English Translation:
This is a translation of the original release in Japanese. In the event of any discrepancy, the original release in Japanese shall prevail.

Non-consolidated Financial Results for the Three Months Ended October 31, 2024 [Japanese GAAP]

December 11, 2024

Company name: StemRIM Inc.
Stock exchange listing: Tokyo Stock Exchange
Stock code: 4599
URL: https://stemrim.com
Representative: Masatsune Okajima, President & Chief Executive Officer
Contact: Shuhei Uematsu, Management & Administration Dept.
Phone: +81-72-648-7152

Scheduled date of commencing dividend payments: —
Supplementary briefing materials on financial results: None
Explanatory meeting on financial results: None

(Amounts of less than one million yen are rounded down)

1. Financial Results for the Three Months Ended October 31, 2024 (August 1,2024 to October 31, 2024)

(1) Operating results

	Operating revenue		Operating income		Ordinary income		Net income	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
October 31, 2024	—	—	(573)	—	(573)	—	(560)	—
October 31, 2023	—	—	(491)	—	(491)	—	(467)	—

	Earnings per share Basic	Earnings per share diluted
Three months ended	Yen	Yen
October 31, 2024	(9.11)	—
October 31, 2023	(7.66)	—

Note: Earnings per share diluted is not stated because of a net loss per share.

(2) Financial position

	Total assets	Net assets	Equity ratio
	Million yen	Million yen	%
As of October 31, 2024	8,671	8,397	81.0
As of July 31, 2024	9,080	8,894	83.5

(Reference) Equity capital: As of October 31, 2024 7,023 Million yen
As of July 31, 2024 7,579 Million yen

2. Payment of Dividends

	Annual dividends				
	End Q1	End Q2	End Q3	Year-end	Total
Fiscal year ended	Yen	Yen	Yen	Yen	Yen
July 31, 2024	—	0.00	—	0.00	0.00
July 31, 2025	—				
July 31, 2025(forecast)		0.00	—	0.00	0.00

Note: Revisions to the forecast of cash dividends most recently announced: None

3. Financial Forecasts for the Fiscal Year Ending July 31, 2025 (August 1, 2024 to July 31, 2025)

Most of the Company's current operating revenue comes from milestone revenues associated with the progress of development, and these revenues are highly dependent on the development strategies and schedules of our business partners. Therefore, it is difficult to predict when the Company will receive milestone revenues, and the amount of business revenue for each fiscal year may fluctuate significantly. Hence, the Company has not provided a forecast for the fiscal year ending July 31, 2025.

The Company will continue to research and develop the " Regeneration-Inducing Medicine™ " Redasemtide (a peptide medicine created from HMGB1; development code: PJ1) in the fiscal year ending July 31, 2025. In addition, the Company expects to continue to progress the development of Regeneration-Inducing Medicine™ candidate that follows Redasemtide for the clinical trials and negotiations for licensing out.

The cash outflow for the fiscal year ending July 31, 2025, is expected to be as follows.

・Forecast cash R&D expenses in the range of 1,200 million yen to 1,600 million yen.

・Forecast cash other selling, general and administrative expenses in the range of 230 million yen to 310 million yen.

・There is a possibility that upfront payments related to new partnerships.

・There is a possibility that milestone payments from existing partners for out-licensed pipelines.

The Company has secured sufficient funds for research and development activities through 2028.

*Notes

(1) Application of specific accounting for preparing the quarterly non-consolidated financial statements: None

(2) Changes in accounting policies, changes in accounting estimates and retrospective restatements

(a)	Changes in accounting policies due to amendment to the accounting standards, etc.	: None
(b)	Changes in accounting policies other than (a) above	: None
(c)	Changes in accounting estimates	: None
(d)	Retrospective restatements	: None

(3) Number of shares issued (common stock)

(a) Number of shares issued at the end of the period (including treasury stock)

As of October 31, 2024	61,538,200 shares
As of July 31, 2024	61,523,200 shares

(b) Number of treasury stock at the end of the period

As of October 31, 2024	121 shares
As of July 31, 2024	121 shares

(c) Average number of shares during the period

Three months ended October 31, 2024	61,525,525 shares
Three months ended October 31, 2023	60,972,883 shares

* Review of the accompanying quarterly financial statements by a certified public accountant or auditing firm: None

* Explanation of the appropriate use of business forecasts and other special instructions

The forward-looking statements in this document are based on information currently available to the Company and certain assumptions deemed to be reasonable, and the Company does not assure the achievement of any of these. Furthermore, actual results may differ significantly due to various factors.

Attached Documents

Index of Appendix

1. Qualitative Information on Quarterly Financial Results for the Period under Review

(1) Explanation of operating results

The forward-looking statements in the text are based on the Company's judgment as of the date of submission.

During the three months ended October 31, 2024 (August 1, 2024, to October 31, 2024), in Japan's regenerative medicine and pharmaceutical industry, the government has implemented various initiatives to promote the creation of innovative new drugs and novel modalities. These include public support to improve the investment environment for academia and startups, support for drug discovery research, and incentives for new drug creation and addressing off-label drug usage. Efforts are also underway to foster the establishment of an innovation-generating ecosystem through collaboration among pharmaceutical companies, academia, and venture companies, aimed at advancing innovative drug discovery. Additionally, the Ministry of Economy, Trade and Industry (METI) plans to embark on platform development for automation in regenerative medicine and gene therapy manufacturing starting in fiscal year 2025 as part of its "Project for Fundamental Technology Development toward Industrialization of Regenerative Medicine and Gene Therapy." The budget proposal for fiscal year 2025 includes a request for 3.9 billion yen to support foundational technology development for the industrialization of regenerative medicine and gene therapy, signaling accelerated progress toward practical application in the field of regenerative medicine.

However, significant challenges remain, including technical issues related to safety and manufacturing technology, soaring research and development costs, and legal challenges such as regulatory and institutional improvements.

Currently, the global market size for regenerative medicine is projected to grow from 38 billion USD (approximately 6 trillion yen) in 2024 to 115 billion USD (approximately 18 trillion yen) by 2029. This indicates a steady increase in demand for regenerative medicine in the coming years.

Under these circumstances, our company has continued to make progress in the research and development of "Regeneration-Inducing Medicine™" called Redasemtide (a peptide medicine created from HMGB1), toward the initiation of new clinical trials. Additionally, for next-generation "Regeneration-Inducing Medicine™", TRIM3 and TRIM4, non-clinical development and business development activities aimed at licensing out have also shown continued progress.

"Regeneration-Inducing Medicine™" is a next-generation drug with a completely new mechanism of action, unlike conventional regenerative medicine. It does not require the transplantation of artificially cultured cells but induces mesenchymal stem cell accumulation within the patient's body through drug administration. This allows for easier and more cost-effective tissue regeneration, with effects comparable to or greater than those of traditional regenerative medicine and cell therapy. The administered substances include peptides and proteins, which can be manufactured, transported, stored, and administered using the same methods as traditional pharmaceuticals. As a result, compared to conventional regenerative medicine or cell therapy, it offers a more convenient and cost-effective means of promoting tissue regeneration, while delivering effects that are equal to or potentially greater than those of traditional methods.

Based on the concept of "realizing Regeneration-Inducing Medicine™ and cell therapy without the use of living cells, but through the administration of substances (compounds)," "Regeneration-Inducing Medicine™" is expected to overcome numerous challenges associated with transplantation therapies and conventional regenerative medicine. As an innovative regenerative medical technology, it is anticipated to become a game changer not only in Japan but also globally within the regenerative medicine industry.

The progress of R&D in each pipeline is shown in the figure below.

Project code	Development candidate	Indication	Investigator	Status	Development Stage	Out-license partner
PJ1-01	Redasemtide (HMGB1 cell mobilization domain peptides)	Epidermolysis bullosa	Shionogi & Co., Ltd.	Additional P2 Study Ongoing	Phase 3 study *	Shionogi & Co. Ltd. (S-005151)
PJ1-02		Acute Ischemic Stroke	Shionogi & Co., Ltd.	Global P2b Study Ongoing	Phase 2 study	
PJ1-03		Ischemic Cardiomyopathy	Osaka University	Physician-Initiated P2 Study Ongoing	Phase 2 study	
PJ1-04		Osteoarthritis of the knee	Hirosaki University	Physician-Initiated P2 Study Primary endpoint achieved	Phase 2 study	
PJ1-05		Chronic liver disease	Niigata University	Physician-Initiated P2 Study Primary endpoint achieved	Phase 2 study	
PJ2-01	TRIM3 (Novel Regeneration-Inducing peptide for Systemic administration)	Multiple tissue damage diseases	In-house (partnership is planned)	Pre-clinical	Pre-clinical	-
PJ2-02	TRIM4 (Novel Regeneration-Inducing peptide for Systemic administration)	Multiple tissue damage diseases	In-house (partnership is planned)	Pre-clinical	Pre-clinical	-
PJ3	TRIM5 (Novel Regeneration-Inducing peptide for Local administration)	Multiple tissue damage diseases	In-house (partnership is planned)	Pre-clinical	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	-

* Application for approval is planed after Additional Phase2.

Currently, clinical development is progressing for Redasemtide, candidate licensed out to Shionogi & Co., Ltd. The development targets include dystrophic epidermolysis bullosa (PJ1-01), acute ischemic stroke (PJ1-02), ischemic cardiomyopathy (PJ1-03), osteoarthritis of the knee (PJ1-04), and chronic liver disease (PJ1-05).

In addition, for the next-generation "Regeneration-Inducing Medicine™" candidates TRIM3 and TRIM4 (PJ2), experimental data have been steadily accumulated using various disease model animals, and business development activities aimed at licensing out have continued to progress.

Furthermore, regarding SR-GT1 (PJ5), a stem cell gene therapy aimed at a curative treatment for epidermolysis bullosa, as disclosed on December 6, 2024, the project has been selected for the fiscal year 2024 "Project for Fundamental Technology Development toward Industrialization of Regenerative Medicine and Gene Therapy" conducted by the Japan Agency for Medical Research and Development (AMED).

This research builds upon the manufacturing framework for genetically modified cell products established in the fiscal year 2022 "Practical Research Project for Rare and Intractable Diseases" and incorporates advice received through the Risk-Based Approach (RS) consultation with the Pharmaceuticals and Medical Devices Agency (PMDA). The objective is to swiftly transition to physician-initiated clinical trials by producing investigational drugs with a focus on clinical application. For this research, two-thirds of the expenses incurred can be covered by subsidies from AMED, with a maximum total grant of 179 million yen over three years.

Under these circumstances, for the three months ended October 31, 2024, operating revenue was nothing (operating revenue was nothing in the same period of the previous year), operating loss was 573,218 thousand yen (operating loss of 491,517 thousand yen in the same period of the previous year), ordinary loss was 573,160 thousand yen (ordinary loss of 491,584 thousand yen in the same period of the previous year), and net loss was 560,405 thousand yen (net loss of 467,145 thousand yen in the same period of the previous year).

(2) Explanation of financial position

Assets

Total current assets at the end of the first quarter of the fiscal year under review were 8,436,602 thousand yen, a decrease of 440,886 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 387,661 thousand yen in cash and cash deposits. Total non-current assets were 234,488 thousand yen, an increase of 31,562 thousand yen from the end of the previous fiscal year, mainly due to an increase of 31,899 thousand yen in property, plant, and equipment. As a result, total assets amounted to 8,671,090 thousand yen, a decrease of 409,324 thousand yen from the end of the previous fiscal year.

Liabilities

Total current liabilities at the end of the first quarter of the fiscal year under review were 155,299 thousand yen, an increase of 87,771 thousand yen from the end of the previous fiscal year, mainly due to an increase of 75,098 thousand yen in accounts payable-other. Total non-current liabilities were 118,396 thousand yen, an increase of 43 thousand yen from the end of the previous fiscal year, due to an increase of 43 thousand yen in asset retirement obligations. As a result, total liabilities amounted to 273,695 thousand yen, an increase of 87,814 thousand yen from the end of the previous fiscal year.

Net assets

Total net assets at the end of the first quarter of the fiscal year under review were 8,397,395 thousand yen, a decrease of 497,138 thousand yen from the end of the previous fiscal year. This was mainly due to the recording of 560,405 thousand yen in net loss, and an increase of 2,200 thousand yen in capital stock and capital surplus as a result of the exercise of stock acquisition rights and the issuance of new shares through restricted stock compensation.

(3) Financial forecasts for the fiscal year ending July 31, 2025

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The cash outflow for the fiscal year ending July 31, 2025, is expected to be as follows.

・Forecast cash R&D expenses in the range of 1,200 million yen to 1,600 million yen.
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・There is a possibility that upfront payments related to new partnerships.
・There is a possibility that milestone payments from existing partners for out-licensed pipelines.

The Company has secured sufficient funds for research and development activities through 2028.

2. Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousands of yen)

	As of July 31, 2024	As of October 31, 2024
Assets		
Current assets		
Cash and deposits	8,410,449	8,022,787
Supplies	29,334	27,954
Prepaid expenses	242,326	149,710
Other	195,379	236,149
Total current assets	8,877,489	8,436,602
Non-current assets		
Property, plant, and equipment	185,847	217,746
Intangible assets	2,439	2,273
Investments and other assets	14,638	14,467
Total non-current assets	202,925	234,488
Total assets	9,080,415	8,671,090
Liabilities		
Current liabilities		
Accounts payable-other	35,533	110,631
Accrued expenses	24,365	22,323
Income taxes payable	3,630	907
Deposits received	3,999	21,436
Total current liabilities	67,527	155,299
Non-current liabilities		
Asset retirement obligations	108,380	108,423
Deferred tax liabilities	9,973	9,973
Total non-current liabilities	118,353	118,396
Total liabilities	185,880	273,695
Net assets		
Shareholders' equity		
Capital stock	10,750	12,950
Capital surplus	9,422,825	9,425,025
Retained earning	(1,853,816)	(2,414,221)
Treasury shares	(118)	(118)
Total shareholders' equity	7,579,640	7,023,635
Stock acquisition rights	1,314,893	1,373,759
Total net assets	8,894,534	8,397,395
Total liabilities and net assets	9,080,415	8,671,090

(2) Quarterly Statements of Income

For the Three Months Ended October 31, 2024

(Thousands of yen)

	For the three months ended October 31, 2023	For the three months ended October 31, 2024
Operating revenue	—	—
Operating expenses		
Research and development expenses	348,284	379,111
Other selling, general and administrative expenses	143,233	194,107
Total operating expenses	491,517	573,218
Operating income or loss	(491,517)	(573,218)
Non-operating income		
Interest and dividend income	0	4
Subsidy income	—	53
Total non-operating income	0	58
Non-operating expenses		
Interest expenses	1	—
Foreign exchange loss	66	—
Total non-operating expenses	67	—
Ordinary income or loss	(491,584)	(573,160)
Extraordinary income		
Gain on reversal of stock acquisition rights	25,346	13,663
Total extraordinary income	25,346	13,663
Income or Loss before income taxes	(466,238)	(559,496)
Income taxes - current	907	908
Total income taxes	907	908
Net income or loss	(467,145)	(560,405)

(3) Notes to the Quarterly Financial Statements

(Notes regarding going concern assumption)
None

(Notes on significant changes in the amount of shareholders' equity)
None

(Notes on the quarterly cash flow statement)
The quarterly cash flow statement for the first quarter cumulative period has not been prepared.
However, the depreciation expenses for the first quarter cumulative period (including amortization of intangible fixed assets) are as follows:

	For the three months ended October 31, 2023	For the three months ended October 31, 2024
Depreciation Expenses	11,002 thousand yen	11,299 thousand yen

(Segment information, etc.)
[Segment information]
Since the Company is a single segment of the "Regeneration-Inducing Medicine™" business, the business results by segment are omitted.

(Significant Subsequent Events)
(Issuance of new shares as restricted stock compensation)
At the Board of Directors meeting held on November 25, 2024, our company resolved to issue new shares under the Restricted Stock Compensation Plan as outlined below. The payment procedures were completed on December 11, 2024.

1) Outline of the issuance

Payment date	December 11, 2024
Type and number of shares	475,000 shares of common stock
Issue Price	358 yen per share
Total amount of issued stocks	170,050,000 yen
Capitalized amount	179 yen per share
Allottees	Directors of the Company: 2 peoples 425,000 shares Auditors of the Company: 3 peoples 50,000 shares

2) Purpose of issuance of new shares as restricted stock compensation
The Company resolved at a meeting of the Board of Directors held on September 22, 2021, to introduce a stock-based compensation plan with restrictions on transfer that allocates shares with restrictions on transfer to the Company's directors (including outside directors) and corporate auditors. The purpose of issuance of new shares as restricted stock compensation is to promote the sustainable enhancement of the Company's corporate value over the medium to long term, to increase incentives for future increases in market capitalization, and to promote further value sharing with shareholders, including not only the benefits of rising stock prices but also the risks associated with falling stock prices. At the 16th Ordinary General Meeting of Shareholders of the Company held on October 27, 2021, a resolution was passed on the total amount of monetary remuneration claims to be paid as remuneration for the allotment of shares with transfer restrictions to the subject officers under this plan. It was decided at the meeting that the issue price of the restricted stock shall be up to 300 million yen per year for directors (including up to 60 million yen for outside directors) and up to 30 million yen per year for corporate auditors, the total number of shares of common stock to be issued up to 500 thousand shares per year for directors (including up to 100 thousand shares for outside directors) and up to 50 thousand shares per year for corporate auditors, the Company's board of directors shall determine the specific timing and distribution of the payment to each subject officer.