FY2025 Q3 Financial Results

Company

HEALIOS K.K.

Date

November 13, 2025

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Business Overview

Update

Healios

Announcements in FY2025 Q3 (July - September)

- 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)
- Healios UDC Patent granted in Japan (Our technology's uniqueness and novelty officially recognized within Japan)

Announcements in October 2025

- Advancing collaboration with Minaris Advanced Therapies for commercial production of HLCM051 (Preparing for commercial production of our cell therapy product, invimestrocel, using our proprietary 3D bioreactor manufacturing process)
- Termination of business and capital alliance agreement with Nikon Corporation (Establishment of CDMO infrastructure for regenerative and cell therapy capable of independently addressing the global market)
- Subgroup analysis results from the MUST-ARDS trial regarding kidney dysfunction (Data from the Phase 1/2 trial (MUST-ARDS trial) conducted in the United States and Europe for ARDS patients. Recovery of kidney dysfunction is the primary endpoint in the Phase 2 trial (MATRICS-1 trial) for trauma in the US.)

Target Milestones

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- File / Rolling Submission (SAKIGAKE designation) for conditional and time-limited approval in Japan for **Ischemic Stroke**. (2025 or ASAP)

- File for conditional and time-limited approval in Japan for HLCM051 (invimestrocel) for **ARDS**.
  (While managing Ischemic Stroke, plan to determine priorities and timing.)

- Initiation of global Phase 3 trial for **ARDS**, mainly in the U.S. (2026)

- Sales of **Culture Supernatant**. (2026)

Conditional and time-limited approval in Japan

- Secure necessary manufacturing capacity required at the time of application, including the establishment of a 4x50L bioreactor-based commercial manufacturing suite at Minaris in Japan.
- Concurrently advance 500L bioreactor-based manufacturing facility and equipment for manufacturing scale up to ensure adequate product supply readiness following approval.
- Advance regulatory discussions regarding ischemic stroke filing, aiming to maximize sales for both indications.
- Establish commercial organization including sales & marketing team to prepare for commercial launch.

（Reference）

- Using FY2024 supplementary budget “Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities” by METI (a subsidy of about 7 Billion yen) to expand the global CDMO business.
- Advancing collaboration with Minaris Advanced Therapies for commercial production of HLCM051

Link from underlined parts

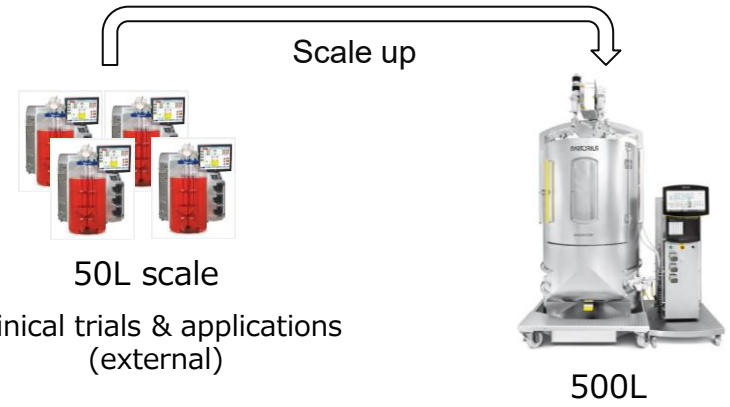
Initiation of Global Phase 3 trial mainly in the U.S.

- Consult with the FDA regarding final protocol enhancement of REVIVE-ARDS trial, intended to further improve probability of successful efficacy confirmation.
- After obtaining FDA agreement, consult with PMDA regarding protocol enhancement in Japan.
- After confirming the above, submit IND (Investigational New Drug) application and launch trial.

Importance of CDMO business

- 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 a 3D bioreactor-based manufacturing process.
- Achieved the world's largest scale of allogeneic cell culture at 500L within Healios and have confirmed that quality is maintained.
- Utilizing the METI Subsidy Program, we will establish the world's largest commercial-scale cell production in Japan.
- Advance the efficiency and quality assurance of our in-house manufacturing while establishing contract manufacturing services for domestic and international pharmaceutical companies as a new source of cash flow.

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



Will establish production capacity of 40,000 units / year

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

x

Robotics
Obtain reproducible data with minimal variation in results.

High-precision data x highly efficient search
A virtuous cycle

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

Manufacturing Facilities in Japan (Minaris / Healios)

Minaris in Yokohama

- Preparing for commercial production of HLCM051 using our proprietary 3D bioreactor-based manufacturing process.

- 4F Shibusawa ABC Building #1
- 48,400 sq. ft.
- GMP clinical and commercial manufacturing capabilities
- Manufacturing development capabilities
- 6 clean rooms
- Cryopreservation facility
- Close proximity to Narita and Haneda airports

Global Manufacturing Facilities of Minaris

Healios in Kobe

- Using FY2024 supplementary budget “Subsidy Program to Support Capital Investment in Regenerative, Cell, and Gene Therapy Manufacturing Facilities” by METI (a subsidy of about 7 Billion yen) to build infrastructure and commercialize a CDMO business capable of serving the global market. Preparations are underway to establish a base for future in-house production.

Kobe Biomedical Innovation Cluster (Link in Jpanese)

Conditional and time-limited approval in Japan

- While proceeding with the ARDS application, continue preparations for Ischemic Stroke.
- Continue discussions with PMDA regarding the details of verification studies, aiming for a conditional and time-limited approval application in Japan utilizing the SAKIGAKE designation scheme.

Shipment and sales of culture supernatant

- Promptly conclude the joint research with AND medical and receive the final milestone payment of ¥60 million (total contract amount: ¥180 million).
- Subsequently, discuss orders with AND medical based on the supply agreement (which includes an initial order for product worth ¥420 million).
- Finalize additional supply contracts with Saishunkan Pharmaceutical Co., Ltd. (Material Transfer Agreement concluded in August 2025) and other prospective customers with whom discussions are proceeding.

HLCM051 ARDS: Development Status

Update

Healios

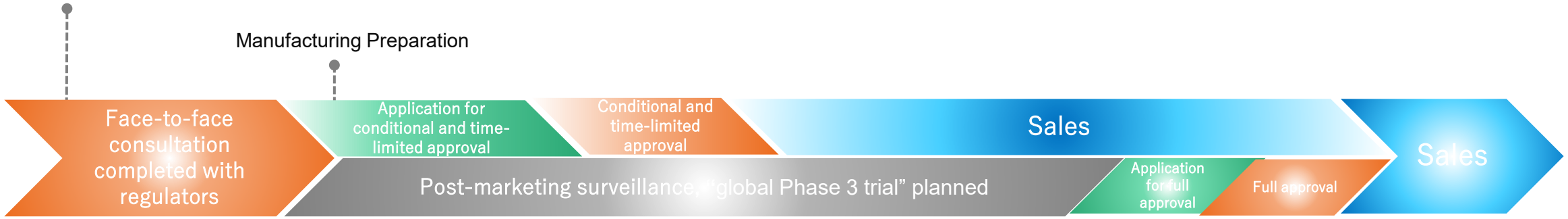
Inflammatory Conditions

Application for conditional and time-limited approval and Global Phase 3 clinical trial (REVIVE-ARDS Study) scheduled for implementation

ARDS

- **Preparing for global Phase 3 trial in the U.S. (Consultation with the FDA on protocol enhancement)**
- **Preparing 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. Manufacturing preparations underway.**

December 2024, January and April 2025
Agreed with PMDA on manufacturing / clinical package and inclusion of patients from Japan in global phase 3 trial



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

Update Healios

Three pillars to monetization

Medical Materials

HLCM051 Culture Supernatant

Universal Donor Cell

iPS cell lines, etc.

SIFU®

Culture Supernatant

Joint Research
AND medical group
Milestone Receipt / Entered into Supply contract

FY2026: Commencement of sales

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

Conditional and Time-Limited Approval Application for ARDS / Ischemic Stroke in Japan

Preparation for 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..

Target Cash Flow Plan
(Short-term: Existing Warrant Exercises, Mid-term: Culture Supernatant, Long-term: ARDS)

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Base cost (business operations)

Global Phase 3 Trial Cost

Contract and In-house manufacturing for Japan (HLCM051)

＊Not simply an expense but reflects the building up of inventory to be sold after approval in Japan.
In-house manufacturing supported through subsidies from METI (the Ministry of Economy, Trade and Industry).

Warrant exercises

Sales of Culture Supernatant and cosmetics materials expanding customer base and sales

Start of order

Start of shipment

Target profitability on monthly basis

ARDS (Japan) Sales

ARDS (non-Japan) Partnership

4Q 2025 | 1Q 2026 | 2Q | 3Q | 4Q | 1Q 2027 | 2Q | 3Q | 4Q | 1Q 2028 | 2Q | 3Q | 4Q

Pipeline

Update

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	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 Orphan designation
				Global (USA)		Preparing for Phase 3				Consulting with FDA on Global Phase 3 protocol enhancement. Patients included from Japan Fast Track and RMAT designation (USA)*1
	HLCM051	Ischemic Stroke	invimestrocel	Japan		Phase 2/3 completed and consulting for approval				Discussing with PMDA aiming to apply for conditional and time-limited approval SAKIGAKE designation (Japan)
				Global (USA)		Phase 3				Fast Track and RMAT designation (USA)
	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 AMD	RPE*2	Japan		Phase 1/2				Joint research with RACTHERA Co., Ltd. Scheduled to be launched in FY2028

*2 Retinal Pigment Epithelium

Immuno-Oncology	AKT-01/ HLCN061	Solid Tumors*3	eNK	Global						Akatsuki leads research and development (Development code AKT-01 added)
	–	Solid Tumors	CAR-eNK	Global						

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

Note: Excludes pipeline assets scheduled to be carved out

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: Centers for Disease Control and Prevention

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

Subgroup Analysis Results from the MUST-ARDS Trial Regarding Kidney Dysfunction

New Healios

From the Phase 1/2 clinical trial (trial name: MUST-ARDS trial[*1]) previously conducted in the United States and Europe targeting ARDS patients.

This subgroup analysis **extracted patients who had concomitant severe kidney dysfunction**

Compared to the placebo group, a significant trend toward improved kidney function was observed in the HLCM051 group.

Comparison of results between HLCM051 treatment group and Placebo group after 28 days Post-Administration

	AKI[*2] or low kidney function (CC[*3]<80)	AKI Free or restored kidney function (CC≥80) 28 Days post-administration	Improvement Rate
HLCM051	13 patients	8 patients	61.5%
Placebo	7 patients	1 patients	14.3%

＊1: This trial was not originally designed to evaluate the efficacy of HLCM051 for kidney dysfunction.
＊2: Acute Kidney Injury (AKI): AKI is a condition characterized by a rapid decline in kidney function, making it difficult to excrete waste products and maintain water and electrolyte balance.
＊3:Creatinine Clearance (CC): Creatinine clearance is an indicator of how much blood the kidneys can filter creatinine per minute and is used to evaluate kidney function.

Conference Presentations and Articles (FY2025)

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.
The 87th Annual Meeting of the Japanese Society of Hematology	Oct.12／Kobe, Japan	Heparan Sulfate-Linked Laminin Fragment Promotes HPC Differentiation from hiPSCs in a Defined System (Japanese)	Masashi Yamada et al. Kobe Research Institute, Healios K.K.
The 40th Annual Meeting of the Japanese Society for the Study of Xenobiotics	Oct.21／Kyoto, Japan	Development of a highly sensitive direct qPCR method for cell therapy products quantification in non-clinical biodistribution studies	Yoichi Naritomi et al. Kobe Research Institute, Healios K.K.

Financial Highlights

Consolidated Statement of Income

Update

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(Units: millions of yen)

	FY2024 Q3(YTD)	FY2025 Q3(YTD)		
			YoY variance	Main reasons for increase/decrease
Revenue	542	79	-464	
Operating profit	-1,976	-2,333	-357	Decrease in SG&A expenses ＋206 Increase in R&D expenses -59
Profit	-4,475	-4,146	329	Increase in finance income +337 Decrease in finance costs +389 (Primarily non-cash activity; please refer to the next page for details)
R&D expenses	1,474	1,533	59	
Number of employees	58	**60**	2	

(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

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Details of finance income and finance costs

In the nine months ended September 30, 2025, we recorded finance income of ¥767 million and finance costs of ¥2,568 million.

Finance income was mainly due to the recording of ¥676 million in profit or loss transferred to equity interests held by external investors in the Saisei Fund [*1] ,¥54 million in gain on remeasurement of investment securities and ¥ 37 million in interest income.

Finance costs were mainly due to the recording of ¥2,495 million in loss on remeasurement of derivatives [*2], ¥24 million in interest expenses on bonds, ¥20 million in interest expenses, and ¥17 million in share acquisition rights issuance costs.

*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 3rd 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	September 30, 2025		
				Variance	Main reasons for increase/decrease
	Current assets	4,275 (30.1%)	7,171 (41.4%)	2,895	Increase in cash and cash equivalents +2,825 (Cash and cash equivalent balance at 9/30/25 was 6,498)
	Non-current assets	9,916 (69.9%)	10,156 (58.6%)	240	Increase in other financial assets +291
Total assets		14,191 (100.0%)	17,327 (100.0%)	3,135	
	Current liabilities	3,350 (23.6%)	5,422 (31.3%)	2,073	Increase in other financial liabilities +2,472
	Non-current liabilities	8,758 (61.7%)	8,949 (51.6%)	191	Increase in equity interests held by external investors in Saisei Fund +167
Total liabilities		12,108 (85.3%)	14,371 (82.9%)	2,263	
Total equity		2,084 (14.7%)	2,955 (17.1%)	872	Recording of loss -4,146 Issuance of new shares +4,986
Total liabilities and equity		14,191 (100.0%)	17,327 (100.0%)	3,135	

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

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