FY2026 Q1 Financial Results

Company

HEALIOS K.K.

Date

May 14, 2026

Important Note on Future Events, etc

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Business Overview

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Unparalleled cell therapy market position

Business Strategy Scaling from Japan to the World

Number of Patients in Japan and the US
Over 1.5 million per year
"3 Indications"

Bone marrow-derived cells (Mid-term) → **iPS cells** (Long-term)

Market size
Developed countries
The leading cause of death: cancer

ARDS	Focus Area	Global Phase 3 trial initiated Preparing for conditional approval filing in Japan
Ischemic Stroke		Development policy review
Trauma		Phase 2 trial funded by the U.S. Department of Defense budget

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

By-product

Replacement Therapies RPE	Joint development with RACTHERA Co., Ltd.
Immuno-Oncology Gene-engineered NK cells	Akatsuki Therapeutics Inc. leads research and development

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

By-product

Sales of medical supplies

Selling UDC and culture supernatant, a byproduct obtained during the manufacturing process

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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.

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Key Achievements in Q1 2026 and April

Update

Healios

Bone marrow-derived cells

Start of ARDS Clinical Trial in Japan for the Global Phase 3 REVIVE-ARDS Study

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

iPS cells

Academic Paper on the anti-tumor effects of Healios eNK cells against lung cancer in “Cancer Immunology, Immunotherapy”

Medical materials

Agreement with JENECELL to Supply Culture Supernatant

Letter of Intent with Alfresa Corporation regarding the Sale and Purchase of Somatic Stem Cell Culture Supernatant

Initiating Production of Culture Supernatant at In-house Cell Processing Facility

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.

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Healios' Enabling of Stable Mass Cell Production

World's first — Approval for 3D manufacturing

Production Efficiency

Stability

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

World's largest — 3D production capability

500L successfully manufactured

Secured METI grant

Capacity to produce for 40,000 people annually

Previous 2D culture
Production Efficiency ✕ Stability ✕

Innovation — AI x Robots

Continuous pursuit of production efficiency

Strengthening the supply chain

AI experimental design	×	Robotics
Discovering high-performance culture conditions with fewer experiments		Obtain reproducible data with minimal variation in results

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New Healios

Compared with manual 2D culture methods

3D culture enables large-scale, stable production

Source: Sartorius AG

This image is of a 500L bioreactor system currently envisioned for use by Healios. Please note that future use is not guaranteed.

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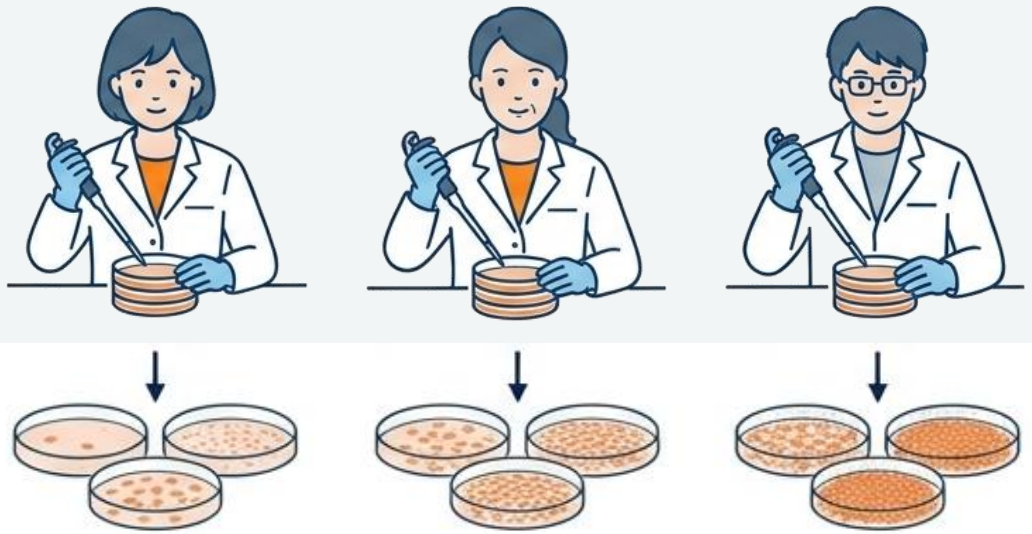
New Healios

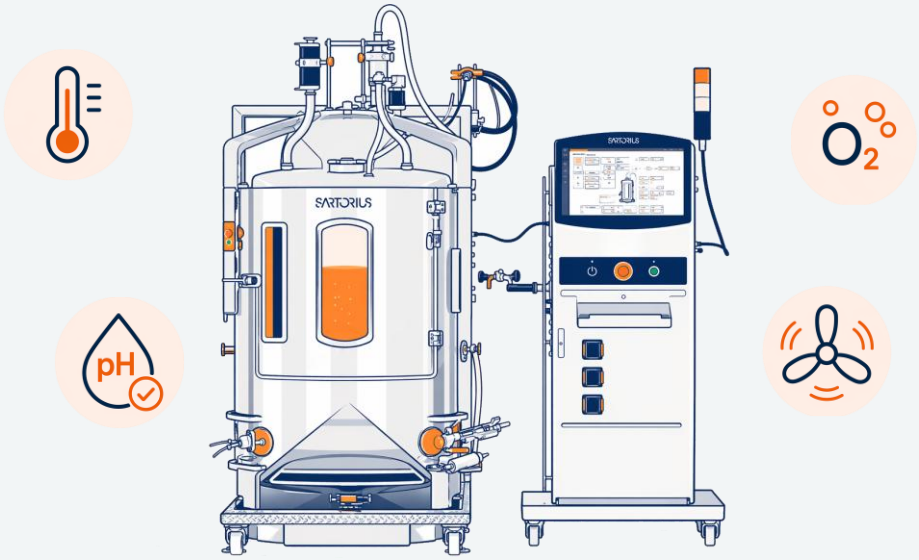
From manual, small-scale production to industrialized manufacturing. A turning point for the commercialization of cell therapy.

2D Culture (Conventional Method)



- Manual work in culture dishes
- Lot-to-lot variability among operators
- More personnel = higher costs = less consistent quality
- Skilled personnel must be dispatched for technology transfer

3D Culture



- Fully automated using a closed bioreactor
- High reproducibility with reduced lot-to-lot variability
- Minimal personnel
- Ease of technology transfer

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Manufacturing Facilities in Japan (Minaris / Healios)

Update

Healios

Minaris／Yokohama

50L 3D culture in operation

4F Shibusawa ABC Building #1, 1 Ebisu-cho, Kanagawa-ku, Yokohama, Kanagawa, Japan

Close to Narita and Haneda airports

48,400 sq. ft.
6 clean rooms

Global Manufacturing Facilities of Minaris

Healios／Kobe

Scheduled to begin operations in January 2028

Inside DP-Lab KOBE, Minatojima-Minamimachi, Chuo-ku, Kobe, Hyogo, Japan

Utilizing the FY2024 supplementary budget of METI to build infrastructure and commercialize a CDMO business capable of serving the global market
Installation of a 500L bioreactor planned, with capacity to supply 40,000 patients annually

DP-Lab, a rental lab operated by Daiwa House (Japanese)

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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)

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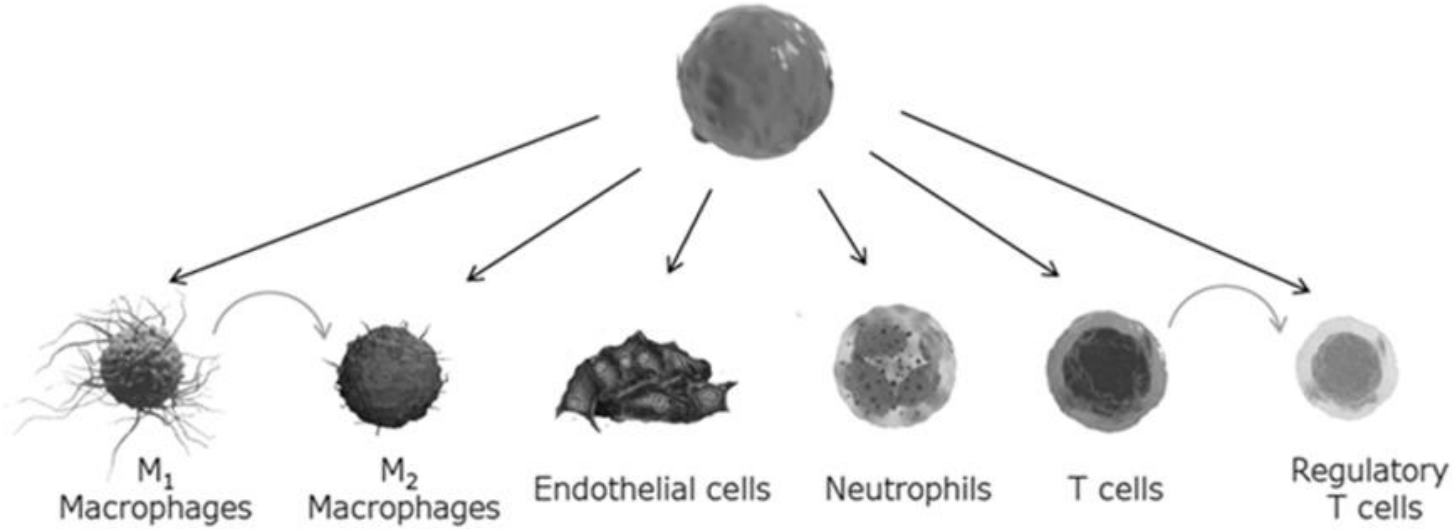
MoA of MAPC (Invimestrocel): Immunomodulation and Vascular Endothelial Protection

Invimestrocel



Expected effects of MAPC	Key publications
Immunomodulation	Kovacsovics-Bankowski et al. ”Clinical scale expanded adult pluripotent stem cells prevent graft-versus-host disease” Cellular immunology 2009
Anti-inflammatory effects	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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Strengths of the MAPC (Invimestrocel) Platform

Systemic inflammatory response-related conditions (SIRC)

In this group of extremely severe conditions with no available therapies, we will first obtain approval for ARDS and then pursue label expansion.

Core pathology

Treatable through the immunomodulation and vascular endothelial protection of invimestrocel

(Runaway inflammation → multi-organ dysfunction)

Platform strengths

Strong efficacy data across multiple conditions

A large market with no competitors

In-house commercialization focused on emergency care is achievable

Indications	Affected organs	Efficacy and development stage of HLCM051
ARDS	**Lung**	Preparing for Japan filing, Global Phase 3, approximately 40% improvement in mortality
AKI	**Kidney**	U.S. Phase 2, 60% improvement in mortality, 47% improvement in kidney function
Acute ischemic stroke	**Brain**	Japan/U.S. Phase 3, 17% improvement in mRS <2, 15% improvement in mRS <3
Post-traumatic multiple organ failure	**Multiple organs**	
Sepsis	**Systemic**	

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Pipeline

	Development Code	Therapeutic Area	Therapy	Region	Discovery	Pre-Clinical	Clinical P1	Clinical P2	Clinical P3	Application	Approval	Comments
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 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

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HLCM051　ARDS

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Key Milestone

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

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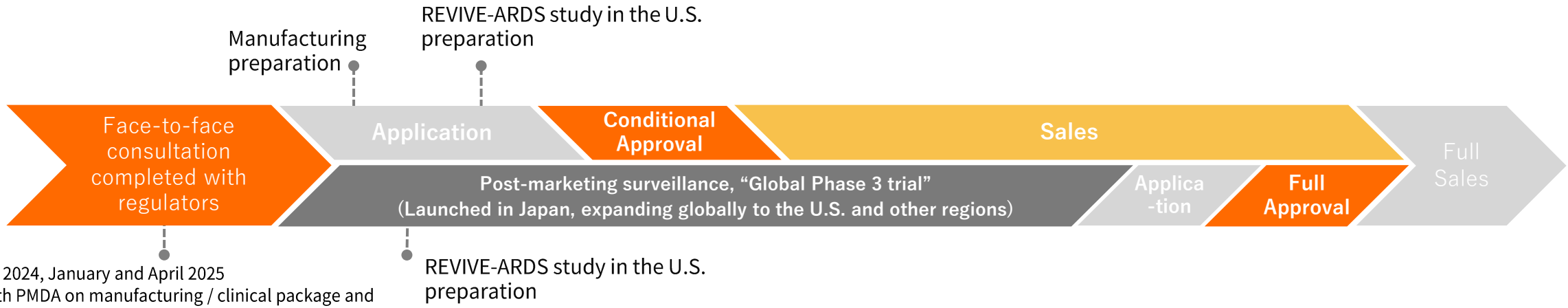
Overview of Invimestrocel (HLCM051) ARDS

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: 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 an application for manufacturing and marketing 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 (aiming for conditional and time-limited approval) Preparing a commercial production system for the pharmaceutical product in anticipation of the application



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REVIVE-ARDS Study: Trial Overview

Overview	Double-blind, randomized, placebo-controlled (administered within 48 hours after ARDS diagnosis)
Subjects	ARDS patients caused by pneumonia
Regions	United States, Japan, Asia-Pacific, and Europe
Number of cases (patients)	Up to 550 cases (HLCM051: 275; placebo: 275) (Interim analysis will be conducted at 300 and 400 cases. If statistically significant efficacy of the investigational product is confirmed at either point, the trial will be completed.) *Regional enrollment numbers have not yet been determined
Primary endpoint	VFD (number of days without mechanical ventilation during the 28-day period)
Secondary endpoints (partial)	Mortality (within 90 days after administration)

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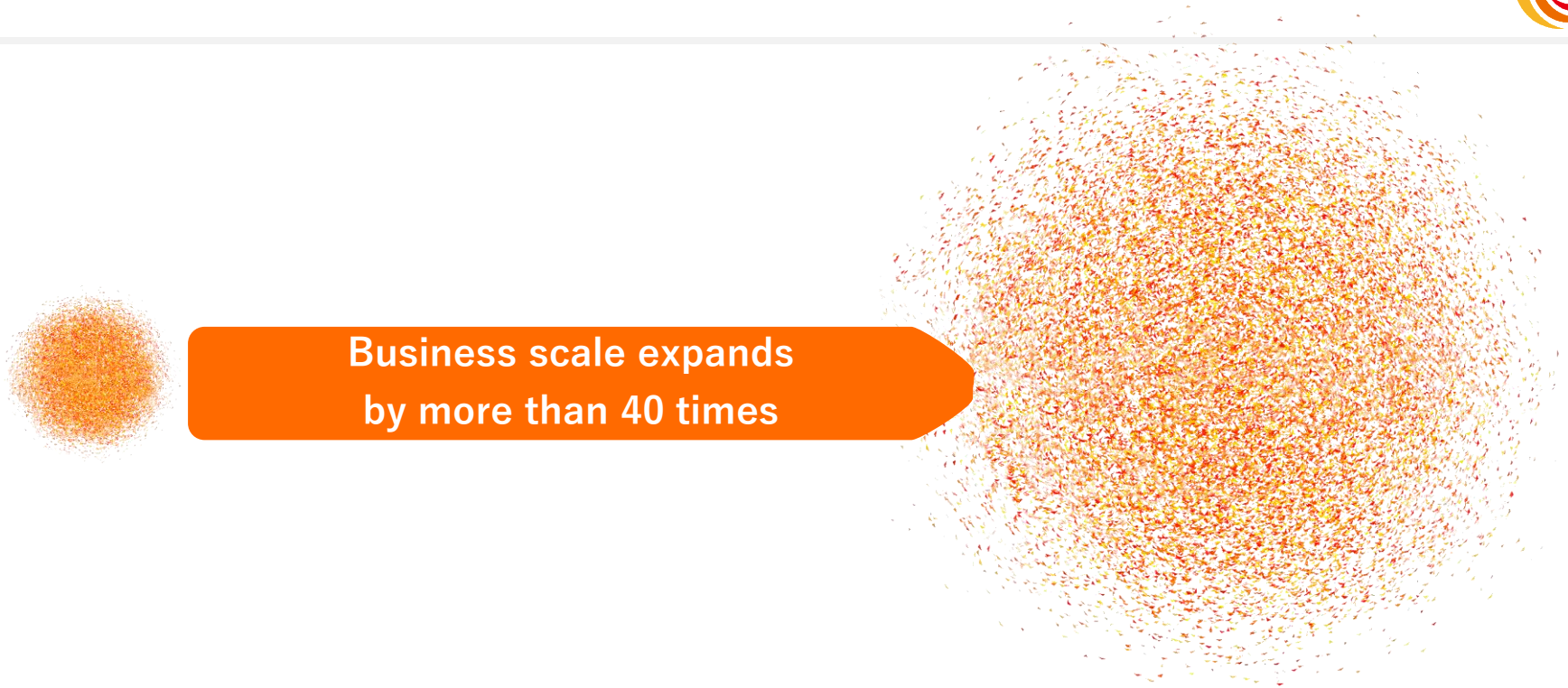
Potential Global ARDS Market



Japan: 28,000 patients

Worldwide: over 1.1 million patients

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 order of market size)

Japan: Company estimate based on epidemiological incidence data and Japan's total population statistics
US：Diamond M et al. 2023 Feb 6. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–.PMID: 28613773
EU：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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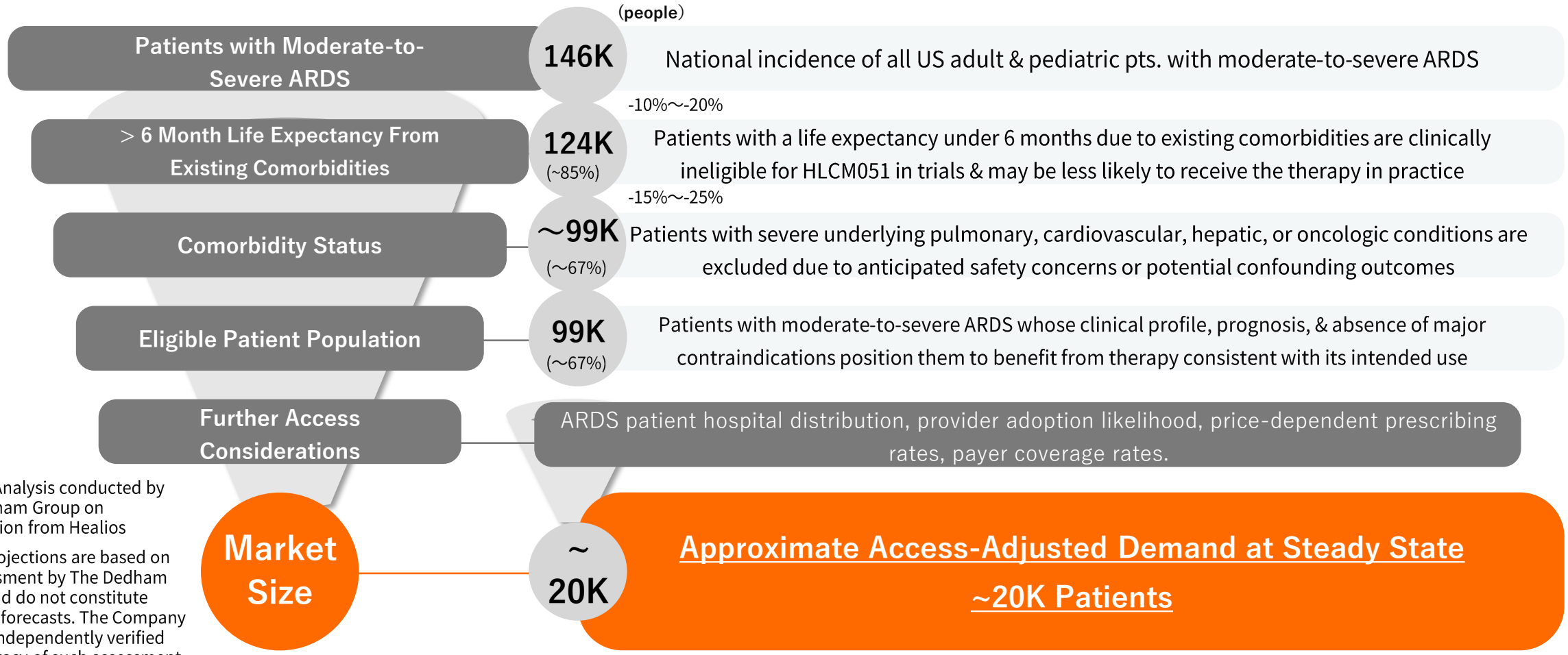
Invimestrocel ARDS: U.S. Market Size Estimates

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



Source: Analysis conducted by The Dedham Group on commission from Healios

These projections are based on an assessment by The Dedham Group and do not constitute earnings forecasts. The Company has not independently verified the accuracy of such assessment and does not guarantee these results.

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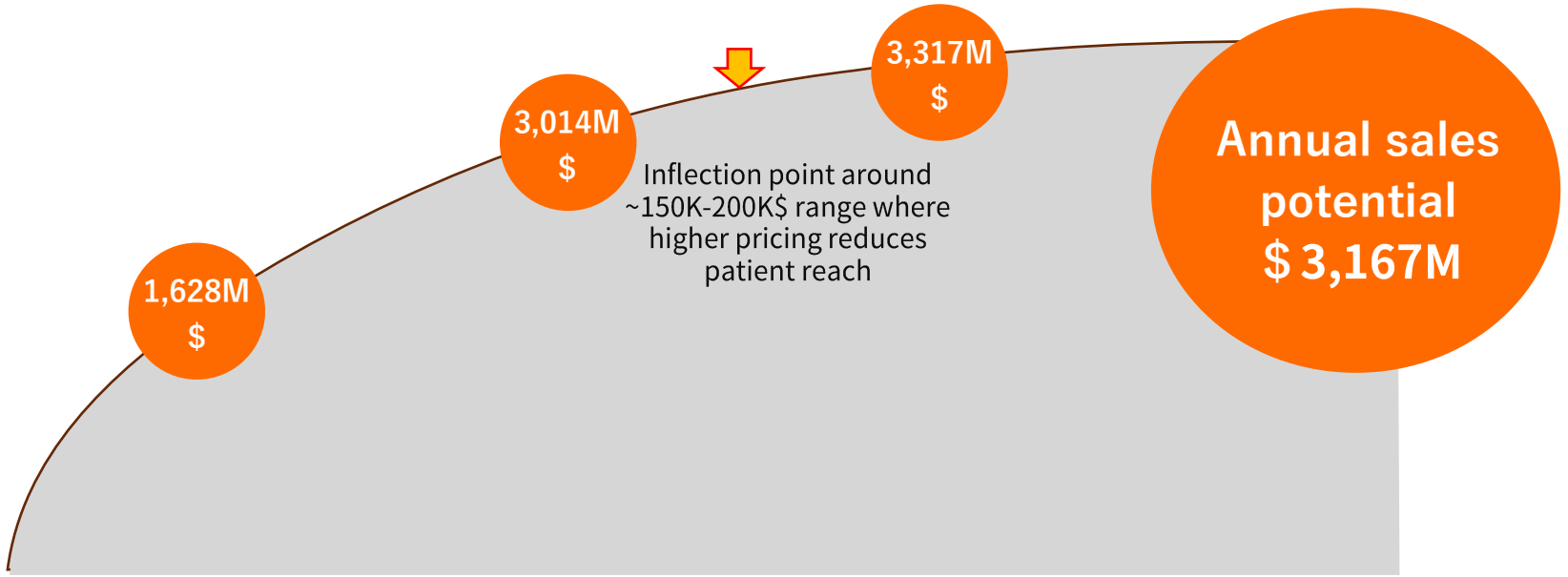
Invimestrocel ARDS: US Revenue Potential

Projected relationship between sales and unit price



Source: Analysis conducted by The Dedham Group on commission from Healios

These projections are based on an assessment by The Dedham Group and do not constitute earnings forecasts. The Company has not independently verified the accuracy of such assessment and does not guarantee these results.

Drug pricing	$ 75,000	$ 150,000	$ 250,000
Total number of treated patients from Year 5 onward	21.7K	20.1K	13.3K

Pricing scenarios up to $200K threshold support broad access, high treatment volumes, & stable long-term commercial

Approximate Access-Adjusted Demand at Steady State ~20K Patients

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HLCM051　ISCHEMIC STROKE

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Overview of Invimestrocel (HLCM051) Stroke

Update

Healios

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

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HLCM051　Trauma induced AKI

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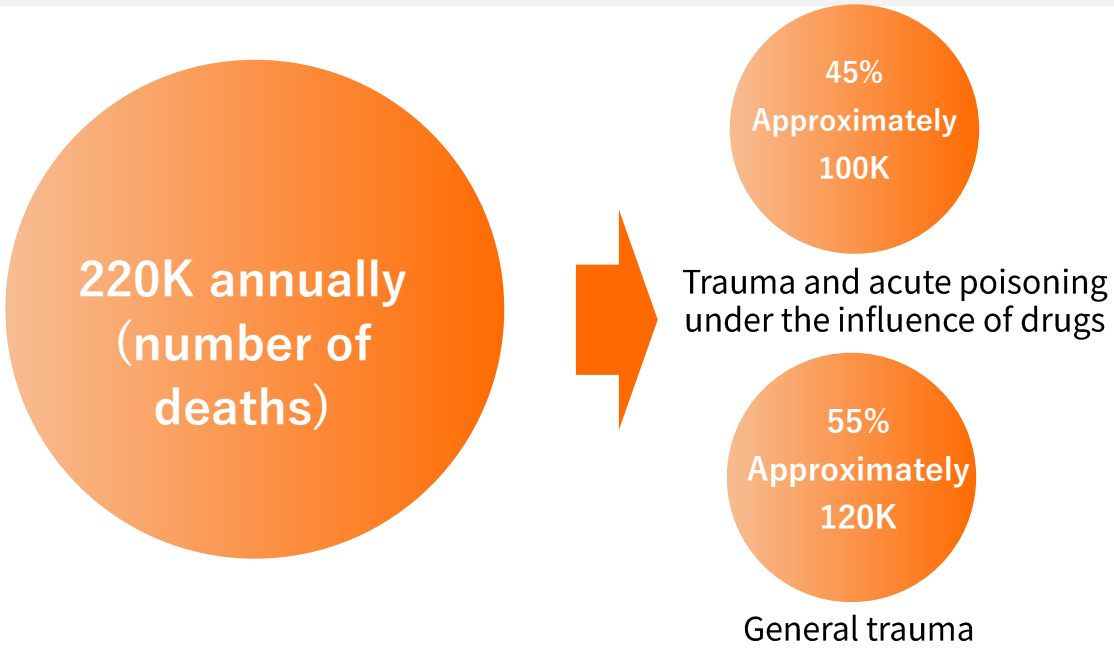
U.S. Trauma Market



Cause of death	3rd leading cause of death across all age groups	Leading cause of death in people under the age of 45
	220K deaths annually	87K deaths annually

Combat trauma	Afghanistan	Iraq War
	Fatalities: 2,354 Wounded: 20,149	Fatalities: 4,431 Wounded: 31,994

(Source) DOD CDC NIH

Pathophysiological progression from trauma to death

Systemic Inflammatory Response Syndrome (SIRS) caused by trauma is an excessive self-defense response to external stressors such as trauma (traffic accidents, gunshot wounds, etc.), drugs, and infection, initially resulting in autonomic, endocrine, hematologic, and immunologic changes.
SIRS: Systemic Inflammatory Response Syndrome

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)

Update

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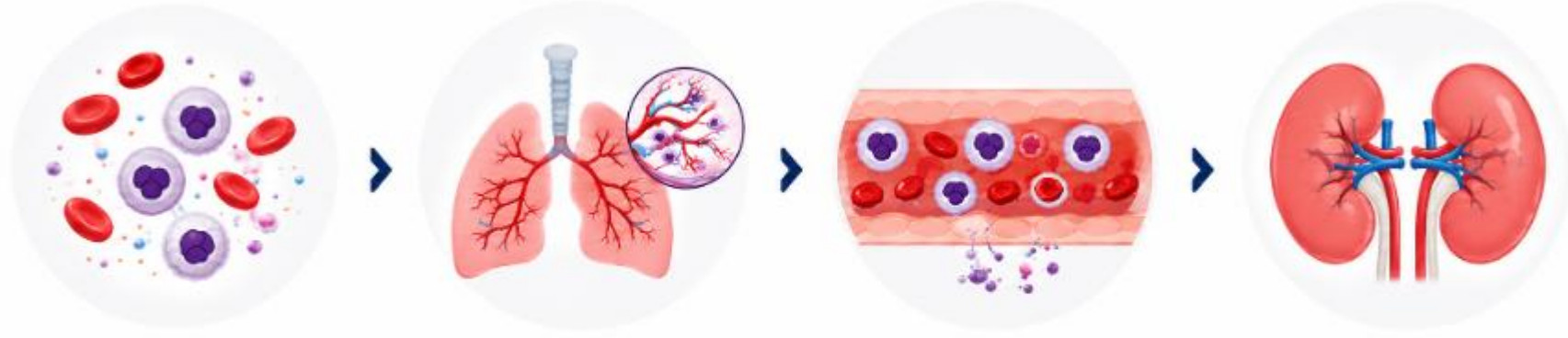
Development of AKI following trauma caused by traffic accidents, industrial accidents, gunshot wounds, etc.

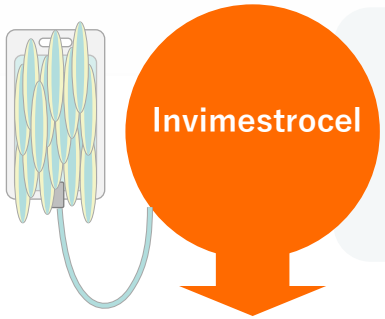


1 Systemic Inflammatory Response (SIRS)

2 Endothelial Dysfunction & Microcirculatory Impairment

3 Renal Hypoperfusion & Inflammatory Cell Infiltration

4 Acute Kidney Injury (AKI)



Anti-inflammatory effects through induction of macrophage polarization from M1 to M2

IL-10 ↑ (anti-inflammatory)

TNF-α / IL-1β ↓ (inflammation suppression)

Suppression of systemic inflammation

Stabilization of vascular endothelium

Improvement of microcirculation

Reduction of kidney injury (suppression of AKI)

Suppression of progression to multiple organ failure

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Analysis of existing data confirmed the potential for additional effects of Invimestrocel

Important findings regarding the pharmacological characteristics of HLCM051 have been obtained from trial data in ARDS patients conducted in the United States and the United Kingdom, particularly in a subgroup of severely ill patients with concomitant acute kidney injury (AKI).

Reduced mortality in severely ill patients

↓ 60 %

In a subgroup of severely ill pneumonia patients, HLCM051 treatment showed a trend toward a 60% reduction in mortality

Improvement in kidney failure in patients with concomitant AKI

↑ 47.2 %

In patients with concomitant acute kidney injury (AKI), kidney dysfunction was improved by 47.2%

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Overview of the Invimestrocel Trauma MATRICS-1 Study

MATRICS-1 Study（U.S.）

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

* Centers for Disease Control and Prevention

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MATRICS-1 Study: Trial Overview

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

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HLSI071　Culture Supernatant

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Conclusion of Supply Agreements, etc., with Customers

Update

Healios

Currently engaged in individual 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 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.

April 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

Healios has received an order for products worth 144 million yen as the initial order and will begin shipping the products to JENECELL, Co., Ltd. in stages starting in July 2026.

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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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New Healios

Provided in two presentations, “lyophilized” and “liquid,” depending on the intended use and 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 as is

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

Recommended applications
Cosmetic 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

New Healios

Lyophilized

Single-use design*

*Reduced contamination risk

Convenience

Easy to transport and store
Optimal for global deployment

Stability

Long-term storage possible with stable quality

Safety

Sterility testing completed

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

Overview of the CPC

CPC begins full-scale operations

(1) Address:
1-5-5 Minatojima-Minamimachi, Chuo-ku, Kobe City, Hyogo Prefecture. Within the Business Support Center for Biomedical Research Activities (BMA)

(2) Total floor area: Approximately 80m²

(3) Purpose of use: Production of Culture Supernatant

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Financial Highlights

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Consolidated Statement of Income

Update

Healios

(Units: millions of yen)

	FY2025 Q1(YTD)	FY2026 Q1(YTD)		
			YoY variance	Main reasons for increase/decrease
Revenue	38	8	-29	
Operating profit	-744	-1,130	-386	Increase in SG&A expenses -65 Increase in R&D expenses -315
Profit	-2,562	-3,457	-895	Increase in finance income +52 Increase in finance costs -552 (Primarily non-cash activity; please refer to the next page for details)
R&D expenses	482	798	315	
Number of employees	57	72	15	

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

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Supplemental Explanation of Finance Income and Finance Costs

Update

Healios

Details of finance income and finance costs

In the three months ended March 31, 2026, we recorded finance income of ¥326 million and finance costs of ¥2,659 million.

Finance income was mainly due to the recording of ¥260 million in profit on remeasurement of investment securities, ¥48 million in profit or loss transferred to equity interests held by external investors in the Saisei Fund *1 and ¥ 16 million in interest income.

Finance costs were mainly due to the recording of ¥2,573 million in loss on remeasurement of derivatives *2,and ¥71 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 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. 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.

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Consolidated Statement of Financial Position

Update

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(Units: millions of yen)

		December 31, 2025	March 31, 2026		
				Variance	Main reasons for increase/decrease
	Current assets	6,441 (37.8%)	11,837 (50.4%)	5,396	Increase in cash and cash equivalents +5,188 (Cash and cash equivalent balance at 3/31/26 was 10,868)
	Non-current assets	10,613 (62.2%)	11,647 (49.6%)	1,034	Increase in other financial assets +1,081
Total assets		17,054 (100.0%)	23,484 (100.0%)	6,430	
	Current liabilities	3,224 (18.9%)	5,783 (24.6%)	2,559	Increase in other financial liabilities +2,607
	Non-current liabilities	8,932 (52.4%)	10,124 (43.1%)	1,192	Increase in equity interests held by external investors in Saisei Fund +1,209
Total liabilities		12,155 (71.3%)	15,907 (67.7%)	3,752	
Total equity		4,899 (28.7%)	7,577 (32.3%)	2,678	Recording of loss -3,457 Issuance of new shares +6,098
Total liabilities and equity		17,054 (100.0%)	23,484 (100.0%)	6,430	

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