



Linical Co., Ltd.

Fast growing niche CRO (Contract Research Organization)

www.linical.co.jp

Linical Co., Ltd. 1-6-1 Miyahara Yodogawa-ku Osaka, 532-003 JAPAN	Founded in No. of employees State of Ownership Primary stock exchange	2005 132 Public TYO 2183
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January 2010: Linical has a competitive advantage owing to its client base including the top 10 Japanese pharmaceutical companies and its focus on clinical services in phase II to III. Its sales have rapidly grown 17-fold from 119 million JPY (approx. 1.3 million USD) in 2006 to 2,034 million JPY (approx. 22 million USD) in 2009. For the fiscal year ending March 31, 2010, Linical anticipates a 50.6% sales increase over the previous year. The company has been listed on the Tokyo Stock Exchange since 2008.



Venture Valuation (VV) interviewed Mr. Akihiro Takahashi, Senior Managing Director and CFO.

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

Takahashi: Linical was founded in 2005 by nine drug development experts, former employees of Fujisawa Pharmaceutical (now part of Astellas Pharma). We provide Japanese pharmaceutical companies with clinical development services specifically in phase II to III. We concentrate on clinical, medical and safety monitoring, quality control, and consulting services. Our current key client companies are Eisai, Otsuka, Takeda, Daiichi Sankyo, and a few others.

VV: **What are your strengths?**

Takahashi: Our strengths are our business focus and our employees. As a strategic outsourcing partner of major Japanese pharmaceutical companies, we are able to offer robust performance of phase II to III contract research services. We are also prepared to develop global simultaneous clinical studies in the U.S. and Europe.

Employee turnover is a tremendous expense for CROs. We invest in programs that create high employee retention. As a result, our sales per employee ratio is 1.5 to 4 times higher than other CROs and our profit per employee is 2 to 6 times higher.

VV: **What are your current objectives?**

Takahashi: We are developing our CSO (Contract Sales Organization) business in order to strengthen our CRO activities. CSO business consists of various product marketing services, such as planning sales strategies, training representatives, building relationships with medical doctors and academics, analyzing market intelligence, organizing conferences, supporting sales & marketing offices, etc. Product marketing is vital prior to launching new products in the market.



VV: What opportunities are you exploring in the market?

Takahashi: The more the worldwide pharmaceutical industry grows, the more research and development outsourcing services are used. CROs are expanding geographical territories. As a front-runner in promoting our business outside Japan, we established in 2008 Linical USA Ltd., a U.S. subsidiary in San Francisco. With an American partner, we are supporting our clients to conduct clinical studies in the U.S.

Based on the international guidelines for harmonizing the production and use of clinical data involving diverse ethnic and racial groups (ICH E5¹), we can use and apply clinical data approved by the U.S. authorities in order to accelerate the new drug approval process in Japan.

In Europe we are opening a subsidiary in Germany or UK in the near future. Our growth strategy is to extend operations in three crucial territories of the pharmaceutical market: Japan, USA and Europe.

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

Takahashi: So far there is no competitor with the same business model as ours. Generally speaking, the leading global CROs are full-service providers acting as one-stop shops for all services from preclinical through marketing. Linical is a niche CRO providing cost-effective and high-quality services in phase II and III.

Besides, when Japanese companies conduct clinical trials, for instance, in the U.S., they normally prefer to work with us rather than local CROs due to cultural difference and language barrier. We are better able to understand how to implement their requirements in clinical development.

VV Comments after the Interview:

While leading global CROs are actively expanding in Asian market, Linical is steadily building up operations in the U.S. and Europe. By leveraging its own network of clinical experts in the American and European markets, and adding oncology to its therapeutic areas, Linical intends to become a global player by supporting Japanese pharmaceutical companies.

According to Business Insights Report² and Drug Delivery Technology Magazine³, the global CRO industry was valued at \$18 billion in 2008. The growth is driven by cost containment pressures in the pharmaceutical industry that have encouraged research and development outsourcing. There are over 1,100 CROs globally and top 10 companies accounted for 56.1% of the market. The market is expected to reach \$24 billion by 2010. Increasing pressures to reduce costs and to time-to-market will continue to lead to a rapid expansion of the CRO market. The annual growth rate is estimated at 14% to 16%.

¹ International Conference on Harmonization (ICH) - Guidance for Industry: E5 - Ethnic Factors in the Acceptability of Foreign Clinical Data

² The Top 10 CRO Companies, March 2009

³ Specialty Pharma, April 2008, Vol.8 No.4

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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.