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 Nine Months Ended April 30, 2022 [Japanese GAAP]

June 9, 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 Nine Months Ended April 30, 2022 (August 1,2021 to April 30, 2022)

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

	Operating revenue		Operating income		Ordinary income		Net income	
Nine months ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
April 30, 2022	22	(89.1)	(1,506)	—	(1,497)	—	(1,500)	—
April 30, 2021	210	(47.5)	(1,294)	—	(1,296)	—	(1,294)	—

	Earnings per share Basic	Earnings per share diluted
Nine months ended	Yen	Yen
April 30, 2022	(25.38)	—
April 30, 2021	(22.37)	—

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 April 30, 2022	9,958	9,765	89.8
As of July 31, 2021	10,909	10,696	94.4

(Reference) Equity capital: As of April 30, 2022 8,942 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	—	0.00			
July 31, 2022(forecast)				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, 2022 (August 1, 2021 to July 31, 2022)

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, 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 1,100 million yen to 1,300 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 April 30, 2022	59,342,700 shares
As of July 31, 2021	58,851,600 shares

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

As of April 30, 2022	— shares
As of July 31, 2021	— shares

(c) Average number of shares during the period

Nine months ended April 30, 2022	59,129,412 shares
Nine months ended April 30, 2021	57,868,901 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.

In addition, from the first quarter accounting period, "Accounting Standard for Revenue Recognition" (Accounting Standards Board of Japan No. 29 March 31, 2020) etc. have been applied.

During the nine months ended April30, 2022 (August 1, 2021, to April 30, 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 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 needed to confirm the reproducibility of the study results.

PJ1-02 (for Cerebral Infarction): Shionogi & Co., Ltd., the licensee of Redasemtide, announced that the primary endpoint of the Phase II clinical trial was achieved in December 2021. This was a phase II, 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 24 hours after the onset of cerebral infarction and were unable to undergo vascular recanalization (thrombolysis or thrombus retrieval). The modified Rankin Scale (mRS: a scale to evaluate the severity of cerebrovascular disorders such as cerebral hemorrhage and cerebral infarction) after 90 days of drug administration was evaluated as the primary endpoint, and the results confirmed the achievement of the primary endpoint and confirmed the efficacy of Redasemtide in patients with acute cerebral infarction. In terms of safety, a secondary endpoint, the incidence of adverse events was similar in the Redasemtide and placebo groups, confirming that the drug was well tolerated. 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. Redasemtide treatment options, which are less time-consuming than conventional angiolytic and mechanical thrombus retrieval therapies, are expected to meet these unmet medical needs. Based on the positive results of this clinical trial, Shionogi & Co., Ltd. plans to proceed with preparations for the transition to global Phase III study.

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 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.

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.

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 have therapeutic effects on various diseases. A cure for the disease can be expected. 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 nine months ended April 30, 2022, 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 1,506,320 thousand yen (operating loss of 1,294,216 thousand yen in the same period of the previous year), ordinary loss was 1,497,934 thousand yen (ordinary loss of 1,296,699 thousand yen in the same period of the previous year), and net loss was 1,500,555 thousand yen (net loss of 1,294,412 thousand yen in the same period of the previous year).

(2) Explanation of financial position

Assets

Total current assets at the end of the third quarter of the fiscal year under review were 9,603,692 thousand yen, a decrease of 893,802 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 1,056,448 thousand yen in cash and cash deposits. Total non-current assets were 354,324 thousand yen, a decrease of 57,459 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 36,132 thousand yen in property, plant, and equipment and 21,030 thousand yen in investments and other assets.

Liabilities

Total current liabilities at the end of the third quarter of the fiscal year under review were 70,185 thousand yen, a decrease of 17,439 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 18,944 thousand yen in accounts payable-other. Total non-current liabilities were 122,795 thousand yen, a decrease of 2,218 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 2,348 thousand yen in lease obligations.

Net assets

Total net assets at the end of the third quarter of the fiscal year under review were 9,765,036 thousand yen, a decrease of 931,603 thousand yen from the end of the previous fiscal year. This was mainly due to the recording of 1,500,555 thousand yen in net loss, an increase of 424,174 thousand yen in stock acquisition rights, and an increase of 72,338 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, 2022

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, 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 1,100 million yen to 1,300 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 April 30, 2022
Assets		
Current assets		
Cash and deposits	10,172,222	9,115,773
Supplies	12,111	3,773
Prepaid expenses	269,644	400,924
Other	43,516	83,221
Total current assets	10,497,494	9,603,692
Non-current assets		
Property, plant, and equipment	323,122	286,989
Intangible assets	1,249	953
Investments and other assets	87,412	66,381
Total non-current assets	411,784	354,324
Total assets	10,909,279	9,958,017
Liabilities		
Current liabilities		
Accounts payable-other	49,333	30,388
Accrued expenses	27,677	30,069
Income taxes payable	3,628	2,722
Lease obligations	3,060	3,121
Deposits received	3,925	3,883
Total current liabilities	87,625	70,185
Non-current liabilities		
Lease obligations	3,673	1,324
Asset retirement obligations	107,858	107,989
Deferred tax liabilities	13,481	13,481
Total non-current liabilities	125,013	122,795
Total liabilities	212,638	192,980
Net assets		
Shareholders' equity		
Capital stock	32,424	66,876
Capital surplus	10,500,407	10,610,732
Retained earning	(234,686)	(1,735,242)
Total shareholders' equity	10,298,145	8,942,366
Stock acquisition rights	398,495	822,670
Total net assets	10,696,640	9,765,036
Total liabilities and net assets	10,909,279	9,958,017

(2) Quarterly Statements of Income

For the Nine Months Ended April 30, 2022

(Thousands of yen)

	For the nine months ended April 30, 2021	For the nine months ended April 30, 2022
Operating revenue	210,000	22,976
Operating expenses		
Research and development expenses	1,157,869	1,073,275
Other selling, general and administrative expenses	346,346	456,021
Total operating expenses	1,504,216	1,529,296
Operating loss	(1,294,216)	(1,506,320)
Non-operating income		
Interest and dividend income	8	0
Subsidy income	293	273
Foreign exchange gains	24	5
Business consignment income	—	8,000
Miscellaneous income	20	220
Total non-operating income	346	8,499
Non-operating expenses		
Interest expenses	171	112
Loss on removal	2,657	—
Miscellaneous loss	0	—
Total non-operating expenses	2,829	112
Ordinary loss	(1,296,699)	(1,497,934)
Extraordinary income		
Gain on reversal of share acquisition rights	7,784	—
Total extraordinary income	7,784	—
Loss before income taxes	(1,288,915)	(1,497,934)
Income taxes - current	2,722	2,621
Income taxes – deferred	2,774	—
Total income taxes	5,496	2,621
Net loss	(1,294,412)	(1,500,555)

(3) Notes to the Quarterly Financial Statements

(Notes regarding going concern assumption)

None

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

Reduction in capital stock took effect on December 1, 2021. As a result, the amount of capital stock decreased by 37,936 thousand yen and the amount of capital surplus increased by 37,936 thousand yen based on the resolution of the 16th Ordinary General Meeting of Shareholders held on October 27, 2021. At the end of the third quarter of the fiscal year under review, capital stock amounted to 66,876 thousand yen and capital surplus amounted to 10,610,732 thousand yen.

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

(Thousands of yen)

	For the nine months ended April 30, 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