FY2024 Q1 Financial Results

Company

HEALIOS K.K.

Date

May 13, 2024

Important Note on Future Events, etc

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Business Overview

Acquisition of the Assets of Athersys

New Healios

On April 3, 2024, completed the acquisition, becoming the owner of MultiStem® and other assets of Athersys.

- No longer subject to milestones and royalty payments to Athersys regarding the license for MultiStem®
- Now the owner of all global rights to MultiStem® and an intellectual property portfolio that currently includes over 400 patents
- Acquired assets of substantial value for an amount equal to US$2.25 million financed by a DIP loan

Acquired Assets

- MultiStem® assets including 3 INDs and clinical data for ischemic stroke, ARDS, and trauma
  The phase 3 MASTERS-2 study in ischemic stroke conducted mainly in the U.S.
  The phase 2 MUST-ARDS study in ARDS in the U.S. and Europe
  The phase 2 MATRICS study in trauma conducted in the U.S.
- MultiStem® biological materials including 3D clinical product
  Hundreds of doses of MultiStem® and 3D bioreactor manufactured clinical product.
- License agreement in the animal field
  Out-licensing of MultiStem® for use in non-human mammals with a focus on dogs, cats, and horses in the U.S. domestic market
- SIFU technology
  Advanced frozen cell product storage device called SIFU™ (“Secure Integrated Freezer Unit”) for extremely low temperature storage and logistics

Pipeline

Update

Healios

	Development Code	Therapeutic Area	Therapy	Region	Discovery	Pre-Clinical	Clinical P1	Clinical P2	Clinical P3	Comments
Inflammatory Conditions	HLCM051	ARDS	MultiStem®	Japan			Phase 3			Started clinical trial in Japan Orphan designation
			MultiStem®	Global (USA)			Phase 2/3			Global Phase 3 trial under consideration Fast Track and RMAT designation (USA)*1
	HLCM051	Ischemic Stroke	MultiStem®	Global (USA / Japan)			Phase 3			Global Phase 3 study under consideration with integrated data analysis of Phase 3 study (MASTERS-2 study) in the U.S. and Phase 2/3 study (TREASURE study) in Japan. SAKIGAKE designation(Japan) Fast Track and RMAT designation (USA)

*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

*2 Retinal Pigment Epithelium

Immuno-Oncology	HLCN061	Solid Tumors*3	eNK	Global						Pre-IND started IND: 2025 planned
	–	Solid Tumors	CAR-eNK	Global						

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

Excludes pipeline assets scheduled to be carved out

Update Healios

Three pillars to monetization

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

Medical Materials	Bone marrow-derived cells	iPS cells
HLCM051 Culture Supernatant **Universal Donor Cell** **iPS cell lines, etc.** **SIFU™**	**ARDS** **Global Phase 3 trial under consideration** **Ischemic Stroke** **Global Phase 3 trial under consideration** **Trauma** **Phase 2 trial underway with U.S. DoD budget**	**Replacement Therapies** **RPE** **Immuno-Oncology** **Gene-engineered NK cells** **Presentation at "AACR Annual Meeting 2024" in San Diego on Apr. 8**

Culture Supernatant:
FY2024: Promote joint research AND medical group
FY2025: Commencement of sales

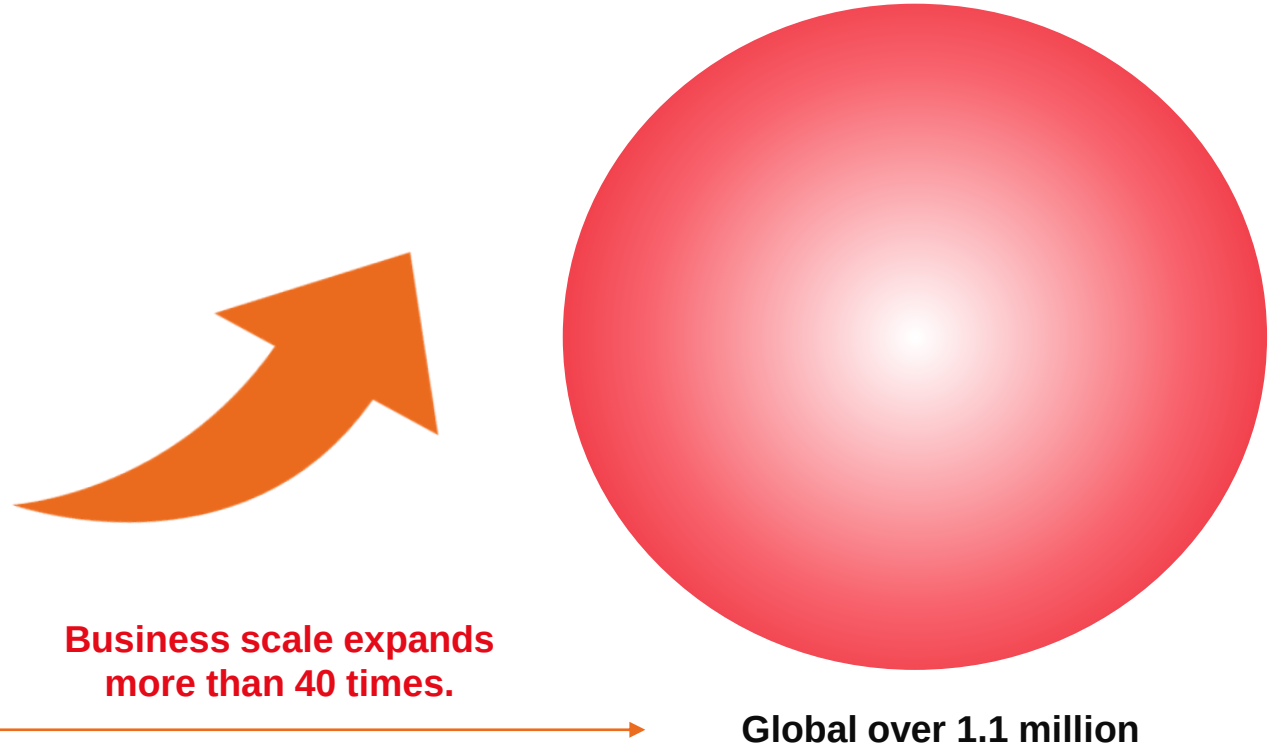
SIFU technology:
In discussions with Japanese and U.S. potential partners.

Business scale expansion by securing global rights

Steady progress toward the start of two Phase 3 trials in the U.S., the world's largest market, in ischemic stroke, ARDS and trauma

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

HLCM051 ARDS Global Market (Expansion)



Business Policy

1) In-house clinical trials in the U.S. and Japanese markets with the highest investment efficiency

   Focus on subsidiary financing

   Specific options include royalty investment, third-party allotment of subsidiary shares, etc.

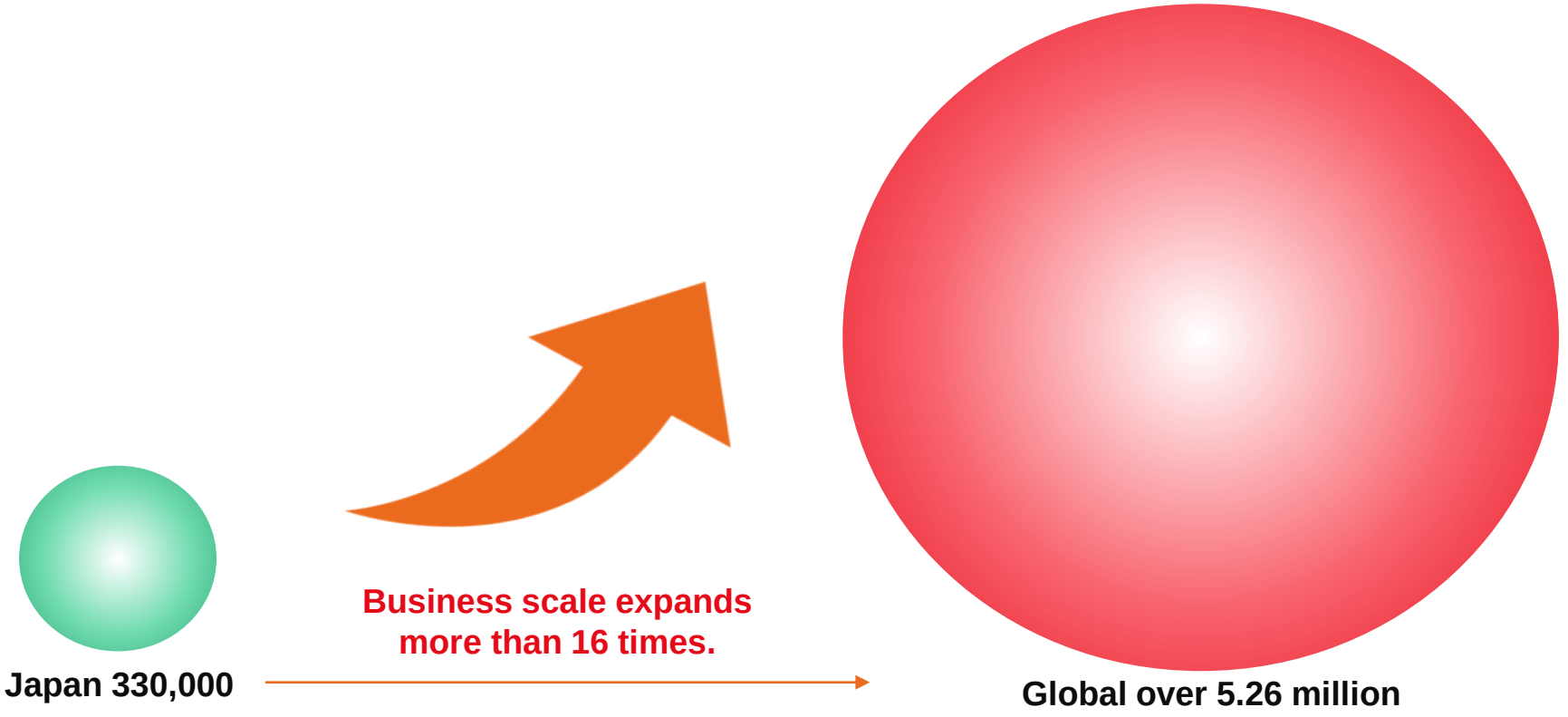
2) Outside of the U.S. market (Japan, Korea, Taiwan, and China), conclude licensing agreements and aim for early monetization.

Estimated number of ARDS patients worldwide

China 670k、US 262k、Europe 133k、Japan 28k

(Source)
Japan: Estimated by Healios based on the incidence rate of epidemiological data and the total demographical population in Japan.
USA: 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

HLCM051 Ischemic Stroke Global Market (Expansion)



Business Policy

1) In-house clinical trials in the U.S. market with the highest investment efficiency

   Focus on subsidiary financing

   Specific options include royalty investment, third-party allotment of subsidiary shares, etc.

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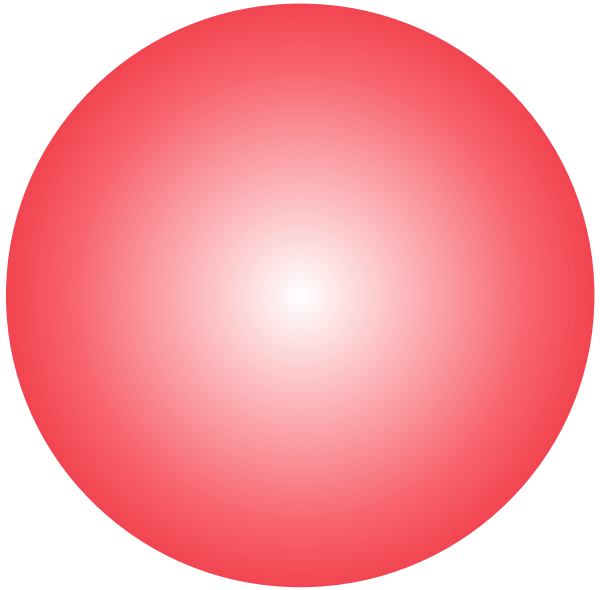
Estimated number of Stroke patients worldwide

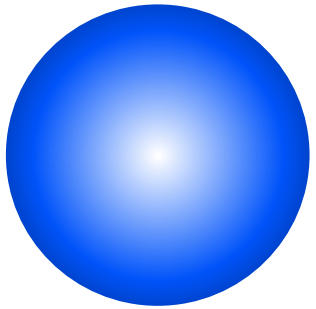
China 3.4mn、Europe 840k, US 690k, Japan 330k

（Source）
Japan： Estimated the annual number of new patients according to materials issued by the Ministry of Health, Labour and Welfare.
USA： “Stroke Facts” by CDC
Europe：Burden of Stroke in Europe: An Analysis of the Global Burden of Disease Study Findings From 2010 to 2019
China: Estimated Burden of Stroke in China in 2020

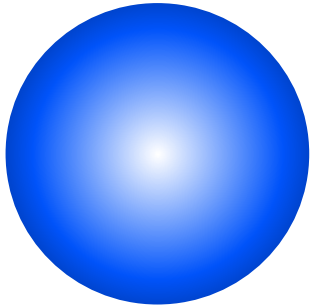
HLCM051 Trauma US Market (New Pipeline)



Yearly 220,000 (deaths)



45% About 100,000
Trauma or acute poisoning under the influence of drugs



55% About 120,000
General trauma

Market Characteristics

1) 3rd cause of death: 220,000 per year.

   1st cause of death under age 45: 87,000 per year

2) Wartime Injury

   Afghanistan: Casualties 2,354 / Injured and Sick 20,149

   Iraq War: Casualties 4,431 / Injured and Sick 31,994

(Source)
DOD: Department of Defense (U.S.)
https://www.defense.gov/casualty.pdf

CDC: Centers for Disease Control and Prevention
https://wisqars.cdc.gov/lcd/?o=LCD&y1=2022&y2=2022&ct=10&cc=ALL&g=00&s=0&r=0&ry=0&e=0&ar=lcd1age&at=groups&ag=lcd1age&a1=0&a2=199

NIH: National Institutes of Health (U.S.)
https://www.ncbi.nlm.nih.gov/books/NBK547669/

Pathological conditions leading from trauma to death

Systemic inflammatory response syndrome (SIRS) resulting from trauma is an excessive self-protective response to external stresses, including trauma (e.g., car accidents, gunshot wounds), drugs, and infection, which first results in autonomic, endocrine, hematologic, and immunologic changes.

These changes, initially intended to protect the body, become an unregulated cytokine storm, leading to a massive inflammatory cascade, organ damage, and death.

Currently, there is no effective treatment for patients who have reached this point, and only coping therapies are available for each symptom.

Expected effects of MultiStem®

As shown in ARDS and other clinical trials, the ability to suppress inflammation in the acute phase is expected to suppress cytokine storms and have an effect on patient prognosis. In clinical trials for trauma, we are conducting clinical trials with renal function as the primary endpoint to facilitate evaluation of efficacy.

HLCM051 ARDS: Development Status

Update

Healios

Inflammatory Conditions

Global Phase 3 clinical trial under consideration

ARDS

- **Started the clinical trial (Phase 2/3) in Japan adjusting patient inclusion**
- **Global clinical trial in the US under consideration (To be discussed in end of Phase 2 meeting with FDA in FY2024/Q3)**

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.

October 2023
Obtained global license from Athersys and secured clinical trial product.

January 2024
Started Clinical Trial in Japan

Note: Completed Global Clinical Trial
MUST-ARDS study: Phase 2 in the U.S. and U.K. MultiStem® 20 / Placebo 10

HLCM051 Ischemic Stroke: Development Status

Update

Healios

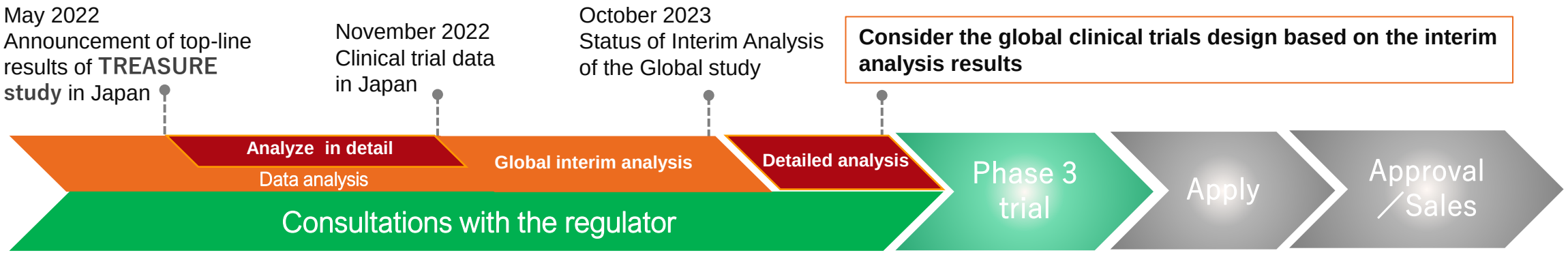
Inflammatory Conditions

Consider global Phase 3 clinical trial based on the results of an interim analysis in the U.S.

Ischemic stroke

Based on the results of further data analysis on the interim analysis*1 of the global clinical trial*2, we will conduct an analysis of data from a total of more than 400 people in Japan and the U.S. (about 200 people each in country) to determine a design and development policy that can obtain approval in Japan and the U.S. with a high degree of certainty.

*1 An analysis performed by an independent statistician during the course of a clinical trial. The results can be used to redefine the number of patients required.
*2 A Phase 3 study for ischemic stroke mainly in the U.S. (MASTERS-2 study)



HLCM051 Trauma: Development Status

New Healios

MATRICS-1 study（USA）

Inflammatory Conditions

Trauma

Took control of a 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

Update

Healios

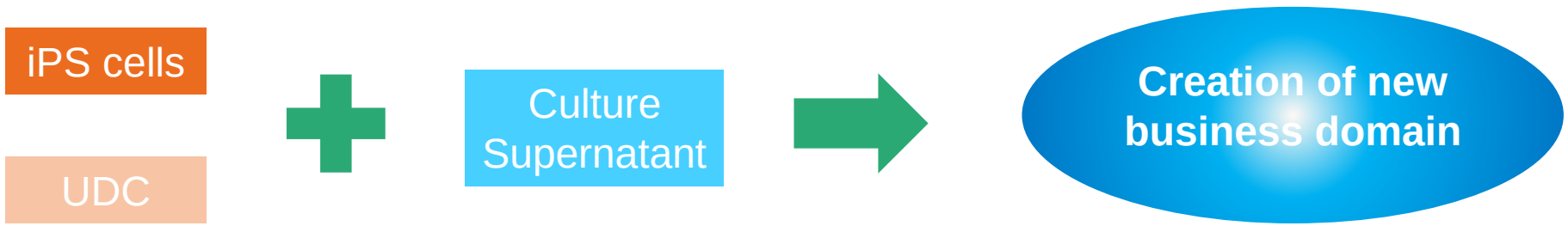
On April 9, 2024, Joint Research Agreement with AND medical group

Outline of the Agreement

- Healios will provide regenerative medicine technology and raw materials to AND medical for use in the development of a new therapy.
- Healios will receive 60 million yen as an upfront payment. Subsequently, the company will receive milestone payments based on the progress of the research, which together with the upfront payment will total 180 million yen.
- After the manufacturing method and system for the raw materials have been established and the objectives of the Agreement have been achieved, Healios expects to enter into an agreement to supply culture supernatant to AND Medical on an ongoing basis.

Utilization of medical materials generated during the production of regenerative medicine products

Aiming to strengthen our financial position as well as effective use of resources by increasing sales as soon as possible.



Financial Highlights

Consolidated Statement of Income

Update

Healios

(Units: millions of yen)

	FY2023 Q1(YTD)	FY2024 Q1(YTD)		
			YoY variance	Main reasons for increase/decrease
Revenue	7	10	3	
Operating profit	-888	-1,049	-161	Increase in SG&A expenses ＋28 Increase in R&D expenses +139
Profit	-728	-2,421	-1,692	Increase in finance income +113 Increase in finance costs -1,728 (Primarily non-cash activity; please refer to the next page for details)
R&D expenses	544	683	139	
Number of employees	64	**60**	-4	

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

Supplemental Explanation of Finance Income and Finance Costs

Update

Healios

Details of finance income and finance costs

In the three months ended March 31, 2024, we recorded finance income of ¥303 million and finance costs of ¥1,765 million.

Finance income was mainly due to the recording of ¥285 million in profit or loss transferred to equity interests held by external investors in the Saisei Fund[*1] and ¥17 million in interest income.

Finance costs were mainly due to the recording of ¥1,426 million in loss on remeasurement of derivatives[*2] ,¥244 million in loss on remeasurement of investment securities, ¥55 million in share acquisition rights issuance costs and ¥28 million in interest expenses on bonds[*3].

*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 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 1st quarter of the fiscal year ended December 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 28 million yen posted for the three months ended March 31, 2024, 18 million yen was charged to income using the amortized cost method. This is a non-cash expense recorded in accordance with IFRS.

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

Consolidated Statement of Financial Position

Update

Healios

(Units: millions of yen)

	December 31, 2023	March 31, 2024		
			Variance	Main reasons for increase/decrease
Current assets	7,683 (50.7%)	9,130 (55.4%)	1,447	Increase in cash and cash equivalents +1,325 (Cash and cash equivalent balance at 3/31/24 was 8,048)
Non-current assets	7,471 (49.3%)	7,354 (44.6%)	-117	
Total assets	15,155 (100.0%)	16,484 (100.0%)	1,330	
Current liabilities	5,169 (34.1%)	6,803 (41.3%)	1,634	Increase in other financial liabilities +1,452
Non-current liabilities	6,118 (40.4%)	5,965 (36.2%)	-153	
Total liabilities	11,287 (74.5%)	12,768 (77.5%)	1,481	
Total equity	3,867 (25.5%)	3,716 (25.4%)	-151	Recording of loss -2,421 Issuance of new shares +2,181
Total liabilities and equity	15,155 (100.0%)	16,484 (100.0%)	1,330	

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

Healios

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