January 17, 2025

Company Name: HEALIOS K.K.
Representative: Hardy TS Kagimoto, Chairman & CEO
(TSE Growth Code: 4593)

Launch of Medical Materials and Equipment Division

HEALIOS K.K. (“Healios”) has established a Medical Material and Equipment Division (the “Division”) to ensure a stable supply of medical supplies, mainly culture supernatants, and to expand the related business. The purpose of the establishment of the Division and its future activities are described below.

Organization: Medical Materials Division
Director: Masanori Sawada, Executive Vice President CMO

Overview of Organization
Healios today has entered into an Agreement (the "Agreement") with AND medical group (“AND medical” https://and-mg.com/) to supply culture supernatant to be used as a raw material for new treatments and cosmetics to be offered by AND medical in the future (announced on January 17, 2025: “Agreement with AND medical to Supply Culture Supernatant”).

The Division will play a central role in the future stable supply of culture supernatant products and the expansion of the business. The Division will take the lead in the following areas: 1) optimization of manufacturing, quality control, and inventory control of culture supernatant; 2) preparation of materials necessary for responding to customers and regulatory authorities; 3) market research, formulation of sales strategies, and collection of customer needs; 4) product planning and customer promotion activities; and 5) establishment of a post-sales maintenance system, etc.

Healios is preparing to submit an application for conditional and time-limited approval in Japan for the treatment of acute respiratory distress syndrome (ARDS*[1]), utilizing our proprietary cell therapy MultiStem®*[2] (See “Status of Conditional and Time-Limited Approval Application for ARDS in Japan (Clinical Part)” announced January 15, 2025). After the approval, as the production of regenerative medicine products utilizing our 3D manufacturing process increases, a large amount of culture supernatant will be generated. The Division will play a central role in planning and promoting business for the utilization of such raw material.

*1 Acute Respiratory Distress Syndrome (ARDS)
ARDS is a general term for respiratory failure that occurs suddenly in a variety of critically ill patients. Although there are many causes of ARDS, approximately one-third of ARDS cases are caused by pneumonia, and it has been confirmed that ARDS also occurs in critically ill patients with COVID-19. There is currently no approved drug therapy that can directly improve the prognosis of patients with ARDS, and respiratory failure is treated with mechanical ventilation. The mortality rate after the onset of ARDS is 30~58%[*a], and there is a need for new therapies that can improve the prognosis of patients with ARDS. Currently, the

number of patients in Japan is estimated to be approximately 28,000[*b] per year, and ARDS is designated as a rare disease. However, it is estimated that 262,000[*c] patients in the United States, 133,000[*d] in Europe, 670,000 in China, and more than 1.1 million people worldwide are affected annually[*e].
(Source)
*a ARDS Diagnostic Guidelines 2016
*b Healios Estimates Based on the Incidence Rate of Epidemiological Data and the Total Population of Japan by Demography
*c Diamond M et al. 2023 Feb 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–. PMID: Estimates for our company based on 28613773 Data and US Population Based on the Ministry of Foreign Affairs Basic Data
*d Community Research and Development Information Service (CORDIS) 2020 7-9.
*e song-et-al-2014-acute-respiratory-distress-syndrome-emergingresearch-in-china

*2 MultiStem®
MultiStem (HLCM051) is a somatic stem cell regenerative medicine product comprised of multipotent adult progenitor cells ("MAPCs") derived from the bone marrow of healthy adult donors. MultiStem 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. MultiStem is a proprietary technology wholly owned by Healios. Healios has a long history developing MultiStem. It originally added MultiStem to its pipeline in 2016 through an exclusive license to develop and distribute the product to treat ischemic stroke in Japan. Further, in 2018 Healios expanded its license to include development and distribution to treat ARDS in Japan, and in 2023 it expanded its ARDS license to include global territories. Having acquired the full technology platform in April 2024, Healios is seeking to advance MultiStem on a global basis for ischemic stroke, ARDS, and trauma. In the U.S., MultiStem for the treatment of ischemic stroke and ARDS has received Fast Track and RMAT designation from the FDA, which allows for expedited approval of drugs that meet certain criteria for serious or life-threatening diseases or those for which no treatment is available.

About AND medical group:
AND medical group is a general medical group operating clinics in 31 locations nationwide (as of December 31, 2024). AND medical was incorporated in 2020, and from 2023, has offered cosmetic dermatology, cosmetic surgery, plastic surgery, and urology services under the AND medical group brand, and has also begun working in the field of regenerative medicine using stem cells at its affiliated institutions that provide regenerative medicine and other services.

The company's vision is "To be beautiful is a human being's right". Based on this vision, AND medical group believes that there are various kinds of "beauty" depending on the different personalities, preferences, and values that each person possesses, and we aim to realize "a world where everyone can pursue their own beauty" regardless of gender, age, nationality, etc. We provide a variety of medical services to alleviate patients' dissatisfaction and complexes about their appearance.

In the future, AND medical group will advance joint research with Healios in the field of regenerative medicine. Together we will conduct scientific verification of safety and therapeutic efficacy at the level required by the government, aiming to establish stem cell-

based therapeutic approaches and to manufacture cosmetic as well as medical products utilizing cultures supernatants. By doing so, we aspire to explore the potential of stem cell therapies across various disease affected areas.

Name of the company: AND medical group
Location: Roppongi, Minato-ku, Tokyo
Representative: Masaomi Kusano, Representative of Board of Directors
https://and-mg.com/

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 MultiStem® (HLCM051), a proprietary cell product comprised of multipotent adult progenitor cells ("MAPCs") derived from the bone marrow of healthy adult donors. MultiStem 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 MultiStem on a global basis for ischemic stroke, ARDS, and trauma.

In the iPSC regenerative medicine field, Healios' lead candidate, HLCN061, is 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. 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

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