

**Interview with Setsuko Hashimoto, President and CEO, CellSeed Inc.**

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**For readers who may not yet be familiar with CellSeed, could you introduce the company and its core activities?**

CellSeed is a spinout company originating from academia, built around a proprietary technology called cell sheet engineering developed by Professor Teruo Okano at Tokyo Women's Medical University. The company was established in May 2001 to commercialize this innovation and is celebrating its 25th anniversary this year. The technology uses temperature-responsive cell cultureware to harvest cells intact without harmful enzymes such as trypsin, recovering them in sheet form and making them highly suitable for regenerative medicine applications.

Today, the business operates across three main areas. The first is cell sheet regenerative medicine therapies, particularly in knee osteoarthritis treatment through allogeneic chondrocyte sheets. The company is currently advancing a Phase III clinical trial in Japan. The second area focuses on intelligent cell cultureware products, including UpCell®, RepCell®, HydroCell®. The third area is regenerative medicine contract services and CDMO-type support. Together, these activities position CellSeed as a specialized player in the growing regenerative medicine industry, combining scientific expertise with practical commercial applications.

**What have been the company's most important achievements over the past year?**

The most significant milestone has been the launch of the Phase III clinical trial for knee osteoarthritis treatment in Japan using the allogeneic chondrocyte cell sheet product CLS2901C. The first patient was enrolled in October 2025, marking a major step toward commercialization of the therapy. The study is progressing across multiple clinical sites in Japan and represents one of the company's most important development programs to date.

Beyond clinical development, the company has continued to expand its international business activities. A large portion of sales in the cell cultureware division already comes from outside Japan, and efforts are now focused on strengthening global sales network. Participation in the ISSCR 2026 Annual Meeting in Montréal in July 2026 is part of this strategy and reflects the company's intention to increase visibility among international researchers and biotechnology partners.

The company also continues to attract attention for its ability to bridge advanced science with commercial execution. Operating successfully for more than two decades in a highly specialized and evolving sector has provided valuable experience in navigating technical, regulatory, and market challenges within regenerative medicine.

**What are CellSeed's international ambitions, and what kind of partnerships are you seeking globally?**

The United States remains the primary target market because it is the largest healthcare and biotechnology market globally. At the same time, the company is actively exploring opportunities across Europe and Asia, where regulatory systems of cell and gene therapies are often similar to that of Japan.

The company is open to multiple forms of collaboration, whether through strategic partnerships, joint development initiatives, or market-entry alliances. Discussions with pharmaceutical companies, biotechnology firms, hospitals, and research institutions are all considered important avenues for future growth. The approach remains flexible, including the possibility of pursuing opportunities independently or through partners depending on the market and regulatory environment.

One of the company's strengths is its openness and experiences to international cooperation. Foreign companies seeking access to the Japanese market often face cultural and language barriers, but CellSeed aims to position itself as a reliable bridge between Japan and overseas partners. The company believes mutual benefit and transparent communication are essential to building long-term collaborations in this sector.

**How is CellSeed incorporating artificial intelligence into its operations and research activities?**

Artificial intelligence is becoming an increasingly important part of daily operations and research activities. Internally, AI systems have already been introduced across the company's computer infrastructure, and employees are encouraged to use them actively. Training sessions and seminars are conducted to help staff integrate AI into their workflows and improve efficiency.

Within research activities, AI is primarily being used for data analysis. Regenerative medicine generates large amounts of complex scientific data, and AI tools can help accelerate interpretation and improve decision-making processes. Although these initiatives are still in the early stages, the company has set it as one of the targets of VISION 2030.

The broader objective is to combine scientific innovation with digital tools that can enhance both productivity and research outcomes. As regenerative medicine evolves, the integration of AI is expected to play a larger role not only in operational efficiency but also in therapy development, quality control, and clinical evaluation. The company sees this as a long-term strategic direction rather than a short-term trend.

**How do you evaluate Japan's current position in biotechnology and regenerative medicine internationally?**

Japan possesses a remarkable amount of untapped technological potential, particularly in advanced scientific fields such as regenerative medicine. However, many Japanese companies remain hesitant to expand internationally. Historically, businesses were comfortable focusing on

the domestic market of more than 120 million people, but global opportunities are significantly larger.

There are several barriers that continue to limit international expansion. Language differences, cultural gaps, and financial constraints can make overseas growth challenging, especially for smaller technology-driven companies. In regenerative medicine specifically, many Japanese firms possess highly promising technologies but lack the confidence or infrastructure to enter foreign markets aggressively.

At the same time, the environment is gradually changing. The Japanese government increasingly recognizes the importance of commercializing scientific research and encouraging startups emerging from universities. More support is being directed toward transforming academic discoveries into businesses that can create social and economic impact.

The belief is that Japan still holds many technologies and ideas that remain relatively unknown internationally. Greater communication, openness, and collaboration with overseas partners will be essential to unlocking that potential and positioning Japanese innovation more strongly on the global stage.

**What would you define as CellSeed's core value proposition for international collaborators and investors?**

The company's strongest asset is its proprietary technological expertise combined with more than 25 years of practical experience operating in a highly complex and emerging field. Regenerative medicine often requires companies to build entirely new markets while navigating evolving regulations and scientific uncertainty. Surviving and growing under those conditions has created significant operational know-how.

Another important strength is the diversity of expertise within the organization. The company combines scientific, technical, and business capabilities across multiple functions, allowing it to approach challenges from different perspectives. This multidisciplinary structure has helped build resilience and adaptability over time.

The company also places strong emphasis on market orientation. While scientific innovation remains central, the ultimate focus is always the patient and the practical application of the technology. That balance between research excellence and commercial relevance is viewed as essential for long-term success.

Internally, there is also a strong focus on bridging science to business. Employees, many of whom come from research backgrounds, are encouraged to develop a broader understanding of commercial realities. The philosophy is that individuals should have "dual receptors" — the ability to understand both scientific and business signals and connect the two effectively.