Global Life Sciences Database, Biotechgate.com and this "*Let's Interview Series*" with leading Life Sciences companies. We select and interview thriving companies and organizations all over the world.

[2] Published by Mark Colby and Michael Birt in 1997

[3] Editorial in Yakuji Nippo, 27 November 2009

[4] Developing Japan intent on clinical trials catch-up by Kirsty Barnes, 04-Apr-2007