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, 2022 [Japanese GAAP]

December 14, 2022

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

Scheduled date of filling quarterly securities report: —
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, 2022 (August 1,2022 to October 31, 2022)

(1) Operating results (% indicates changes from the same period of the previous fiscal year)

	Operating revenue		Operating income		Ordinary income		Net income	
Three months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
October 31, 2022	—	—	(512)	—	(512)	—	(513)	—
October 31, 2021	22	(89.1)	(1,506)	—	(1,497)	—	(1,500)	—

	Earnings per share Basic	Earnings per share diluted
Three months ended	Yen	Yen
October 31, 2023	(8.62)	—
October 31, 2022	(8.32)	—

Note: Diluted earnings per share 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, 2022	9,303	9,080	87.3
As of July 31, 2022	9,597	9,404	88.7

(Reference) Equity capital: As of October 31, 2022 8,121 Million yen
As of July 31, 2022 8,513 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, 2022	—	0.00	—	0.00	0.00
July 31, 2023	—				
July 31, 2023(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, 2023 (August 1, 2022 to July 31, 2023)

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 have not provided a forecast for the fiscal year ending July 31, 2023. We will continue to research and develop of the “Regeneration-Inducing Medicine” Redasemtide (a peptide medicine created from HMGB1; development code: PJ1) in the fiscal year ending July 31, 2023. 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, 2023, 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 300 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 2026.

*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, 2022	59,659,600 shares
As of July 31, 2022	59,402,400 shares

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

As of October 31, 2022	121 shares
As of July 31, 2022	37 shares

(c) Average number of shares during the period

Three months ended October 31, 2022	59,560,279 shares
Three months ended October 31, 2021	58,937,622 shares

* Quarterly financial results reports are exempted from quarterly review conducted by certified public accountants or an audit corporation.

* 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 ····· 2
(1) Explanation of operating results ····· 2
(2) Explanation of financial position ····· 2
(3) Financial forecasts for the fiscal year ending July 31, 2022 ····· 4
2. Quarterly Financial Statements and Primary Notes ····· 5
(1) Quarterly Balance Sheets ····· 5
(2) Quarterly Statements of Income ····· 6
(3) Notes to the Quarterly Financial Statements ····· 7

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, 2022 (August 1, 2022, to October 31, 2022), we continued to make progress in the research and development of "Regeneration-Inducing Medicine" called Redasemtide (a peptide medicine created from HMGB1) for multiple ongoing clinical trials and the launch of new trials.

In the regenerative medicine industry, which is the business domain of our company, social expectations and interest in regenerative medicine technology has been increasing, as the foundation for promoting the industrialization of regenerative medicine has been laid by the Act on Securing Safety of Regenerative Medicine and the revised Pharmaceutical Affairs Law enacted in November 2014, with continued approvals of several new regenerative medicine products. The market scale of regenerative medicine is expected to increase significantly, from 95 billion yen in Japan in 2020 to 2.5 trillion yen in 2050, and from 1 trillion yen worldwide in 2020 to 38 trillion yen in 2050. This shows a tremendous need for new medical treatments for diseases that are difficult to treat with conventional drugs or medical care. Under these circumstances, we believe that it is our social mission to deliver " Regeneration-Inducing Medicine" which realizes in vivo regeneration therapy by recruitment of patient's own mesenchymal stem cells (MSCs) without utilizing in vitro cultured cells, to patients around the world suffering from various diseases including Epidermolysis Bullosa (EB) and other intractable diseases.

In the current fiscal year, the progresses of research and development on Redasemtide for each target disease are, as follows.

PJ1-01 (for Dystrophic Epidermolysis Bullosa (DEB)): An additional investigator-initiated clinical trial (Additional Phase II study) in patients with DEB was started in July 2022. The investigator-initiated clinical trial and follow-up study (Phase II) in patients with DEB was completed in March 2020. The results of these data analyses showed statistically significant improvement in the primary endpoint (rate of change in the total area of blisters, erosions, and ulcers of the whole body from the pretreatment value) as a result of Redasemtide treatment in all patients (9 patients) in this study. At the last observation point (28 weeks after the end of administration), 7 of 9 patients showed improvement below the pretreatment value, and 4 of them showed a marked improvement of 50% or more. In addition, since the efficacy was shown at the observation point after the end of the follow-up study (52 weeks after the end of administration), long-term effect of Redasemtide on DEB was also confirmed. Furthermore, since no adverse events of concern were observed in the secondary evaluation (safety evaluation), both the safety and efficacy of Redasemtide in patients with DEB were confirmed in this study. DEB is a rare intractable disease with 400 patients in Japan, and there is currently no effective treatment. In addition, it is difficult to plan a large-scale Phase III study. Therefore, Shionogi & Co., Ltd., the licensee of Redasemtide, has been in discussions with Pharmaceuticals and Medical Devices Agency (PMDA) to file an application for approval of the drug based on the results of the Phase II and follow-up study. Although the results of this study showed that there were significant cases of efficacy, it was concluded that further efficacy cases need to be accumulated. Therefore, additional study will be needed to confirm the reproducibility of the study results.

PJ1-02 (for Cerebral Infarction): Shionogi & Co., Ltd. disclosed the trial data from the Phase II clinical trial in October 2022. This trial was a placebo-controlled, double-blind, randomized, controlled study to evaluate the efficacy and safety of Redasemtide in patients who have had a cerebral infarction between 4.5 hours and 25 hours after the onset of cerebral infarction and were unable to undergo vascular recanalization (thrombolysis or thrombus retrieval). The results of evaluation of mRS after 90 days of drug administration showed that the percentage of patients who needed assistance (mRS≥3) on the day following completion of 5 days of treatment and who were no longer in need of assistance (mRS≤2) after 90 days of treatment was 34% in the Redasemtide group compared to 18% in the placebo group. The results suggest that Redasemtide is effective in patients with acute cerebral infarction. The social impact of improving the symptoms of cerebral infarction patients who require nursing care to a level where they no longer require assistance and can be socially independent is significant. Redasemtide is expected to improve the quality of life of patients with acute cerebral infarction.

In the treatment of acute cerebral infarction, thrombolytic therapy is available up to 4.5 hours after onset, and mechanical thrombus retrieval therapy is available up to 8 hours after onset. Both therapies have time limitations from onset to treatment, and this is an area in which adequate therapeutic effects have not been achieved. The option of treatment with Redasemtide, which is less time-constrained than these therapies, is expected to satisfy these unmet medical needs.

Based on the positive results of this Phase II study, Shionogi is preparing to start a global Phase III study. This study is planned to be a placebo-controlled, double-blind, randomized, comparative study to verify the efficacy of Redasemtide, and will be conducted in Japan, Europe, North America, China, and other countries.

PJ1-03 (for Cardiomyopathy): In joint research with the Department of Cardiovascular Surgery, Osaka University Graduate School of Medicine, we have demonstrated remarkable therapeutic effects and mechanisms of action in drug

efficacy tests using animal models of myocardial infarction and various cardiomyopathies. Currently, preparations are underway at Osaka University for phase II study. The results were reported at international conferences such as American Heart Association (AHA) Scientific Sessions 2018. At the 18th Annual Meeting of the Japanese Society for Regenerative Medicine in March 2019, we reported successful observation of the accumulation of GFP (green fluorescent protein)-positive bone marrow-derived cells in myocardial infarction model animals treated with Redasemtide and their active migration around blood vessels. These results have been highly evaluated.

PJ1-04 (for Osteoarthritis of the Knee): An investigator-initiated clinical trial (Phase II study) for patients with osteoarthritis of the knee has been underway at Hirosaki University since November 2020, and patient enrollment was completed in December 2021. Data analysis and evaluation will be conducted after a 4 week-treatment period and a 48 weeks follow-up period. Osteoarthritis of the Knee is a disease that causes deformity, pain and swelling of the knee due to wear and tear of the knee joint cartilage. It is estimated that the number of potential patients in Japan is about 25 million, of which about 8 million have subjective symptoms. The main cause of the disease is aging, and it occurs mostly in middle-aged people in their 40s or older. It is known that damaged articular cartilage does not repair itself easily, and it is desired to develop a new treatment method to accelerate the repair of damaged cartilage tissue or to avoid the need for joint replacement surgery. In non-clinical trials using a mouse model of cartilage defects in the knee joint, Redasemtide has been shown to have cartilage repairing effects, and is expected to become a new treatment for patients with Osteoarthritis of the Knee.

PJ1-05 (for Chronic Liver Disease): In November 2020, we started an investigator-initiated clinical trial (Phase II study) for patients with Chronic Liver Disease at Niigata University, and patient enrollment completed in June 2022. Data analysis and evaluation will be conducted after a 6 months follow-up period. Liver cirrhosis with advanced fibrosis is a disease that can cause various problems that affect the prognosis of life, such as decreased liver function, increased portal pressure, and carcinogenesis. Currently, there is no established treatment for cirrhosis with advanced fibrosis that can be expected to completely cure the disease, except for liver transplantation. Redasemtide has been confirmed to have high anti-inflammatory and fibrosis-improving effects in liver cirrhosis model mice and may become a new treatment option for patients with chronic liver disease and cirrhosis accompanied by fibrosis.

As for the projects to discover “new Regeneration-Inducing Medicine” other than Redasemtide, we have identified several new candidate compounds with remarkable activities through the multifaceted development of screening methods with continuing active R&D.

PJ5 (stem cell gene therapy) that we are developing in joint research with Osaka University is based on our own development technology that collects MSCs from the skin of patients with EB in a minimally invasive manner using a lentiviral vector. It is a radical EB treatment technology that efficiently introduces VII collagen genes into MSCs derived from the patient's skin and returns them to the patient's skin to enable a continuous supply of type VII collagen. EB model skin tissue was prepared using patient derived MSCs, and blisters were artificially formed by the aspiration method. We have confirmed that blisters do not form in skin tissue. In addition to pluripotency, MSCs have immunoregulatory functions and therapeutic effects on various diseases. A cure for the disease can be expected.

Compared to transplantation of transgenic cells via epidermal sheets or intradermal administration, stem cell gene therapy, which is less burdensome for patients and shows high and long-lasting efficacy, is expected to be a curative treatment for DEB, for which no effective curative therapy currently exists.

From April 2022, we will participate as a joint research company in the 2022 "Research Project for Practical Use of Intractable Diseases" implemented by the Japan Agency for Medical Research and Development (AMED). In this AMED-approved research, we will realize a radical treatment for DEB by utilizing the abundant data and knowledge accumulated by our company in stem cell gene therapy research.

Under these circumstances, for the three months ended October 31, 2022, operating revenue was nothing (operating revenue of 22,976 thousand yen in the same period of the previous year), operating loss was 512,755 thousand yen (operating loss of 489,861 thousand yen in the same period of the previous year), ordinary loss was 512,593 thousand yen (ordinary loss of 489,801 thousand yen in the same period of the previous year), and net loss was 513,501 thousand yen (net loss of 490,608 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 8,988,387 thousand yen, a decrease of 274,605 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 284,851 thousand yen in cash and cash deposits. Total non-current assets were 315,378 thousand yen, a decrease of 19,001 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 11,844 thousand yen in property, plant, and equipment and 7,058 thousand yen in investments and other assets. As a result, total assets amounted to 9,303,766 thousand yen, a decrease of 293,606 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 103,565 thousand yen, an

increase of 31,735 thousand yen from the end of the previous fiscal year, mainly due to an increase of 26,946 thousand yen in accounts payable-other. Total non-current liabilities were 120,110 thousand yen, a decrease of 488 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 531 thousand yen in lease obligations. As a result, total liabilities amounted to 223,676 thousand yen, an increase of 31,247 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 9,080,089 thousand yen, a decrease of 324,854 thousand yen from the end of the previous fiscal year. This was mainly due to the recording of 513,501 thousand yen in net loss, and an increase of 61,051 thousand yen in capital stock and capital surplus as a result of the exercise of stock acquisition rights and issuance of new shares through restricted stock compensation.

(3) Financial forecasts for the fiscal year ending July 31, 2023

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. Therefore, as it is difficult to calculate a reasonable forecast at this time, we have not provided a forecast for the fiscal year ending July 31, 2023. We will continue to research and develop of the “Regeneration-Inducing Medicine” Redasemtide (a peptide medicine created from HMGB1; development code: PJ1) in the fiscal year ending July 31, 2023. 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 balance for the fiscal year ending July 31, 2023, 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 300 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 2026.

2.Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousands of yen)

	As of July 31, 2022	As of October 31, 2022
Assets		
Current assets		
Cash and deposits	8,880,191	8,595,340
Supplies	4,348	14,571
Prepaid expenses	270,412	238,640
Other	108,040	139,835
Total current assets	9,262,992	8,988,387
Non-current assets		
Property, plant, and equipment	274,375	262,530
Intangible assets	855	756
Investments and other assets	59,149	52,091
Total non-current assets	334,380	315,378
Total assets	9,597,373	9,303,766
Liabilities		
Current liabilities		
Accounts payable-other	31,517	58,464
Accrued expenses	29,634	23,480
Income taxes payable	3,629	15,106
Lease obligations	3,141	2,895
Deposits received	3,907	3,618
Total current liabilities	71,830	103,565
Non-current liabilities		
Lease obligations	531	—
Asset retirement obligations	108,032	108,075
Deferred tax liabilities	12,034	12,034
Total non-current liabilities	120,598	120,110
Total liabilities	192,429	223,676
Net assets		
Shareholders' equity		
Capital stock	76,315	137,367
Capital surplus	10,620,172	10,681,224
Retained earning	(2,182,994)	(2,696,495)
Treasury shares	(31)	(118)
Total shareholders' equity	8,513,462	8,121,977
Stock acquisition rights	891,481	958,112
Total net assets	9,404,943	9,080,089
Total liabilities and net assets	9,597,373	9,303,766

(2) Quarterly Statements of Income

For the Three Months Ended October 31, 2022

(Thousands of yen)

	For the three months ended October 31, 2021	For the three months ended October 31, 2022
Operating revenue	22,976	—
Operating expenses		
Research and development expenses	358,857	370,267
Other selling, general and administrative expenses	153,979	142,487
Total operating expenses	512,837	512,755
Operating loss	(489,861)	(512,755)
Non-operating income		
Interest and dividend income	0	0
Foreign exchange gains	5	—
Subsidy income	85	210
Miscellaneous income	12	—
Total non-operating income	102	210
Non-operating expenses		
Interest expenses	42	22
Miscellaneous loss	—	26
Total non-operating expenses	42	48
Ordinary loss	(489,801)	(512,593)
Loss before income taxes	(489,801)	(512,593)
Income taxes - current	807	907
Total income taxes	807	907
Net loss	(490,608)	(513,501)

(3) Notes to the Quarterly Financial Statements

(Notes regarding going concern assumption)
None

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

(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.

(Information broken down by revenue from contracts with customers)
The Company's business is a single segment of the Regeneration-Inducing Medicine business, and operating revenues broken down by major goods and services are as follows.

(Thousands of yen)

	For the three months ended October 31, 2021	For the three months ended October 31, 2022
Lump-sum payment	—	—
Milestone income	—	—
Royalty income	—	—
Collaborative research income	—	—
Other lump-sum payments	22,976	—
Revenue from contracts with customers	22,976	—
Other income	—	—
Net income from external customers	22,976	—

(Significant Subsequent Events)
(Reduction in capital stock)
At the 17th Ordinary General Meeting of Shareholders held on October 26, 2022, the Company resolved on the "reduction in capital stock", which took effect on December 1, 2022.

1) Details of capital reduction
According to Article 447, Paragraph 1 of the Companies Act, the amount of capital stock as of September 22, 2022, of 128,960,500 yen is to be reduced by 118,960,500 yen to 10,000,000 yen, and the entire amount of capital stock to be reduced is to be transferred to other capital surplus.

2) Details of reduction in capital reserve
According to Article 448, Paragraph 1 of the Companies Act, the amount of capital reserve as of September 22, 2022, of 10,672,817,472 yen is to be reduced by 2,064,033,607 yen to 8,608,783,865 yen and the entire amount of capital reserve to be reduced is to be transferred to other capital surplus.

3) Details of appropriation of retained earnings
According to Article 452 of the Companies Act, and subject to the reduction of capital stock and capital reserve as described in 1 and 2 above becoming effective, other capital surplus will be transferred to retained earnings brought forward as follows to cover the deficit.
(1) Amount of surplus to be reduced
Other capital surplus 2,182,994,107 yen
(2) Amount of surplus to be increased
Retained earnings brought forward 2,182,994,107 yen

4) Schedule

(1) Resolution of the board of directors	September 22, 2022
(2) Resolution of the Ordinary General Meeting of Shareholders	October 26, 2022
(3) Announcement to creditors for submitting their objections	October 28, 2022
(4) Deadline for creditor objections	November 28, 2022
(5) Effective date of the capital reduction	December 1, 2022

(Issuance of new shares as restricted stock compensation)

At a meeting of the Board of Directors held on November 9, 2022, the Company resolved to issue new shares of stock as a restricted stock compensation plan with a payment completion date of December 7, 2022. The outline is as follows.

1) Outline of the issuance

Payment date	December 7, 2022
Type and number of shares	280,000 shares of common stock
Issue Price	827 yen per share
Total amount of issued stocks	231,560,000 yen
Capitalized amount	413.5 yen per share
Allottees	Directors of the Company: 2 peoples 245,000 shares Auditors of the Company: 3 peoples 35,000 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.