# FY2025 Q2 Financial Results

Company

HEALIOS K.K.

Date

August 13, 2025

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# Business Overview

# FY2025 Target Milestones

- File for conditional and time-limited approval in Japan for HLCM051 (invimestrocel) for **ARDS**.
- Initiation of global Phase 3 trial for **ARDS**, mainly in the U.S.
- Application for conditional and time-limited approval in Japan for **Ischemic Stoke**.
- Full-scale shipment and sales of **culture supernatant**.

Update

Healios

## Results for FY2025 Q2 (April - June)

- Agreed with PMDA on inclusion of Japanese patients in global Phase 3 trial of ARDS (REVIVE-ARDS study).

- Selected for NEDO project and in accordance with that policy decided to apply for conditional and time-limited approval for Ischemic Stroke in Japan. (Conditional on conducting a post-marketing study using a registry linked to electronic health records using a Large Language Model (LLM).)

## Results for July 2025

- Selected for FY2024 supplementary budget: “Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities” by METI (global CDMO business expansion supported by a subsidy to Healios of about 7 Billion yen)

# Selected for “Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities” by METI (July 2025)

New Healios

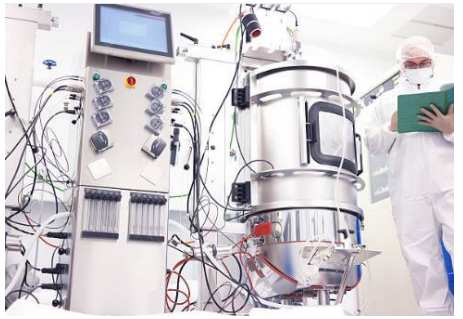
## FY2024 supplementary budget: “Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities” by METI

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

- 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

3D cell culture



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.

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



Note: The above image of 3D culture differ from the actual instruments and techniques used in our products.

# Selected for “Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities” by METI (July 2025)

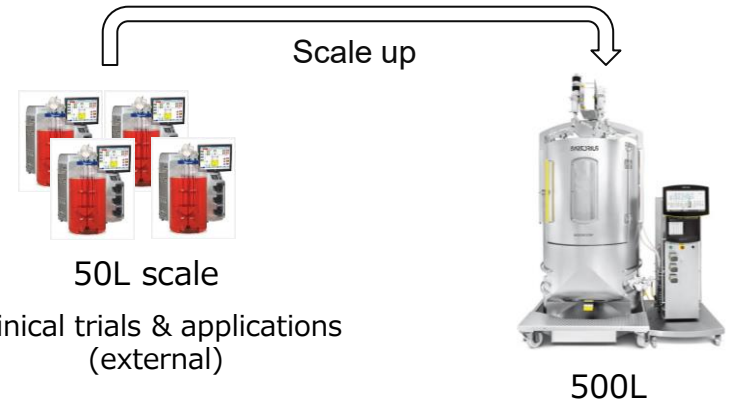
New Healios

## Importance and specificity of the project

- In order for regenerative medicine to have a real impact on society, it is essential that it can be mass-produced with allogeneic cells, and our product is expected to be the world's first approved regenerative medicine product manufactured in 3D cell culture.
- Achieved the world's largest scale of cell culture at 500L within Healios and have confirmed that quality is maintained.
- Utilizing the results of this project, we will establish the world's largest commercial-scale cell production in Japan.
- Supportive of Healios programs and a new source of cash flow through contracts from Japanese and overseas pharmaceutical companies.
- The business and capital alliance with Nikon Corporation, which was concluded in February 2017, is currently under discussions to dissolve in light of the focus on this business.

Link

## Solving the challenges of mass cultivation by reducing costs using AI and robots




**AI experimental design**
Discovering high-performance culture conditions with fewer experiments

×

**Robotics**
Obtain reproducible data with minimal variation in results.

High-precision data x highly efficient search
A virtuous cycle

**Will establish production capacity of 40,000 units / year**

Aiming to reduce the cost of expensive raw materials and ensure stable supply, we conduct cultivation condition and raw material evaluations with high efficiency.

## Three pillars to monetization

Accelerate development in the U.S. market as a growth driver while monetizing other assets

### Medical Materials

**HLCM051 Culture Supernatant**

Universal Donor Cell

iPS cell lines, etc.

SIFU®

**Culture Supernatant:**
FY2024: Promote joint research
Received milestone from AND medical group
Entered into initial supply contract
FY2025: Commencement of sales

**SIFU technology:**
In discussions with Japanese and U.S. potential partners

### Bone marrow-derived cells

**ARDS**

Global Phase 3 trial under preparation

Preparing to apply for Conditional and Time-limited Approval in Japan

**Ischemic Stroke**

Conditional Approval Application Policy in Japan

**Trauma**

Phase 2 trial with U.S. DoD budget

### iPS cells

**Replacement Therapies**
RPE
Joint development with RACTHERA Co., Ltd.*

**Immuno-Oncology**
Gene-engineered NK cells
Akatsuki Therapeutics Inc. leads research and development

**Business scale expansion by securing global rights**

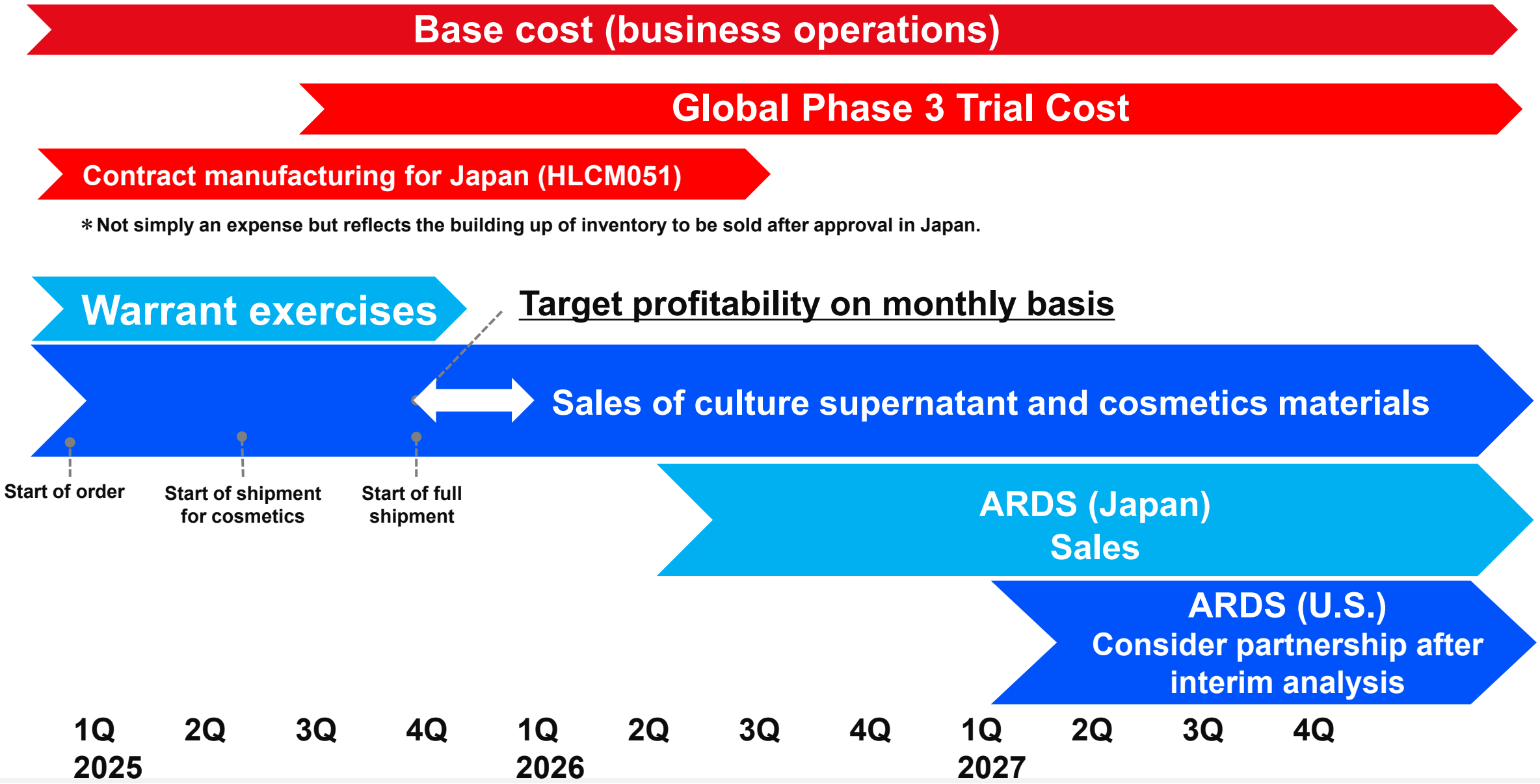
**Steady progress toward the start of Phase 3 trial for ARDS in the U.S., the world's largest market.**

**Proceed with a combination of partnering, carve-outs, and grants**



*Succeeded the regenerative medicine business from Sumitomo Pharma Co. Ltd..

# Cash Flow Plan (short-term: existing warrant exercises, mid-term: culture supernatant, long-term: ARDS)



# HLCM051 ARDS: Global Phase 3 Trial and Conditional and Time-limited Approval in Japan

## Dec. 25, 2024: Confirmed the post approval manufacturing method and quality control with PMDA

Link

- Confirmed the relevant manufacturing details required for the approval application package and the Master Cell Bank to be used post launch of the product.
- Proceed with various preparations, including those related to commercial manufacturing, which is required for approval.

## Jan. 15, 2025: Agreed on the clinical data package for the application with PMDA

Link

- Clinical endpoints in the global Phase 3 trial (REVIVE-ARDS study) for full approval in Japan.
- Percentage of Japanese included in the above study and clinical endpoints to be seen in post-marketing surveillance.

## Apr. 23, 2025: Completed formal regulatory consultation for ARDS and agreed with PMDA on inclusion of Japanese patients in global Phase 3 trial

Link

- Agreed with PMDA on necessary matters regarding the application for conditional and time-limited approval and post-marketing study
  Prepare for the application for conditional and time-limited approval
- Continue the preparations for REVIVE-ARDS study
  Enables inclusion of Japanese patients in global Phase 3 trial and accelerates the promotion of clinical trial.

# HLCM051 Ischemic Stroke: Policy for Conditional and Time-limited Approval in Japan

## Apr. 23, 2025: Decided the policy to apply for conditional and time-limited approval in Japan

- Conducted and completed a placebo-controlled, double-blind, phase 2/3 study (clinical trial name: TREASURE study) in Japan to evaluate the efficacy and safety of HLCM051 in acute stroke patients, and continued discussions with the regulatory authorities regarding future data acquisition and application policies

Link

- Aim to apply for conditional and time-limited approval, including agreement with PMDA on investigation items in the HLCM051 post-marketing surveillance. (SAKIGAKE designation)

## Background of Policy Decisions

- Conduct post-marketing surveillance using a registry linked to electronic health records using Large Language Model "LLM"（Capable of registering several hundred cases per year）
- NEDO (The New Energy and Industrial Technology Development Organization) has selected HEALIOS to participate in the publicly solicited project "Verification and Validation of Safety Toward Social Implementation of Japanese Medical-Specialized LLM" to construct the above LLM.
- With the participation of multiple medical institutions centered on Kyushu University that have stroke registry data, identify issues in database linkage between medical institutions for stroke patients, materialize the project concept, and verify whether the acquisition of patients' data by LLM functions appropriately.
- Running a validated registry of stroke patients and accumulating real-world data on HLCM051 non-treated patients in post-marketing surveillance of HLCM051.
- In this registry, it is considered possible to accumulate enough data on the number of cases to meet this approval within 7 years, which is the maximum period of post-marketing surveillance after conditional and time-limited approval, and there is a high possibility of showing statistical superiority in the target indicator.

# Pipeline

| | Development Code | Therapeutic Area | Therapy | Region | Discovery | Pre-Clinical | Clinical P1 | Clinical P2 | Clinical P3 | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| Inflammatory Conditions | HLCM051 | ARDS | invimestrocel | Japan | | Preparing for approval | | | | Agreed with PMDA on manufacturing/clinical package to apply for Conditional and Time-Limited Approval<br>Orphan designation |
| | | | | Global (USA) | | Preparing for Phase 3 | | | | Agreed with FDA on Global Phase 3 trial design in the U.S. Patients included from Japan<br>Fast Track and RMAT designation (USA)*1 |
| | HLCM051 | Ischemic Stroke | invimestrocel | Japan | | Phase 2/3 completed and consulting for approval | | | | Aim to apply for conditional and time-limited approval conditional on conducting post-marketing surveillance using LLM.<br>SAKIGAKE designation (Japan)<br>Fast Track and RMAT designation (USA) |
| | | | | Global (USA) | | Phase 3 | | | | |
| | HLCM051 | Trauma | invimestrocel | Global (USA) | | Phase 2 | | | | Funded by MTEC (United States Department of Defense) and the Memorial Hermann Foundation |

*1 Fast Track and RMAT designations relate to a system that allows for expedited approval of drugs (RMAT is for cellular processed products) that meet certain conditions for the development of new drugs for serious or life-threatening diseases or diseases for which no treatment is available.

| | Development Code | Therapeutic Area | Therapy | Region | Discovery | Pre-Clinical | Clinical P1 | Clinical P2 | Clinical P3 | Comments |
|---|---|---|---|---|---|---|---|---|---|---|
| Replacement Therapies | HLCR011 | RPE tear<br>AMD | RPE*2 | Japan | | Phase 1/2 | | | | Joint research with RACTHERA Co., Ltd.<br>Scheduled to be launched in FY2028<br>First subject enrollment initiated |

*2 Retinal Pigment Epithelium

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Immuno-Oncology | HLCN061 | Solid Tumors*3 | eNK | Global | | | | | | Akatsuki leads research and development |
| | – | Solid Tumors | CAR-eNK | Global | | | | | | |

*3 Mesothelioma, Lung cancer, Hepatocellular carcinoma and Gastric cancer,

**Note: Excludes pipeline assets scheduled to be carved out**

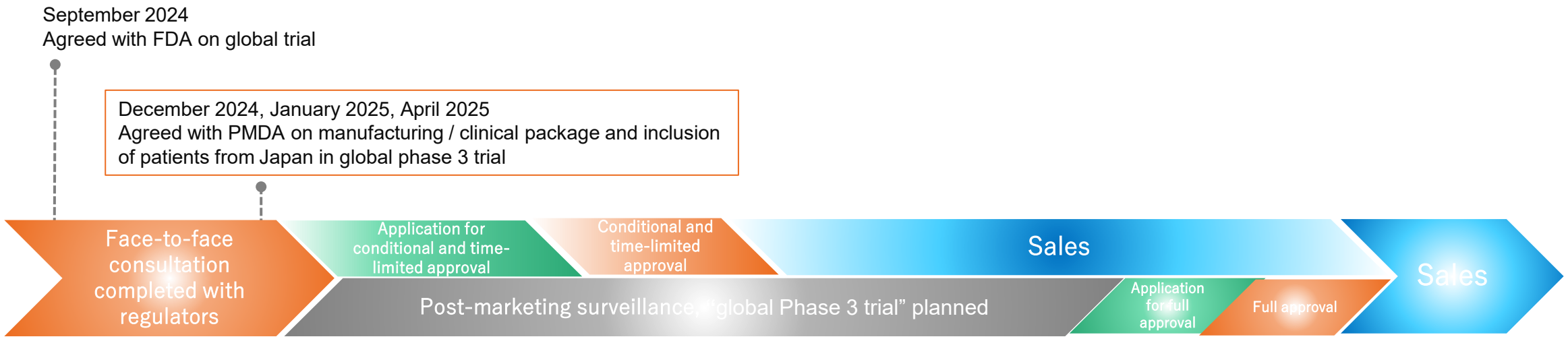
# HLCM051 ARDS: Development Status

Inflammatory Conditions

## Application for conditional and time-limited approval and Global Phase 3 clinical trial (REVIVE-ARDS Study) progressing steadily

**ARDS**

- **Preparing for global Phase 3 trial in the U.S. (agreed with the FDA)**
- **Decided to apply for conditional and time-limited approval in Japan based on the positive results of the Phase 2 study (ONE-BRIDGE study) and on the premise that the REVIVE-ARDS study will be conducted as a confirmatory study**
- **Agreed with PMDA on manufacturing/clinical package for application and inclusion of patients from Japan in global Phase 3 study**



# HLCM051 Ischemic Stroke: Development Status

**Inflammatory Conditions**

## Application for conditional and time-limited approval in Japan under preparation

**Ischemic stroke**

- **Develop a medical-specific LLM and establish a data collection system linked to electronic medical records**
- **Aim to apply for conditional and time-limited approval, including agreement with PMDA on investigation items in the HLCM051 post-marketing surveillance (SAKIGAKE designation)**

April, 2025
Decided LLM construction in the NEDO publicly solicited project “Verification and Validation of Safety Toward Social Implementation of Japanese Medical-Specialized LLM”

2025～
Post-marketing surveillance will be conducted using a registry linked to electronic medical records using LLM as a validation study

# HLCM051 Trauma: Development Status

## MATRICS-1 study（USA）

Inflammatory Conditions

**Trauma**

**Ongoing 156 patient, Phase 2 clinical trial in trauma**

**Funded almost entirely by MTEC (United States Department of Defense) and the Memorial Hermann Foundation**

**Conducted at University of Texas Health Science Center at Houston (UTH) and Memorial Hermann Texas Medical Center, the busiest level 1 trauma center in the U.S.**

- The trauma being treated in this study is that which results from car accidents, industrial accidents, gun shot wounds, etc.
- The leading cause of death for people under the age of 45, third leading cause of all deaths in the U.S. and the leading cause of quality-of-life years lost*
- The use of HLCM051 in the treatment of trauma also has meaningful potential US military applicability

* Source: the Centers for Disease Control (CDC)

### MATRICS-1 study

Overview: HLCM051 for Treatment of Trauma Induced Multiple Organ Failure/Systemic Inflammatory Response Syndrome (SIRS).
Single center, prospective, randomized, double-blind, pragmatic phase 2 clinical study.
Primary endpoint: Kidney injury stage (Day 30)
Secondary endpoint: Mortality etc.
Participant: Severely injured trauma patients within hours of hospitalization who have survived initial resuscitation

# Conference Presentations and Articles (FY2025)

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Link from underlined parts

| Conference／Article | Date／Venue | Title | Author／Department |
|---|---|---|---|
| Regenerative Therapy | Jan.29／Academic paper | Clinical efficacy of invimestrocel for acute respiratory distress syndrome caused by pneumonia: Comparison with historical data using propensity score analysis | Dr. Kazuya Ichikado MD, Saiseikai Kumamoto Hospital et al. |
| Cancer Immunology, Immunotherapy | Feb.4／Academic paper | Antitumor effects of natural killer cells derived from gene-engineered human-induced pluripotent stem cells on hepatocellular carcinoma | Mayuna Nakamura, Hiroshia University et al. |
| Stem Cell Research & Therapy | Jul.15／Academic paper | Human iPSC-derived NK cells armed with CCL19, CCR2B, high-affinity CD16, IL-15, and NKG2D complex enhance anti-solid tumor activity | Yuma Fukutani et al. Kobe Research Institute, Healios K.K. |

Update

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# Supply Culture Supernatant to AND medical

## Supply Agreement

- Healios will receive an initial order of 420 million yen for the subject product. From that amount, we will receive 200 million yen as an advance payment after Q3 FY2025.
- The timing of future orders and the volume and timing of product shipments will be determined in consultation with AND medical.

## Joint Research Agreement

- Healios expects to receive 60 million yen after Q3 FY2025 as compensation for achieving the final milestone in the joint research underway since 2024. (Upfront payment of 60 million yen at the time of contract signing and milestone payment of 60 million yen in Q4 2024 were already received.)

Link

## MTA with Saishunkan Pharmaceutical Co.,Ltd.

- In August 2025, Material Transfer Agreement is concluded, and samples will be shipped to examine the possibility of using them for the company's products.

# Financial Highlights

# Consolidated Statement of Income

Update

Healios

(Units: millions of yen)

| | FY2024 Q2(YTD) | FY2025 Q2(YTD) | | |
|---|---|---|---|---|
| | | | YoY variance | Main reasons for increase/decrease |
| Revenue | 508 | 60 | -448 | |
| Operating profit | -1,331 | -1,573 | -243 | Decrease in SG&A expenses ＋164<br>Decrease in R&D expenses +53 |
| Profit | -2,951 | -4,708 | -1,758 | Increase in finance income +37<br>Increase in finance costs -1,530<br>(Primarily non-cash activity; please refer to the next page for details) |
| R&D expenses | 1,119 | 1,066 | -53 | |
| Number of employees | 59 | **58** | -1 | |

(Note)
* For details of the financial figures, please refer to the summary of the financial results announced today.

# Supplemental Explanation of Finance Income and Finance Costs

Update

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## Details of finance income and finance costs

In the six months ended June 30, 2025, we recorded finance income of ¥500 million and finance costs of ¥3,629 million.

Finance income was mainly due to the recording of ¥349 million in profit or loss transferred to equity interests held by external investors in the Saisei Fund [*1] ,¥127 million in gain on remeasurement of investment securities and ¥ 24 million in interest income.

Finance costs were mainly due to the recording of ¥3,571 million in loss on remeasurement of derivatives [*2] , ¥17 million in share acquisition rights issuance costs, ¥16 million in interest expenses on bonds, and ¥13 million in interest expenses.

*1. Profit or loss transferred to equity interests held by external investors in the Saisei Fund

Profit or loss transferred to equity interests held by external investors in the Saisei Fund is the transfer amount of profits and losses of Saisei Bioventures, L.P., the consolidated subsidiary of our company, to limited partners other than our company. Saisei Bioventures, L.P. is a limited partnership established by Saisei Capital Ltd., the general partner and consolidated subsidiary of our company.

*2. Loss on remeasurement of derivatives

This is a non-cash gain/loss item, which represents the loss on remeasurement of the 21st, 22nd, and 26th stock acquisition rights issued by the Company at fair value as of the end of the 2nd quarter of the fiscal year ending December 2025 .

Under Japanese GAAP (JGAAP), the amount to be paid in for stock acquisition rights is recorded as equity. Under IFRS, the amount to be paid in for stock acquisition rights is recorded as a liability, and the fair value is measured at the end of each period and the gain or loss on remeasurement is recorded in financial income or financial costs.

# Consolidated Statement of Financial Position

Update

Healios

( Units: millions of yen )

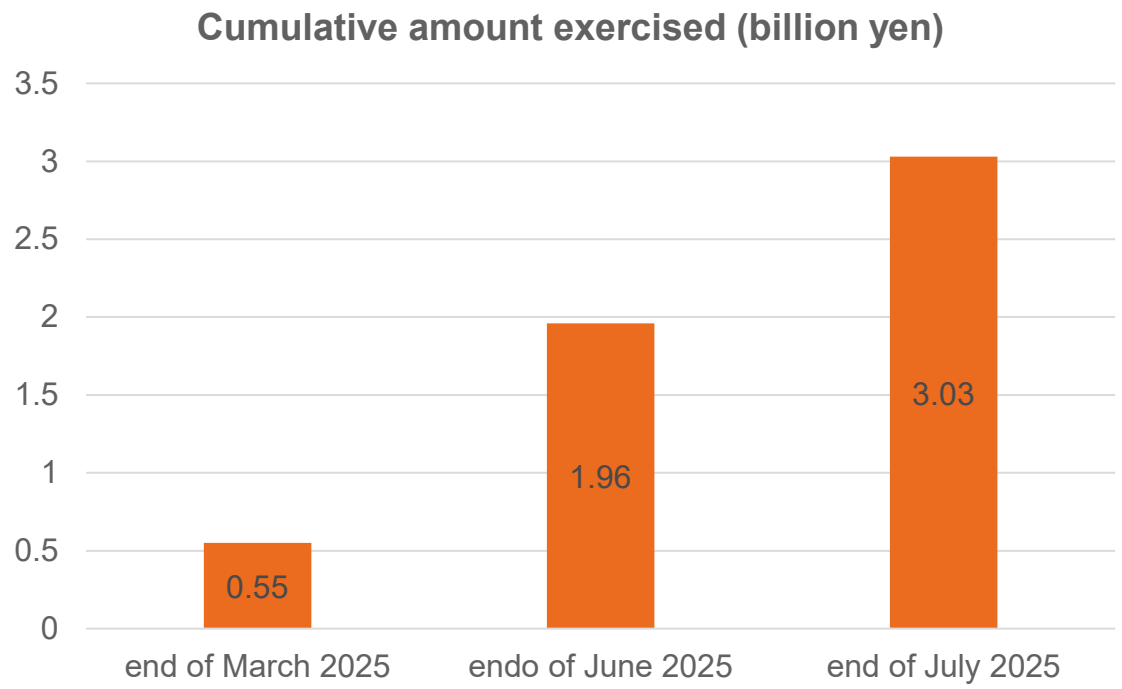
| | | December 31, 2024 | June 30, 2025 | | |
|---|---|---|---|---|---|
| | | | | Variance | Main reasons for increase/decrease |
| | Current assets | 4,275 (30.1%) | 6,819 (40.5%) | 2,543 | Increase in cash and cash equivalents +2,573<br>(Cash and cash equivalent balance at 6/30/25 was 6,245) |
| | Non-current assets | 9,916 (69.9%) | 10,020 (59.5%) | 104 | Increase in other financial assets +226 |
| Total assets | | 14,191 (100.0%) | 16,839 (100.0%) | 2,647 | |
| | Current liabilities | 3,350 (23.6%) | 6,448 (38.3%) | 3,098 | Increase in other financial liabilities +3,554 |
| | Non-current liabilities | 8,758 (61.7%) | 9,115 (54.1%) | 357 | Increase in equity interests held by external investors in Saisei Fund +358 |
| Total liabilities | | 12,108 (85.3%) | 15,563 (92.4%) | 3,455 | |
| Total equity | | 2,084 (14.7%) | 1,276 (7.6%) | -808 | Recording of loss -4,708<br>Issuance of new shares +3,900 |
| Total liabilities and equity | | 14,191 (100.0%) | 16,839 (100.0%) | 2,647 | |

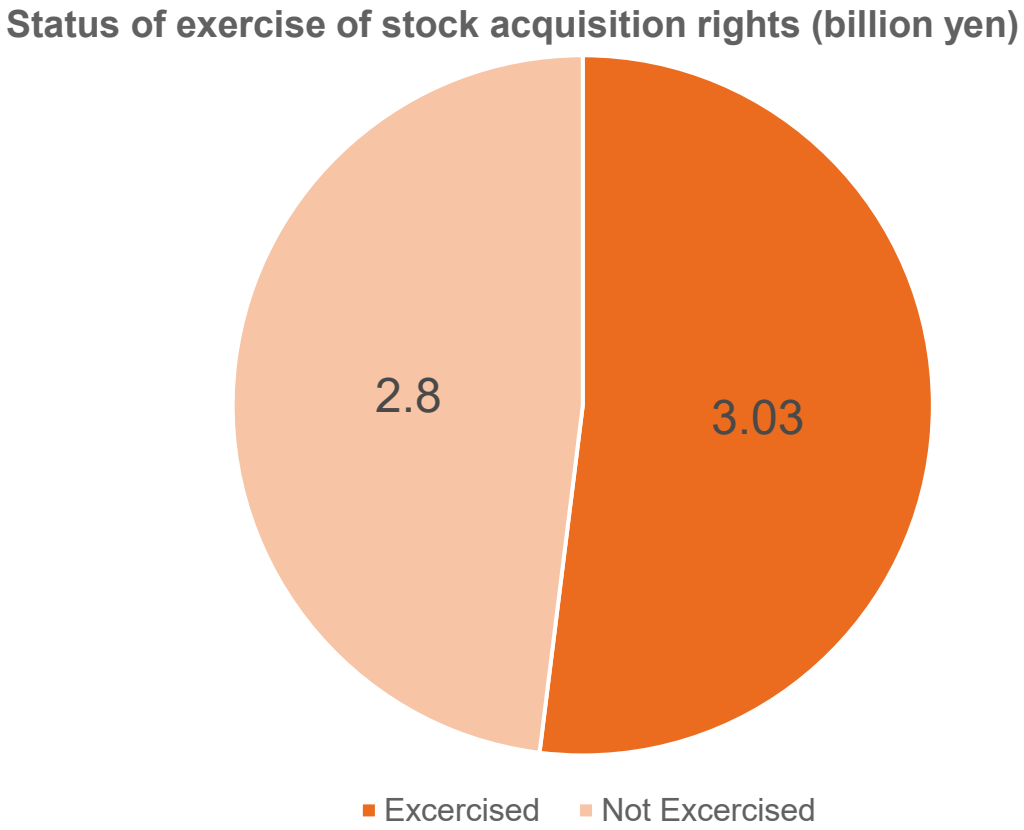
(Note) * For details of the financial figures, please refer to the summary of the financial results announced today.

# Status of exercise of stock acquisition rights (end of July 2025)

(Unit: billion yen)

| | Planned procurement amount | Amount exercised |
|---|---|---|
| 21st Stock Acquisition Rights | 1.90 | 1.06 |
| 22nd Stock Acquisition Rights | 2.81 | 1.97 |
| 26th Stock Acquisition Rights | 1.12 | – |

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