Presentation Material Financial Results for the Six Months Ended Janualy31,2025

StemRIM Inc.(Stock code:4599)

Masatsune Okajima, President&Chief Executive Officer March 14,2025



Agenda

Company Overview

- Corporate Mission
- Mode of Action of "Regeneration-Inducing Medicine™"
- Business Model
- Research and Development Structure
- Management Indicators

Progress in Research and Development

•Highlights for the Half-Year Ending July 2025

Pipeline



Summary of Activities the Half-Year Ending July 2025

Financial Summary

- •IP Strategy
- Business Development Activities

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1. Company Overview



Overcoming Refractory Diseases by "Regeneration-Inducing Medicine™"



StemRIM is a biotech company aiming to develop T^{M}

"Regeneration-Inducing Medicine"

a next generation of regenerative medicine.

"Regeneration-Inducing MedicineTM" 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 MedicineTM" helps patients all over the world suffering from refractory diseases.

Mode of Action of "Regeneration-Inducing Medicine™"™"

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



A business model that generates income by licensing out product development, manufacturing, and marketing rights to pharmaceutical companies in Japan and overseas.



Research and Development Structure

StemRIM Institute of Regeneration-Inducing Medicine, Osaka University will be established in June 2020 on the Suita Campus of Osaka University as a world-leading research and development center for "Regeneration-Inducing Medicine[™]" research.



Our Management Indicators

Annual Research and Development Expenses



(One-year period from February 2024 to January 2025)

Cash Burn Rate for Month



(Half-Year Results for the Fiscal Year Ending July 2025) Sufficient funds secured for research and development activities until 2028.

Cash and Deposits

7.6 billion yen

(As of the end of January 2025)

Number of Clinical Development Pipelines



Clinical trials have been initiated in patients for epidermolysis bullosa, acute ischemic stroke, ischemic cardiomyopathy, chronic liver disease, and osteoarthritis.

2. Progress in Research and Development

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Redasemtide • Global Phase 2b Trial for Acute Ischemic Stroke / Amendment to Clinical Trial Protocol

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Phase 2 Investigator-Initiated Clinical Trial for Ischemic Cardiomyopathy / First Patient In

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Stem Cell Gene Therapy Development Using Japan Agency for Medical Research and Development (AMED) Grant Program

IV.

Reorganizing our Development Piplines

Redasemtide Global Phase 2b Trial for Acute Ischemic Stroke / Amendment to Clinical Trial Protocol

Background of the Clinical Trial Protocol Amendment

- Advancements in endovascular reperfusion therapy have transformed the treatment paradigm
- Amendment to clinical trial protocol to accommodate a broader patient population
- Interim analysis conducted

Key Points of the Trial Amendment

- Establishment of an additional cohort for patients who have undergone endovascular reperfusion therapy
- Relaxation of NIHSS score criteria from "8-22" to "6-22
- Increase in the number of eligible patients for the clinical trial

Market Impact

- The stroke market size is projected to reach \$10.56 Billion by 2027.
- Key clinical trial amendment in response to changing market conditions



The relaxation of patient enrollment criteria and the increase in the number of clinical trial patients, there are not expected to result in a significant extension of the trial period.

*Global Data 2018

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**If certain conditions are met, it can be performed up to 24 hours.

Image: Phase 2 Investigator-Initiated Clinical Trial for Ischemic Cardiomyopathy/ First Patient In

Overview of the Phase 2 Investigator-Initiated Clinical Trial

Ischemic Cardiomyopathy Infarct site Myocardial infarction Mecrosis

December 2024 : First Patient In

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				



*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).

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Status

Stem Cell Gene Therapy Development Using Japan Agency for Medical Research and Development (AMED) Grant Program

Developing gene therapy technology aimed at a curative treatment for dystrophic epidermolysis bullosa.

Ex vivo gene therapy involving the introduction of correct type VII collagen gene into autologous mesenchymal stem cells (MSCs) and administration of the cells in the blisters of the patient.



Preparation for clinical development is accelerating.

Using the grant associated with this funding, preparations for the initiation of the clinical trial are progressing. The clinical trial is ready to investigational new drug application in March 2027.



Cost burden reduction through grants

Conducting clinical trials requires a significant financial investment; however, this grant allows for two-thirds of the total research costs to be covered by AMED. Out of the total research budget of 269 million yen, a subsidy of 179 million yen will be provided.

Application



Research expenses and expenditure on outsourcing costs

Two-thirds of the expenditure amount will be subsidized.

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IV. Reorganizing our Development Piplines

Reorganization of pipeline development codes aimed at the optimal allocation of R&D resources.

Development Pipeline (Revised)

Project code	Indication	Status	Investi- gator
	Epidermolysis bullosa	Additional P2	Shionogi & Co., Ltd.
Redasemtide/	Acute Ischemic Stroke	Global P2b	Shionogi & Co., Ltd.
(HMGB1 cell mobilization domain	Ischemic Cardiomyopathy	Physician- Initiated P2	Osaka University
peptides)	Osteoarthritis of the knee	Physician- Initiated P2	Hirosaki University
	Chronic liver disease	Physician- Initiated P2	Niigata University
TRIM3 (Novel Regeneration- Inducing peptide for Systemic administration)	(Not disclosed)	_	In-house (partnership is planned)
TRIM4 (Novel Regeneration- Inducing peptide for Systemic administration)	(Not disclosed)	_	In-house (partnership is planned)
TRIM5 (Novel Regeneration- Inducing peptide for Local administration)	(Not disclosed)	—	In-house (Expansion of animal model data)
SR-GT1 (Stem cell gene therapy)	Epidermolysis Bullosa		In-house (partnership is planned)

Development Pipeline (Before Revision)

Project code		Development candidate	Indication		
	-01	Epidermolysis bullosa			
	-02	Redasemtide	Acute Ischemic Stroke Ischemic Cardiomyopathy Osteoarthritis of the knee		
PJ1	-03	(HMGB1 cell mobilization domain			
	-04	peptides)			
	-05		Chronic liver disease		
	-01	Novel Regeneration-Inducing peptide for Systemic administration (TRIM3)	Not disclosed		
PJZ	-02	Novel Regeneration-Inducing peptide for Systemic administration (TRIM4)	Not disclosed		
PJ3		Novel Regeneration-Inducing peptide for Local administration (TRIM5)	Not disclosed		
PJ4		Autologous cell collection device for treatment	Multiple tissue damage diseases		
PJ5		Stem cell gene therapy (SR-GT1)	Epidermolysis bullosa		

Development Pipeline(Redasemtide)

Bone marrow mesenchymal stem cell mobilizing active domain peptide of HMGB1 (HMGB1 peptide) Progress in FY2025 in red



Development Pipeline(TRIM3、TRIM4、TRIM5、SR-GT1)

Next-generation "Regeneration-Inducing Medicine™" TRIM3, TRIM4, TRIM5, and stem cell gene therapy SR-GT1 Progress in FY2025 in red

Project code	内容	Indication	Investi- gator	Research	Pre- clinical	Phase 1	Phase 2	Phase 3	Status
TRIM3	Novel Regeneration- Inducing peptide for Systemic administration	(Not disclosed)	In-house						Promote out-licensing activities with multiple domestic and international companies
TRIM4	Novel Regeneration- Inducing peptide for Systemic administration	(Not disclosed)	In-house						Promote out-licensing activities with multiple domestic and international companies
TRIM5	Novel Regeneration- Inducing peptide for Local administration	(Not disclosed)	In-house						Expanded experimental data on model animals
SR-GT1	Stem cell gene therapy	Epidermolysis bullosa	In-house						AMED grant to promote preparation for Phase 1/2 trials in Japan

TRIM3, TRIM4

We have identified several peptides that mobilize mesenchymal stem cells from the bone marrow into the bloodstream, accumulate in damaged tissues, and induce functional regeneration. Among them, two peptides with particularly prominent activity have been selected as candidates for the next-generation "Regeneration-Inducing Medicine[™]" : TRIM3 and TRIM4, and out-licensing activities have been initiated.



*TRIM; Tissue Regeneration-Inducing Medicine

3. Summary of Activities the Half-Year Ending July 2025



Fiscal Year Ending July 2025, Second Quarter Financial

 For FY 2025, there were no recognition of milestone revenues related to research progress or upfront payments from contracts. As a result, operating revenue was none. Since we are a drug discovery bio-venture, we have an unstable revenue structure considering our business model.
 As of the end of FY 2024, we hold 7,662 million yen in cash and deposits.

The estimated annual expenditure for the FY 2025 is between 1,430 million yen and 1,910 million yen (cash outflows related to R&D: 1,200 million yen to 1,600 million yen, cash outflows for general administrative expenses: 230 million to 310 million yen). At present, we have secured sufficient funds to sustain stable R&D activities until 2028.

(Millions of yen)

	FY2023.7 2Q	FY2024.7 2Q	FY2025.7 2Q	Function (2Q on 2Q)
Operating revenue		—	—	_
R&D expenses	739	732	739	+7
Total operating expenses	1,042	1,033	1,066	+33
Operating Income(loss)	(1,042)	(1,033)	(1,066)	-33
Ordinary Income(loss)	(1,039)	(1,033)	(1,065)	-32
Net Income(loss)	(1,016)	(1,005)	(1,048)	-43
	FY2023.7	FY2024.7	FY2025.7 2Q	
Cash and deposit	10,217	8,410	7,662	

IP Strategy

Patents related to "Regeneration-Inducing Medicine[™]" have been granted in various countries. We are steadily promoting the intellectual property protection of our research outcomes, paving the way for global expansion.



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

Business Development

Continuing from last year, out-licensing negotiations were conducted with multiple pharmaceutical companies both domestically and internationally.









2025.1.13~16 @San Francisco



Bio International Convention

> 2024.6.3~6 @San Diego



4. Appendix

Discovery of in-vivo mechanism inducing tissue regeneration

Discovery of crosstalk mechanism between damaged skin and bone marrow mesenchymal stem cells via necrotic tissue-derived factor



Discovery of in-vivo mechanism inducing tissue regeneration

•Differences between normal skin and epidermolysis bullosa skin

In normal skin (Figure A), type 7 collagen functions like an adhesive, bonding the epidermis and dermis, the superficial layers of skin. In epidermolysis bullosa congenita (Figure B), the epidermis and dermis are easily detached with the slightest irritation due to abnormal type 7 collagen.

Since epidermal stem cells, which are responsible for supplying epidermal cells, reside in the epidermis, the epidermal stem cells are lost from the skin of patients with epidermolysis bullosa, and the epidermis loses its regenerative capacity.



Discovery of in-vivo mechanism inducing tissue regeneration

The beginning of the research and development on "Regeneration-Inducing Medicine[™]" : Hypothesis of stem cell recruitment mechanism from bone marrow to damaged skin.



References:

468;2018

HMGB1 peptide drugs with improved safety

Designing highly safe, chemically synthesized peptide drug from A-Box domain of HMGB1 protein



Advantages of "Regeneration-Inducing Medicine™"

Epidermis formation during human development



Advantages of "Regeneration-Inducing Medicine™"

Ectodermal mesenchymal stem cells have high pluripotency and differentiation ability to various tissues.



Expanding Indications and Markets(Number of patients)



Functions of mesenchymal stem cells

In-vivo mesenchymal stem cells have 5 distinctive capabilities

1. Cell migration ability

Mesenchymal stem cells migrate to damaged tissue via the bloodstream

3. Trophic factor secretion ability

Promotes cell proliferation and tissue repair by secreting growth factors and cytokines to cells in damaged tissue



In vitro culture reduces the functions of MSCs

"Regeneration-Inducing Medicine[™]" can avoid functional degradation of mesenchymal stem cells due to in vitro culture



Summary of advantages of "Regeneration-Inducing Medicine™"

"Regeneration-Inducing Medicine[™]" includes advantages in both cell therapy and chemicals



Expanding Indications and Markets(Number of patients)



Summary of advantages of "Regeneration-Inducing Medicine™"



Activities of "StemRIM Institute of Regeneration-Inducing Medicine, Osaka University"





StemRIM Institute of Regeneration-Inducing Medicine In June 2020, StemRIM Institute of Regeneration-Inducing Medicine, Osaka University (covering an area of 1,540 square meters) was established on the 6th and 7th floors of the Techno Alliance Building at Osaka University's Suita Campus. Professor Masayuki Endo (Department of Children's and Women's Health, Graduate School of medicine and Division of Health Sciences, Osaka University) was appointed as the institute's director. The team includes distinguished members such as Specially Appointed Professor Shinya Murakami (Department of Periodontology and Regenerative Dentistry, Osaka University, Graduate School of Dentistry.), Professor Masaru Ishii (Department of Immunology and Cell Biology, Graduate School of medicine and Frontier Biosciences, Osaka University), and Professor Manabu Fujimoto (Department of Integrated Medicine, Graduate School of medicine, Osaka University). Together, they aim to explore and advance the multi-faceted development of "Regeneration-Inducing MedicineTM". To date, several collaborative research projects have made significant progress.

Joint Research Projects (number of events)							
	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025 2Q	FY on 2Q	Notes
Division of Health Sciences	1	2	3	2	2	±0	Neonatal-Associated Diseases
Division of Biofunctional Research	—	_	_	_	_	±0	
Division of Medical Research	_	1	2	2	3	+1	Nervous System Diseases, Orthopedic- Related Diseases
Division of Dentistry	3	5	5	5	6	+!	Periodontitis-Related Diseases
Total	4	8	10	9	11	+2	



Website (Japanese): https://stemrim -osaka-u.jp/



Corporate Information

Corporate Name	StemRIM Inc.	Head Office 7-7-15, Saito-Asagi, Ibaraki-City, Osaka, 567-0085, Japan				
Chief Executives	Masatsune Okajima (Representative Director)					
Established	October 30, 2006	StemRIM Institute of Regeneration-Inducing Medicine, Osaka University				
Business Description	Research and Development of " Regeneration Inducing-Medicine™ "	Techno-Alliance Building, 2-8, Yamadaoka, Suita-City, Osaka, 565-0871, Osaka, Japan				
Shareholders' Equity	7,579 million yen					
Equity Ratio	80.6%	 Endowed Chair for Regeneration-Inducing Medicine/ Joint Research Course in Stem Cell and Gene Therapy The Center of Medical Innovation and Translational Research, 2-2, Yamadaoka, 				
Number of Employees	71	Suita-City, Osaka, 565-0871, Osaka, Japan				

As of the End of January 2025

StemRIM Management



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)



Katsuto Tamai, Founder, Director

Director, StemRIM Inc. (Oct. 2022 – Present) Guest Professor, Endowed course of Regeneration-Inducing Medicine Graduate School of Medicine/ Faculty of Medicine, Osaka University (Oct. 2023 – Present) Professor, Endowed course of Regeneration-Inducing Medicine Graduate School of Medicine/ Faculty of Medicine, Osaka University (Oct. 2010 – Sep. 2023) 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)

Yoji Kudo, External audit

Akihiro Mizukami, External audit Yoichiro Shimada, External audit This document is based on economic, regulatory, market, and other conditions as of its publication date, and neither the company nor its representatives guarantee the accuracy or completeness of the information contained herein. The information may change without prior notice, and such changes could be significant.

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