

Japan Tissue Engineering Co., Ltd. (J-TEC)

Leader in Regenerative Medicine

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Japan Tissue Engineering Co., Ltd.
6-209-1 Miyakitadori, Gamagori City, JAPAN
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JAPAN

Founded in: 1999
No. of employees: 85
State of Ownership: Public
Primary stock exchange: JASDAQ

March 2009: Japan Tissue Engineering Co., Ltd. (J-TEC) was founded in February 1999 in Gamagori City, Aichi Prefecture, around 250 km south west of Tokyo, Japan. J-TEC is a pioneer company commercializing autologous cultured epidermis "JACE", and developing two products: autologous cultured cartilage and autologous cultured corneal epithelium. The Company was listed on the NEO market under the JASDAQ (code 7774) in December 2007. Venture Valuation (VV) interviewed Mr. Yosuke Ozawa, President and CEO (see below).



VV: Would you please describe your business and its strengths?

Ozawa: J-TEC develops, manufactures, and sells high-quality products in regenerative medicine. We currently have three products in the pipeline. (see chart below)



J-TEC's Pipelines			
	Autologous Cultured Epidermis	Autologous Cultured Cartilage	Autologous Cultured Corneal Epithelium
Product outlook			
Alliance	Prof. Minoru Ueda, Nagoya Univ., JP Prof. Howard Green, Harvard Univ., USA	Prof. Mitsuo Ochi, Hiroshima Univ., JP	Veneto Eye Bank, IT Prof. Michele De Luca & Prof. Graziella Pellegrini, Modena Univ., IT
Business territory	Japan	World	Asia
Indication	Severe burn: DDB + DB >= 30%	-Traumatic cartilage deficiency -Osteochondrosis dissecans -Osteoarthritis	-Chemical burn -Stevens-Johnson syndrome -Relapsed pterygium -Pemphigus, others
Reg. status	(Manufacturing & Sales) Approved Oct. 2007 (Health Insurance) Listed Jan. 2009	Completed clinical trial	Submitted an application for starting clinical trial

The autologous cultured epidermis product "JACE" (shown on the left in the above chart) was listed on January 1st, 2009 as an item covered by the National Health Insurance in Japan. This is a historically significant major milestone in the development of the Japanese regenerative medicine industry because it represents official recognition by the Ministry of Health, Labor, and Welfare (MHLW). We are proud of being the first company to commercialize the regenerative medicine.

As for the second product (shown in the middle of the chart), the autologous cultured cartilage, we are in the process of submitting an application for approval at MHLW. Our target is to have it approved no longer than two years after submission. This product was developed in collaboration with the Hiroshima University in Japan. With the dramatic aging of the world's population, the market for this product is expected to be huge. We plan to look for partners worldwide.

The third product (shown on the right in the chart), the autologous cultured corneal epithelium was licensed from the Veneto Eye Bank Foundation in Italy. The application has been submitted to MHLW for starting clinical trials.

With regard to our strengths, I would be happy to mention that:

- (1) We actively license-in prominent technologies in regenerative medicine all over the world and make new business models.
- (2) We have world-class GMP manufacturing facilities and well-trained skilled staff members (currently 85 employees).
- (3) From its inception, J-TEC has been supported by three well-established companies: Nidek Co., Ltd., Toyama Chemical Co., Ltd. (now Fuji Film), and INAX Corp. We have access to their business networks and take advantage of their expertise such as sales & marketing, manufacturing, etc.

VV: What are your objectives in the future?

Ozawa: First of all, we are going to successfully market and sell the autologous cultured epidermis product "JACE" (8cm x 10cm sheet) in Japan and establish a solid business case. By being listed as an item covered by the National Health Insurance, around 70% of the price will be reimbursed by the government. However, the insurance coverage is limited to 20 sheets per patient. (Realistically a patient with severe burns needs 40 sheets or more.) The Japanese market size would be around 1 to 3 billion yen (approximately 10 to 30 million US\$). The product is not only useful for patients with severe burns but also for several other conditions such as scars, vitiligo, ulcers, and so on.

The autologous cultured cartilage will be marketed and commercialized worldwide. And the autologous cultured corneal epithelium will be marketed only in Asia due to the agreement with the Veneto Eye Bank Foundation. Just in Japan, the market size would be 10 to 30 billion yen (approximately 100 to 300 million US\$).

VV: In what geographical areas would you like to develop your business?

Ozawa: It depends on the products. The market for JACE is limited to Japan by the agreement with the licensor, Harvard University. We are interested in having discussions with big pharma and biotech companies to market the autologous cultured cartilage globally as well as the autologous cultured corneal epithelium in Asia. We are also willing to talk with investors.

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

Ozawa: There are a few competitors in Europe, specifically in Germany and Belgium. From those companies, we differentiate with high quality. American companies are more oriented in the genetic treatment approach so that we do not view them as our competitors.

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