Non-consolidated Financial Results for the Nine Months Ended April 30, 2021 [Japanese GAAP]

June 10, 2021

Company name: StemRIM Inc.
Stock exchange listing: Tokyo Stock Exchange
Stock code: 4599
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Scheduled date of filling quarterly securities report: —
Scheduled date of commencing dividend payments: —
Supplementary briefing materials on financial results: —
Explanatory meeting on financial results: —

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

1. Financial Results for the Nine Months Ended April 30, 2021 (August 1,2020 to April 30, 2021)

(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, 2021	210	47.5	(1,294)	—	(1,296)	—	(1,294)	—
April 30, 2020	400	300.0	(391)	—	(443)	—	(446)	—

	Net income per share	Diluted net income per share
Nine months ended	Yen	Yen
April 30, 2021	(22.97)	—
April 30, 2020	(8.37)	—

Note: Diluted net income 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, 2021	10,091	9,880	94.9
As of July 31, 2020	11,281	10,850	95.5

(Reference) Equity capital: As of April 30, 2021 9,574 Million yen
As of July 31, 2020 10,768 Million yen

2. Payment of Dividends

	Annual dividends				
	End Q1	End Q2	End Q3	Year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal Year ended July 31, 2020	—	0.00	—	0.00	0.00
Fiscal Year ended July 31, 2021	—	0.00	—		
Fiscal Year ended July 31, 2021(forecast)				0.00	0.00

3. Financial Forecasts for the Fiscal Year Ending July 31, 2021 (August 1,2020 to July 31, 2021)

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

	Operating revenue		Operating income		Ordinary income		Net income		Net income per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Fiscal Year ending July 31, 2021	2,300	9.5	138	(66.6)	138	(61.6)	135	(61.1)	2.37

*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 April 30, 2021	58,802,700 shares
As of July 31, 2020	56,789,400 shares

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

As of April 30, 2021	— shares
As of July 31, 2020	— shares

(c) Average number of shares during the period

Nine months ended April 30, 2021	57,868,901 shares
Nine months ended April 30, 2020	53,280,256 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. Qualitive Information on Quarterly Financial Results for the Period under Review

(1) Explanation of operating results

Regarding our business overview, the company engaged in R&D of "a kind of" regenerative medicine named "Regeneration-Inducing Medicine". As described here, "Regeneration-Inducing Medicine" is new class of medicine that induces functional regeneration of damaged tissues or organs by maximizing the patient's innate ability of tissues repairing.

HMGB1 peptide, a Regeneration-Inducing Medicine, is a peptide preparation created from the bioactive domain of the in vivo HMGB1 protein. When Regeneration-Inducing Medicine, chemically synthesized drug including HMGB1 peptide, is injected intravenously, the administered drug in blood stream acts as a SOS signal in the patient's body, and stimulates and mobilizes patient's mesenchymal stem cells stored in bone marrow into the bloodstream. Then the mesenchymal stem cells released into the blood stream will sense, reach, accumulate the damaged tissue expressing specific signals including SDF1a, and eventually the damaged tissue are functionally repaired. So, this medicine is different from usual regenerative medicine using transplantation of cells expanded or in vitro. This is unique regenerative medicine that stimulates our native but poised repair mechanism by our drug. In non-clinical drug efficacy studies using disease model animals conducted so far, cerebral infarction, myocardial infarction / cardiomyopathy, epidermolysis bullosa, refractory skin ulcer, spinal cord injury, amyotrophic lateral sclerosis (ALS), trauma. We have confirmed a good therapeutic effect on sexual brain injury, ulcerative colitis, etc.

During the nine months ended April 30, 2021 (August 1, 2020, to April 30, 2021), we continued to make progress in the research and development of "Regeneration-Inducing Medicine" called Redasemtide (a peptide medicine created from HMGB1) toward clinical trials.

As for the concrete progress, we have partially achieved the conditions for receiving the lump-sum payment and received 210 million yen for the agreement with Shionogi & Co., Ltd. on June 30, 2020, to accelerate the clinical development of Redasemtide for multiple diseases. In the future, we will utilize the evidence of non-clinical research that we have accumulated through joint research with multiple academia groups with Shionogi &Co., Ltd. and preparing to start investigator-initiated clinical trial (Phase II study) for three new indications diseases (chronic liver disease and knee osteoarthritis, cardiomyopathy).

In January 2021, we expanded the Head Office Research Laboratory and built a new animal experiment facility (223 ㎡) in the same building. In this animal experiment facility, we plan to conduct screening of new seeds, drug efficacy testing using laboratory animals, and testing of in vivo stem cell integration devices, etc. With the completion of this animal testing facility, we have been able to dramatically increase the efficiency of our non-inflammatory research in the development of Regeneration-Inducing Medicine. We believe that this facility will contribute to the further expansion of target disease areas for Regeneration-Inducing Medicine in the future.

In addition, won a grant from Japan Agency for Medical Development (AMED), titled "Development of therapeutic drug for new coronavirus infections (COVID-19) (3rd round of public offering)". Mesenchymal stem cells, which accumulate in damaged tissues from bone marrow after administration of Redasemtide, have been shown to have anti-inflammatory and anti-fibrotic effects, as well as regenerating epithelial and vascular tissues. Therefore, Redasemtide is expected to be the first therapeutic agent in the world to reduce the risk of sequelae of COVID-19 pneumonia.

In the current fiscal year, we have been conducting research and development on the Regeneration-Inducing Medicine development project using Redasemtide, which is the most developed in our company, as follows.

As PJ1-01, Regarding the development a therapeutic drug for Epidermolysis Bullosa (EB), at the 41st EB Study Group held in January 2020 and the 1st International EB Conference (The 2020 EB World Congress) flush results of a investigator-initiated clinical trial (Phase II study) in patients with Dystrophic Epidermolysis Bullosa (DEB) were reported, and all patients (n=9) with DEB participated in this trial. In the result, Redasemtide administration confirmed 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 time after the end of Redasemtide administration (6 months 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, and long-term therapeutic of Redasemtide effect on malnourished EB was also confirmed. In addition, no adverse events of concern were observed in the secondary evaluation (safety evaluation), confirming the efficacy and safety of Redasemtide administration in patients with nutritionally impaired EB.

Regarding EB treatment, the target nutritional disorder type EB is a rare intractable disease with 200 patients in Japan, and there is currently no effective treatment. In addition, it is estimated that there will be about 15 new patients per year, and it is difficult to plan a large-scale Phase III study. Therefore, based on the results of the Phase II study, we expecting to apply for approval of the drug.

As PJ1-02, Regarding the development of a therapeutic drug for Cerebral Infarction, a phase II clinical trial has started at Shionogi & Co., Ltd., the licensee of this drug. In November 2019, the first patient was enrolled in the clinical trial,

the inclusion of patients and confirmation of safety has progressed smoothly so far, and we expect that administration to patients will proceed in the future.

As PJ1-03, Regarding the development of a therapeutic drug 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. The results were reported at international conferences such as AHA (American Heart Association) Scientific Sessions 2018. At the 18th Annual Meeting of the Japanese Society for Regenerative Medicine in March 2019, we successfully observed 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.

As PJ1-04, Regarding the development of a therapeutic drug for Osteoarthritis of the Knee, in November 2020, we started investigator-initiated clinical trial (Phase II study) for patients with Osteoarthritis of the Knee at Hirosaki University. In February 2021, the first patient was enrolled in the clinical trial. 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 desirable 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.

As PJ1-05, Regarding the development of a therapeutic drug 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. In May 2021, the first patient was enrolled in the clinical trial. 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 mouse, and may become a new treatment option for patients with chronic liver disease and cirrhosis accompanied by fibrosis, for which there has been no effective treatment.

As for the project to search for new Regeneration-Inducing Medicine candidates other than Redasemtide, we have identified several new candidate compounds with remarkable activity because of the multifaceted development of candidate screening while continuing active R&D investment for the selection of next-generation development candidates. As a result, we have been able to identify several new candidate compounds with remarkable activity.

Financial results for the nine months ended April 30,2021, operating revenue was 210,000 thousand yen (operating revenue of 400,000 yen in the same period of the previous year), operating loss was 1,294,216 thousand yen (operating loss of 391,591 thousand yen in the same period of the previous year), ordinary loss was 1,296,699 thousand yen (ordinary loss of 443,334 thousand yen in the same period of the previous year), and net loss was 1,294,412 thousand yen (net loss of 446,070 thousand yen in the same period of the previous year).

(2) Explanation of financial position

Asset

Total current assets at the end of the third quarter of the fiscal year under review were 9,657,980 thousand yen, a decrease of 1,308,730 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 1,536,721 thousand yen in cash. Total non-current assets were 433,448 thousand yen an increase of 118,744 thousand yen from the end of the previous fiscal year, mainly due to an increase of 107,824 thousand yen in property, plant, and equipment and 10,676 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 85,518 thousand yen, a decrease of 269,011 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 214,206 thousand yen in accounts payable-other. Total non-current liabilities were 125,742 thousand yen, an increase 48,911 thousand yen from the end of the previous fiscal year, mainly due to an increase of 48,425 thousand yen in asset retirement obligations.

Net assets

Total net assets at the end of the third quarter of the fiscal year under review were 9,880,167 thousand yen, a decrease of 969,887 thousand yen from the end of the previous fiscal year, mainly due to the recording of 1,294,412 thousand yen in net loss, an increase of 224,241 thousand yen in stock acquisition rights, and an increase of 50,141 thousand yen in capital stock and capital surplus as a result of the exercise of stock acquisition rights.

3.Quarterly Financial Statements and Primary Notes

(1) Quarterly Balance Sheets

(Thousands of yen)

	As of July 31, 2020	As of April 30, 2021
Assets		
Current assets		
Cash and deposits	10,675,242	9,138,520
Supplies	18,047	11,878
Prepaid expenses	266,630	388,853
Other	6,790	118,727
Total current assets	10,966,711	9,657,980
Non-current assets		
Property, plant, and equipment	229,006	336,830
Intangible assets	1,104	1,348
Investments and other assets	84,592	95,269
Total non-current asset	314,704	433,448
Total assets	11,281,415	10,091,428
Liabilities		
Current liabilities		
Accounts payable-other	252,956	38,749
Accrued expenses	19,192	23,007
Income taxes payable	3,286	2,721
Lease obligations	2,980	3,040
Deposits received	14,867	4,316
Other	61,245	13,683
Total current liabilities	354,529	85,518
Non-current liabilities		
Lease obligations	6,733	4,445
Asset retirement obligations	59,390	107,815
Deferred tax liabilities	10,707	13,481
Total non-current liabilities	76,830	125,742
Total liabilities	431,360	211,260
Net assets		
Shareholders' equity		
Capital stock	49,288	26,416
Capital surplus	10,371,245	10,494,400
Retained earning	347,761	(946,651)
Total shareholders' equity	10,768,294	9,574,165
Stock acquisition rights	81,760	306,002
Total net assets	10,850,054	9,880,167
Total liabilities and net assets	11,281,415	10,091,428

(2) Quarterly statements of income

For the Nine Months Ended April 30, 2021

(Thousands of yen)

	For the nine months ended April 30, 2020	For the nine months ended April 30, 2021
Operating revenue	400,000	210,000
Operating expenses		
Research and development expenses	584,677	1,157,869
Other selling, general and administrative expenses	206,913	346,346
Total operating expenses	791,591	1,504,216
Operating loss	(391,591)	(1,294,216)
Non-operating income		
Interest and dividend income	12	8
Subsidy income	13,049	293
Foreign exchange gains	—	24
Miscellaneous income	18	20
Total non-operating income	13,080	346
Non-operating expenses		
Interest expenses	229	171
Share issuance cost	55,221	—
Listing related costs	9,363	—
Foreign exchange loss	9	—
Loss on removal	—	2,657
Miscellaneous loss	—	0
Total non-operating expenses	64,824	2,829
Ordinary loss	(443,334)	(1,296,699)
Extraordinary income		
Gain on reversal of share acquisition rights	—	7,784
Total extraordinary income	—	7,784
Loss before income taxes	(443,334)	(1,288,915)
Income taxes - current	2,722	2,722
Income taxes - deferred	13	2,774
Total income taxes	2,736	5,496
Net loss	(446,070)	(1,294,412)

(3) Notes to the 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, 2020. As a result, the amount of capital stock decreased by 73,013 thousand yen and the amount of capital surplus increased by 73,013 thousand yen based on the resolution of the 15th Ordinary General Meeting of Shareholders held on October 28, 2020.As a result, at the end of the third quarter of the fiscal year under review, capital stock and capital surplus amounted to 26,416 thousand yen and 10,494,400 thousand yen, respectively.

(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.