

Non-consolidated Financial Results for the Six Months Ended January 31, 2020 [Japanese GAAP]

March 11, 2020

Company name: StemRIM Inc.
 Stock exchange listing: Tokyo Stock Exchange
 Stock code: 4599
 URL: <https://stemrim.com/>
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Scheduled date of filing quarterly securities report: March 12, 2020
 Scheduled date of commencing dividend payments: —
 Supplementary briefing materials on financial results: No
 Explanatory meeting on financial results: Yes (for institutional investors and analysts)

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

1. Financial Results for the Six Months Ended January 31, 2020 (August 1, 2019 to January 31, 2020)

(1) Operating results (% indicates changes from the previous corresponding period)

	Net Sales		Operating income		Ordinary income		Net income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Six months ended January 31, 2020	—	—	(465)	—	(519)	—	(520)	—
Six months ended January 31, 2019	—	—	—	—	—	—	—	—

	Net income per share		Diluted net income per share	
	Yen		Yen	
Six months ended January 31, 2020	(9.96)		—	
Six months ended January 31, 2019	—		—	

Notes: 1. Since the Company did not disclose quarterly financial results for the second quarter of the fiscal period ending July 2019, the figures for the second quarter of the fiscal period ending July 2019 and the year-on-year changes for the second quarter are not stated herein.

2. 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	%
Six months ended January 31, 2020	9,969	9,861	98.9
Fiscal Year ended July 31, 2019	2,687	2,595	96.5

(Reference) Equity capital: Six months ended January 31, 2020 9,861 Million yen
Fiscal Year ended July 30, 2019 2,595 Million yen

2. Payment of Dividends

	Annual dividends				
	1st net assets quarter-end	2nd net assets quarter-end	3rd net assets quarter-end	Year-end Total	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal Year ended July 31, 2019	—	0.00	—	0.00	0.00
Fiscal Year ended July 31, 2020	—	0.00	—	—	—
Fiscal Year ended July 31, 2020 (forecast)	—	—	—	0.00	0.00

(Note) Revision to the forecast for dividends announced most recently: No

3. Financial Forecasts for the Fiscal Year Ending July 31, 2020 (August 1,2019 to July 31, 2020)

(% indicates changes from the previous corresponding period))

	Net Sales		Operating income		Ordinary income		Net income		Net income per share
	Million yen	%	Million yen	%	Million yen	%	Million yen	%	Yen
Fiscal Year ended July 31, 2020	400	300.0	(1,090)	—	(1,134)	—	(1,137)	—	(21.68)

(Note) Revision to the financial results forecast announced most recently: No

*Notes

(1) Application of specific accounting for preparing the quarterly 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 January 31, 2020	53,104,800 shares
As of July 31, 2019	44,282,700 shares

b. Number of treasury stock at the end of the period

As of January 31, 2020	— shares
As of July 31, 2019	— shares

c. Average number of shares during the period

Six months ended January 31, 2020	52,298,632 shares
Six months ended January 31, 2019	— shares

(Note) Since the Company did not disclose quarterly financial results for the second quarter of the fiscal period ending July 2019, the average number of shares during the second quarter of the fiscal period ending July 2019 is not stated.

* 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

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1. Qualitative information on quarterly financial results

(1) Explanation of operating results

During the six months ended January 31, 2020 (from August 1, 2019 to January 31, 2020), the Company listed its stock on the Mothers market of the Tokyo Stock Exchange on August 9, 2019. Since its foundation, the Company has been promoting research and development toward the realization of “Regeneration-Inducing Medicine” that the company has been working on since its establishment. “Regeneration-Inducing Medicine” is based on a new mechanism of action that promotes the functional regeneration and healing of tissues that have been damaged due to injury or disease.

As for the specific progress, investigator-initiated phase II clinical trial of HMGB1 peptide, which had started in December 2017 for treatment of an intractable hereditary skin disease Epidermolysis Bullosa, continued to make good progress at Osaka University Hospital, Keio University Hospital, and Toho University Medical Center. The corporate phase II clinical trial for cerebral infarction conducted by Shionogi & Co., Ltd, which had started in April 2019, has also progressed as scheduled. In addition to these two indications, the efficacy of HMGB1 peptide against multiple target diseases has been confirmed so far, and the research and development toward realization of Regeneration-Inducing Medicine has been steadily progressed.

In the Japanese regenerative medicine industry, in which the Company operates, the foundation for promoting the industrialization of regenerative medicine has been nurtured by the Act on the Safety of Regenerative Medicine and the Revised Pharmaceutical Affairs Act that came into effect in November 2014. As multiple regenerative medicine products continue to be approved, social expectations and interest in regenerative medicine technology are increasing.

During the current first quarter, the company has focused on research and development of HMGB1 peptide, which is the most advanced candidate of Regeneration-inducing Medicine, mainly on the clinical or pre-clinical development in the following three indications.

- a. Epidermolysis bullosa (PJ1-01): Doctor-initiated clinical trial (Phase II study) for clinical efficacy evaluation at Osaka University is ongoing, and the enrollment of subjects is progressing smoothly. Prior to this trial, a clinical study conducted at Osaka University last year showed that, when this drug was administered intravenously to healthy volunteers, bone marrow mesenchymal stem cells were mobilized into the peripheral blood circulation and the number of mesenchymal stem cells were significantly increased. From these results, the mechanism of action of HMGB1 peptide has been proved as we have anticipated. Based on the same mechanism of action, we expect that HMGB1 peptide, also in the ongoing Phase II trials, mobilize mesenchymal stem cells in patients' body and can treat the epidermolysis bullosa patients.
- b. Cerebral infarction (PJ1-02): and The enrollment of the subjects and safety evaluation are making good progress so far, in Phase II clinical trial initiated by Shionogi & Co., Ltd., the licensee of HMGB1 peptide, On November 4, 2019, the administration to the first patient started, and it is expected that the following administration to the enrolled patients will progress as planned.
- c. Cardiomyopathy (PJ1-03): Through joint research with Osaka University Graduate School of Medicine, Department of Cardiovascular Surgery, our research team demonstrated a remarkable therapeutic effect of HMGB1 peptide on myocardial infarction and several types of cardiomyopathies in animal disease models and proved the mechanism of action of this drug. These results were reported at international academic conferences such as the American Heart Association (AHA) Scientific Sessions 2018. At The 18th Congress of The Japanese Society for Regenerative Medicine held in March 2019, we reported that we successfully observed GFP (green fluorescent protein)-positive bone marrow-derived cells, accumulating in myocardial infarction area and actively moving at the periphery of the blood vessels, in myocardial infarction model animals administered with HMGB1 peptide, by using in-vivo imaging method with a multiphoton microscope. Our report and presentation were highly evaluated.

In addition to the above, we have continued to actively invest in research and development for the discovery of new Regeneration Inducing Medicine candidates other than HMGB1 peptide. As a result of our multifaceted drug screening approaches, we have succeeded in identifying multiple candidates with remarkable pharmacological activities. During this quarter, the company won a research grant for this drug discovery project from the Japanese Small and Medium Enterprise Agency's FY2017 Strategic Fundamental Technology Advancement Support Project. In addition, the company raised funds through initial public offering. With these achievements, we were able to further increase investment in this project and lay the foundation for accelerating research and development.

Under these circumstances, for the six months ended January 31, 2020, operating loss was 465,224 thousand yen, ordinary loss was 519,131 thousand yen, and net loss was 520,982 thousand yen.

The Company consists of a single business segment, Regeneration-Inducing Medicine business. Therefore, description of business performance by segment is omitted.

(2) Explanation of financial position

Asset

Total current assets at the end of the second quarter were 9,948,839 thousand yen, an increase of 7,279,759 thousand yen from the end of the previous fiscal year. This was mainly due to an increase of 7,330,968 thousand yen in cash. Total fixed assets were 21,051 thousand yen, an increase of 2,270 thousand yen from the end of the previous fiscal year. This was mainly due to an increase of 2,206 thousand yen in property, plant and equipment and an increase of 208 thousand yen in investments and other assets. As a result, total assets were 9,969,891 thousand yen, an increase of 7,282,030 thousand yen from the end of the previous fiscal year.

Liabilities

Total current liabilities at the end of the second quarter were 93,236 thousand yen, a decrease of 17,602 thousand yen from the end of the previous fiscal year. This is mainly due to an increase of 38,259 thousand yen in deposits received and decrease in income taxes payable of 17,704 thousand yen. In addition, long-term liabilities totaled 14,930 thousand yen, declined 1,392 thousand yen compared with the end of the previous fiscal year. This is mainly due to lease obligations decreased 1,480 thousand yen. As a result, liabilities totaled 108,166 thousand yen, now as before 16,210 thousand yen decrease compared to the fiscal year-end.

Net assets

Net assets at the end of the second quarter were 9,861,724 thousand yen, an increase of 7,265,820 thousand yen from the end of the previous fiscal year. This is due to the increase in capital and capital surplus of 3,893,026 thousand yen due to funding in the public offering due to the initial listing conducted in August 2019. And, This is also due to the decrease in capital of 4,675,501 thousand yen, an increase in capital reserve of 3,656,365 thousand yen and an increase in other capital surplus of 1,019,135,000 yen mainly in December 2019 due to a capital reduction to cover loss. In addition, by transferring the increased other capital surplus of 1,019,135 thousand yen to retained earnings carried forward, the loss carried forward has been eliminated. As a result, the capital is 30,375 thousand yen, capital surplus is 10,352,332 thousand yen, and retained earnings are (520,982) thousand yen.

(3) Explanation of cash flows status

Cash and cash equivalents (hereinafter referred to as “cash”) at the end of the second quarter of the fiscal year under review were 9,827,391 thousand yen, an increase of 7,330,968 thousand yen compared to the end of the previous fiscal year. Cash flows in each area of activity and their respective contributing factors are as follows:

Cash flows from operating activities

Net cash used in operating activities for the six months ended January 31, 2020 was 385,218 thousand yen. This was primarily due to a loss before income taxes of 519,131 thousand yen, a loss prepaid expenses of 61,945 thousand yen and a share issuance cost of 55,221 thousand yen.

Cash flows from investing activities

Net cash used in operating activities for the six months ended January 31, 2020 was 4,591 thousand yen. This was primarily due to outflows of 3,348 thousand yen for purchase of property, plant and equipment and 1,243 thousand yen for security deposit.

Cash flows from financing activities

Net cash provided by financing activities for the six months ended January 31, 2020 was 7,720,776 thousand yen. This was primarily due to proceeds from issuance of shares of 7,731,581 thousand yen and listing-related expenses of 9,363 thousand yen.

(4) Explanation of future forecast information such as business forecasts

There are no changes to the full-year earnings forecasts announced on September 12, 2019. If any change is recognized in the future, it will be disclosed appropriately.

2. Quarterly financial statements and significant notes thereto

(1) Quarterly balance sheet

(Thousands of yen)

	As of July 31, 2019	As of January 31, 2020
Assets		
Current assets		
Cash and deposits	2,496,422	9,827,391
Raw materials and stocks	12,648	8,957
Prepaid expenses	109,651	48,740
Other	50,356	63,749
Total current assets	2,669,080	9,948,839
Non-current assets		
Property, plant and equipment	9,727	11,933
Intangible assets	1,393	1,249
Investments and other assets	7,660	7,869
Total non-current asset	18,780	21,051
Total assets	2,687,861	9,969,891
Liabilities		
Current liabilities		
Accounts payable-other	34,846	33,102
Accrued expenses	15,955	14,708
Income taxes payable	19,518	1,814
Lease obligations	2,903	2,942
Deposits received	2,410	40,669
Total current liabilities	75,634	93,236
Non-current liabilities		
Lease obligations	9,714	8,233
Asset retirement obligations	5,881	5,933
Deferred tax liabilities	726	763
Total Non-current liabilities	16,322	14,930
Total liabilities	91,956	108,166
Net assets		
Shareholders' equity		
Capital stock	812,475	30,375
Capital surplus	2,802,565	10,352,332
Retained earning	(1,019,135)	(520,982)
Total shareholders' equity	2,595,904	9,861,724
Total net assets	2,595,904	9,861,724
Total liabilities and net assets	2,687,861	9,969,891

(2) Quarterly statements of income and comprehensive income

(Thousands of yen)

	Six months ended January 31, 2020
Net sales	—
Operating expenses	
Research and development expenses	354,987
Other selling, general and administrative expenses	110,237
Total operating expenses	465,224
Operating loss	(465,224)
Non-operating income	
Interest and dividend income	6
Subsidy income	10,808
Foreign exchange gains	2
Miscellaneous income	18
Total non-operating income	10,835
Non-operating expenses	
Interest expenses	157
Share issuance cost	55,221
Listing related costs	9,363
Total non-operating expenses	64,742
Ordinary loss	(519,131)
Loss before income taxes	(519,131)
Income taxes - current	1,815
Income taxes - deferred	36
Total income taxes	1,851
Net loss	(520,982)

(3) Quarterly consolidated statements of cash flows

(Thousands of yen)

	Six months ended January 31, 2020
Cash flows from operating activities	
Loss before income taxes	(519,131)
Depreciation	1,711
Interest and dividend income	(6)
Subsidy income	(10,808)
Interest expenses	157
Foreign exchange losses (gains)	(2)
Share issuance expenses	55,221
Listing-related costs	9,363
Decrease (increase) in inventories	3,691
Decrease (increase) in prepaid expenses	61,945
Decrease (increase) in consumption taxes refund receivable	8,412
Increase (decrease) in accounts payable - other	(2,169)
Increase (decrease) in accrued expenses	(1,246)
Increase (decrease) in deposits received	38,259
Other	(11,106)
Subtotal	(365,708)
Interest and dividends received	6
Subsidy received	161
Interest expenses paid	(157)
Income taxes paid	(19,521)
Income taxes refund	2
Net cash provided by (used in) operating activities	(385,218)
Cash flows from investing activities	
Purchase of property, plant and equipment	(3,348)
Payments of leasehold deposits	(1,246)
Net cash provided by (used in) investing activities	(4,591)
Cash flows from financing activities	
Repayment of lease obligations	(1,442)
Proceeds from issuance of shares	7,731,581
Payments of listing related costs	(9,363)
Net cash provided by (used in) financing activities	7,720,776
Effect of exchange rate change on cash and cash equivalents	2
Net increase (decrease) in cash and cash equivalents	7,330,968
Cash and cash equivalents at beginning of period	2,496,422
Cash and cash equivalents at end of period	9,827,391

(4) Notes to the quarterly financial statements

(Notes regarding going concern assumption)
Not applicable.

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

Public offering

Capital stock and additional paid-in capital increased by 3,766,500 thousand yen each due to the issuance of new shares upon listing of the Company's common shares on the Tokyo Stock Exchange Mothers, and new shares by third-party allotment related to the sale of the Company's shares through over-allotment.

Capital reduction and disposal of surplus

Capital decreased by 4,675,501 thousand yen, capital reserve increased by 3,656,365 thousand yen, and other capital surplus increased by 1,019,135 thousand yen each due to capital reduction. And, the loss carried forward has been eliminated by transfer of increased capital surplus of 1,019,135 thousand yen to retained earnings carried forward.

As a result, the capital was 30,375 thousand yen, the capital surplus was 10,352,332 thousand yen, and the retained earnings were (520,982) thousand yen.

(Segment information, etc.)

[Segment information]

Since the Company is a single segment of the regeneration inducing medicine business, the business results by segment are omitted.

(Important subsequent events)

(Conclusion of important contract)

StemRIM Inc. resolve the establishment of a research institute called "Regeneration-Inducing Medicine Collaboration Laboratory" with Osaka University at the Board of Directors meeting held on February 13, 2020. This overview is as follows:

Purpose

This Collaboration Laboratory will be established by StemRIM Inc. and Osaka University jointly with the National University Corporation, to conduct advanced evaluation research on new Regeneration-Inducing Medicine candidate compounds and specialized development aimed at expanding the indications for various target diseases.

Contract partner

Osaka University

Contract date

March 2020

Main contract details

Name	:	StemRIM Institute of Regeneration-Inducing Medicine, Osaka University
Address	:	Osaka University Techno Alliance Building 6F, 7F, 2-8 Yamadaoka, Suita-city, Osaka, Japan
Occupied area	:	1,540m ²
Date of establishment	:	After April, 2020
Contract period	:	10 years
Installation period	:	Total 2.1 billion yen (Rental and labor costs for 10 years of contract period, R & D costs such as reagent consumables costs)