FY2026 Q3 Financial Results

Company

HEALIOS K.K.

Date

November 12, 2026

Important Note on Future Events, etc

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Business Overview

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Update

Healios

Unparalleled Cell Production Capacity

Business Strategy Scaling from Japan to the World

JP+US Patient Number
Over 1.5 million people per year
"3 Indications"

Bone Marrow-Derived Stem Cells (Mid-Term) → **iPS cells** (Long-Term)

Cancer
Leading cause of death in developed countries

ARDS **Focus**	Global Phase 3 Trial Launch Preparation for JP Approval
Ischemic Stroke	Development Policy Review
Trauma	Phase 2 trial under U.S. Department of Defense budget

Replacement Therapies RPE Cells	Jointly developed with RACTHERA Co., Ltd.
Immuo-Oncology Gene-engineered NK Cells	Research and development led by Akatsuki Therapeutics Inc.

Establish world's leading cell production infrastructure
World's First 3D-Cultured Product
Achieving the World's Largest Stable Production

→ **A virtuous cycle of value creation driven by manufacturing and development capabilities**

By-Product

By-Product

Sales of Medical Supplies

Selling of UDCs, and culture supernatant (by product of manufacturing process)

CDMO Business

End-to-end support from feasibility study through to cGMP manufacturing

* The material patent for the next-generation iPS cell foundation technology "Universal Donor Cell (UDC)" has been granted in China (August 2026 / August 2025 in Japan).

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New Vision Mission Philosophy

New Healios

Vision | Lighting the way beyond disease.

Mission | Steadily. First.
Making regenerative medicine a reality for all.

Philosophy | Heal Patients

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

By achieving cell supply with high reproducibility and scalability for the manufacturing of the world’s first 3D cell culture product, Healios will demonstrate that Japan’s technology can be successfully implemented in the field of cell therapy on a global scale.

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Key Milestones

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Invimestrocel (HLCM051) for the Treatment of ARDS
Prioritization of Application for Manufacturing and Marketing Approval in Japan

Initiation of Global Phase 3 Trials

(REVIVE-ARDS study in Japan) Jan 20 Clinical Trial Notification submitted
Feb 3 Trial started

Establishment of Sales & Marketing System

Obtained license for manufacturing and sales of regenerative medicine products and established an Account Management Division

REVIVE-ARDS study begins in the U.S. and other countries outside Japan

Establishment of Commercial Production System at Minaris

Application for Manufacturing and Marketing Approval in Japan

(Aiming for conditional and time-limited approval)

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Approval in Japan and Global Expansion: Two Independent Paths

Conditional approval application proceeds without waiting for results from REVIVE-ARDS study

Japan Aiming for Conditional and Time-Limited Approval	**ONE-BRIDGE** Study Completed	**Preparation for Commercial Manufacturing System** Process Verification	**Application for Manufacturing and Marketing Approval** Aiming for Conditional and Time-Limited Approval	**Approval and Domestic Sales** First product revenue	**Full Approval** Apply with confirmatory study results
Global Confirmatory Study REVIVE-ARDS	**Initiation** February 2026 Within Japan	**Patient Enrollment** Soon to begin in Japan	**Expansion in US, Europe & APAC** IND Preparation Sequential launch	**Interim Analysis** 300 / 400 cases At each stage	**Application for US & Europe Approval** Expansion into largest global market

All steps required for initial approval have been identified and are progressing.

Must demonstrate effectiveness through confirmatory study within the period of conditional and time-limited approval.
REVIVE-ARDS results are a prerequisite for full approval and deployment in US and Europe.

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Overview of Invimestrocel (HLCM051) for ARDS

Update

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Overview

Application for manufacturing and marketing approval in Japan (aiming for conditional and time-limited approval)
Implementation of a Global Phase 3 trial (REVIVE-ARDS study)

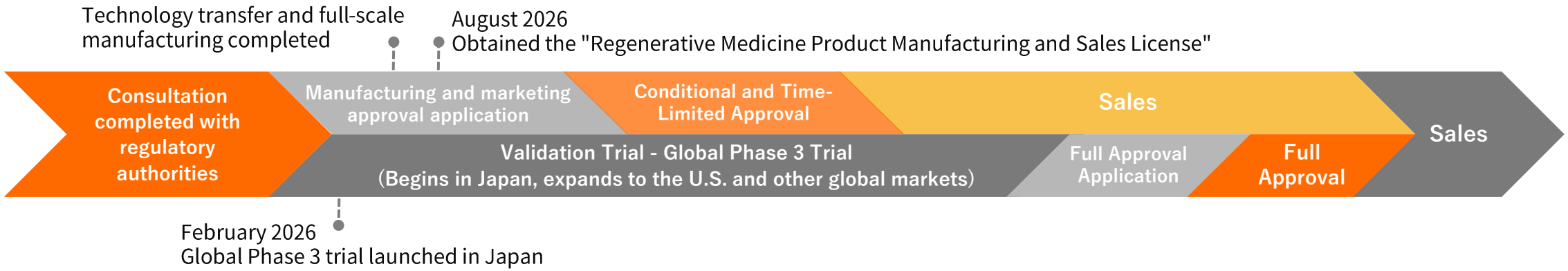
ARDS

February 2026: Global REVIVE-ARDS study initiated.

Patient enrollment will begin in Japan, followed by accelerated preparation for a global clinical trial centered in the U.S.

Preparing for manufacturing and marketing approval applications in Japan based on favorable results from the Phase 2 trial (ONE-BRIDGE study), and the implementation of REVIVE-ARDS as a confirmatory study (aiming for conditional and time-limited approval).

Established a commercial manufacturing system at Minaris and completed full-scale production using a 50L bioreactor. Engineering runs currently in progress.



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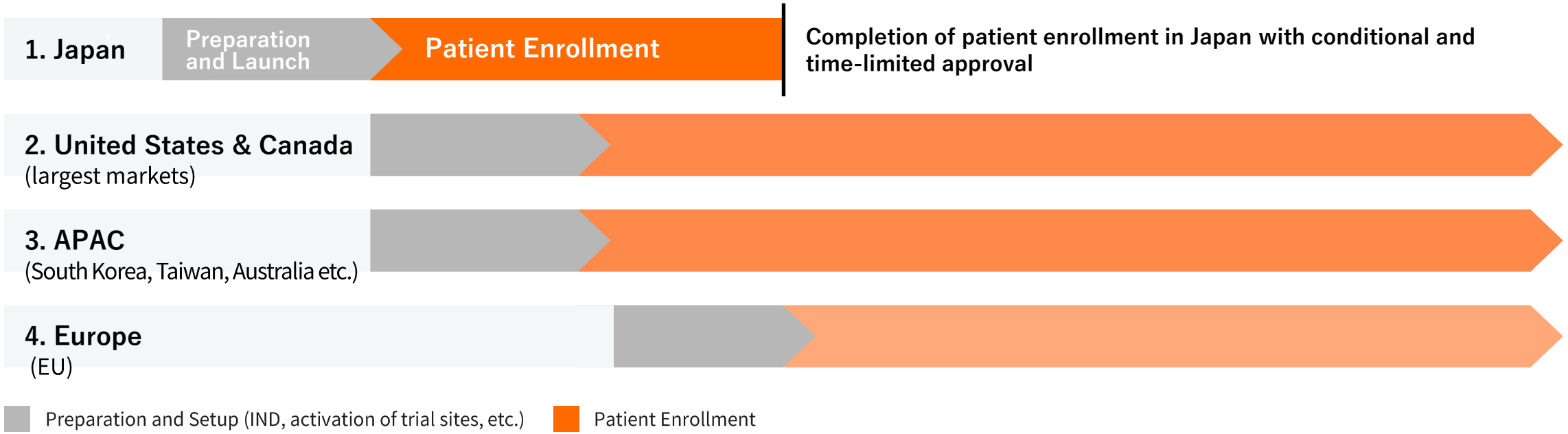
Patient Enrollment starts in Japan Sequential Expansion into the United States, Canada, APAC, and Europe (EU)



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HLCM051 ARDS: Commercial Manufacturing Progress and Pathway to Approval

Update

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Carefully conducted manufacturing process verification as the world's first three-dimensional culture product



Completed	**In Progress**	Schedule

Full-scale manufacturing: Establishing a stable manufacturing system at the same scale (50L) as commercial supply.

Engineering run: Process of implementing commercial production procedures under the same conditions as actual production to systematically verify process stability in preparation for PPQ runs.

PPQ (Process Performance Qualification) Run: Process that provides the final demonstration that quality stably meets standards in commercial-scale iterative manufacturing under GCTP.

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Commercial manufacturing base relocated from overseas to Minaris Advanced Therapies in Japan

To ensure stable supply and product quality after approval,
the site change has extended the filing timeline.
To avoid supply and quality issues after approval,
Healios chose not to take shortcuts.

Prioritizing Stable Supply

Commercial manufacturing was initially planned overseas and later switched to Minaris.
Technology transfer was initiated again.

As the world's first 3D culture product – technology transfer, full-scale manufacturing, engineering runs, PPQ - no essential stages are skipped.

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Unmatched Manufacturing Capability: Manufacturing Base (Minaris/Healios)

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50L 3D Culture in Operation

Minaris/Yokohama in Japan

Location
4th Floor, Building 1, Shibusawa ABC Building, 1 Ebisu-cho, Kanagawa-ku, Yokohama City, Kanagawa Prefecture

Size
Approx. 4,500m^2 cleanrooms, 6 rooms

Nearest Airport
Tokyo International Airport (Haneda Airport)
Narita International Airport

Minaris Inc.
Global Manufacturing Sites (English)



Scheduled to Operate by Jan 2028

Healios/KOBE Cell Innovation Center (KCIC)

Location
Minami-cho, Minatoshima, Chuo-ku, Kobe City, Hyogo Prefecture (Within DP-Lab KOBE)

Oct 2026: DP-lab Kobe completed

Building manufacturing systems that meet regulatory requirements in Japan, the US, and Europe

Integrated management from process development to quality evaluation and GMP manufacturing

4th Floor: Process Development and Quality Control Area
5th and 6th Floors: Cell Processing and Manufacturing area

Ministry of Economy, Trade and Industry FY2024 Supplementary Budget







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Large-Scale and Stable Production enabled by Three-Dimensional (3D) Culture



Image courtesy: Sartorius AG

This image shows the 500L bioreactor that Healios currently intends to use.
Please note that future use is not guaranteed.



Using a Bioreactor for 3D Cell Culture (non-GMP) Video

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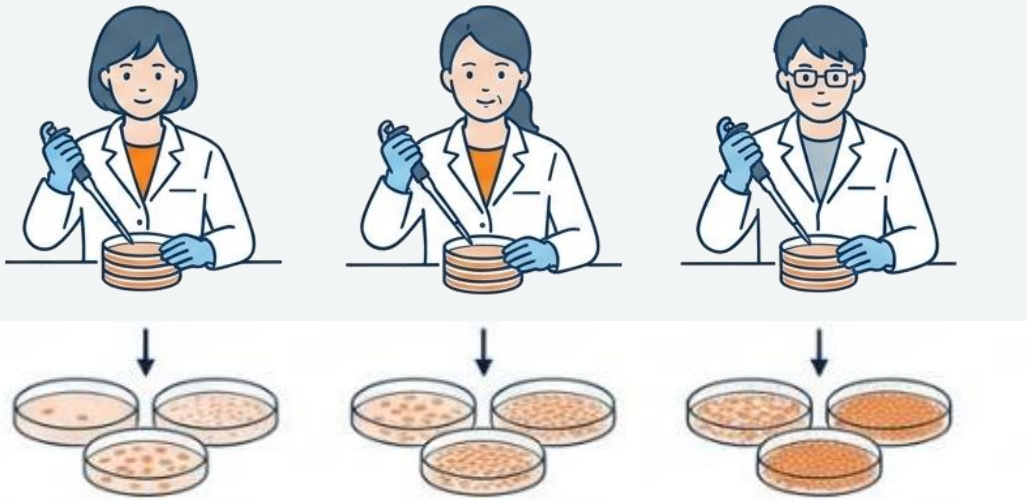
Unmatched Manufacturing Capability: Difference Between 2D and 3D Cell Culture

From manual, small-scale production to industrial-scale manufacturing.
A vantage point in the commercialization of cell therapy.

2D Culture (Conventional Method)



Manual work in culture dishes	Lot-to-lot and personnel variability
⬆Personnel, ⬆Cost ⬇Quality consistency	Skilled personnel essential for technology transfer

3D Culture (Healios' Method)



Fully automated, closed bioreactor	High reproducibility (reduced lot-to-lot variability)
Minimal personnel required	Ease of technology transfer

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Stable Mass Cell Production made possible by Japan

World's First

Approval in 3D Manufacturing

Production Efficiency

Stability

Application for approval (GMP) for 50L Successfully manufactured at Minaris

World's Largest

3D Production Capability

Success in 500L Manufacturing (non-GMP)

Secured METI Grant

Capacity to produce for 40,000 people annually

Conventional 2D Culture
Efficiency × Stability×

Innovation

AI × Robots

Continuous Pursuit of Production Efficiency

Strengthening of Supply Chain

AI Experiment Design
Optimization of culturing conditions with fewer experiments

×

Robotics
Highly reproducible data with minimal variation

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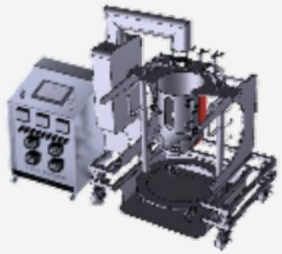
Unmatched Manufacturing Capability: cGMP Manufacturing (CDMO services)

New Healios

From clinical trials (Phase I–III) to commercial applications, centered on three-dimensional culture.

Integrated support for API manufacturing, harvesting/purification, filling and cryopreservation.

(1) Three-dimensional Cultivation



- Track record of three-dimensional culture using a wide variety of bioreactors
- Scaling up and stirring mechanism evaluated through CFD analysis

(Image courtesy of Satake Multimix Co., Ltd.)

(2) Harvesting and Refining



- High productivity and cell viability in closed-end systems
- Continuous centrifugation (Image courtesy of Carr Biosystems)/ concentration and washing using hollow fiber membranes

(3) Filling and Finalization



- In-house developed automatic filling machine (patent pending)
- Filling capacity 1–20mL / Accuracy±2%
- Up to approximately 1,000 vials per batch

(4) Freezing and Storage



- Uniform cooling with in-house developed racks
- Supports large-scale cell freezing with liquid nitrogen-controlled freezing

What We Offer

Clinical-Grade UDC (iPSC) Cell Stock

Starting Material for Partner Development Programs

Process Development & Scale-Up

Developing and optimizing culture processes, from laboratory to commercial scale

Gene Editing Services

Provided upon customer request

Process Optimization with AI

Accelerating condition screening and improving reproducibility (Physical AI)

GMP Contract Manufacturing

From upstream (cultivation and scaling) to downstream (harvest and purification), formulation and freezing

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Grants from the Japanese and U.S. governments

Ministry of Economy, Trade and Industry (METI)

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

World's first 3D culture production Supply system for 40,000 people annually

U.S. Department of Defense Memorial Herman Foundation

Clinical Trial Cost Burden

Ongoing clinical trials at the University of Texas Houston Health Science Center (UTH) and Memorial Harman Texas Medical Center

U.S. Third leading cause of death

Treatment of trauma-induced multiple organ failure and systemic inflammatory response conditions (SIRC)

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Funding Structure Focused on Non-Dilution

Multiple funding sources secured for development and commercialization.

GOALS

Grant Support

FY2024 supplementary budget for regenerative medicine and gene therapy facilities ~7 billion yen

Capital investment in Kobe CDMO facility

U.S. DoD

Clinical Trial Costs

Trauma trial (MATRICS-1 study) cost covered by Memorial Hermann Foundation

Trauma Phase 2 trial No in-house cost

Supernatant

Revenue Income

Transaction agreement with Alfresa (January 2026) Supply contract with Jenecell (April 2026)

First order: ¥144M

Third Pillar

CDMO Business

Kobe's 500L bioreactor Building supply system for 40,000 people annually Targeting global market manufacturing contract manufacturing

Operation starts in Jan 2028

Cash and equivalents as of the end of September 2026: **7.42 billion** yen / Total assets 22.8 billion yen

Diversified development funding from subsidized capital investment, U.S. government-funded trauma trial, revenue from culture supernatant and CDMO businesses

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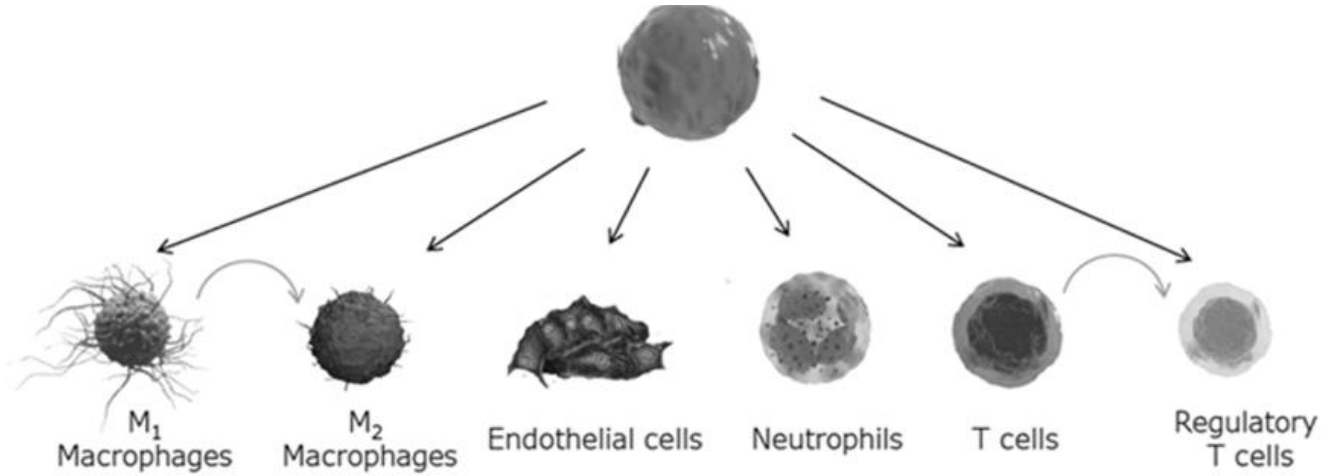
MoA of MAPC (Invimestrocel): Immunomodulation and Vascular Endothelial Protection

Update

Healios

Invimestrocel



Expected Effects of HLCM051	Major Papers
Immunoregulation	Kovacsovics-Bankowski et al. “Clinical scale expanded adult pluripotent stem cells prevent graft-versus-host disease” Cellular immunology 2009
Anti-inflammatory effect	Walker PA et al. “Intravenous multipotent adult progenitor cell therapy after traumatic brain injury: modulation of the resident microglia population” Journal of Neuroinflammation 2012
Vascular endothelial protection	Aranguren XL et al. “Multipotent adult progenitor cells sustain function of ischemic limbs in mice” J Clinical Investigation 2008
Organ protection	Metheny L et al. “Human Multipotent Adult Progenitor Cells Effectively Reduce Graft-vs-Host Disease While Preserving Graft-Vs-Leukemia Activity” Stem Cells 2021

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First secure approval in ARDS, then expand to cover systemic inflammatory response conditions (SIRC).

Target Diseases	Main Affected Organ	Development Stage
ARDS (Acute Respiratory Distress Syndrome)	Lungs	Japan: preparing conditional and time-limited approval Global Phase 3 trial (REVIVE-ARDS study) underway
Trauma-Induced Acute Kidney Injury (AKI)	Kidney	U.S. Phase 2 trial (MATRICS-1 study) underway Funded by U.S. Department of Defense and Memorial Hermann Foundation
Ischemic Stroke	Brain	Phase 3 completed in Japan and U.S. Development and application strategy under review
Multiple Organ Failure	Multiple organs	Candidate for future expansion on coverage
Sepsis	Whole body	Candidate for future expansion on coverage

The Core of Pathology

Targets the common pathology shared by these diseases: runaway inflammation leading to multiple organ dysfunction, through immune regulation and vascular endothelial protection.

Targets the underlying pathology rather than a specific organ – single mechanism of action can be applied across multiple diseases.

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Pipeline

	Development Code	Therapeutic Area	Therapy	Region	Discovery / Preclinical / Clinical (P1 / P2 / P3) / Application / Approval	Notes
SIRC	HLCM051	ARDS	Invimestrocel	Japan	Phase 2 completed, preparing for approval	Preparing to apply for Conditional and Time-Limited Approval Orphan designation
			Invimestrocel	Global (Japan/U.S. /others)	Phase 3 begins	Initiated Global P3 trial (REVIVE-ARDS study), Preparing for the REVIVE-ARDS study in U.S. Fast Track and RMAT designation (U.S.)*1
	HLCM051	Ischemic Stroke	Invimestrocel	Japan / Global (U.S.)	Phase 2/3 (Completed in Japan)	Reviewing development and application policy SAKIGAKE designation (Japan) Fast Track and RMAT designation (U.S.)*1
	HLCM051	Trauma	Invimestrocel	Global (U.S.)	Phase 2	Funded by MTEC (United States Department of Defense) and the Memorial Hermann Foundation

*1 Received Fast Track and RMAT designations from the U.S. FDA.
(RMAT, which enables rapid approval for drugs that meet certain conditions for the development of new drugs for serious or life-threatening diseases or diseases without treatment)

	Development Code	Therapeutic Area	Therapy	Region	Discovery / Preclinical / Clinical (P1 / P2 / P3) / Application / Approval	Notes
Replace-ment Therapies	HLCR011	RPE*2 Tear Age-Related Macular Degeneration	RPE*2	Japan	Phase 1/2	Joint research with RACTHERA Co., Ltd. *3 Scheduled to be launched in FY2028

*2 RPE: retinal pigment epithelial cells *3 Acquired regenerative and cell medicine business from Sumitomo Pharma Co., Ltd.

Immuno-oncology	AKT-01/ HLCN061	Solid Tumours	eNK	Global		Research and development lead by Akatsuki Therapeutics (development code AKT-01)
	—	Solid Tumours	CAR-eNK	Global		

Pipelines scheduled for carve-out are excluded from the listings.

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HLCM051 Acute Respiratory Distress Syndrome (ARDS)

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REVIVE-ARDS Study: Trial Overview

Overview	Double-blind, randomized, placebo-controlled (administered within 48 hours after ARDS diagnosis)
Subject	ARDS patients caused by pneumonia
Regions	USA, Japan, Asia-Pacific, Europe
Number of cases (patients)	Up to 550 cases (HLCM051: 275; placebo: 275) (Intermediary analysis will be conducted at the stages of 300 and 400 cases. If statistically significant efficacy of the investigational product is confirmed at either point, the trial will be considered complete.) *Regional enrollment numbers to be determined
Primary endpoint	VFD (number of days without ventilator within 28 days)
Secondary endpoint (partial)	Mortality (within 90 days after administration)

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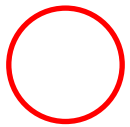
Potential Global ARDS Market



Japan: 28,000 patients

Business scale expanded to over 40 times

Over 1.1 million patients worldwide

Business Policy

1) Conduct company-sponsored clinical trials in the U.S. and Japan, where investment efficiency is highest
2) Enter into licensing agreements for markets outside the U.S. (Korea, Taiwan, and China) to achieve early monetization

Estimated number of ARDS Patients

China: 670,000, United States: 262,000, Europe: 133,000, Japan: 28,000 (in the order of market size)

(Sources)
Japan: Our estimate based on epidemiological data and total population statistics from Japan's total population
US: Diamond M et al. 2023 Feb 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–. PMID: 28613773
Europe: Community Research and Development Information Service (CORDIS) 2020 7-9
China: Song et al. 2014 acute-respiratory-distress-syndrome-emerging-research-in-china

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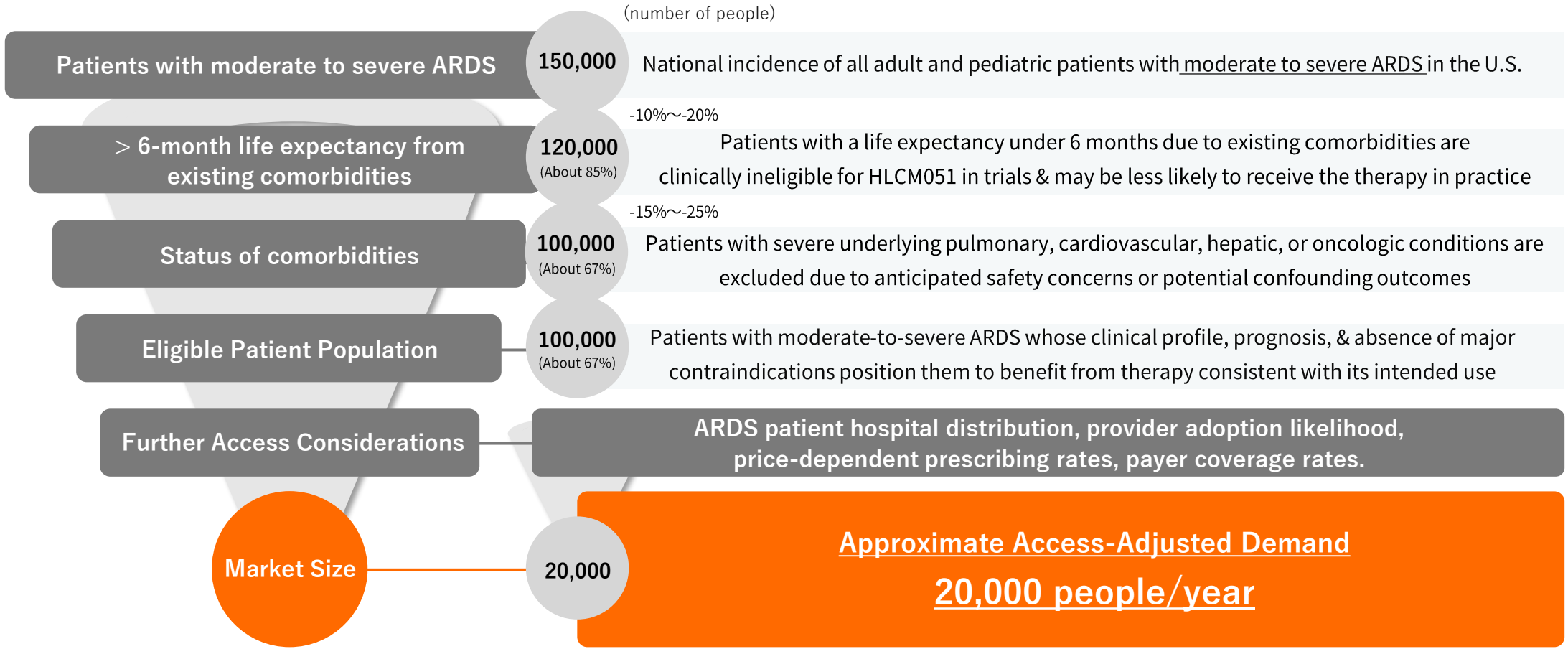
ARDS U.S. Market Size Forecast

Estimated Market Size & Potential Demand of ARDS Indication in the United States



Source: Analysis conducted by Dedham Group based on commission from our company

Please note that these forecasts are based on evaluations by the Dedham Group and do not constitute earnings forecasts. Our company has not independently verified the accuracy of this evaluation and does not guarantee these results.

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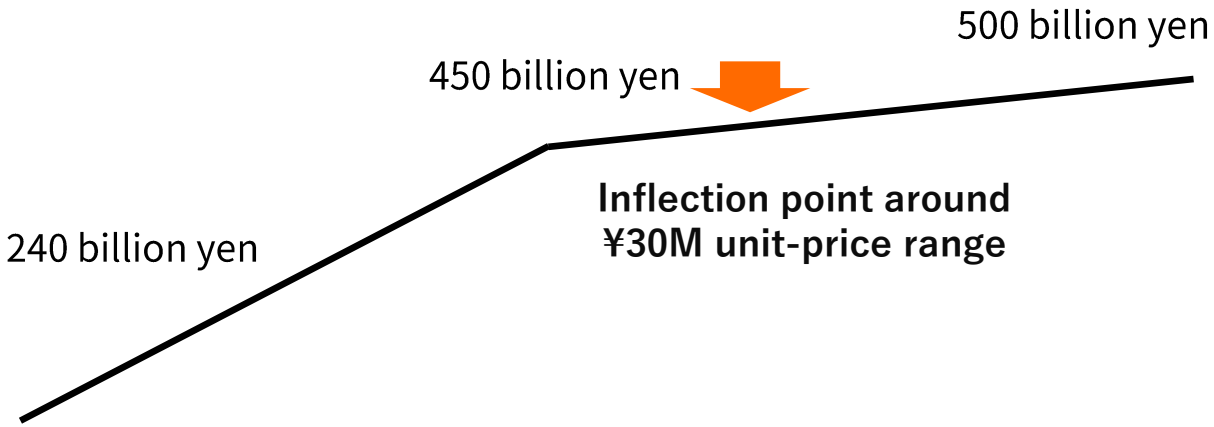
Projected Relationship between Sales and Unit Price



Annual Sales Potential
475 billion yen

Drug Pricing	Approximately 11.25 million yen ($75,000)	Approximately 22.5 million yen ($150,000)	Approximately 37.5 million yen ($250,000)
Total number of treated patients from Year 5 onwards	21,000	20,000	13,000

In the U.S., optimal unit price is approximately 30 million yen ($200,000)

Approximate Access-Adjusted Demand at Steady State

Source: Analysis conducted by Dedham Group based on commission from our company

Please note that these forecasts are based on evaluations by the Dedham Group and do not constitute earnings forecasts. Our company has not independently verified the accuracy of this evaluation and does not guarantee these results.

Estimated at $1 = 150 yen

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HLCM051 Ischemic Stroke

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Overview of Invimestrocel (HLCM051) for Ischemic Stroke

Overview	Development and application policy under review
Ischemic Stroke	Planning to establish a data collection system linked with electronic medical records using a medical-specific LLMs Continuing discussions with PMDA (SAKIGAKE designation) Re-evaluating development policy in light of the status of discussions with regulatory authorities and company’s resource situation

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HLCM051 Trauma-Induced AKI

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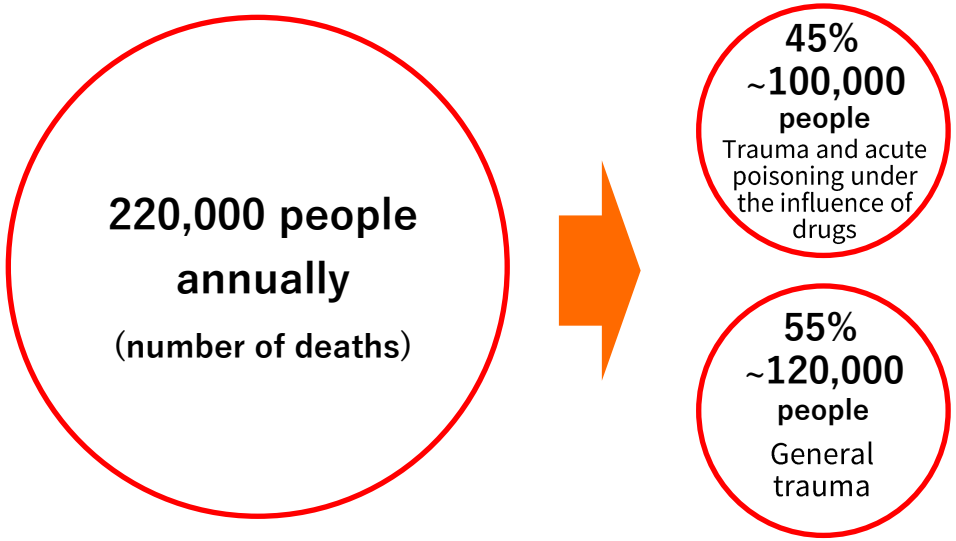
The U.S. Trauma Market



Market Characteristics

	Afghanistan	Iraq War
Combat Trauma	Casualties: 2,354 Wounded: 20,149	Casualties: 4,431 Wounded: 31,994
Cause of Death	3rd leading cause of death across all age groups	Leading cause of death in people under the age of 45
	220,000 deaths annually	87,000 people annually

(Source) U.S. Department of Defense DOD CDC National Institutes of Health (NIH)

Pathological conditions from trauma to death

Systemic inflammatory response syndrome caused by trauma is an excessive self-defense response to external stresses such as trauma (traffic accidents, gunshot wounds, etc.), drugs, and infections, initially resulting in autonomic, endocrine, hematologic, and immunologic changes.

Although these changes are initially intended to protect the body, they can develop into an uncontrollable cytokine storm, triggering a large-scale inflammatory cascade that causes organ damage and ultimately leads to death.

Currently, there are no effective therapies for patients who reach this condition, and only symptomatic treatment is available for each individual symptom.

Expected Effects of Invimestrocel

Invimestrocel is expected to suppress cytokine storms through its ability to control acute-phase inflammation, thereby improving patient outcomes. In the trauma trial, the primary endpoint is kidney function to facilitate the evaluation of efficacy.

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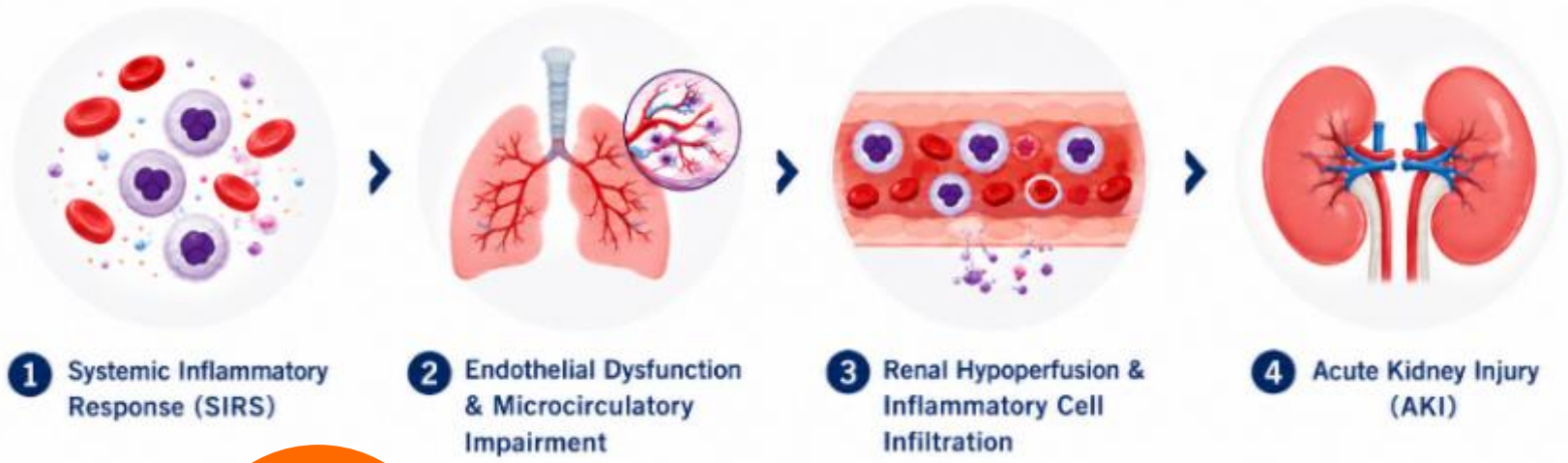
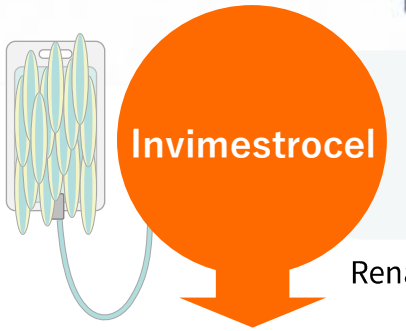
MoA of Invimestrocel (HLCM051) for the Prevention of Kidney Dysfunction (AKI)

Developing AKI from trauma caused by traffic accidents, occupational injuries, gunshot wounds and similar injuries





Anti-inflammatory effects through induction of macrophage polarization from M1 to M2
IL-10 ↑ (anti-inflammatory)
TNF-α/IL-1β ↓ (inflammation, suppression)

Renal protective effects are indirect effects mediated by systemic immune regulation.

Suppression of systemic inflammation → **Stabilization of vascular endothelium** → **Microcirculation improvement** → **Reduction of kidney damage (AKI suppression)** → **Suppression of progression to multiple organ failure**

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MUST-ARDS Trial Subgroup Analysis (Renal Dysfunction and Severe Cases)

In post-hoc subgroup analysis of the Phase 1/2 trial, suggestive trends were seen in severe cases with comorbid AKI

Lower mortality in severe cases (trend)

↓60%

In severe pneumonia patients, HLCM051 Administration a 60% reduction in mortality was seen

Renal function improvement with AKI

↑47.2%

With comorbid acute kidney injury (AKI), a 47.2% improvement was observed

How to read this data

- Source: MUST-ARDS trial (US/UK, Phase 1/2, randomized, double-blind, placebo-controlled)
- 30 cases total (20 HLCM051 / 10 control); results are from subgroups not pre-specified.
- Given the small sample, no statistical testing was performed; the trend is suggestive only. Verification is underway in the Phase 2 trauma trial (MATRICS-1).

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Overview of Invimestrocel (HLCM051) for Trauma: MATRICS-1 Study

MATRICS-1 Trial (U.S.)

Overview	Phase 2 trial in trauma patients
Trauma	**Ongoing with funding from the U.S. Department of Defense and the Memorial Hermann Foundation** University of Texas Houston Health Science Center (UTH) Clinical trials ongoing at Memorial Hermann Texas Medical Center

- Targeting trauma caused by traffic accidents, industrial accidents, gunshot wounds, etc.
- **The leading cause of death in people under the age of 45, the 3rd leading cause of death in the U.S., and the leading cause of quality-of-life years lost***
- Following approval, trauma treatment with Invimestrocel may have the **potential for large-scale adoption by the U.S. military**

* Source: Centers for Disease Control and Prevention

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MATRICS-1 Study: Clinical Trial Overview

Overview	Randomized, double-blind, placebo-controlled Phase 2 trial in patients with trauma-induced multiple organ failure / systemic inflammatory response syndrome
Subject	Trauma patients who survived initial resuscitation after hemorrhagic shock and were admitted to the ICU
Region	United States
Number of cases (patients)	156
Primary endpoint	Renal function (Day 30) < Highest AKI stage within 30 days or until discharge>
Secondary endpoint (partial)	Mortality

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HLSI071 Bone Marrow-derived Stem Cell Culture Supernatant

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Available in two formats: lyophilized and liquid, tailored to suit the intended use and specific needs

Lyophilized

Suitable for long-term storage and transport
An optimal presentation for stable supply

Features
- Long-term storage possible
- Lightweight, reducing transportation costs
- Suitable for global deployment
- Reconstituted before use



Recommended applications
Research reagents

Liquid

Ready to use

Features
- Ready for immediate use without dilution or reconstitution
- Minimal component denaturation, preserving original characteristics of culture supernatant
- Short manufacturing lead time
- Requires refrigerated or frozen storage



Recommended applications
Cosmetics ingredients

This image is for illustrative purposes only and may differ from the actual product to be provided.

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Product Image and Manufacturing Site



This image is a product illustration and does not match the actual product provided.
*Reduced contamination risk

Overview of the Manufacturing Facility (CPC)

Cell Processing and Manufacturing Facility (CPC) fully operational.

Location
Minami-cho, Minatoshima, Chuo-ku, Kobe City, Hyogo Prefecture
1-chome 5-5
Inside Kobe Biomedical Creation Center

Facility Area
Approximately 80㎡

Manufacturing Details
Production of cell culture supernatant

Operational Status
Fully operational (commercial production supported)

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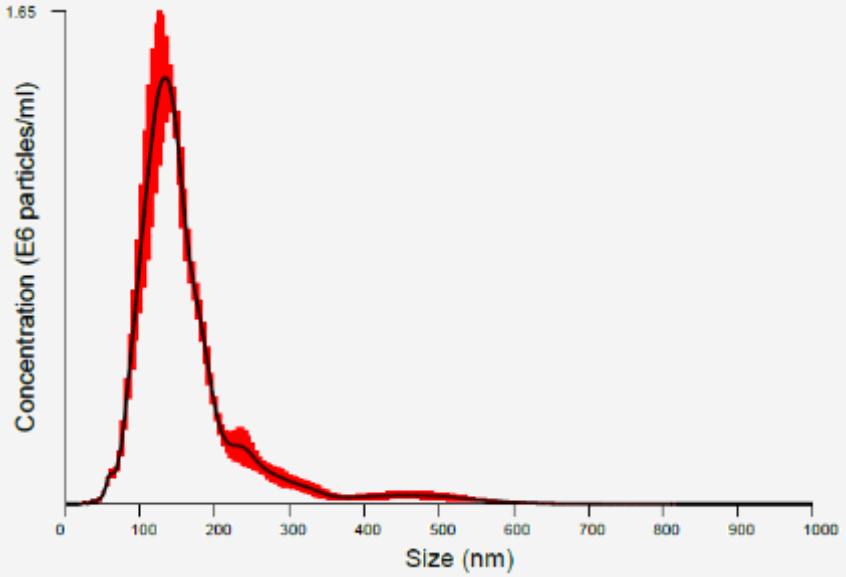
HLSI071: Extracellular Vesicle (EV) Characteristics

New Healios

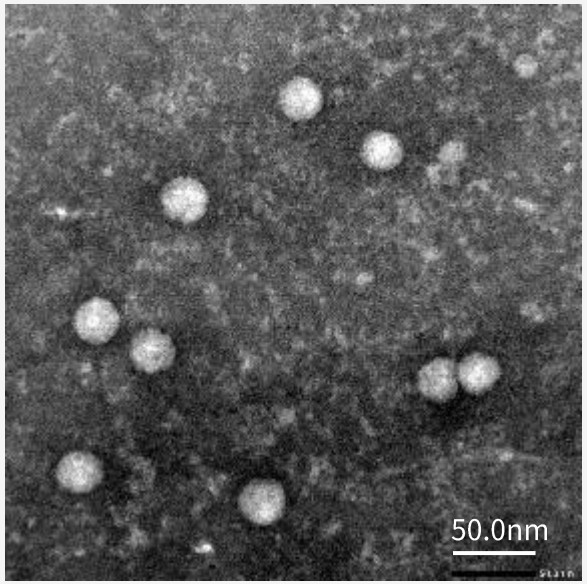
Evaluation of extracellular vesicles (EVs) in HLSI071 culture supernatant using NTA and TEM

Nanoparticle Tracking Analysis (NTA)



Particle size distribution (horizontal axis: particle diameter nm / vertical axis: concentration)

Transmission Electron Microscopy (TEM)



NTA and TEM analyses confirmed that EVs isolated from HLSI071 culture supernatant have a particle size distribution and morphology characteristics with exosomes.

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HLSI071: Growth Factor Profile and Functional Evaluation

New Healios

Detected Growth Factors (Representative Examples)

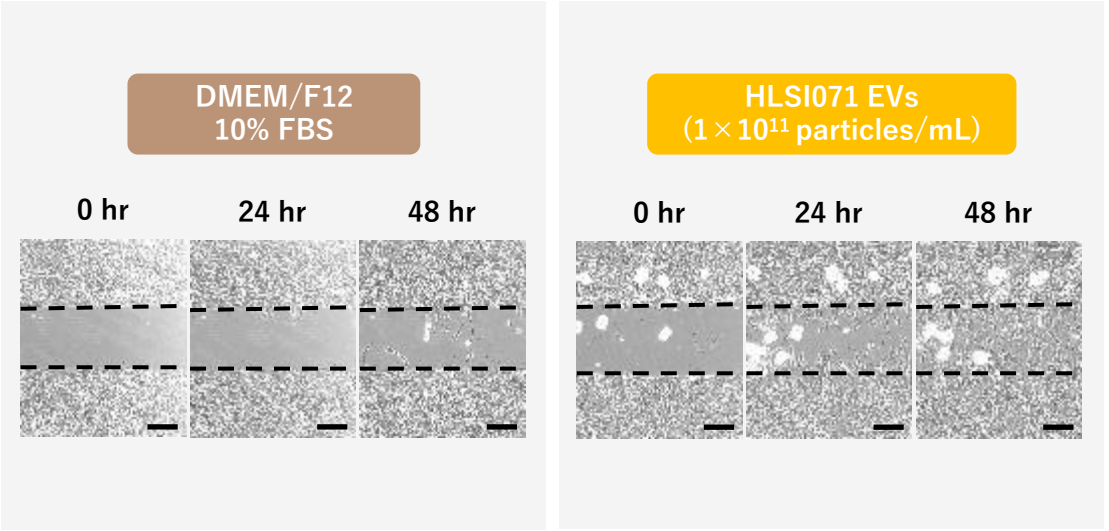
Amphiregulin	Growth Hormone	Neurotrophin-4
Brain-Derived Neurotrophic Factor	Heparin-Binding EGF-Like Growth Factor	Osteoprotegerin
Bone Morphogenetic Protein 5	Hepatocyte Growth Factor	Platelet-Derived Growth Factor AA
Bone Morphogenetic Protein 7	Insulin-Like Growth Factor Binding Protein 1	Placenta Growth Factor
Beta-Nerve Growth Factor	Insulin-Like Growth Factor Binding Protein 2	Stem Cell Factor Receptor (c-Kit)
Epidermal Growth Factor	Insulin-Like Growth Factor Binding Protein 3	Transforming Growth Factor Alpha
EGF Receptor	Insulin-Like Growth Factor Binding Protein 4	Transforming Growth Factor Beta 3
Endocrine Gland-VEGF (PROK1)	Insulin-Like Growth Factor Binding Protein 6	Vascular Endothelial Growth Factor A
Fibroblast Growth Factor 4	Insulin-Like Growth Factor 1	Vascular Endothelial Growth Factor Receptor 2
Fibroblast Growth Factor 7 (KGF)	Macrophage Colony-Stimulating Factor Receptor	Vascular Endothelial Growth Factor Receptor 3
Growth Differentiation Factor 15	Nerve Growth Factor Receptor	Vascular Endothelial Growth Factor D
Glial Cell-Derived Neurotrophic Factor	Neurotrophin-3	

Tissue regeneration, angiogenesis and neurotrophic support

Contains diverse growth factors, including HGF, VEGF, IGF, BDNF and GDNF. Promotes cell migration and wound healing, supporting its value as a cosmetic ingredient and for research.

(Detected by RayBiotech Human Growth Factor Array)

Functional Evaluation: Scratch Assay (Human Chondrocytes)



Scale Bar; 200 µm

※ EVs purified by ExoQuick-TC

HLSI071-derived EVs promoted wound healing (cell migration).

Control: DMEM/F12 + 10% FBS / EVs: 1×10^{11} particles/mL

*EVs purified using ExoQuick-TC / scale bar: 200 µm

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Update

Healios

Ongoing discussions with promising prospective customers to finalize supply arrangements

Jan 21, 2026

LOI with Alfresa Corporation regarding the Sale and Purchase of Culture Supernatant

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

As announced in the "**Basic Business Alliance Agreement and Bond Purchase Agreement with Alfresa Corporation**" dated June 5, 2024, Healios has entered into a basic business alliance agreement with Alfresa concerning the distribution and sale of HLSI071. 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.

Apr 7, 2026

Agreement with JENECELL to Supply Culture Supernatant

Supply agreement for culture supernatant (product name: HLSI071) as a raw material for cosmetics provided in Korea and worldwide

Oct 5, 2026

Healios has received an order worth 144 million yen as the initial order, **and completed shipment in October 2026, recognizing revenue in Q4 of the fiscal year ending December 2026. This was the first commercial shipment of its culture supernatant-based products.**

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Introduction of JENECELL, Co., Ltd.

Forever Young
JENECELL

Bringing Japan's Advanced
Stem Cell Science to Life in Korea

Company Overview

Company Name
JENECELL, Co., Ltd.

Location
397 Seochodae-ro #A-1907, Seocho-gu,Seoul, 06616, South Korea

Representative
CEO Hee-seok Ju

Business
Manufacturing, wholesale, and retail of pharmaceuticals, cosmetics, cosmetic raw materials, medical devices, and related products.

Date of Establishment
September 2025

Major Shareholders
Alfresa Corporation 100%

Pharmaceuticals Solutions

Advanced stem cell technology is used to develop customized regenerative pharmaceuticals that meet global standards of quality and safety.





Cosmetics Solutions

Stem cell culture media are used to develop premium functional cosmetics—innovative solutions for skin health and youth.

Ingredients Solutions

Human stem cell culture media are used to develop advanced ingredients applicable to a wide range of products.



Citation:https://www.jenecell.com/en/

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Financial Summary

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Overview of the Consolidated Income Statement (P/L)

Update

Healios

Compared to the same period last year, research and development expenses increased by 1.34 billion yen, resulting in a net loss of -4.53 billion yen.

(Unit: million yen)

	Fiscal Year Ending December 2025 Third Quarter	Q3 for the fiscal year ending December 2026		
			YoY Variance	Main Factors Driving Increase/Decrease
Revenue	79	22	-57	
Operating Profit	-2,333	-3,916	-1,583	Increase in Selling, General, and Administrative Expenses -282 Increase in R&D expenses -1,324
Profit	-4,146	-4,527	-381	Increase in financial income +507 Decrease in financial costs +1,028 (Financial income and financial costs mainly consist of non-cash profit and loss items; see explanations on the next page and onward.)
R&D Expenses	1,533	2,875	1,342	
Number of employees (full-time only)	60	90	30	

(Note) For details on the financial figures, please refer to the third quarter earnings summary p.9 announced today.

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Update

Healios

Details of finance income and finance costs

In the nine months ended September 30, 2026, we recorded finance income of ¥1,275 million and finance costs of ¥1,541 million.

Finance income was mainly due to the recording of ¥1,223 million in profit on remeasurement of investment securities, and ¥ 52 million in interest income.

Finance costs were mainly due to the recording of ¥763 million in loss on remeasurement of derivatives *1, ¥655 million in profit or loss transferred to equity interests held by external investors in the Saisei Fund *2, ¥71 million in share acquisition rights issuance costs, ¥27 million in interest expenses , and ¥24 million in interest expenses on bonds.

*1. 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, 26th and 27th stock acquisition rights issued by our 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.

*2. 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.

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Overview of the Consolidated Statement of Financial Position (B/S)

Update

Healios

Current assets as of the end of September 2026 amounted to 8.6 billion yen (+2.2 billion yen year-on-year), bringing total assets to 22.8 billion yen.

(Unit: million yen / Lower tier: composition ratio)

	Year-end of December 2025	End of Q3 for the fiscal year ending December 2026		
			vs. Prior Year-end	Main Factors Driving Increase/Decrease
Current Assets	6,441 (37.8%)	8,613 (37.7%)	2,172	Increase in cash and cash equivalents +1,743 (Balance of cash and cash equivalents: 7,423)
Non-Current Asset	10,613 (62.2%)	14,217 (62.3%)	3,604	Increase in other financial assets +2,395 Increase in right of use assets +1,110
Total Assets	17,054 (100.0%)	22,831 (100.0%)	5,777	
Current Liabilities	3,224 (18.9%)	4,993 (21.9%)	1,769	Increase in bonds and borrowings +800 Increase in other financial liabilities +795
Non-Current Liabilities	8,932 (52.4%)	11,155 (48.9%)	2,223	Increase in equity interests held by external investors in Saisei fund +1,798 Increase in lease liabilities +833 Decrease in bonds and borrowings: -800
Total Liabilities	12,155 (71.3%)	16,148 (70.7%)	3,993	
Total Capital	4,899 (28.7%)	6,683 (29.3%)	1,784	Profit Recorded: -4,527 Issuance of new shares +6,098
Total Liabilities and Equity	17,054 (100.0%)	22,831 (100.0%)	5,777	

(Note) For details of the financial figures, please refer to pages 7-8 of the third quarter earnings summary announced today.

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Healios

Expanding life. Exponentially.

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