July 16, 2025

Company Name:	HEALIOS K.K.
Representative:	Hardy TS Kagimoto, Chairman & CEO (TSE Growth Code: 4593)
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Notice of Selection for FY2024 Supplementary Budget: "Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities" by METI
- CDMO Business Expansion Supported by a Subsidy of JPY 7 Billion–

HEALIOS K.K. ("Healios") is pleased to announce that our application for the development and manufacturing support services for regenerative medicine products (hereinafter, the "CDMO Business") has been selected under the "Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities"* (FY2024 Supplementary Budget) by the Ministry of Economy, Trade and Industry (METI) of Japan (hereinafter, the "Subsidy Program").

This Subsidy Program is positioned as a key initiative within the government's strategy to promote next-generation manufacturing infrastructure. With this selection, Healios will receive a subsidy of JPY 7 billion and will commence the full-scale expansion of our CDMO Business.

1. Strategic Significance of the Selected Project
Over more than a decade, Healios group has accumulated deep expertise and advanced manufacturing technologies related to cell therapy through research and development involving iPS cells and somatic stem cells. With the selection under this Subsidy Program, Healios will rapidly establish a competitive advantage and accelerate the development and commercialization of infrastructure for a globally competitive CDMO Business across the following strategic areas:

・Integration of world-class large-scale 3D cell culture technology and AI-driven process development
・Optimization of quality and cost through automation and closed-system platforms
・Establishment of an end-to-end support system from early-stage development to commercial manufacturing
・Development of an international, export-ready CDMO platform focused on regenerative medicine products

We believe that our know-how has been highly evaluated, including the capability to supply products for critical indications such as ARDS, acute ischemic stroke and war-related trauma which may become the world's first commercially manufactured product using 3D cell culture technology. Through our CDMO Business, we aim to broadly provide this expertise to a wide range of clients and contribute to the advancement of the regenerative and cell therapy industry. Looking ahead to global expansion, we are also considering the establishment of a production facility in the United States, with the potential to supply product to U.S. government agencies.

These initiatives represent a significant step toward promoting the global deployment of regenerative medicine under the strong foundation of the U.S.-Japan relationship.

Our strategy is fully aligned with the Japanese government's industrial policy promoting the commercialization and export of regenerative medicine. As a leader in both the policy and business realms of this growth sector, Healios will strengthen the following medium and long-term growth pillars:

・Establishment of a recurring, high-margin business model through contract manufacturing
・Expansion of new partnerships with domestic and international biotech ventures and pharmaceutical companies
・Enhancement of revenue streams that directly contribute to shareholder value

2. Future Outlook
As a result of the implementation of this project, we expect to incur related expenses and record corresponding subsidy income in the future. The capital investments and process development covered by this subsidy are scheduled to commence during the fiscal year ending December 2025; however, specific details remain subject to ongoing discussions with METI. The details are currently under review, and we will promptly disclose any material impact on our financial results for the fiscal year ending December 2025 as soon as it becomes clear.

***Summary of the Subsidy Program (From METI's Application Guidelines)**
This program supports capital investment in CDMO facilities for regenerative, cell, and gene therapy products, including the installation of advanced automation systems and quality control infrastructure required for next-generation manufacturing. It also provides assistance in developing skilled personnel in the manufacturing domain, an area currently lacking in Japan. Through these initiatives, the program aims to enable the stable and efficient development of drug manufacturing processes, strengthen Japan's drug discovery capabilities, and promote the export of CDMO services for regenerative, cell, and gene therapy products as a globally competitive industry.

Subsidy Rate: Two-thirds (for Small and Medium-sized Enterprises)
Subsidy Amount (Minimum Threshold): 1 billion yen or more

For details of the adoption results, please refer to the link below. (Japanese only)
https://www.meti.go.jp/press/2025/07/20250715002/20250715002.html

About Healios:
HEALIOS K.K. is Japan's leading clinical stage biotechnology company harnessing the potential of stem cells for regenerative medicine. It aims to offer new therapies for patients suffering from diseases without effective treatment options. Healios is a pioneer in the development of regenerative medicines in Japan and owns proprietary, global platforms utilizing both somatic stem cells and iPS cells.

In the somatic stem cell field, Healios is developing invimestrocel (HLCM051), a proprietary cell product comprised of multipotent adult progenitor cells ("MAPCs") derived from the bone marrow of healthy adult donors. Invimestrocel has been shown to exhibit powerful anti-inflammatory and immunomodulatory properties with applicability in a range of disease states, has been tested in hundreds of patients in late stage clinical trials, is manufactured consistently

at scale in 3D bioreactors, and has demonstrated both safety and suggested efficacy in hundreds of patients across multiple indications. Healios is seeking to advance invimestrocel on a global basis for ischemic stroke, ARDS, and trauma.

In the iPSC regenerative medicine field, Healios is developing HLCN061, a next generation NK cell treatment for solid tumors that has been functionally enhanced through gene-editing. These cells have demonstrated robust anti-tumor efficacy in animal models, benefit from a scalable 3D bioreactor manufacturing process, and are currently being prepared for initial human testing in collaboration with Akatsuki Therapeutics. The company has also established a proprietary, gene-edited "universal donor" induced pluripotent stem cell line to develop next generation regenerative treatments in immuno-oncology, ophthalmology, liver diseases, and other areas of severe unmet medical need.

Healios was established in 2011 and has been listed on the Tokyo Stock Exchange since 2015 (TSE Growth: 4593). https://www.healios.co.jp/en