



FY2025 Financial Results

Company

HEALIOS K.K.

Date

February 16, 2026

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Business Overview

HEALIOS

From a biotech startup to the world's leading cell therapy maker.

Healios is pioneering high reproducibility and scalability in cell therapy manufacturing. By obtaining the world's first allogeneic cell therapy approval utilizing three-dimensional (3D) bioreactor production, Healios' technology will prove that cell therapy can be implemented worldwide.

Bone marrow-derived cells

Advancing collaboration with Minaris for commercial production of invimestrocel

Preparing for commercial production of invimestrocel (HLCM051) using our proprietary three-dimensional manufacturing process

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

Establishing the infrastructure for a CDMO business in regenerative and cell therapy capable of serving the global market

Subgroup analysis results from the MUST-ARDS trial regarding kidney dysfunction

A trend toward improvement in kidney dysfunction was observed in the invimestrocel treatment group.

Development and application policy for invimestrocel (ARDS and ischemic stroke treatment)

Prioritize the development for ARDS and reevaluate our development policy for ischemic stroke

iPS cells

UDC patent granted

Initiated joint research for CAR eNK with Kyushu University

Medical materials

Letter of Intent with Alfresa Corporation regarding the sale and purchase of somatic stem cell culture supernatant

For the continuous sale and purchase of culture supernatant (product name: HLSI071)

Initiated production of culture supernatant at in-house cell processing facility

To prepare for the anticipated full-scale production of culture supernatant

Concrete steps toward Japan-U.S. approval:

Clarity of application strategy

Focus on ARDS. Agreement has been reached with Japanese regulatory authorities regarding the approval application and the process leading to full approval.

Initiation of global Phase 3 trial, which offers the highest probability of success for the company and has been clearly agreed upon with regulatory authorities

Unmatched manufacturing capacity

With subsidy from METI, our own facility can produce enough product for 40,000 people annually

Establishing CDMO infrastructure for regenerative and cell therapies capable of serving global markets

Commercial manufacturing preparation at Minaris is progressing smoothly

Building a stable supply system through multiple manufacturing sites

Strengthening and improving the financial foundation

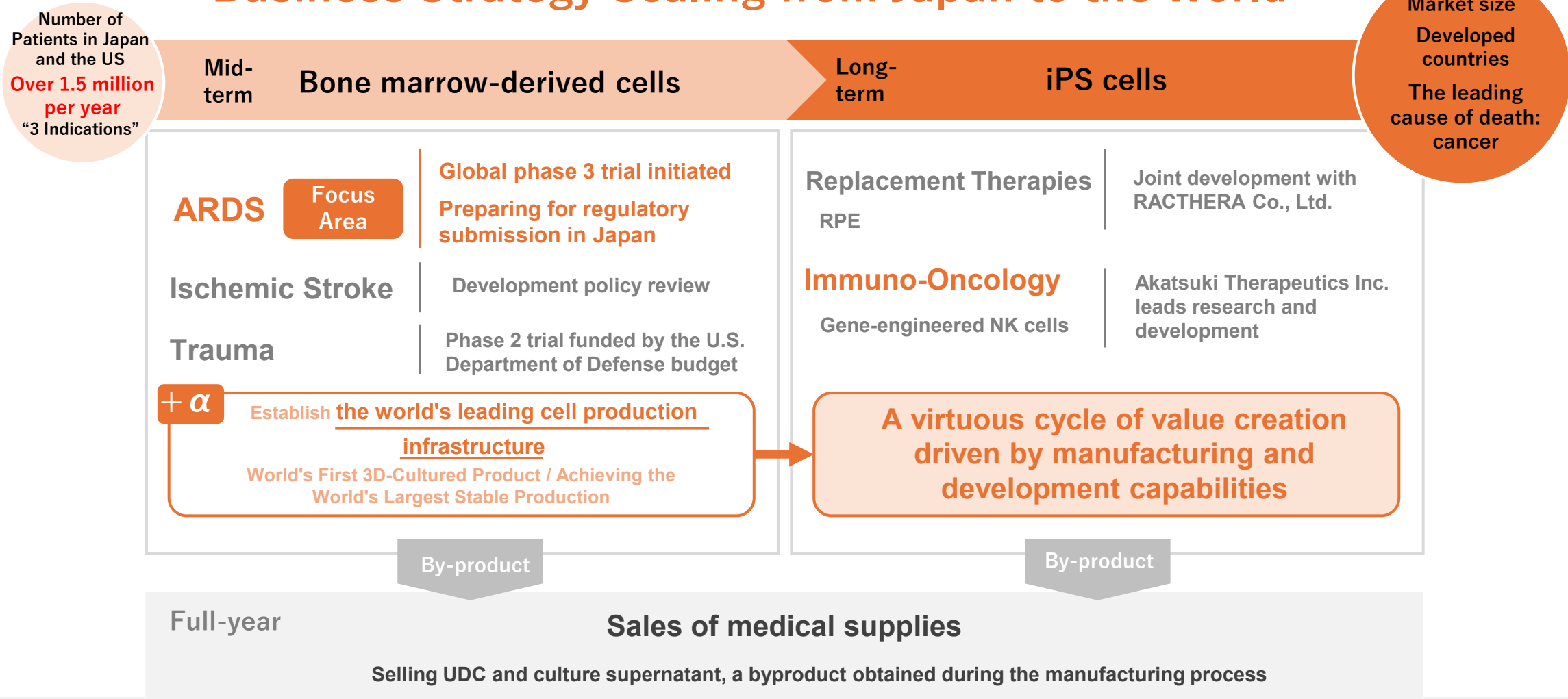
After raising ¥6.3 billion, cash position exceeds ¥10 billion

Additional ¥6.51 billion can be raised through full warrant* exercise

* This refers to the 21st, 22nd, 26th, and 27th series of stock acquisition rights issued by Healios in the past and not yet exercised as of today.

Unparalleled cell therapy market position

Business Strategy Scaling from Japan to the World



Healios' Enabling of Stable Mass Cell Production

World's first Approval for 3D manufacturing

Healios

✓ Production Efficiency

✓ Stability

- Submission for approval at 50L scale (GMP)
- Production is proceeding smoothly at Minaris.

Previous 2D culture
→ Manual work in culture dishes

Production Efficiency ✗

Stability ✗

World's largest 3D production capability

Healios

✓ 500L successfully
manufactured
(nonGMP)

✓ Secured METI
grant

✓ Capacity to produce
for 40,000 people
annually

AI x Robots

Healios

✓ Continuous pursuit of
production efficiency

✓ Strengthening the
supply chain

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



Robotics
Obtain reproducible
data with minimal
variation in results

Grants from the Japanese and U.S. governments



Ministry of Economy, Trade
and Industry

Facility & equipment cost burden

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



World's First
Production via 3D culture
method
Establishing a supply system for
40,000 people per year



United States Department of Defense
The Memorial Hermann Foundation

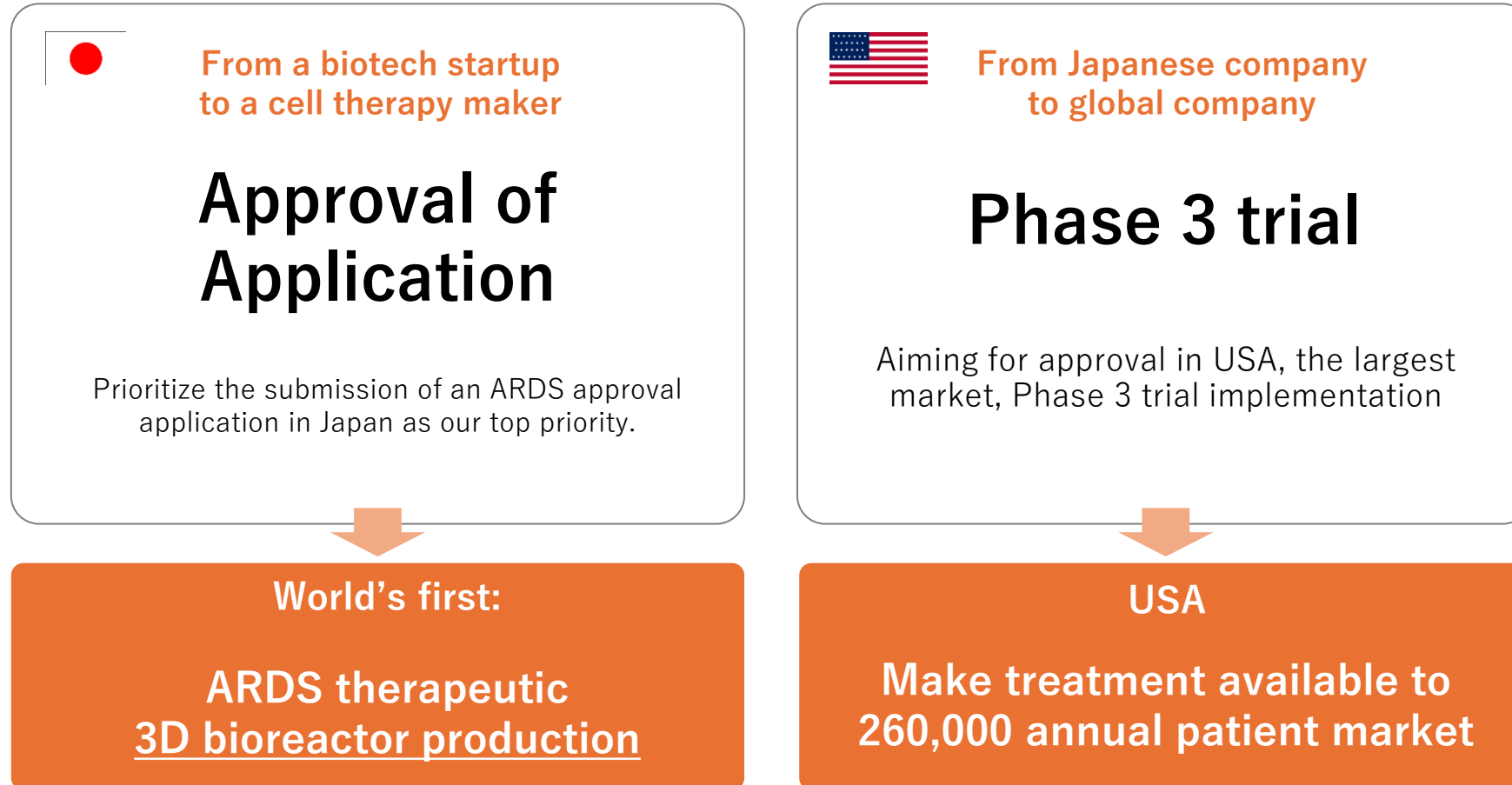
Clinical trial cost burden

Ongoing clinical trial at University of Texas
Health Science Center at Houston (UTH) and
Memorial Hermann Texas Medical Center



The 3rd leading cause of death in the U. S.
Treatment of Trauma Induced
Multiple Organ Failure/
Systemic Inflammatory
Response Syndrome (SIRS)

Focus on ARDS



Invimestrocel (HLCM051) ARDS Therapy Prioritizing the application for manufacturing and marketing approval in Japan as the top priority



Global Phase 3 trial initiated for ARDS

(REVIVE-ARDS Study)
Japan, January 20:
Clinical trial application
submitted / February 3:
Clinical trial commenced)



REVIVE-ARDS trial begins in the U.S. and other countries

(Confirmatory study after conditional and time-limited approval)



Establishment of commercial production System at Minaris



Sales and marketing system establishment



Application for manufacturing and marketing approval in Japan

	Development Code	Therapeutic Area	Therapy	Region	Discovery	Pre-Clinical	Clinical			Applica-tion	Approval	Comments
							P1	P2	P3			
Inflammatory Conditions	HLCM051	ARDS	invimestrocel	Japan	Phase 2 completed, Preparing for approval							Preparing to apply for Conditional and Time-Limited Approval Orphan designation
				Global (Japan / USA / Others)	Phase 3 initiated							Initiated Global P3 trial (REVIVE-ARDS study), Preparing for the REVIVE-ARDS study in USA Fast Track and RMAT designation (USA)*1
	HLCM051	Ischemic Stroke	invimestrocel	Japan / Global (USA)	Phase 3 (completed in Japan)							Reviewing development and application policy SAKIGAKE designation (Japan) Fast Track and RMAT designation (USA)*1
	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			Comments
							P1	P2	P3	
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



Financial Highlights

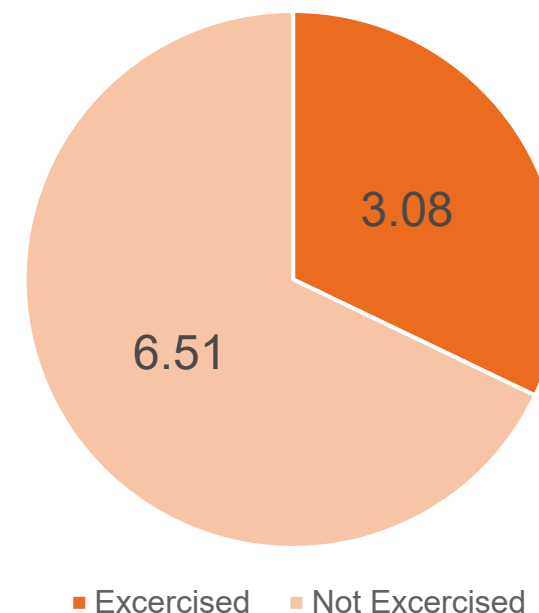
Through the issuance of new shares via a third-party allotment and the 27th series of stock acquisition rights, approximately ¥6.3 billion in funds was secured, bringing our cash and deposits balance to over ¥10 billion and significantly improving our financial position.

Additionally, if all outstanding warrants are exercised, approximately ¥6.51 billion in funds will be secured in addition to the above funds.

(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	—
27th Stock Acquisition Rights	3.76	—

Status of exercise of stock acquisition rights (billion yen)



(Units: millions of yen)

	FY2024	FY2025		
			YoY variance	Main reasons for increase/decrease
Revenue	560	104	-456	Decrease mainly due to the absence of the revenue impact from the licensing agreement for RPE cell manufacturing methods, which had been recorded in the previous fiscal year.
Operating profit	-2,843	-3,340	-497	Decrease in SG&A expenses +109 Increase in R&D expenses -64
Profit	-4,227	-2,229	1,998	Increase in finance income +1,042 Decrease in finance costs +1,390 (Primarily <u>non-cash</u> activity; please refer to the next page for details)
R&D expenses	1,960	2,024	64	
Number of employees	58	66	8	

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

Details of finance income and finance costs

In the fiscal year ended December 31, 2025, we recorded finance income of ¥1,415 million and finance costs of ¥200 million.

Finance income was mainly due to the recording of ¥923 million in profit or loss transferred to equity interests held by external investors in the Saisei Fund^{*1}, ¥390 million in gain on remeasurement of derivatives^{*2}, ¥52 million in gain on remeasurement of investment securities and ¥50 million in interest income.

Finance costs were mainly due to the recording of ¥106 million in loss on sale of investment securities, ¥32 million in interest expenses on bonds, ¥27 million in interest expenses, ¥17 million in share acquisition rights issuance costs, and ¥17 million in foreign exchange loss.

*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 and Akatsuki Therapeutics, Inc., which receives investment from Saisei Bioventures, L.P., 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. Gain or loss on remeasurement of derivatives

This is a non-cash gain/loss item, which is primarily due to changes in the fair value of the 21st, 22nd, and 26th stock acquisition rights issued by the Company.

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

(Units: millions of yen)

		December 31, 2024		December 31, 2025	
				Variance	Main reasons for increase/decrease
	Current assets	4,275 (30.1%)	6,441 (37.8%)	2,166	Increase in cash and cash equivalents +2,007 (Cash and cash equivalent balance at 12/31/25 was 5,679)
	Non-current assets	9,916 (69.9%)	10,613 (62.2%)	697	Increase in other financial assets +709
	Total assets	14,191 (100.0%)	17,054 (100.0%)	2,863	
	Current liabilities	3,350 (23.6%)	3,224 (18.9%)	-126	Decrease in trade and other payables -123 Increase in bonds and borrowings +450 Decrease in other financial liabilities -413
	Non-current liabilities	8,758 (61.7%)	8,932 (52.4%)	174	Decrease in bonds and borrowings -450 Increase in equity interests held by external investors in Saisei fund +523
	Total liabilities	12,108 (85.3%)	12,155 (71.3%)	48	
Total equity		2,084 (14.7%)	4,899 (28.7%)	2,815	Issuance of new shares +5,036 Recording of loss -2,229
Total liabilities and equity		14,191 (100.0%)	17,054 (100.0%)	2,863	

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



Healios

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Appendix

Inflammatory
Conditions

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

ARDS

- **January 2026: Initiated the REVIVE-ARDS study. Patient enrollment will begin in Japan, followed by accelerated global clinical trial implementation centered in the United States.**
- **Preparing for the REVIVE-ARDS study in the U.S.**
- **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**
- **Preparing commercial production for pharmaceuticals in preparation for application**

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

January 2026,
Started global P3 clinical trial in Japan



Inflammatory
Conditions

Ischemic
stroke

Development and application policy under review

- **Completion of Phase 2/3 Clinical Trial in Japan (TREASURE study)**
- **Develop a medical-specific LLM and establish a data collection system linked to electronic medical records**
- **Continuing discussions with PMDA and considering future development and application policy (SAKIGAKE designation)**

- We continued discussions with regulatory authorities regarding the details of verification trials for the application (rolling submission under SAKIGAKE designation) for manufacturing and marketing approval in Japan within 2025 (aiming for conditional and time-limited approval). However, considering the status of these discussions and our current company resources, we have decided not to proceed with the rolling submission of the application documents.
- We will continue discussions with regulatory authorities and re-examine our development policy to advance invimestrocel for ischemic stroke.

| 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

Link from underlined parts

Conference / Article	Date / Venue	Title	Author / Department
Regenerative Therapy	Jan.29 / Academic paper	<u>Clinical efficacy of invivestrocel for acute respiratory distress syndrome caused by pneumonia: Comparison with historical data using propensity score analysis</u>	Dr. Kazuya Ichikado MD, Saiseikai Kumamoto Hospital et al.
Cancer Immunology, Immunotherapy	Feb.4 / Academic paper	<u>Antitumor effects of natural killer cells derived from gene-engineered human-induced pluripotent stem cells on hepatocellular carcinoma</u>	Mayuna Nakamura, Hiroshia University et al.
Stem Cell Research & Therapy	Jul.15 / Academic paper	<u>Human iPSC-derived NK cells armed with CCL19, CCR2B, high-affinity CD16, IL-15, and NKG2D complex enhance anti-solid tumor activity</u>	Yuma Fukutani et al. Kobe Research Institute, Healios K.K.
The 87 th Annual Meeting of the Japanese Society of Hematology	Oct.12 / Kobe, Japan	<u>Heparan Sulfate-Linked Laminin Fragment Promotes HPC Differentiation from hiPSCs in a Defined System (Japanese)</u>	Masashi Yamada et al. Kobe Research Institute, Healios K.K.
The 40 th Annual Meeting of the Japanese Society for the Study of Xenobiotics	Oct.21 / Kyoto, Japan	<u>Development of a highly sensitive direct qPCR method for cell therapy products quantification in non-clinical biodistribution studies</u>	Yoichi Naritomi et al. Kobe Research Institute, Healios K.K.

| Minaris in Yokohama

- Preparing for commercial production



- 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, scheduled for completion by the end of 2027.

Efforts toward commercialization

Jan. 21: LOI with Alfresa Corporation regarding the Sale and Purchase of Culture Supernatant

- For the continuous sale and purchase culture supernatant manufactured by Healios (product name: HLSI071)
- As announced in the [“Basic Business Alliance Agreement and Bond Purchase Agreement with Alfresa Corporation”](#) dated June 5, 2024, Healios has already entered into a basic business alliance agreement with Alfresa concerning the distribution and sale of Healios’ products. The LOI is intended to further develop this existing business alliance. Based on the LOI, Healios and Alfresa will continue discussions regarding the detailed terms of the transaction, including specific arrangements for product distribution and supply systems.

Jan. 21: Initiates Production of Culture Supernatant at In-house Cell Processing Facility

- To prepare for the anticipated full-scale production of culture supernatant, we have been developing a Cell Processing Center (CPC) within the Business Support Center for Biomedical Research Activities (BMA) in Kobe.

Currently engaged in individual discussions with promising prospective customers to finalize supply arrangements.



Existing contracts

- In April 2024, we entered into a joint research agreement with AND medical for the utilization of culture supernatant (total milestone amount: ¥180 million). In January 2025, we concluded a supply agreement to provide raw materials from Healios to AND medical.
- In December 2025, AND medical filed a lawsuit seeking damages related to a joint research agreement. However, we believe we have properly fulfilled the contract entered into with the plaintiff and will demonstrate our legitimacy through the litigation process.

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

A significant improvement trend in kidney function (47.2%) and a significant improvement in survival rate (34.0%) were confirmed in the treatment 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.