



(TSE Growth : 4599)



Presentation Material

Financial Results for the Six Months
Ended January 31, 2024

March 15, 2024


Center of Medical Innovation
and Translational Research

旭光薬業イノベーションセンター



Stem cell Regeneration-Inducing Medicine

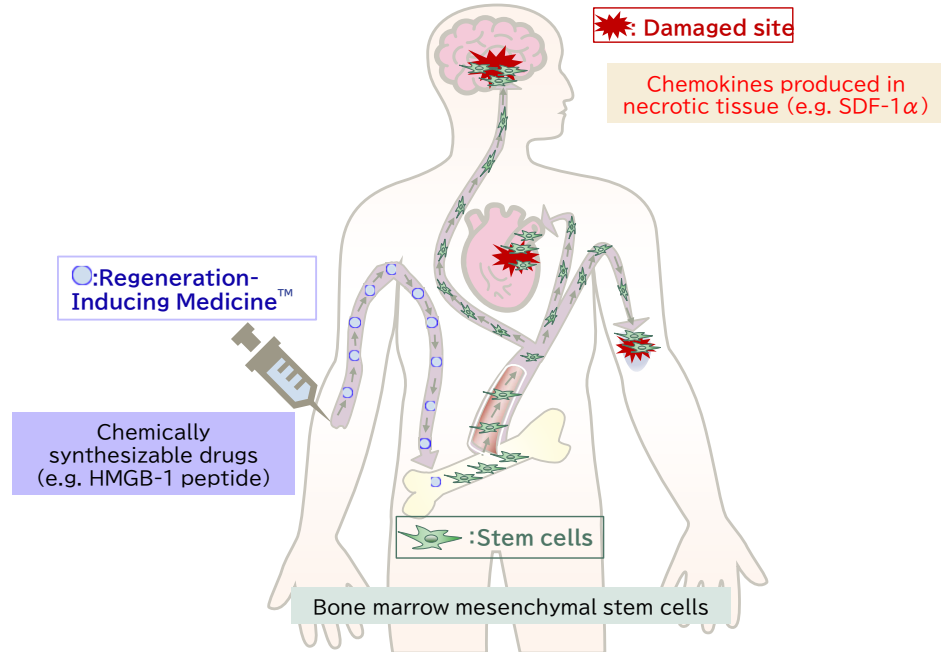
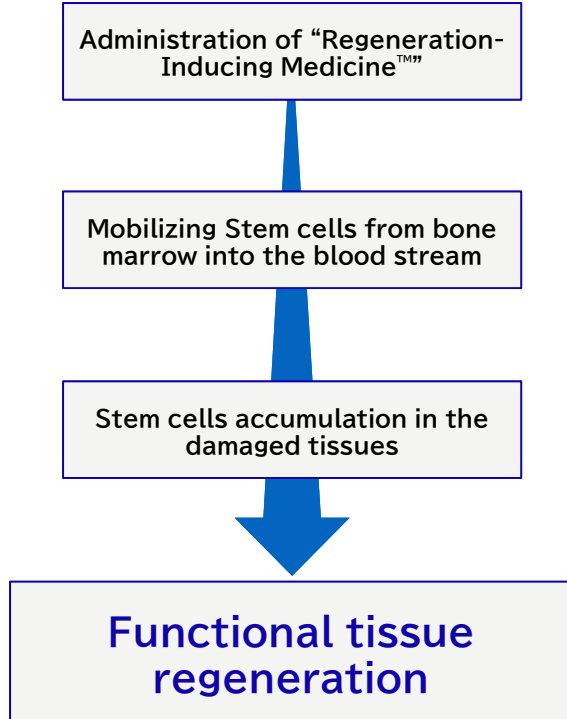
Overcoming Refractory Diseases by “Regeneration-Inducing Medicine™”

StemRIM is a biotech company aiming to develop
“Regeneration-Inducing Medicine™”
a next generation of regenerative medicine.

“Regeneration-Inducing Medicine™” is new class of medicine that induces functional regeneration of damaged tissues or organs by maximizing the patient’s innate ability of tissue repairing.

We aim for a future in which “Regeneration-Inducing Medicine™” helps patients all over the world suffering from refractory diseases.

Bone marrow mesenchymal stem cells mobilized into the peripheral blood stream induce the tissue regeneration.



1

Summary of Financial Results
for the Six Months Ended January 31, 2024

2

Summary of Business Activities
for the Six Months Ended January 31, 2024

1. Summary of Financial Results for the Six Months Ended January 31, 2024

Statements of Income



(Millions of yen)

	FY2023.7		FY2024.7 2Q	Function (2Q on 2Q)
	2Q	FY		
Operating revenue	—	2,350	—	—
R&D expenses	739	1,567	732	-7
SGA expenses	302	640	301	-1
Total operating expenses	1,042	2,207	1,033	-8
Operating Income (loss)	(1,042)	142	(1,033)	+8
Non-operating income	2	3	0	-2
Non-operating expenses	0	0	0	+0
Ordinary Income (loss)	(1,039)	145	(1,033)	+5
Extraordinary income	24	24	29	+5
Income (loss) before income taxes	(1,014)	170	(1,003)	+11
Total income taxes	1	1	1	+0
Net Income (loss)	(1,016)	168	(1,005)	+11

- Non-clinical trials related to New “Regeneration-Inducing Medicine™” are progressing steadily. Research and development expenses, sales expenses, and general administrative expenses are all at similar levels to the previous second quarter.
- **In March 2024, a domestic Phase 2 investigator-initiated clinical trial targeting ischemic cardiomyopathy was initiated for PJ1 Redasemtide.** Clinical trials for Redasemtide follow those for epidermolysis bullosa, acute ischemic stroke, osteoarthritis, chronic liver disease, making cardiomyopathy the 5th indication.

Balance Sheet / Statements of Cash Flows



(Millions of yen)

	FY2023.7		FY2024.7 2Q	Function (2Q on FY2023.7)
	2Q	FY		
Current assets	8,803	10,440	9,827	-612
Of which cash and deposits	8,410	10,217	9,183	-1,033
Non-current assets	296	266	232	-33
Total assets	9,100	10,706	10,060	-646
Current liabilities	91	217	124	-93
Non-current liabilities	120	118	118	+0
Total liabilities	211	336	242	-93
Total net assets	8,888	10,370	9,817	-552
Total liabilities and net assets	9,100	10,706	10,060	-646

	FY2023.7		FY2024.7 2Q
	2Q	FY	
Income (loss) before income taxes	(1,014)	170	(1,003)
Cash flows from operating activities	(569)	1,135	(1,094)
Cash flows from investing activities	—	(0)	(2)
Cash flows from financing activities	99	202	62
Net increase (decrease) in cash and cash equivalents	(469)	1,337	(1,033)
Cash and cash equivalents at beginning of period	8,880	8,880	10,217
Cash and cash equivalents at end of period	8,410	10,217	9,183

• In the second quarter of the fiscal year ending in July 2024, in addition to research and development expenses, there were prepayments of 250 million yen for joint research costs, consumption tax payments from the previous period totaling 117 million yen, with no refund of consumption tax (compared to a refund of 100 million yen in the previous period), and anticipated consumption tax payments for the current period totaling 39 million yen. Consequently, **there was a negative operating cash flow of 1,094 million yen (a decrease of 524 million yen compared to the same period last year).**

• Estimated annual expenditures for the fiscal year ending July 2024 range from 1.43 to 1.91 billion yen (cash expenditures for R&D: 1.2 to 1.6 billion yen, cash expenditures for general and administrative expenses: 0.23 to 0.31 billion yen), **ensuring stable funds for R&D activities through 2028 at this time.**

2. Summary of Business Activities for the Six Months Ended January 31, 2024

Summary of Business Activities for the Six Months Ended January 31, 2024



Phase 2 investigator-initiated clinical trial, targeting ischemic cardiomyopathy using Redasemtide, has been started.

Month/Year	History
Sep. 2023	Patent Registration (China) for the Use of the HMGB1 Fragment Peptide, Redasemtide, as an Additional Therapeutic Indication for Cardio
Sep.	Patent Registration (US) for the Use of the HMGB1 Fragment Peptide, Redasemtide, as an Additional Therapeutic Indication for Cardiomyopathy (Dilated Cardiomyopathy, Ischemic Cardiomyopathy, and Hypertensive Cardiomyopathy)
Nov.	Extension of the Tripartite Collaborative Research Agreement Updated on January 24, 2023
Dec.	Conclusion of Agreement for the Initiation of a Phase2 Clinical Trial for Redasemtide in Ischemic Cardiomyopathy
Jan. 2024	Patent Registration (Russia) for the Use of the HMGB1 Fragment Peptide, Redasemtide, as an Additional Therapeutic Indication of Cartilage Disorders (Traumatic Cartilage Deficiency Syndrome, Osteoarthritis, Dissection Osteochondritis, etc.)
Feb.	Patent Registration (Japan) for the Use of the HMGB1 Fragment Peptide, Redasemtide, as an Additional Therapeutic Indication of Traumatic Cartilage Deficiency Syndrome, Osteoarthritis, and Dissection Osteochondritis
March	Initiation of Phase 2 Clinical Trial for Redasemtide in Ischemic Cardiomyopathy

Overview of Development Pipeline



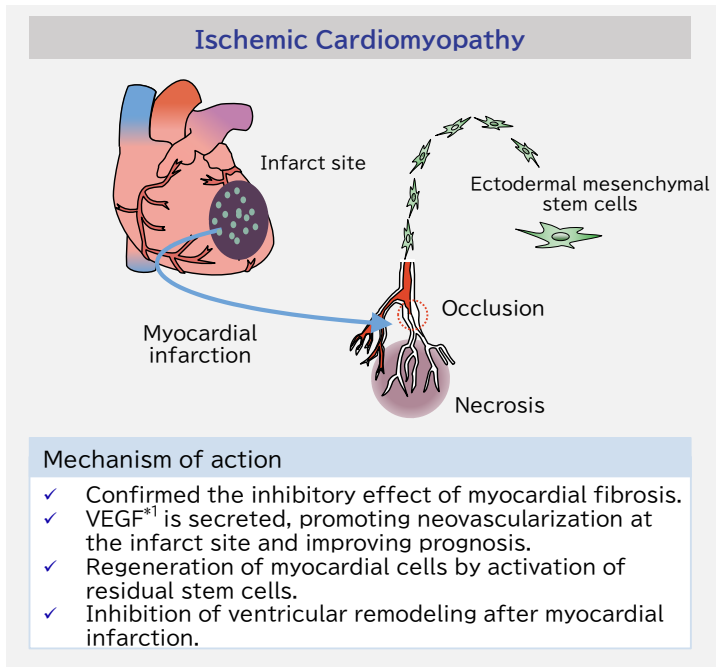
Project code	Development candidate	Indication	Investigator	Status	Development Stage					Out-license partner
					Research	Pre-clinical	Phase 1 study	Phase 2 study	Phase 3 study	
PJ1	Redasemtide (HMGB1 cell mobilization domain peptides)	Epidermolysis bullosa	Shionogi & Co., Ltd.	Additional P2 Study Ongoing					*	Shionogi & Co. Ltd. (S-005151)
		Acute Ischemic Stroke	Shionogi & Co., Ltd.	Global P2b Study Ongoing						
		Ischemic Cardiomyopathy	Osaka University	Physician-Initiated P2 Study Ongoing						
		Osteoarthritis of the knee	Hirosaki University	Physician-Initiated P2 Study Primary endpoint achieved						
		Chronic liver disease	Niigata University	Physician-Initiated P2 Study Primary endpoint achieved						
PJ2	TRIM3 (Novel Regeneration-Inducing peptide for Systemic administration)	Multiple tissue damage diseases	In-house (partnership is planned)	Pre-clinical						-
	TRIM4 (Novel Regeneration-Inducing peptide for Systemic administration)	Multiple tissue damage diseases	In-house (partnership is planned)	Pre-clinical						-
PJ3	TRIM5 (Novel Regeneration-Inducing peptide for Local administration)	Multiple tissue damage diseases	In-house (partnership is planned)	Pre-clinical						-
PJ4	Autologous cell collection device for treatment	Multiple tissue damage diseases	In-house (partnership is planned)	Pre-clinical	ND					-
PJ5	SR-GT1 (Stem cell gene therapy)	Epidermolysis bullosa	In-house (partnership is planned)	Under preparation for clinical trial	P1/P2 study		None			-

UPDATE

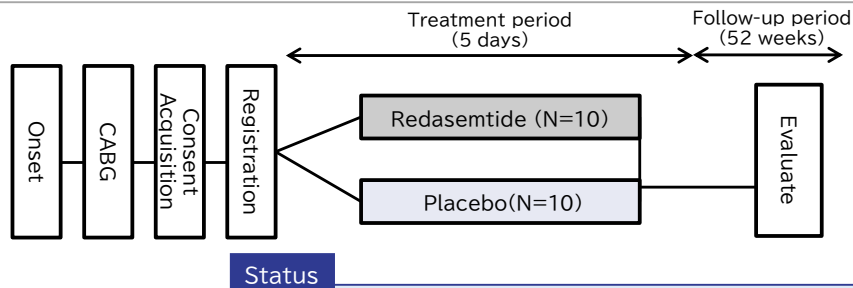
Initiation of Phase 2 Clinical Trial

* Application for approval is planned after Additional Phase2.

PJ1-03:Phase 2 Clinical Trial in Ischemic Cardiomyopathy



Phase 2 Protocol	
Study objectives	Evaluation of the efficacy and safety of Redasemtide in patients with ischemic cardiomyopathy
Study design	Multicenter, Randomized, Double-blind, Placebo-controlled
Subject population	Patients with ischemic cardiomyopathy who have undergone coronary artery bypass grafting (CBAG*2)
Intervention	Redasemtide : 10 cases Placebo : 10 cases total 20 cases
Regimen	Intravenous administration, 5 days
Efficacy endpoint	Various cardiac function tests such as echocardiography at 52 weeks after treatment



**March 2024:
Phase 2 Clinical Trial started in Japan**

*1 VEGF(vascular endothelial growth factor); A protein that promotes angiogenesis; when VEGF acts on vascular endothelial cells, it induces cell division, migration, and differentiation, resulting in the formation of new blood vessels that branch off from existing vessels.

*2 CABG(coronary artery bypass grafting); Surgery to bypass a blockage in a coronary artery and install a new blood vessel (bypass).

Out-licensing activities for new “Regeneration-Inducing Medicine™”



FY 2024.7 Conference Participation (including planned)

BioJapan 2023

2023.10.11~13 @Yokohama

42nd Annual J.P. Morgan Healthcare Conference

2024.1.8~11 @San Francisco, CA

BIO International Convention 2024

2024.6.3~6 @San Diego, CA

FY 2023.7 Conference Participation

BioJapan 2022

2022.10.11~13 @Yokohama

EU-Japan Biotech & Pharma Partnering Conference 2022

2022.10.11 @Osaka

41st Annual J.P. Morgan Healthcare Conference

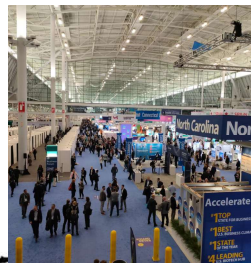
2023.1.9~12 @San Francisco, CA

BIO International Convention 2023

2023.6.5~8 @Boston, MA

Jefferies 2023 Global Healthcare Conference New York

2023.6.7~9 @New York, NY



Luncheon & Pitch Event

Scheduled Time : 12:00 - 12:30

Supported by

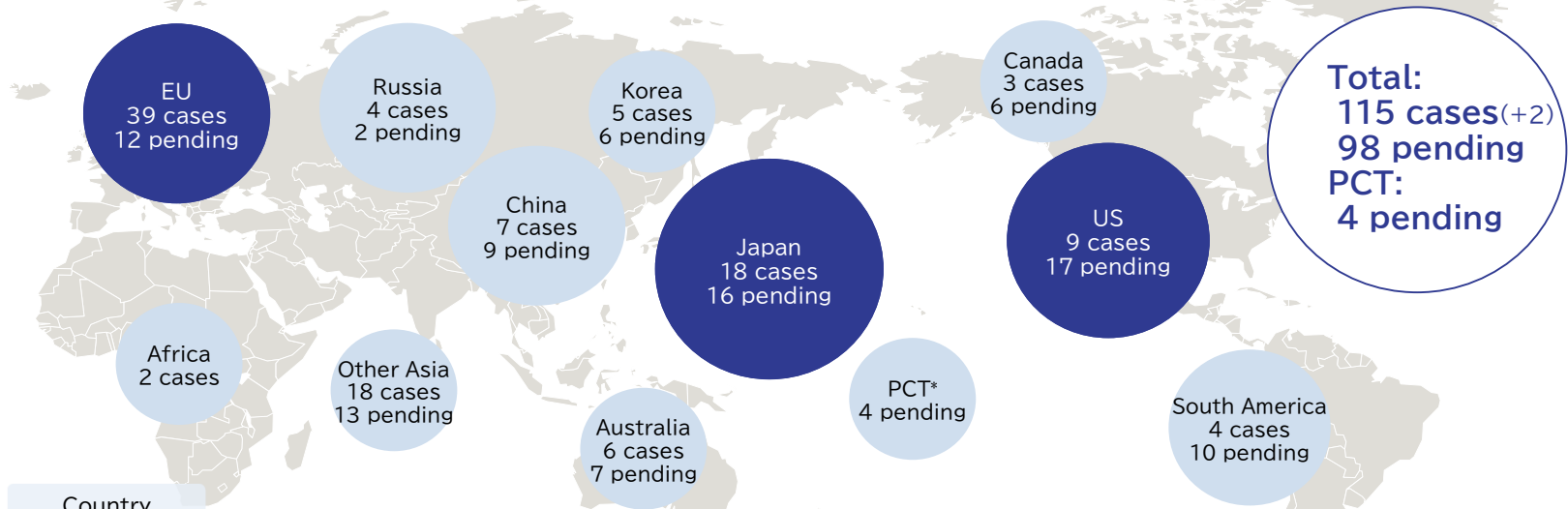


TIME TABLE	
12:00	Registration
12:05	Opening Remarks
12:10	Keynote Speech
12:15	Panel Discussion
12:20	Networking
12:25	Remarks
12:30	Event Ends



Participated in multiple national and international conferences as part of out-licensing activities for new “Regeneration-Inducing Medicine™”.

Patents related to “Regeneration-Inducing Medicine™” granted worldwide.
Aiming for Global Expansion



Country															
JPN	USA	CHN	GER	KOR	IND	ESP	POL	SWD	RUS	BEL	IDN	BRA	MEX	ZAF	
ISR	HKG	GBR	FRA	AUS	CAN	ITA	IRL	NLD	CHE	DNK	FIN	TUR	SGP	TWN	

*PCT: Members of the Patent Cooperation Treaty
** As of February 2024

SDGs: Achieving a Sustainable Future



Health and Well-Being for All

StemRIM is dedicated to achieving a sustainable future by providing therapeutic solutions to people worldwide suffering from refractory diseases through the realization of “Regeneration-Inducing Medicine™”. We aim to support healthy and prosperous lives for all.

We aim to bring smiles to patients suffering from rare diseases worldwide in the future.

Target



Our SDGs Target*; 3.4, 3.8

SUSTAINABLE DEVELOPMENT GOALS



*SDGs Target;
 3.4 | Noncommunicable diseases and mental health: By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being
 3.8 | Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all

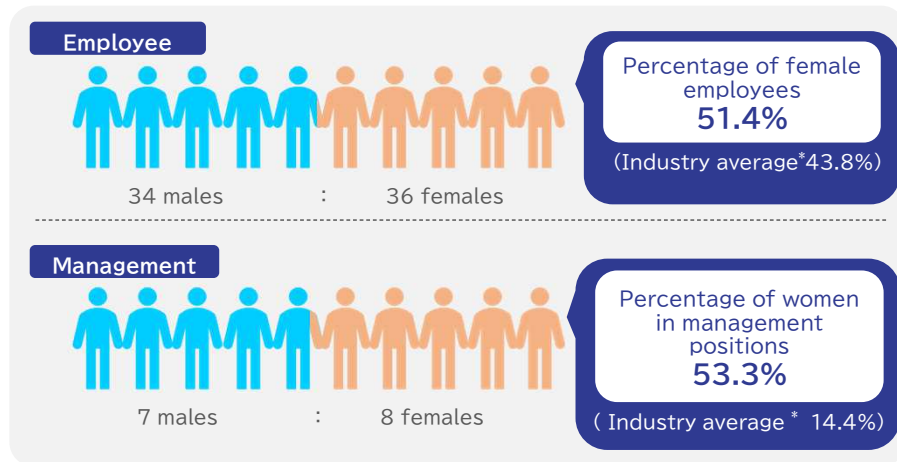
SDGs: Specific actions for the year ending July 31, 2024



We are committed to the development of human resources and the improvement of our internal environment with "gender equality" in mind.

We secure and develop diverse human resources with a high level of expertise, skills, and experience to realize our growth strategy, without discrimination between men and women.

Ratio of male to female (as of March 2024)



Specific Initiatives

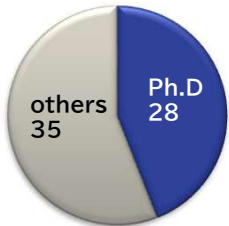
- Introduction of flextime system and expansion of core hours to achieve work-life balance
- Encouragement of male employees to take childcare leave (75% take rate)
- Expansion of employees eligible for shorter working hours

*From the Ministry of Health, Labor and Welfare's "Database of Companies Promoting Women's Activities"

Appendix.

Corporate information



Company name	StemRIM Inc.
Chief Executives	Masatsune Okajima (Representative Director)
Address	Saito Bio-Incubator 3F, 7-7-15 Saito-Asagi, Ibaraki City, Osaka, 567-0085 Japan
Established	October 30, 2006
Shareholders' equity	8,573 million yen(as of January 2024)
Number of Employees	71 (as of January 2024)
Number of R & D staff	<p>63 research staff</p>  <p>*28 staff with Ph.D, including MD and Veterinarian *In-house patent attorney and pharmacist *Numbers as of January 2024</p>

Month/Year	History
Oct. 2006	Established a company aiming to develop new drugs based on the discovery of bone marrow multi-potent stem cell mobilization factors identified by Professor Katsuto Tamai of the Graduate School of Medicine, Osaka University.
Apr. 2010	Transferred our head office to Saito Bio Incubator (Ibaraki City, Osaka Prefecture) and set up a laboratory there. Signed joint research agreement with Shionogi & Co., Ltd. on bone marrow-derived stem cell mobilization factors
Nov. 2014	Signed a license agreement with Shionogi & Co., Ltd. regarding Redasemtide (HMGB1 peptides)
Jan. 2018	An investigator-initiated phase 2 clinical trial of Redasemtide for dystrophic epidermolysis bullosa patients started at Osaka University. (to be completed in March 2020)
Apr. 2019	A company-initiated phase 2 clinical trial of Redasemtide for cerebral infarction patients started at Shionogi & Co., Ltd. (to be completed in December 2021)
Aug. 2019	Listed on the Tokyo Stock Exchange Mothers
June 2020	Established a new R&D base, "StemRIM Institute of Regeneration-Inducing Medicine, Osaka University".
Nov. 2020	An investigator-initiated phase 2 clinical trial of Redasemtide for Osteoarthritis of the knee patients started at Hirosaki University.
Nov. 2020	An investigator-initiated phase 2 clinical trial of Redasemtide for Chronic liver disease patients started at Niigata University.
Feb. 2021	Signed joint research agreement with Shiseido Co., Ltd. and Osaka University on anti-aging skin.
July 2022	An investigator-initiated additional phase 2 clinical trial of Redasemtide for DEB* patients started.
Mar. 2023	Notification of Preliminary Results of Data Analysis of Physician-Initiated Clinical Trial (Phase 2) on Redasemtide in Patients with Knee Osteoarthritis
April 2023	A global Phase 2b clinical trial of Redasemtide for Acute Ischemic Stroke started in Japan and US.
April 2023	Notification of Preliminary Results of Data Analysis of Physician-Initiated Clinical Trial (Phase 2) on Redasemtide in Patients with Chronic Liver Disease.
July 2023	A global Phase 2b clinical trial of Redasemtide for Acute Ischemic Stroke started in EU and China.
Mar. 2024	A Phase 2 investigator-initiated trial of Redasemtide in ischemic cardiomyopathy has been initiated.

Director

**Masatsune Okajima, President and CEO**

President and CEO, StemRIM Inc. (Oct. 2023 – Present)
 President, StemRIM Inc. (March 2019 – Oct. 2023)
 Vice president, Medicinova Inc. (Sep. 2006 – March 2019)
 Deputy General Manager, Daiwa Securities SMBC Co., Ltd. (April 2002 – Aug. 2006)
 Manager, Daiwa Securities SB Capital Markets Co., Ltd. (currently Daiwa Securities SMBC Co., Ltd.) (April 1999 – March 2002)
 Sumitomo Capital Securities Co., Ltd. (Oct. 1996 – April 1999)
 Sumitomo Bank, Ltd. (currently Mitsui Sumitomo Bank) (April 1991 – Oct. 1996)

**Kensuke Tomita, Chairman**

Chairman, StemRIM Inc. (Oct. 2023 – Present)
 Chairman and CEO, StemRIM Inc. (March 2019 – Oct. 2023)
 President, StemRIM Inc. (April 2018 – March 2019)
 Director, StemRIM Inc. (July 2013 – April 2018)
 External director, MEDINET Co., Ltd. (Oct. 2014 – Jan. 2016)
 Advisor, StemRIM Inc. (April 2012 – June 2013)
 President and CEO, OncoTherapy Science, Inc. (April 2003 – June 2012)
 President and CEO, Angec MG (currently Angec Inc.) (June 2000 – March 2003)
 Vice president, Rhône Poulenc Roller Inc. (currently Sanofi S.A.) (Aug. 1994 – March 2000)
 Sandoz KK (currently Novartis Pharma KK) (Nov. 1991 – July 1992)
 Roller Japan Inc. (currently Sanofi S.A.) (July 1989 – Sep. 1991)
 Eli Lilly Japan KK (July 1987 – April 1989)
 Sankyo Co., Ltd. (currently Daiichi Sankyo Co., Ltd.) (April 1974 – July 1987)

**Katsuto Tamai, Founder, Director**

Director, StemRIM Inc. (Oct. 2022 – Present)
 Professor, Endowed course of Regeneration-Inducing Medicine Graduate School of Medicine/ Faculty of Medicine, Osaka University (Oct. 2010 – Present)
 Director, StemRIM Inc. (Feb. 2007 – Aug. 2010)
 Associate professor, Department of Gene Therapy, Graduate School of Medicine/ Faculty of Medicine, Osaka University (May 2003 – Sep. 2009)

**Noriko Sawai, External director**

Head of healthcare team, Social Innovation and Investment Foundation (Aug. 2022 – present)
 Impact Officer, Social Innovation and Investment Foundation (Feb. 2020 – July 2022)
 External director, StemRIM Inc. (Oct. 2019 – Present)
 DeNA Co. (June 2014 – Jan. 2020)
 CSK Venture Capital Co. (April 1995 – May 2014)

**Hirotada Nagai, External director**

President, HyakusanSoken KK (July 2022 - Present)
 External directors, StemRIM Inc. (Oct. 2020 - Present)
 Auditor, Regional Fish Institute, Ltd. (May 2020 – Present)
 Director, PRDM Co., Ltd. (March 2018 – Present)
 Director, PorMedTec Co., Ltd. (Dec. 2017 – Present)
 Director, Kyoya KK (Dec. 2017 – Present)
 Pharmaceuticals and Medical Devices Agency (PMDA) (Sep. 2012 – July 2014)
 Pharmaceutical and Food Safety Bureau of Ministry of Health, Labour and Welfare (April 2001 – Sep. 2017)

External Audit & Supervisory Board Member

Yoji Kudo, External audit**Akihiro Mizukami, External audit****Yoichiro Shimada, External audit**