

Non-consolidated Financial Results for the Nine Months Ended April 30, 2020 [Japanese GAAP]

June 11, 2020

Company name: StemRIM Inc.
 Stock exchange listing: Tokyo Stock Exchange
 Stock code: 4599
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 Scheduled date of commencing dividend payments: —
 Supplementary briefing materials on financial results: No
 Explanatory meeting on financial results: No

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

1. Financial Results for the Nine Months Ended April 30, 2020 (August 1, 2019 to April 30, 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	%
Nine months ended April 30, 2020	400	300	(391)	—	(443)	—	(446)	—
Nine months ended April 30, 2019	100	—	(506)	—	(506)	—	(505)	—

	Net income per share		Diluted net income per share	
	Yen		Yen	
Nine months ended April 30, 2020	(8.37)		—	
Nine months ended April 30, 2019	(12.09)		—	

Notes: 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, 2020	10,030		9,961		99.1	
As of July 31, 2019	2,687		2,595		96.5	

(Reference) Equity capital: Nine months ended April 30, 2020 9,941 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
Fiscal Year ended July 31, 2019	Yen —	Yen 0.00	Yen —	Yen 0.00	Yen 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 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, 2020	55,894,800 shares
As of July 31, 2019	44,282,700 shares

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

As of April 30, 2020	— shares
As of July 31, 2019	— shares

c. Average number of shares during the period

Nine months ended April 30, 2020	53,280,256 shares
Nine months ended April 30, 2019	41,815,500 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	4
(1) Explanation of operating results	4
(2) Explanation of financial position	4
(3) Explanation of future forecast information such as business forecasts	5
2. Quarterly financial statements and significant notes thereto	6
(1) Quarterly balance sheet	6
(2) Quarterly statements of income	7
(3) Notes to the quarterly financial statements	8

1. Qualitative information on quarterly financial results

(1) Explanation of operating results

During the nine months ended April 30, 2020 (from August 1, 2019 to April 30, 2020), a clinical trial (Phase II doctor-initiated clinical trial) of the bone marrow mesenchymal stem cell mobilization drug KOI2 (HMGB1 peptide), which is under development as PJ1-01 for dystrophic epidermolysis bullosa, has been completed. As a result, StemRIM achieved the milestone payment specified in the license agreement and the memorandum of understanding with Shionogi & Co., Ltd. (Osaka, Japan), and recorded the milestone income of 400,000 thousand yen as operating revenue.

In this clinical study (Phase II doctor-initiated clinical trial), a data analysis preliminary report was published in January 2020, confirming the long-term sustainability of KOI2 treatment for dystrophic epidermolysis bullosa. In the secondary evaluation (safety evaluation), no adverse events of concern were observed, and it was also reported that the safety of KOI2 administration was confirmed in patients with dystrophic epidermolysis bullosa.

Since the HMGB1 peptide degrades in the body within a short period of time after administration, it is considered that the effect persists for a long period of at least 6 months after the end of drug administration. It is considered that the mechanism of Regeneration-Inducing Medicine, in which stem cells accumulate in the damaged site via the circulating bloodstream and continue to exert its effect for a long period of time, has been proved in epidermolysis bullosa.

In addition, regarding clinical trials for cerebral infarction (Phase II enterprise clinical trial), which is being conducted by Shionogi & Co., Ltd. from April 2019, administration to subjects has started from November 2019. Therefore, acceptance of test subjects and confirmation of safety are steadily progressing.

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 fiscal year, 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 nine months ended April 30, 2020, net sales were 400,000 thousand yen, operating loss was 391,591 thousand yen, ordinary loss was 443,334 thousand yen, and net loss was 446,070 thousand yen.

In June 2020, we established the “StemRIM Institute of Regeneration-Inducing Medicine, Osaka University” that owns a floor space of 1,540 square meters in the existing facility on the Osaka University campus. This institute is most important for implementing our medium- to long-term growth strategy. We have secured a new research base capable of responding to expanding research work, which is an important management issue. With the establishment of this collaborative research institute, we will further accelerate leading edge evaluation of research and development for new regeneration-inducing drug candidate compounds, aiming at expanding the adaptation to various target diseases. In addition, it is possible to greatly accelerate the expansion of indications from a comprehensive search. We also believe that it will be possible to further solidify our position as a world-leading company for regenerative medicine.

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 third quarter were 10,011,193 thousand yen, an increase of 7,342,113 thousand yen from the end of the previous fiscal year. This was mainly due to an increase of 6,646,650 thousand yen in cash. Total fixed assets were 19,076 thousand yen, an increase of 295 thousand yen from the end of the previous fiscal year. This was mainly due to an increase of 1,209 thousand yen in property, plant and equipment and a decrease of 697 thousand yen in investments and other assets. As a result, total assets were 10,030,270 thousand yen, an increase of 7,342,409 thousand yen from the end of the previous fiscal year.

Liabilities

Total current liabilities at the end of the third quarter were 54,312 thousand yen, a decrease of 21,321 thousand yen from the end of the previous fiscal year. This is mainly due to a decrease of 5,169 thousand yen in accounts payable-other and decrease in income taxes payable of 16,797 thousand yen. In addition, long-term liabilities totaled 14,185 thousand yen, declined 2,136 thousand yen compared with the end of the previous fiscal year. This is mainly due to lease obligations decreased 2,228 thousand yen. As a result, liabilities totaled 68,498 thousand yen, 23,457 thousand yen decrease compared to the last fiscal year-end.

Net assets

Net assets at the end of the third quarter were 9,961,771 thousand yen, an increase of 7,365,866 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 thousand 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 32,700 thousand yen, capital surplus is 10,354,657 thousand yen, and retained earnings are (446,070) thousand yen.

(3) 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 April 30, 2020
Assets		
Current assets		
Cash and deposits	2,496,422	9,143,073
Accounts receivable	—	440,000
Supplies	12,648	16,962
Prepaid expenses	109,651	391,857
Other	50,356	19,301
Total current assets	2,669,080	10,011,193
Non-current assets		
Property, plant and equipment	9,727	10,936
Intangible assets	1,393	1,177
Investments and other assets	7,660	6,963
Total non-current asset	18,780	19,076
Total assets	2,687,861	10,030,270
Liabilities		
Current liabilities		
Accounts payable-other	34,846	29,677
Accrued expenses	15,955	15,773
Income taxes payable	19,518	2,720
Lease obligations	2,903	2,961
Deposits received	2,410	3,180
Total current liabilities	75,634	54,312
Non-current liabilities		
Lease obligations	9,714	7,485
Asset retirement obligations	5,881	5,959
Deferred tax liabilities	726	740
Total Non-current liabilities	16,322	14,185
Total liabilities	91,956	68,498
Net assets		
Shareholders' equity		
Capital stock	812,475	32,700
Capital surplus	2,802,565	10,354,657
Retained earning	(1,019,135)	(446,070)
Total shareholders' equity	2,595,904	9,941,287
Subscription rights to shares	—	20,484
Total net assets	2,595,904	9,961,771
Total liabilities and net assets	2,687,861	10,030,270

(2) Quarterly statements of income

(Thousands of yen)

	Nine months ended April 30, 2019	Nine months ended April 30, 2020
Net sales	100,000	400,000
Operating expenses		
Research and development expenses	472,920	584,677
Other selling, general and administrative expenses	133,351	206,913
Total operating expenses	606,272	791,591
Operating loss	(506,272)	(391,591)
Non-operating income		
Interest and dividend income	12	12
Subsidy income	5,280	13,049
Foreign exchange gains	33	—
Miscellaneous income	72	18
Total non-operating income	5,399	13,080
Non-operating expenses		
Interest expenses	218	229
Share issuance cost	5,213	55,221
Listing related costs	—	9,363
Foreign exchange loss	—	9
Total non-operating expenses	5,432	64,824
Ordinary loss	(506,305)	(443,334)
Loss before income taxes	(506,305)	(443,334)
Income taxes - current	1,864	2,722
Income taxes - deferred	(2,521)	13
Total income taxes	(657)	2,736
Net loss	(505,647)	(446,070)

(3) 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 32,700 thousand yen, the capital surplus was 10,354,657 thousand yen, and the retained earnings were (446,070) 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)

(Issuance of the 9th stock options [Stock Acquisition Rights])

At a meeting of Board of Directors held on May 14, 2020, the Company passed a resolution for issuance of the stock options (stock acquisition rights) approved at the Ordinary General Meeting of Shareholders held on October 24, 2019.

Reason for issuance of stock acquisition rights

Purpose of granting stock options (stock acquisition rights) to the qualified directors, corporate auditors, employees and external collaborators is to increase corporate value by encouraging their motivation and morale to contribute to the progress of R&D, promoting an awareness of strict auditing and securing talented people.

Issuance of the 9th stock options

Name	Issuance of the 9th stock options (c).
Allotment date	May 15, 2020
Classification and number of grantees	Directors 4 Corporate auditor 1 Employees 7
Total number of stock options	6,984 units
Type and number of shares	698,400 shares of common stock
Exercise price	547 yen per share
Capital incorporation	The increase in the amount of capital through issue of common stock of the Company by Exercise of the Stock Options shall be one half of the maximum amount of increase in capital (if the calculation yields a fraction of less than 1 yen, this is to be rounded up) calculated according to Article 17, Paragraph 1 of Regulation on Corporate Accounting, and the amount of increase in capital subtracted by the amount of increase in capital.
Conditions for exercising stock acquisition rights	A person who has been allotted the Stock Options is required to have the status of any of the directors, corporate auditors, employees or outside collaborators of the Company or its subsidiaries when exercising the rights. Inheritance of stock acquisition rights will not be accepted. Part of each stock acquisition right cannot be exercised.
Exercise period for stock acquisition rights	From May 16, 2022 to May 14, 2030

Name	Issuance of the 9th stock options (d).
Allotment date	May 29, 2020
Classification and number of grantees	External collaborator 1 Employees 4
Total number of stock options	599 units
Type and number of shares	59,900 shares of common stock
Exercise price	643 yen per share
Capital incorporation	The increase in the amount of capital through issue of common stock of the Company by Exercise of the Stock Options shall be one half of the maximum amount of increase in capital (if the calculation yields a fraction of less than 1 yen, this is to be rounded up) calculated according to Article 17, Paragraph 1 of Regulation on Corporate Accounting, and the amount of increase in capital subtracted by the amount of increase in capital.
Conditions for exercising stock acquisition rights	A person who has been allotted the Stock Options is required to have the status of any of the directors, corporate auditors, employees or outside collaborators of the Company or its subsidiaries when exercising the rights. Inheritance of stock acquisition rights will not be accepted. Part of each stock acquisition right cannot be exercised.
Exercise period for stock acquisition rights	From May 30, 2022 to May 29, 2029