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Enhancing Cell and Gene Therapy scalability in Asia using 3D manufacturing platforms with microcarrier technology

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Dr. Liu Wei Co-founder & CEO, CytoNiche, Shanghai, China "3D cell manufacturing technology products are creating higher value for the Japanese market, in the fields of stem cells, extracellular vesicles, and regenerative medicine"



Dr. Liu Wei Co-founder & CEO, CytoNiche, Shanghai, China

China-based CytoNiche Biotechnology, a pioneer in 3D dissolvable porous microcarriers, has opened the Center of Excellence (CoE) in Shanghai Fengxian District Lingang Nanqiao Science and Technology Park with state-of-the-art research and development facilities. The CoE will provide strong support for expanding overseas markets and accelerating integration into new formats in the global biopharmaceutical industry. Being able to combine CDMO services with international technology innovation partnerships makes CytoNiche a holistic provider that drives development and enhances business value. As part of this strategic partnership, CytoNiche will establish a joint laboratory in Singapore, facilitating ongoing research collaborations and expanding Cytoniche's presence in South East Asia. **Dr. Liu Wei Co-founder & CEO, CytoNiche** shares further insights on this revolutionary development in APAC.

- **What are CytoNiche's strategic initiatives and core technology transformations to align with Asia-Pacific Cell and Gene Therapy (CGT) markets?**

The Shanghai Fengxian District Lingang Nanqiao Science and Technology Park is home to CytoNiche Biotechnology, a biotechnology company dedicated to developing 3D dissolvable porous microcarriers. In early May 2023, we officially opened our new Center of Excellence (CoE) - a state-of-the-art research and development facility. Cytoniche provides a total solution for large-scale customized amplification of cells using 3D microcarriers based on an original 3D cell "intelligent manufacturing" platform.

This CoE shall advance a 3D ‘intelligent manufacturing’ platform for the development of up-to-downstream bioprocesses in the cell and gene therapies. Following the grand opening, we unraveled our Beijing R&D Center and Tianjin cGMP Production Center. CoE shall synergise and strengthen world-class cooperations and innovations along with these new centers. Entrepreneurs & leaders in China witnessed the inauguration of the CoE's new site, along with international partners including Ants Innovate (Singapore) and SEIKO Corporation (Japan).

CytoNiche expanded its Tianjin cGMP production capability (a 4,000 square meters’ facility footprint) with a new 1,200L microcarrier production pipeline. This agile manufacturing approach allowed us to meet the growing demands of domestic cell and gene therapy companies through 3D TableTrix® microcarrier production.

Another initiative made in 2022 was the establishment of our CDMO platform. CytoNiche is differentiated from other CDMO players, as we leverage on our own innovation-led microcarriers-based cell culturing platform to enable technical research, accelerate process development, and cGMP production services for various cell types (such as human mesenchymal stem cells (hMSCs) derived from different tissue sources). Our integrated scientific services are extended from the early PD (process development) to commercial cGMP supply for international partners.

- **How is innovation and development striding at CytoNiche with prolific technological competitiveness in the CGT arena?**

In terms of product development, we enhance our technological competitiveness and expand into multiple application areas to forge international customer relationships. We also introduced the 3D FloTrix® microSPIN 6-channel microreactor, a scale-down PD tool for our proprietary 3D TableTrix® microcarriers in a dynamic culturing condition (gentle stirring) as compared to the norm of static 6-wells plate culture. microSPIN provides research users with more confidence in the first experimental design of process development as customers adopt our technology! We hope to move beyond the traditional service outsourcing model into a true end-to-end collaboration taking on more vested interest to handhold all our customers from the start of their PD work, minimising experimental failure rates that are the pitfalls of any microcarriers-based technology.

In terms of scientific research and innovation, CytoNiche has never ceased its efforts. Our "3D FloTrix®: Automated Large Scale Manufacturing of Stem Cells with Pharmaceutical Grade Microcarrier Tablets (3D TableTrix®)", is a pioneering model in the industry. We have also just established a post-doctoral research station to recruit high caliber talents who are interested in the intersection of industrial bioprocesses and biomaterials innovations.

- **How are the expansion strategies and investor relationships forging for FY 2023 and onwards?**

The proprietary microcarrier technology and its scalability in 3D manufacturing platform is our unique creation. SEIKO Corporation will partner with CytoNiche to explore business cooperation opportunities across a broad range of application areas, including product development and cross-listing in the Japanese market.

In terms of fund-raising activity, CytoNiche successfully completed a Series B1 round financing of nearly¥300 million (nearly $42 million), which will be used to expand our core product capabilities geared for global expansion.

The global biopharmaceutical industry is entering a new stage of rapid growth in supply chain optimization and Shanghai, as a global hub for finance, technology, and trade, has received widespread international attention. CytoNiche "Centre of Excellence" commencement in Shanghai is a crucial move providing strong support and accelerating international expansion through global alliances. The Shanghai CoE demonstrates a suite of equipment utilizing our core technology products such as 3D TableTrix® microcarriers, the 3D FloTrix® series of automated bioreactors, and cell processing and filling systems. In

combination with the 3D FloTrix® mass manufacturing cell culture process, we are aiming to meet the global demand for cell production in clinical application and commercialisation of stem cell products.

- **How is CytoNiche building a unique niche in China’s competitive cell & Gene therapies (CGT) landscape?**

According to market analysis and statistics, there were a total of 36 cell therapies in the field of regenerative medicine in China that made progress in clinical applications and undergoing clinical trials. This includes 21 immunotherapy treatments and 15 stem cell therapies, with 24 Investigational New Drug (IND) applications being accepted. Cell therapy is gradually transitioning from clinical research to industrialization. During this industrialization process, challenges such as scaling up cell production, reducing the cost of goods, and ensuring batch consistency will inevitably arise. This presents a significant opportunity for CytoNiche’s core technology.

With the unique feature of being fully dissolvable, CytoNiche’s microcarriers are poised to resolve the issue of difficulty in harvesting delicate cells from microcarriers after expansion. By providing pharmaceutical grade microcarriers, we ensure that products comply with relevant manufacturing regulations and requirements, so as to facilitate the use of our products for production of cellular drugs. We can meet the increasing demand for cell quantities required by downstream cell and gene therapy (CGT) companies and address practical industry issues by continuously improving the quality of our products and services. We comprehensively optimize our marketing and management systems, aiming for precise, efficient, and intelligent automated operations. After achieving mass production of cells, our next goal is to realise seamless end-to-end automation, intelligence, and even unmanned production processes. In the future, we hope to combine advanced technologies such as AI, big data, and industrial automation with industry partners to drive the cell industry into the era of Industry 4.0.

- **How is CytoNiche leveraging cross border and interdisciplinary collaborations in Asia?**

In 2023, CytoNiche has already established strategic partnerships with companies in Japan and Singapore. CytoNiche and Ants Innovate (Singapore) had announced a cross-disciplinary collaboration to establish a joint laboratory for cellular meat production. By combining core technologies with our collaborator, we are achieving new breakthroughs in research related to cell-cultured meat and expedite the commercialisation process. CytoNiche and Japan's SEIKO Group will jointly promote CytoNiche's 3D cell manufacturing technology products in the Japanese market, creating higher value for Japanese customers in the fields of stem cells, extracellular vesicles, and regenerative medicine.

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