FY2025 Q1 Financial Results

Company

HEALIOS K.K.

Date

May 13, 2025

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Business Overview

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FY2025 Key Milestones

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

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Results for FY2025 Q1 (January - March)

- Agreed with PMDA on the contents of the clinical data package for the conditional and time-limited approval of ARDS in Japan and on all parts including manufacturing.
- Signed an agreement with AND medical to supply culture supernatant and received the first order.
- Concluded a master collaboration agreement and license option agreement with Akatsuki of eNK cells.

Results for 2025 April

- Completed formal regulatory consultation for ARDS and agreed with PMDA on inclusion of Japanese patients in global Phase 3 trial (REVIVE-ARDS study) of ARDS.
- Selected for NEDO project and in accordance with that policy decided to apply for conditional and time-limited approval for Ischemic Stroke in Japan. (Conditional on conducting a post-marketing study using a registry linked to electronic health records using a Large Language Model (LLM).)

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Update Healios

Three pillars to monetization

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

Medical Materials

HLCM051 Culture Supernatant

Universal Donor Cell

iPS cell lines, etc.

SIFU®

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

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

Bone marrow-derived cells

ARDS

Global Phase 3 trial under preparation

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

Ischemic Stroke

Conditional Approval Application Policy in Japan

Trauma

Phase 2 trial with U.S. DoD budget

iPS cells

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

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

Business scale expansion by securing global rights

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

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

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

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

Base cost (business operations)

Global Phase 3 Trial Cost

Contract manufacturing for Japan (HLCM051)

＊Not simply an expense but reflects the building up of inventory to be sold after approval in Japan.

Warrant exercises

Target profitability on monthly basis

Sales of culture supernatant and cosmetics materials

Start of order

Start of shipment for cosmetics

Start of full shipment

ARDS(Japan) Sales

ARDS(U.S.) Lump-sum payment for interim analysis affiliation

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

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

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

Link

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

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

Link

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

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

Link

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

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

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

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

Link

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

Background of Policy Decisions

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

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Rapid advancement of AI / LLM paves new path for conditional and time-Limited approval for the Treatment of Ischemic Stroke

1. Trends in efficacy, safety + new avenues for post-approval validation

- Enables verification through a large registry using the LLM system

2. Issuance of guidance with conditional deadlines

- Guidance issued on conditional and time-limited approvals; further discussions with regulators to identify a path forward

3. Validation by FSR

- Kyushu University has the largest registry for stroke with overlapping indications in Japan (Fukuoka Stroke Registry “FSR”), which enables early validation of the LLM system.
- Accurate and large-scale prognosis of patients treated as usual can be predicted from the data of 17,000 cases in FSR
- This dramatically speeds up the validation of all systems and creates the possibility of the above approaches.

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Pipeline

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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			Agreed with FDA on Global Phase 3 trial design in the U.S. Patients included from Japan Fast Track and RMAT designation (USA)*1
	HLCM051	Ischemic Stroke	invimestrocel	Japan			Phase 2/3 completed and consulting for approval			Aim to apply for conditional and time-limited approval conditional on conducting post-marketing surveillance using LLM. SAKIGAKE designation (Japan) Fast Track and RMAT designation (USA)
				Global (USA)			Phase 3			
	HLCM051	Trauma	invimestrocel	Global (USA)			Phase 2			Funded by MTEC (United States Department of Defense) and the Memorial Hermann Foundation

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

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

*2 Retinal Pigment Epithelium

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

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

Note: Excludes pipeline assets scheduled to be carved out

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HLCM051 ARDS: Development Status

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Inflammatory Conditions

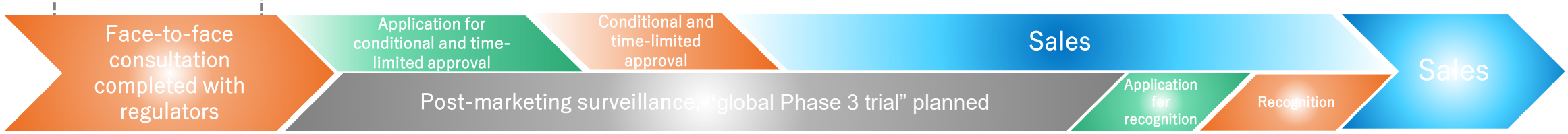
Application for conditional and time-limited approval and Global Phase 3 clinical trial (REVIVE-ARDS Study) under preparation

ARDS

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

September 2024
Agreed with FDA on global trial

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



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HLCM051 Ischemic Stroke: Development Status

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Inflammatory Conditions

Policy decision to apply for conditional and time-limited approval in Japan

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”

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



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HLCM051 Trauma: Development Status

MATRICS-1 study（USA）

Inflammatory Conditions

Trauma

Ongoing 156 patient, Phase 2 clinical trial in trauma

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

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

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

* Source: the Centers for Disease Control (CDC)

MATRICS-1 study

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

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Conference Presentations and Articles (FY2025)

New

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.

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Agreement with AND medical to Supply Culture Supernatant

Link

Outline of the Agreement

- Healios will receive an initial order of 420 million yen for the subject product. From that amount, we will receive 200 million yen as an advance payment beginning in Q2 FY2025.
- The timing of future orders and the volume and timing of product shipments will be determined in consultation with AND medical.

Price: Based on Healios' own market analysis, most culture supernatant products carry a unit price of approximately 10,000 yen to 30,000 yen per cubic centimeter (cc) when sold as a raw material. The final unit price per cc will be determined with AND medical after additional confirmation of the quality of Healios produced culture supernatant.

Reference：

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

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The Conclusion of a Master Collaboration Agreement and License Option Agreement with Akatsuki

Master Collaboration Agreement

Link

- Akatsuki will lead the research and development of eNK cells, and Healios will be contracted by Akatsuki to conduct the research and development work.
- This transition will reduce Healios' financial burden, with a projected reduction of approximately 770 million yen in the fiscal year ending December 2025 and payment by Akatsuki to Healios of 360 million yen was received by February 2025.

License Option Agreement

- Healios has granted Akatsuki an option to enter into a license agreement to research, develop, manufacture, and market eNK cells in all therapeutic areas, particularly in the field of oncology.
- Healios agreed to acquire Akatsuki's shares and stock acquisition rights upon the entering of a license agreement resulting from the exercise of the option. The details of these issuances and other details will be determined after further discussions between the two companies.
- Healios and Akatsuki have agreed on the key terms and conditions of a license agreement that would result from the exercise of the option, including royalties, development and sales milestones.

Benefits of this Cooperation

- Healios focuses on approval and marketing of HLCM051 for ARDS in Japan and executing on the global P3 trial.
- Facilitate future service offerings to other clients and capture new business opportunities.

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Financial Highlights

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Consolidated Statement of Income

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(Units: millions of yen)

	FY2024 Q1(YTD)	FY2025 Q1(YTD)		
			YoY variance	Main reasons for increase/decrease
Revenue	10	38	27	
Operating profit	-1,049	-744	305	Decrease in SG&A expenses ＋85 Decrease in R&D expenses +201
Profit	-2,421	-2,562	-142	Decrease in finance income -30 Increase in finance costs -343 (Primarily non-cash activity; please refer to the next page for details)
R&D expenses	683	482	-201	
Number of employees	60	**57**	-3	

(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

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Details of finance income and finance costs

In the three months ended March 31, 2025, we recorded finance income of ¥273 million and finance costs of ¥2,108 million.

Finance income was mainly due to the recording of ¥255 million in profit or loss transferred to equity interests held by external investors in the Saisei Fund *1 and ¥ 18 million in interest income.

Finance costs were mainly due to the recording of ¥2,045 million in loss on remeasurement of derivatives *2 ,¥24 million in loss on remeasurement of investment securities ,and ¥15 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 1st 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.

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Consolidated Statement of Financial Position

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(Units: millions of yen)

	December 31, 2024	March 31, 2025		
			Variance	Main reasons for increase/decrease
Current assets	4,275 (30.1%)	6,010 (38.3%)	1,734	Increase in cash and cash equivalents +1,791 (Cash and cash equivalent balance at 3/31/25 was 5,463)
Non-current assets	9,916 (69.9%)	9,678 (61.7%)	-238	Decrease in other financial assets -181
Total assets	14,191 (100.0%)	15,688 (100.0%)	1,496	
Current liabilities	3,350 (23.6%)	5,026 (32.0%)	1,676	Increase in other financial liabilities +2,050
Non-current liabilities	8,758 (61.7%)	8,687 (55.4%)	-71	Decrease in equity interests held by external investors in Saisei Fund -72
Total liabilities	12,108 (85.3%)	13,713 (87.4%)	1,605	
Total equity	2,084 (14.7%)	1,975 (12.6%)	-109	Recording of loss -2,562 Issuance of new shares +1,918
Total liabilities and equity	14,191 (100.0%)	15,688 (100.0%)	1,496	

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

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＜Contact information＞
IR & PR Div.
HEALIOS K.K.

Press contact: pr@healios.jp
Investor contact: ir@healios.jp
https://www.healios.co.jp/contact/