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, 2021 [Japanese GAAP]

December 9, 2021

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.
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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: Sone

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

1. Financial Results for the Three Months Ended October 31, 2021 (August 1,2021 to October 31, 2021)

(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, 2021	22	(89.1)	(489)	—	(489)	—	(490)	—
October 31, 2020	210	—	(268)	—	(268)	—	(261)	—

	Earnings per share basic	Earnings per share diluted
Three months ended	Yen	Yen
October 31, 2021	(8.32)	—
October 31, 2020	(4.59)	—

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, 2021	10,586	10,383	92.9
As of July 31, 2021	10,909	10,696	94.4

(Reference) Equity capital: As of October 31, 2021 9,838 Million yen
As of July 31, 2021 10,298 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, 2021	—	0.00	—	0.00	0.00
July 31, 2022	—				
July 31, 2022(forecast)		0.00	—	0.00	0.00

3. Financial Forecasts for the Fiscal Year Ending July 31, 2022 (August 1, 2021 to July 31, 2022)

The majority 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, 2022. 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, 2022. 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, 2022, is expected to be as follows
・Forecast cash R&D expenses in the range of 1,200 million yen to 1,500 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.	:	Yes
(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, 2021	58,964,100 shares
As of July 31, 2021	58,851,600 shares

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

As of October 31, 2021	— shares
As of July 31, 2021	— shares

(c) Average number of shares during the period

Three months ended October 31, 2021	58,937,622 shares
Three months ended October 31, 2020	57,026,410 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

(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, 2021 (August 1, 2021, to October 31, 2021), 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 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 investigator-initiated clinical trial (Phase II study) and the follow-up study in patients with DEB was completed in March 2020. In the result, Redasemtide administration showed a 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). Even at the final observation point after the end of Redasemtide administration (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 200 patients in Japan, and there is currently no effective treatment. In addition, it is estimated that there are only about 15 new patients per year, and 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 need to confirm the reproducibility of the study results.

PJ1-02 (for Cerebral Infarction): A phase II study has started at Shionogi & Co., Ltd., the licensee of this drug. In July 2021, patient inclusion reached and completed the target of 150 cases. This study is a double-blind comparative study of the efficacy of Redasemtide in patients with acute cerebral infarction using the modified Rankin Scale (mRS: a scale to evaluate the severity of cerebrovascular disorders such as cerebral hemorrhage and cerebral infarction) as an index after 90 days of treatment. Currently, data analysis and evaluation are being conducted after the follow-up period of patients enrolled in the clinical trial.

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 (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 the first patient was enrolled in the clinical trial in March 2021. 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.

In addition, we are developing a therapeutic drug for Pulmonary Fibrosis (including COVID-19 pneumonia) with Redasemtide. In a mouse model of pulmonary fibrosis, administration of Redasemtide statistically significantly suppressed the amount of hydroxyproline, an indicator of collagen in the lung, by up to 70%, and histopathological evaluation confirmed a decrease in the fibrosis score. In addition, the results of transcutaneous arterial oxygen saturation (SpO2) measurements showed an improvement in pulmonary function, which is important in clinical practice. In the LPS-induced acute inflammatory pneumonia model, the amounts of cytokines and the number of inflammatory cells in the lung tended to decrease after treatment with Redasemtide. These results suggest the efficacy of Redasemtide against acute hyperinflammation of COVID-19. In addition, in the parabiosis mouse model, mesenchymal stem cells induced by Redasemtide differentiated into Ace2-positive type 2 alveolar epithelium in the injured lung and contributed to the regeneration of alveolar function.

In severe cases of COVID-19 pneumonia, alveolar epithelial cells and vascular endothelial cells around the alveoli are irreversibly damaged. In addition, pulmonary function impairment remains as a long-term sequela after healing from pneumonia. It is known that antiviral drugs and anti-inflammatory drugs cannot be expected to restore the lost lung function. Mesenchymal stem cells, which accumulate in damaged tissues from the bone marrow after the administration of Redasemtide, have been shown to have anti-inflammatory and anti-fibrotic effects, as well as regenerating epithelial and vascular tissues. Redasemtide is expected to be the first drug in the world to reduce the risk of sequelae of COVID-19 pneumonia.

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.

Under these circumstances, for the three months ended October 31,2021, operating revenue was 22,976 thousand yen (operating revenue of 210,000 thousand yen in the same period of the previous year), operating loss was 489,861 thousand yen (operating loss of 268,439 thousand yen in the same period of the previous year), ordinary loss was 489,801 thousand yen (ordinary loss of 268,274 thousand yen in the same period of the previous year), and net loss was 490,608 thousand yen (net loss of 261,525 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 10,194,379 thousand yen, a decrease of 303,115 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 298,645 thousand yen in cash and cash deposits. Total non-current assets were 391,641 thousand yen, a decrease of 20,142 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 12,264 thousand yen in property, plant, and equipment and 7,779 thousand yen in investments and other assets.

Liabilities

Total current liabilities at the end of the first quarter of the fiscal year under review were 77,779 thousand yen, a decrease of 9,845 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 8,240 thousand yen in accounts payable-other. Total non-current liabilities were 124,279 thousand yen, a decrease of 734 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 777 thousand yen in lease obligations.

Net assets

Total net assets at the end of the first quarter of the fiscal year under review were 10,383,962 thousand yen, a decrease of 312,678 thousand yen from the end of the previous fiscal year, mainly due to the recording of 490,608 thousand yen in net loss and an increase of 15,515 thousand yen in capital stock and capital surplus as a result of the exercise of stock acquisition rights.

(3) Outlook for the Fiscal Year Ending July 31, 2022

The majority 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, 2022. 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, 2022. 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, 2022, is expected to be as follows

- Forecast cash R&D expenses in the range of 1,200 million yen to 1,500 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, 2021	As of October 31, 2021
Assets		
Current assets		
Cash and deposits	10,172,222	9,873,576
Supplies	12,111	8,219
Prepaid expenses	269,644	246,480
Other	43,516	66,102
Total current assets	10,497,494	10,194,379
Non-current assets		
Property, plant, and equipment	323,122	310,857
Intangible assets	1,249	1,151
Investments and other assets	87,412	79,633
Total non-current assets	411,784	391,641
Total assets	10,909,279	10,586,020
Liabilities		
Current liabilities		
Accounts payable-other	49,333	41,092
Accrued expenses	27,677	28,952
Income taxes payable	3,628	907
Lease obligations	3,060	3,080
Deposits received	3,925	3,746
Total current liabilities	87,625	77,779
Non-current liabilities		
Lease obligations	3,673	2,895
Asset retirement obligations	107,858	107,902
Deferred tax liabilities	13,481	13,481
Total non-current liabilities	125,013	124,279
Total liabilities	212,638	202,058
Net assets		
Shareholders' equity		
Capital stock	32,424	47,939
Capital surplus	10,500,407	10,515,922
Retained earning	(234,686)	(725,295)
Total shareholders' equity	10,298,145	9,838,566
Stock acquisition rights	398,495	545,395
Total net assets	10,696,640	10,383,962
Total liabilities and net assets	10,909,279	10,586,020

(2) Quarterly Statements of Income

For the Three Months Ended October 31, 2021

(Thousands of yen)

	For the three months ended October 31, 2020	For the three months ended October 31, 2021
Operating revenue	210,000	22,976
Operating expenses		
Research and development expenses	360,456	358,857
Other selling, general and administrative expenses	117,982	153,979
Total operating expenses	478,439	512,837
Operating loss	(268,439)	(489,861)
Non-operating income		
Interest and dividend income	5	0
Foreign exchange gains	—	5
Miscellaneous income	221	97
Total non-operating income	227	102
Non-operating expenses		
Interest expenses	62	42
Foreign exchange loss	0	—
Total non-operating expenses	62	42
Ordinary loss	(268,274)	(489,801)
Extraordinary income		
Gain on reversal of share acquisition rights	7,555	—
Total extraordinary income	7,555	—
Loss before income taxes	(260,718)	(489,801)
Income taxes - current	806	807
Total income taxes	806	807
Net loss	(261,525)	(490,608)

(3) Notes to the Quarterly Financial Statements

(Notes regarding going concern assumption)

None

(Notes on significant changes in the amount of shareholders' equity)

None

(Changes in accounting policies)

(Application of the Accounting Standard for Revenue Recognition, etc.)

From the beginning of the first quarter of the fiscal year ending July 31, 2022, the Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020), etc., and recognizes revenue at the amounts expected to be received in exchange for promised goods or services, at the point when the control of such goods or services is transferred to customers. The Company has adopted the "Accounting Standard for Revenue Recognition" (ASBJ Statement No.84) in accordance with the transitional treatment. There is no effect on the beginning balance of retained earnings brought forward and profit and loss for the first quarter of the current fiscal year.

(Application of the Accounting Standard for Fair Value Measurement, etc.)

From the beginning of the first quarter of the fiscal year ending July 31, 2022, the Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019), etc. In accordance with the transitional treatment prescribed in Paragraph 19 of the Accounting Standard for Fair Value Measurement and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019), the new accounting policies prescribed by the Accounting Standard for Fair Value Measurement, etc. will be applied prospectively. There is no effect of the new standards on the quarterly financial statements.

(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 revenues broken down by major goods and services are as follows.

(Thousands of yen)

	For the three months ended October 31, 2021
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

(Important subsequent events)

(Reduction in capital stock)

At the 16th Ordinary General Meeting of Shareholders held on October 27, 2021, the Company resolved on the "reduction in capital stock", which took effect on December 1, 2021.

1) Purpose of reduction of capital amount

The Company shall reduce the amount of capital stock and transfer it to capital reserve in accordance with Article 447, Paragraph 1 of the Japanese Companies Act for the purpose of ensuring flexibility and mobility in its future capital policy.

2) Details of the reduction in capital stock

(1) Amount of capital stock to be reduced

Capital stock of 47,936 thousand yen will be reduced by 37,936 thousand yen to 10,000 thousand yen.

(2) Method of reduction in capital stock

This reduction in capital stock is a gratuitous capital reduction with no refunds, does not involve any change in the total number of issued shares, and will reduce only the amount of capital stock and transfer it to capital surplus.

3) Schedule

(1) Resolution of the board of directors	September 22, 2021
(2) Resolution of the Ordinary General Meeting of Shareholders	October 27, 2021
(3) Announcement to creditors for submitting their objections	October 30, 2021
(4) Deadline for creditor objections	November 29, 2021
(5) Effective date of the capital reduction	December 1, 2021

(Issuance of new shares as restricted stock compensation)

At a meeting of the Board of Directors held on November 11, 2021, the Company resolved to issue new shares of stock as a restricted stock compensation plan with a payment completion date of December 10, 2021. The outline is as follows.

1) Outline of the issuance

Payment date	December 10, 2021
Type and number of shares	81,000 shares of common stock
Issue Price	512 yen per share
Total amount of issued stocks	41,472,000 yen
Capitalized amount	256 yen per share
Allottees	Directors of the Company (including outside directors): 4 (57,000 shares) Auditors of the Company: 3 (24,000 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.