FY2024 Financial Results

Company

HEALIOS K.K.

Date

February 14, 2025

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Business Overview

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FY2024 Results

- Acquisition of substantially all of the assets of Athersys, Inc.
- Agreement with the FDA to conduct the global Phase 3 trial of MultiStem® for the treatment of ARDS.
- Finalized agreement with the regulator and initiated preparation of the application package for conditional and time-limited approval of Multistem for ARDS in Japan.
- Signed an agreement with AND medical to supply culture supernatant and received the first order.

FY2025 Targets

- File for conditional and time-limited approval in Japan for Multistem for ARDS.
- Initiation of global Phase 3 trial for ARDS.
- Full-scale shipment and sales of culture supernatant.

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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

Consulting with regulatory authorities on application policy in Japan

Trauma

Phase 2 trial with U.S. DoD budget

iPS cells

Replacement Therapies
RPE
First subject enrollment initiated in July 2024

Immuno-Oncology
Gene-engineered NK cells
Akatsuki 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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HLCM051 ARDS: Global Phase 3 Trial and Conditional and Time-limited Approval in Japan

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12/25/2024: Confirmed the post approval manufacturing method and quality control with PMDA

Link

Details of Agreement:

- 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.

01/15/2025: Agreed on the clinical data package for the application with PMDA

Link

Details of Agreement:

- 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.

Timeline and actions are determined. Non-clinical and clinical data are sufficient.

Termination of discussions with Nobelpharma regarding the Development and Commercializing Collaboration Agreement

Link

- Clinical development and its costs are no longer necessary due to the cancellation of Phase 3 trial in Japan.

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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.
- 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.)
- 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.

Letter of Intent with Cell Resources

Link

- Entered into a LOI for a business alliance concerning the production of cell culture supernatant.

(With respect to the start-up and subsequent operation of the manufacturing facility, we will discuss the frame of the business alliance, role and cost sharing, etc.)

Launch of Medical Materials and Equipment Division

Link

- To ensure a stable supply of medical supplies, mainly culture supernatants, and to expand the related business.

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New Healios

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

Master Collaboration Agreement

Link

- Akatsuki Therapeutics Inc. is a wholly-owned subsidiary of Saisei Ventures LLC
- 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 approximately 360 million yen 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 MultiStem® 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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Cash Flow Plan (short-term: existing warrant exercises, mid-term: culture supernatant, long-term: ARDS)

New Healios

Base cost (business operations)

＊Factoring in fixed cost reductions from externalization of eNK cell R&D operations

Global Phase 3 Trial Cost

Contract manufacturing for Japan (MultiStem®)

＊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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Pipeline

Update

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	Development Code	Therapeutic Area	Therapy	Region	Discovery	Pre-Clinical	Clinical P1	Clinical P2	Clinical P3	Comments
Inflammatory Conditions	HLCM051	ARDS	MultiStem®	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. Fast Track and RMAT designation (USA)*1
	HLCM051	Ischemic Stroke	MultiStem®	Japan			Phase 2/3			Consulting with regulatory authorities on application policy in Japan based on clinical trial data from the U.S. and Japan. SAKIGAKE designation (Japan) Fast Track and RMAT designation (USA)
				Global (USA)			Phase 3			
	HLCM051	Trauma	MultiStem®	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 Sumitomo Pharma 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 Gastric cancer, Mesothelioma, Lung cancer and Hepatocellular carcinoma

Note: Excludes pipeline assets scheduled to be carved out

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HLCM051 ARDS: Development Status

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Inflammatory Conditions

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 on September 6)**
- **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 to apply for Japanese approval**

August 2021
Announcement of top-line results of ONE-BRIDGE study

February 2023
After consultations with the regulator, the design of an additional study was determined.

July 2023
Regulator agreed to use of 3D bioreactor-based manufacturing method produced product.

April 2024
Acquired Multistem technology platform including all global rights

September 2024
Agreed with FDA on global trial

December 2024, January 2025
Agreed with PMDA on manufacturing / clinical package
Preparing to apply for conditional and time-limited approval in Japan



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HLCM051 Ischemic Stroke: Development Status

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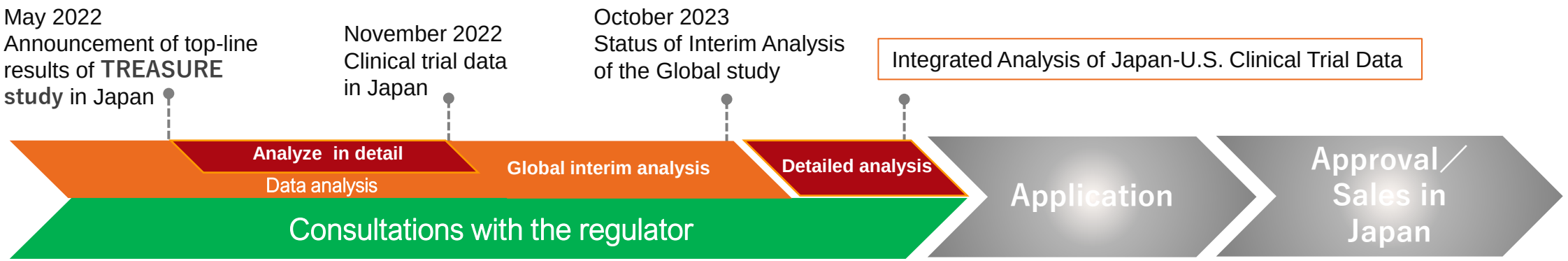
Inflammatory Conditions

Ischemic stroke	**Consulting with regulatory authorities on application policy in Japan based on clinical trial data from the U.S. and Japan.**



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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 MultiStem® in the treatment of trauma also has meaningful potential US military applicability

* Source: the Centers for Disease Control (CDC)

MATRICS-1 study

Overview: MultiStem® 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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Appointment of D.J. Skelton as an Advisor to Healios

Link

New



Career

Special Assistant to the Assistant Secretary of Defense for Health Affairs
United States Department of Defense

US Army
Foreign Area Officer
Dongcheng District, Beijing

Company Commander
Vilseck, GermanyVilseck, Germany
Company Commander for Comanche Company
1st Squadron 2D Cavalry Regiment
Vilseck, Germany

Military Advisor to Deputy Secretary of Defense
United States Department of Defense · Full-time

United States Military Academy at West Point
BS, Political Science1999 - 2003

D.J. Skelton graduated from the United States Military Academy at West Point, and served in Afghanistan, where he was wounded but survived. Later, he served in the U.S. Army as a company commander and as a foreign area officer (China), and then as Military Advisor to Deputy Secretary of Defense and Special Assistant to the Assistant Secretary of Defense for Health Affairs.
Mr. Skelton, who himself suffered from **ARDS** as well as near-fatal **trauma** after being attacked, understands firsthand the need for MultiStem®, which is being developed by Healios.
Healios has invited Mr. Skelton, who has such a background and relationships, to join us as an advisor and he will help us promote our global drug development activities, especially in discussions with the U.S. government and in promoting cooperation with medical facilities conducting clinical trials.

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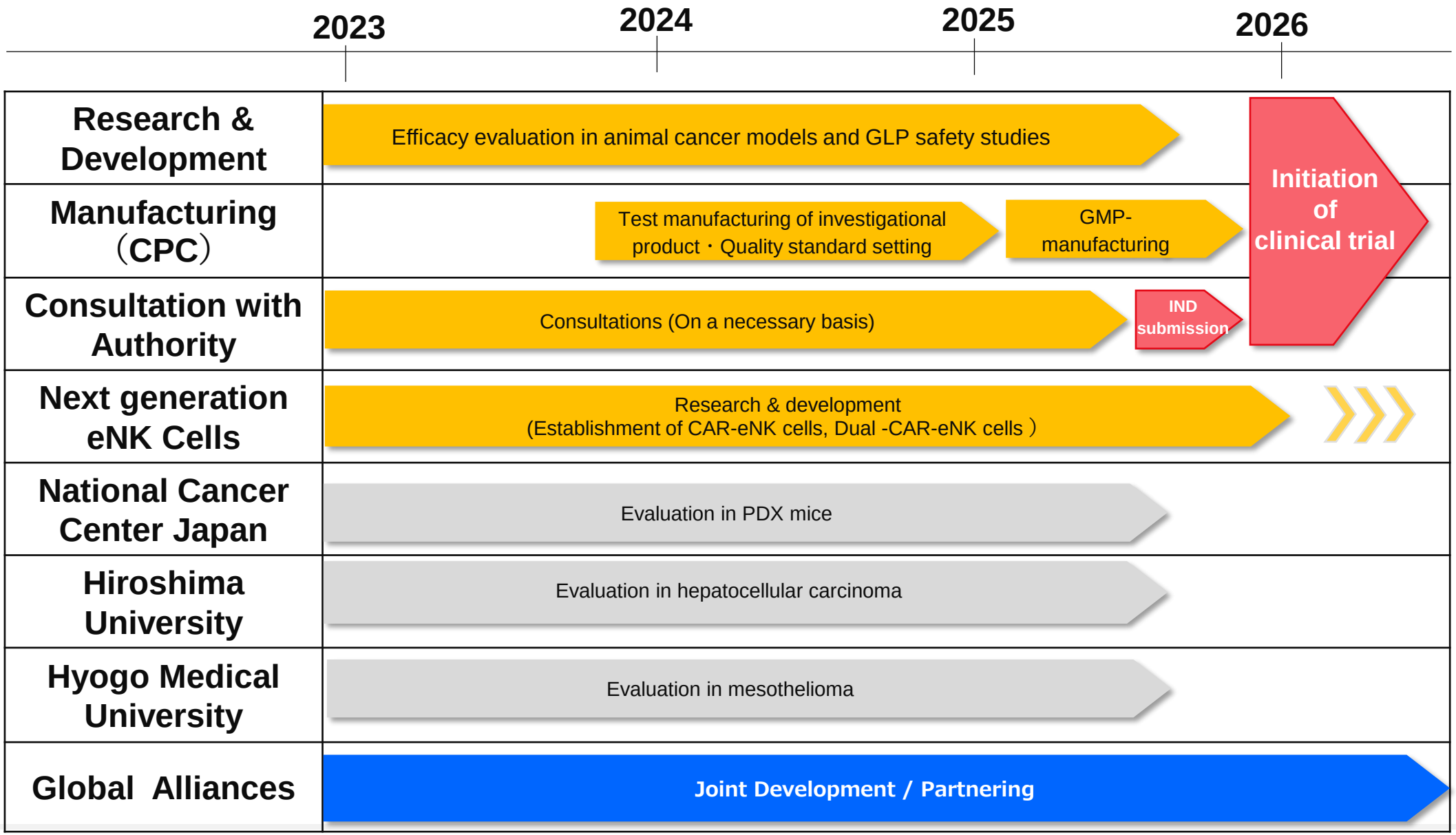
R&D Roadmap of eNK Cells (HLCN061)



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Conference Presentations and Articles (FY2024)

Link from underlined parts

Conference	Date／Venue	Title	Author／Department
AACR Annual Meeting 2024	April 8 / San Diego, U.S.A.	Verification of the effect of human allogeneic iPS cell-derived gene-engineered NK cells (eNK cells HLCN061) on mesothelioma	Dr. Seiji Matsumoto, MD Hyogo Medical University
Stem Cell Research and Therapy	July 2 / Academic paper	Hypoimmunogenic human iPSCs expressing HLA-G, PD-L1, and PD-L2 evade innate and adaptive immunity	Norihiro Tsuneyoshi, et al. Kobe Research Institute, Healios K.K.

Note: The above shows only overseas presentations. In Japan, researchers from the joint research institutions and Healios' Kobe Research Institute have presented their research at numerous academic conferences.

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Issuance of new shares and the 26th Series of stock acquisition rights by way of third-party allotment (announced January 2025)

Approximately 1.95 billion yen has been secured through this issuance. In Japan, we are preparing to file for conditional and time-limited approval of HLCM051 for ARDS, and in the U.S., preparations are underway for the start of the global Phase 3 ARDS trial. The funds raised will be used to prepare for the filing of the approval application and for commercialization in Japan, to establish production, sales and distribution systems, and to fund the global Phase 3 trial and other operations.

Healios has established strong relationships with institutional investors in support of the advancement of its therapeutic programs. Athos is a fund that has built a track record of superior returns investing in innovative companies in the Asia-Pacific region. OrbiMed is a leading healthcare investment fund with over $17 billion in assets under management and more than 25 years of experience investing globally in private and large multinational companies across the entire healthcare industry, from biopharmaceuticals to medical devices to drug discovery tools.

If all of the 26th Series stock acquisition rights are exercised, approximately 1.1 billion yen will be secured in addition to the above funds. Healios will use the funds obtained from the exercise of the warrants, along with the progress of our business, to deliver cures and hope to patients with intractable diseases around the world.

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Financial Highlights

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Consolidated Statement of Income

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(Units: millions of yen)

	FY2023	FY2024		
			YoY variance	Main reasons for increase/decrease
Revenue	121	**560**	438	Increase mainly due to revenues related to license agreements for RPE cell production method.
Operating profit	-3,379	**-2,843**	537	Increase in SG&A expenses -189 Decrease in R&D expenses +344
Profit	-3,813	**-4,227**	-414	Decrease in finance income -83 Increase in finance costs -885 (Primarily non-cash activity; please refer to the next page for details)
R&D expenses	2,304	**1,960**	-344	
Number of employees	61	**58**	-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 fiscal year ended December 31, 2024, we recorded finance income of ¥373 million and finance costs of ¥1,589 million.

Finance income was mainly due to the recording of ¥163 million in profit or loss transferred to equity interests held by external investors in the Saisei Fund[*1] ,¥150 million in gain on remeasurement of investment securities and ¥49 million in interest income.

Finance costs were mainly due to the recording of ¥1,446 million in loss on remeasurement of derivatives[*2] , ¥81 million in interest expenses on bonds[*3] , ¥ 55 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 mainly a non-cash gain/loss item recorded in accordance with the International Financial Reporting Standards (IFRS), which represents the loss on remeasurement of the 21st and 22nd stock acquisition rights issued by the Company at fair value as of the end of the fiscal year ended December 31, 2024.

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.

*3. Interest expenses on bonds

Of the total interest on bonds of 81 million yen posted for the fiscal year ended December 31, 2024, 42 million yen was charged to income using the amortized cost method. This is a non-cash expense recorded in accordance with IFRS.

Under JGAAP, amount of bonds issued were accounted for as liabilities and issue fees were accounted for as expenses. Under IFRS, however, proceeds, after deducting issue fees from amount of bonds issued, based on a certain standard. As a result, the difference between the face value of bonds and the amount recorded as liabilities is amortized (expensed) over the period.

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Consolidated Statement of Financial Position

Update

Healios

(Units: millions of yen)

	December 31, 2023	December 31, 2024		
			Variance	Main reasons for increase/decrease
Current assets	7,683 (50.7%)	4,275 (30.1%)	-3,408	Decrease in cash and cash equivalents -3,050 (Cash and cash equivalent balance at 12/31/24 was 3,672)
Non-current assets	7,471 (49.3%)	9,916 (69.9%)	2,445	Increase in other financial assets +1,807
Total assets	15,155 (100.0%)	14,191 (100.0%)	-963	
Current liabilities	5,169 (34.1%)	3,350 (23.6%)	-1,820	Decrease in bonds and borrowings -3,958 Increase in other financial liabilities +1,724
Non-current liabilities	6,118 (40.4%)	8,758 (61.7%)	2,640	Increase in bonds and borrowings +1,599 Increase in equity interests held by external investors in Saisei fund +671
Total liabilities	11,287 (74.5%)	12,108 (85.3%)	820	
Total equity	3,867 (25.5%)	2,084 (14.7%)	-1,784	Issuance of new shares +2,181 Recording of loss -4,227
Total liabilities and equity	15,155 (100.0%)	14,191 (100.0%)	-963	

(Note) The funds raised through the third-party allotment of new shares and the 26th stock acquisition rights, as resolved on January 27, 2025, are not included.

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

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Healios

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