

Non-consolidated Financial Results for the Fiscal Year Ended July 31, 2020 [Japanese GAAP]

September 10, 2020

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: Tomoyuki Hoshino, Chief Financial Officer
 Phone: +81-72-648-7152
 Scheduled date of filing 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 Fiscal Year Ended July 31, 2020 (August 1, 2019 to July 31, 2020)

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

	Operating revenue		Operating income		Ordinary income		Net income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Fiscal year ended July 31, 2020	2,100	—	415	—	361	—	347	—
Fiscal year ended July 31, 2019	100	(50.0)	(726)	—	(722)	—	(721)	—

	Net income per share	Diluted net income per share	Return on Equity	Ordinary income to total assets	Operating income to net sales
	Yen	Yen	%	%	%
Fiscal year ended July 31, 2020	6.44	5.74	5.2	5.2	19.8
Fiscal year ended July 31, 2019	(16.85)	—	(32.3)	(31.3)	(726.9)

(Reference) Equity in earnings (losses) of affiliates: Fiscal year ended July 31, 2020: — million yen

Fiscal year ended July 31, 2019: — million yen

(Notes)

- Diluted net income per share for the fiscal year ended July 31, 2019, is not stated because of a net loss per share.
- Diluted net income per share for the fiscal year ended July 31, 2020, is calculated as the average stock price from August 9, 2019 (date of stock listing) to July 31, 2020.
- The Company conducted a Hundred-for-one common stock split effective on March 1, 2019, and a three-for-one common stock split effective on March 8, 2019. Net income per share and the number of shares outstanding are calculated as if this stock split had taken place at the beginning of the previous fiscal year.

(2) Financial position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of July 31, 2020	11,281	10,850	95.5	189.62
As of July 31, 2019	2,687	2,595	96.5	58.62

(Reference) Equity: As of July 31, 2020 10,768 Million yen

As of July 31, 2019 2,595 Million yen

(3) Cash flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
	Million yen	Million yen	Million yen	Million yen
Fiscal year ended July 31, 2020	575	△153	7,757	10,675
Fiscal year ended July 31, 2019	△777	△6	1,437	2,496

2. Payment of Dividends

	Annual dividends					Total dividends (Annual) Million yen	Dividend payout ratio %	Dividends to 1st net assets %
	End Q1 Yen	End Q2 Yen	End Q3 Yen	Year-end Yen	Total Yen			
Fiscal Year ended July 31, 2019	—	—	—	0.00	0.00	—	—	—
Fiscal Year ended July 31, 2020	—	—	—	0.00	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 previous corresponding period)

	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) 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

(2) Number of shares issued (common stock)

a) Number of shares issued at the end of the period (including treasury stock)

As of July 31, 2020	56,789,400 shares
As of July 31, 2019	44,282,700 shares

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

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

c) Average number of shares during the period

As of July 31, 2020	54,007,263 shares
As of July 31, 2019	42,799,200 shares

(Note) The Company conducted a Hundred-for-one common stock split effective on March 1, 2019, and a three-for-one common stock split effective on March 8, 2019. Net income per share and the number of shares outstanding are calculated as if this stock split had taken place at the beginning of the previous fiscal year.

* This report of financial results is unaudited.

Attached Documents

Index of Appendix

1. Analysis of Operating Results and Financial Position	4
(1) Explanation of operating results	4
(2) Explanation of financial position	7
(3) Overview of Cash Flows for the Fiscal Year Under Review	7
(4) Forecast for the future	7
2. Basic Approach to Accounting Standards	8
3. Financial Statements	9
(1) Balance Sheets	9
(2) Statements of Income	11
(3) Statements of Changes in Equity	12
(4) Statements of Cash Flows	14
(5) Notes to Financial Statements	15
(Notes regarding going concern assumption)	15
(Segment information, etc.)	15
(Per share information)	15
(Important subsequent events)	16

1. Analysis of Operating Results and Financial Position

(1) Explanation of operating results

Business results for the current period

Regarding our business overview, the company has promoted research and development toward the realization of the “Regeneration-Inducing Medicine” that the company has been aiming for since the founding. Regeneration-inducing Medicine” is a drug based on a new mechanism of action that promotes the functional regeneration and healing of tissues that have been damaged by injury or disease.

As for the concrete progress of this fiscal year (August 1, 2019 to July 31, 2020), We have signed a new contract to go, accelerate clinical development for multiple diseases in the future with Shionogi & Co., Ltd. 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 a doctor-initiated clinical trial for three new indications diseases (Chronic liver disease, Osteoarthritis of the knee and Cardiomyopathy). Under this agreement, we plan to receive a total of up to 3.1 billion yen from Shionogi & Co., Ltd.

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. 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 Medicine” 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 “Regeneration-Inducing Medicine”.

As PJ1-01, With the completion of the Phase II trial (doctor-initiated clinical trial) of the Redasemtide (bone marrow mesenchymal stem cell mobilization medicine HMGB1 peptide) for dystrophic epidermolysis bullosa (DEB), which is being developed, we have achieved the milestone related to this agreement by satisfying the conditions of the milestone payment stipulated in the license agreement with Shionogi & Co., Ltd.

In this clinical trial, the results was published in January 2020, confirming the long-term effectiveness of the Redasemtide therapeutic on DEB, and a secondary endpoint (safety endpoint) reported no adverse events of concern and also the safety of the Redasemtide administration in patients with DEB.

Since the HMGB1 peptide decomposes and disappears in the body in a short time after administration, the long-lasting effects of 6 months or more after the end of medicine administration was released from the bone marrow into the blood vessel by a Regeneration-inducing Medicine. It is thought that the mechanism of Regeneration-inducing Medicine, in which stem cells accumulate in the injured site via circulating blood flow and continue to exert their effects for a long period of time, has been proved in DEB.

Under these circumstances, for the fiscal year ended July 31, 2020, net sales were 2,100,000 thousand-yen, operating income was 415,713 thousand-yen, ordinary income were 361,030 thousand yen, and net income were 347,761 thousand yen.

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

R&D activities

"Regeneration-Inducing Medicine", we have researched and developed with the aim of realizing, does not require the administration of living cells, by activating the stem cells existing in the patient's own body. This medicine will realize high therapeutic effect more easily and safely by the administration of substances. The development of Regeneration-Inducing Medicine will enable the supply of products that realize rapid regenerative medicine with stable quality, which is difficult with living cell preparations, and can become a new regenerative medicine that can be widely used.

The total amount of R & D expenses for the current fiscal year was 1,356,646 thousand yen. In order to strengthen the development system, we established the “StemRIM Institute of Regeneration-Inducing Medicine, Osaka University” reinforced personnel, and promoted research and development as follows.

(i) Redasemtide (Regeneration-Inducing Medicine)

HMGB1 peptide, a Regeneration-Inducing Medicine, is a peptide preparation created from the bioactive domain of the in vivo protein HMGB1. Intravenous administration of Redasemtide mobilizes the patient's intramedullary mesenchymal stem cells into the peripheral blood and accumulates them at the site of injury, promoting tissue regeneration and healing of the affected area. The therapeutic mechanism via mesenchymal stem cells makes a wide range of diseases with tissue damage indicated. We have confirmed a favorable therapeutic effect in nonclinical medical efficacy studies using animal disease models of Cerebral infarction, Myocardial infarction, Cardiomyopathy, Epidermolysis bullosa, Refractory skin ulcer, Spinal cord injury, Amyotrophic Lateral Sclerosis (ALS), Trauma, etc.

In the current fiscal year, we had been conducting research and development on the Regeneration-inducing Medicine, which is the most developed in our company, as follows.

PJ1-01 Regarding the development of DEB therapeutic agent

The results of a clinical trial (Phase II doctor-initiated clinical trial) in patients with DEB(n=9) were reported that 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) at the 41st Epidermolysis Bullosa Study Group held in January 2020 and the 1st International Epidermolysis Bullosa Conference (The 2020 EB World Congress). In the result, 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. Therefore, long-term therapeutic of Redasemtide effects on DEB was also confirmed. In addition, adverse events of concern were not observed in the secondary evaluation (safety evaluation), and these results confirm the efficacy and safety of Redasemtide administration in patients with DEB. With the completion of this clinical trial (Phase II doctor-initiated clinical trial), We received the milestone income by satisfying the conditions of milestone payments stipulated in the license agreement with Shionogi & Co., Ltd.

Regarding DEB treatment, the target nutritional disorder type epidermolysis bullosa 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 trial. Therefore, we expect to apply for approval of the medicine, based on the results of the Phase II trial.

PJ1-02 Regarding the development of a therapeutic medicine for Cerebral infarction

Phase II trial (company initiated clinical trial) has started at Shionogi & Co. Ltd. the license of Redasemtide. In addition, on November 4, 2019, administration to the first subject was performed at the clinical trial site, and it is expected that administration to the subject will continue in the future.

Other

Regarding the development of a therapeutic medicine for Cardiomyopathy (PJ1-03), in a non-clinical experiment in a joint research with the Department of Cardiovascular Surgery, Osaka University Graduate School of Medicine, medicine efficacy studies were conducted with disease animal models of myocardial infarction and various cardiomyopathy. This medicinal effect test has proven a remarkable therapeutic effect and mechanism of action. In the development of a therapeutic medicine for Osteoarthritis of the knee (PJ1-04), in non-clinical studies conducted so far, the therapeutic effect has been confirmed in medicine efficacy tests using disease model animals, and by the end of 2020, clinical trial is planned to begin at the Hirosaki University to evaluate the efficacy and safety of Redasemtide in patients with osteoarthritis of the knee. In the development of a therapeutic medicine for Chronic liver disease (PJ1-05), we had been confirmed to be effective in non-clinical studies using disease model animals, and by the end of 2020, clinical trial is planned to begin at the Niigata University to evaluate the efficacy and safety of Redasemtide in patients with chronic liver disease.

(ii) New Regeneration-Inducing Medicine

We are developing the peptide discovered by a newly developed screening method in collaboration with Osaka University that has the effect of increasing mesenchymal stem cells in peripheral blood by intravenous administration. Like a Redasemtide, it is expected to be a regeneration-inducing therapeutic agent for a wide range of diseases associated with tissue damage. In addition to biological peptides, we are also developing peptides created based on information on biologically active peptides.

We have more than 10 types of candidate peptides from the screening so far, and we plan to proceed with development in order from the one with the highest therapeutic effect. At present, we are conducting non-clinical studies on the three candidate peptides, which are necessary before the start of clinical trials. Good mesenchymal stem cell blood mobilization effect has been confirmed by animal experiments so far, and we are currently conducting medicine efficacy tests using multiple types of disease model animals and selecting the optimal disease to be developed.

(iii) Biologically-derived Regeneration-Inducing Protein

It is a protein preparation derived from in-vivo protein extracted from living tissue. By intravenous or local administration, it has the effect of efficiently accumulating mesenchymal stem cells in the living body in the affected area, and is expected to be a therapeutic medicine for a wide range of diseases accompanied by tissue damage.

From the multiple candidate proteins obtained so far, we plan to select the one with the highest therapeutic effect and proceed with development. We have confirmed good mesenchymal stem cell blood mobilization effects in animal experiments so far, and we are proceeding with the selection of optimal indications through drug efficacy tests using multiple types of disease model animals.

(iv) Therapeutic autologous cell collection device

It is a regeneration-inducing medical device that collects mesenchymal stem cells in the patient's body using a stem cell attractant and transplants them into the affected area to perform tissue regeneration treatment. After impregnating a substance that attracts mesenchymal stem cells found by us in an implantable device, it is implanted under the skin of a patient for a certain period of time, and the patient's own mesenchymal stem cells accumulated in this device are collected for treatment. It is expected that mesenchymal stem cell transplantation will be an effective medical device for a wide range of diseases for which therapeutic effects have been reported.

First, we are planning to develop it as a medical device for diseases associated with bone and cartilage damage, intractable skin ulcers, etc. It has been confirmed in animal experiments so far that this device has a good ability to recover stem cells. We are conducting the necessary non-clinical trials by the start of clinical trials, while advancing the selection of optimal indications through medicine efficacy tests using multiple types of disease model animals.

(v) Stem cell gene therapy

It is a treatment technology that enables Regeneration-Inducing Medical Treatment even for severe hereditary diseases caused by gene defects. It is a regeneration-induced cell therapy product making full use of the unique stem cell culture and regulation technology that we have cultivated so far, we perform gene editing on the patient's own stem cells in vitro, supplement the defective / mutated gene, and then return it to the patient's body.

As the first indication, we plan to proceed with development for severe epidermolysis bullosa with complete gene deficiency. Through experiments in which mesenchymal stem cells incorporating normal genes were transplanted into animals using gene editing technology, it was confirmed that a sufficient amount of the target protein (VII collagen) was stably produced in the transplanted animals, and also we have proved that the assumed mechanism of action works. Currently, we are conducting additional non-clinical studies necessary for the start of clinical trials, such as medicine efficacy studies using disease model animals.

(2) Explanation of financial position

Asset

Total current assets at the end of the year were 10,966,711 thousand yen, an increase of 8,297,631 thousand yen from the end of the previous fiscal year. This was mainly due to an increase of 8,178,820 thousand yen in cash. Total fixed assets were 314,704 thousand yen, an increase of 295,923 thousand yen from the end of the previous fiscal year. This was mainly due to an increase of 219,279 thousand yen in property, plant and equipment and an increase of 76,932 thousand yen in investments and other assets. As a result, total assets were 11,281,415 thousand yen, an increase of 8,593,554 thousand yen from the end of the previous fiscal year.

Liabilities

Total current liabilities at the end of the year were 354,529 thousand yen, an increase of 278,895 thousand yen from the end of the previous fiscal year. This is mainly due to an increase of 218,109 thousand yen in accounts payable-other. In addition, long-term liabilities totaled 76,830 thousand yen, an increase 60,508 thousand yen from the end of the previous fiscal year. As a result, liabilities totaled 431,360 thousand yen, an increase of 339,403 thousand yen from the previous fiscal year.

Net assets

Net assets at the end of the year were 10,850,054 thousand yen, an increase of 8,254,150 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 49,288 thousand-yen, capital surplus is 10,371,245 thousand yen, and retained earnings are 347,761 thousand yen.

(3) Overview of Cash Flows for the Fiscal Year Under Review

Cash and cash equivalents for the current fiscal year were 10,675,242 thousand yen, an increase of 8,178,820 thousand yen from the end of the previous fiscal year.

Net cash provided by operating activities was 575,413 thousand yen (outflow of 777,789 thousand yen in the previous fiscal year). The positive cash flow was mainly generated from profit before income taxes of 361,030 thousand yen, increase in stock-based compensation expenses of 81,760 thousand yen, and increase in the accounts payable of 197,746 thousand yen. The above factors more than compensated for prepaid expenses of 233,412 thousand yen.

Net cash used because of investing activities amounted to 153,711 thousand yen (outflow of 6,553 thousand yen in the previous fiscal year). This is due to the acquisition of fixed assets.

Net cash provided by financing activities was 7,757,140 thousand yen (inflow of 1,437,374 thousand yen in the previous fiscal year). This is due to the issuance of shares.

(4) Forecast for the future

As for the outlook for the next fiscal year, we expect milestone revenue obtained from a license agreement with Shionogi & Co., Ltd. regarding Redasemtide and the agreement to accelerate clinical development research for new indications for Redasemtide.

In addition, R&D expenses are planned to increase due to the progress of the Regeneration-Inducing Medicine development project using Redasemtide and the promotion of the search project for new Regeneration-inducing Medicine candidate substances.

As a result, the company expects operating revenue of 2,300,000 thousand-yen, operating income of 138,951 thousand-yen, ordinary income of 138,745 thousand yen, and net income of 135,115 thousand yen.

2. Basic Approach to Accounting Standards

The Company will prepare its financial statements based on Japanese GAAP for the time being, given its comparability from period to period and between companies.

The Company plans to appropriately respond to the application of International Financial Reporting Standards (IFRS) upon considering the circumstances in Japan and overseas.

3. Financial Statements

(1) Balance Sheets

(Thousands of yen)

	As of July 31, 2019	As of July 31, 2020
Assets		
Current assets		
Cash and deposits	2,496,422	10,675,242
Supplies	12,648	18,047
Prepaid expenses	109,651	266,630
Other	50,356	6,790
Total current assets	2,669,080	10,966,711
Non-current assets		
Property, plant and equipment		
Buildings, Net	6,313	207,748
Tools, furniture and fixtures, Net	3,413	21,257
Total property, plant and equipment	9,727	229,006
Intangible assets		
Software	1,393	1,104
Total intangible assets	1,393	1,104
Investments and other assets		
Long-term prepaid expenses	1,940	78,135
Leasehold and guarantee deposits	5,719	6,457
Total investments and other assets	7,660	84,592
Total non-current asset	18,780	314,704
Total assets	2,687,861	11,281,415

(Thousands of yen)

	As of July 31, 2019	As of July 31, 2020
Liabilities		
Current liabilities		
Accounts payable-other	34,846	252,956
Accrued expenses	15,955	19,192
Income taxes payable	19,518	3,286
Lease obligations	2,903	2,980
Deposits received	2,410	14,867
Other	—	61,245
Total current liabilities	75,634	354,529
Non-current liabilities		
Lease obligations	9,714	6,733
Asset retirement obligations	5,881	59,390
Deferred tax liabilities	726	10,707
Total Non-current liabilities	16,322	76,830
Total liabilities	91,956	431,360
Net assets		
Shareholders' equity		
Capital stock	812,475	49,288
Capital surplus		
Legal capital surplus	2,802,565	10,371,245
Total capital surplus	2,802,565	10,371,245
Retained earnings		
Other retained earnings		
Reserve for special depreciation		
Retained earnings brought forward	(1,019,135)	347,761
Total retained earnings	(1,019,135)	347,761
Total shareholders' equity	2,595,904	10,768,294
Stock Acquisition Rights	—	81,760
Total net assets	2,595,904	10,850,054
Total liabilities and net assets	2,687,861	11,281,415

(2) Statements of Income

(Thousands of yen)

	Year ended July 31, 2019	Year ended July 31, 2020
Operating revenue	100,000	2,100,000
Operating expenses		
Research and development expenses	640,200	1,356,646
Other selling, general and administrative expenses	186,661	327,640
Total operating expenses	826,861	1,684,286
Operating income or loss	(726,861)	415,713
Non-operating income		
Interest and dividend income	15	12
Subsidy income	9,570	13,049
Foreign exchange gains	15	—
Miscellaneous income	184	18
Total non-operating income	9,785	13,080
Non-operating expenses		
Interest expenses	304	296
Share issuance cost	5,213	55,221
Listing related costs	—	9,363
Foreign exchange loss	—	22
Other	—	2,860
Total non-operating expenses	5,518	67,764
Ordinary income or loss	(722,594)	361,030
Loss before income taxes	(722,594)	361,030
Income taxes - current	2,440	3,288
Income taxes - deferred	(3,824)	9,980
Total income taxes	(1,384)	13,268
Net income or loss	(721,209)	347,761

(3) Statements of Changes in Equity

Year ended July 31, 2019

(Thousands of yen)

	Shareholders' equity		
	Capital stock	Capital surplus	
		Legal capital surplus	Total capital surplus
Balance at the beginning of current period	90,000	2,080,090	2,080,090
Changes of items during period			
Issuance of new shares	722,475	722,475	722,475
Net loss			
Reversal of reserve for special depreciation			
Net changes of items other than shareholders' equity			
Total changes of items during period	722,475	722,475	722,475
Balance at the end of current period	812,475	2,802,565	2,802,565

	Shareholders' equity				Total net assets
	Retained earnings			Total shareholders' equity	
	Other retained earnings		Total retained earnings		
	Reserve for special depreciation	Retained earnings brought forward			
Balance at the beginning of current period	7,058	(304,985)	(297,926)	1,872,163	1,872,163
Changes of items during period					
Issuance of new shares				1,444,950	1,444,950
Net loss		(721,209)	(721,209)	(721,209)	(721,209)
Reversal of reserve for special depreciation	(7,058)	7,058	—	—	—
Net changes of items other than shareholders' equity					—
Total changes of items during period	(7,058)	(714,150)	(721,209)	723,740	723,740
Balance at the end of current period	—	(1,019,135)	(1,019,135)	2,595,904	2,595,904

Year ended July 31, 2020

(Thousands of yen)

	Shareholders' equity			
	Capital stock	Capital surplus		
		Legal capital surplus	Other capital surplus	Total capital surplus
Balance at the beginning of current period	812,475	2,802,565	—	2,802,565
Changes of items during period				
Issuance of new shares	3,912,314	3,912,314		3,912,314
Capital reduction	(4,675,501)	3,656,365	1,019,135	4,675,501
Deficiency compensation			(1,019,135)	(1,019,135)
Net loss				
Net changes of items other than shareholders' equity				
Total changes of items during period	(763,187)	7,568,680	—	7,568,680
Balance at the end of current period	49,288	10,371,245	—	10,371,245

	Shareholders' equity			Stock Acquisition Rights	Total net assets
	Retained earnings brought forward		Total shareholders' equity		
	Other retained earnings	Total retained earnings			
	Retained earnings brought forward				
Balance at the beginning of current period	(1,019,135)	(1,019,135)	2,595,904	—	2,595,904
Changes of items during period					
Issuance of new shares			7,824,629		7,824,629
Capital reduction			—		—
Deficiency compensation	1,019,135	1,019,135	—		—
Net loss	347,761	347,761	347,761		347,761
Net changes of items other than shareholders' equity				81,760	81,760
Total changes of items during period	1,366,896	1,366,896	8,172,390	81,760	8,254,150
Balance at the end of current period	347,761	347,761	10,768,294	81,760	10,850,054

(4) Statements of Cash Flows

(Thousands of yen)

	Year ended July 31, 2019	Year ended July 31, 2020
Cash flows from operating activities		
Income (loss) before income taxes	(722,594)	361,030
Depreciation	1,666	7,730
Interest and dividend income	(15)	(12)
Subsidy income	(9,570)	(13,049)
Interest expenses	304	296
Foreign exchange losses (gains)	13	22
Share issuance expenses	5,213	55,221
Listing-related costs	—	81,760
Share-based compensation expenses	—	9,363
Decrease (increase) in inventories	(2,303)	(5,398)
Decrease (increase) in prepaid expenses	(91,831)	(233,412)
Decrease (increase) in consumption taxes refund receivable	(22,745)	41,848
Increase (decrease) in accounts payable - other	8,210	197,746
Increase (decrease) in accrued expenses	3,638	3,237
Increase (decrease) of accrued consumption tax	—	61,245
Increase (decrease) in deposits received	17,080	—
Other	13,792	5,043
Subtotal	(799,139)	572,672
Interest and dividends received	15	12
Subsidy received	23,210	22,545
Interest expenses paid	(304)	(296)
Income taxes paid	(1,571)	(19,522)
Income taxes refund	0	2
Net cash provided by (used in) operating activities	(777,789)	575,413
Cash flows from investing activities		
Purchase of property, plant and equipment	(4,607)	(152,973)
Purchase of intangible assets	(1,441)	—
Payments of leasehold deposits	(505)	(1,243)
Proceeds from refund of leasehold and guarantee deposits	—	505
Net cash provided by (used in) investing activities	(6,553)	(153,711)
Cash flows from financing activities		
Repayment of lease obligations	(2,362)	(2,903)
Proceeds from issuance of shares	1,439,736	7,769,407
Payments of listing related costs	—	(9,363)
Net cash provided by (used in) financing activities	1,437,374	7,757,140
Effect of exchange rate change on cash and cash equivalents	(13)	(22)
Net increase (decrease) in cash and cash equivalents	653,018	8,178,820
Cash and cash equivalents at beginning of period	1,843,404	2,496,422
Cash and cash equivalents at end of period	2,496,422	10,675,242

(5) Notes to the Financial Statements

(Notes regarding going concern assumption)

Not applicable.

(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.

(Per share information)

	Fiscal year ended July 31, 2019	Fiscal year ended July 31, 2020
Net assets per share	58.62 yen	189.62 yen
Net income (loss) per share	(16.85 yen)	6.44 yen
Diluted net income per share	— yen	5.74 yen

(Note)

1. Diluted net income per share fiscal Year ended July 31, 2019 is not stated because of a net loss per share.
2. The Company conducted a Hundred-for-one common stock split effective on March 1, 2019, and a three-for-one common stock split effective on March 8, 2019. Net assets per share and net assets per share are calculated as if this stock split had taken place at the beginning of the previous fiscal year.
3. Diluted net income per share for the fiscal year ended July 31, 2020, is calculated as the average stock price from August 9, 2019 (date of stock listing) to July 31, 2020.
4. Net income (loss) per share and diluted net income per share are calculated based on the following basis:

	Fiscal year ended July 31, 2019	Fiscal year ended July 31, 2020
Net income (loss) per share		
Net income (loss) per share (thousands of yen)	(721,209)	347,761
Net income not attributable to common shareholders (thousands of yen)	—	—
Net income (loss) related to common stock (thousands of yen)	(721,209)	347,761
Average number of common stocks during the period (shares)	42,799,200	54,007,263
Diluted net income per share		
Adjustments to profit attributable	—	—
Increase of common stock	—	6,628,460
[Stock Acquisition Rights]	[—]	[6,628,460]
Dilutive shares that do not have a diluting effect and thus were not included in the calculation of diluted net income per share	15 series stock acquisition rights (Number of stock acquisition rights: 29,309)	—

5. Net assets per share are calculated based on the following basis:

	As of July 31, 2019	As of July 31, 2020
Total net assets (thousands of yen)	2,595,904	10,850,054
Amounts deducted from total net assets (thousands of yen)	—	81,760
[Amounts attributed to stock acquisition rights in total net assets]	[—]	[81,760]
Amounts of net assets related to common stock at the end of the period (thousands of yen)	2,595,904	10,768,294
Number of common stocks at the end of the period used for the calculation of net assets per share (shares)	44,282,700	56,789,400

(Important subsequent events)

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

At a meeting of Board of Directors held on August 13, 2020, and September 4, 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 (e).
Allotment date	August 14, 2020
Classification and number of grantees	Executive Officer and Employees 6
Total number of stock options	1,995 units
Type and number of shares	199,500 shares of common stock
Exercise price	902 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 August 15, 2022 to August 13, 2030

Name	Issuance of the 9th stock options (f).
Allotment date	August 28, 2020
Classification and number of grantees	External collaborator 1
Total number of stock options	300 units
Type and number of shares	30,000 shares of common stock
Exercise price	835 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 August 29, 2022 to August 28, 2029

Name	Issuance of the 9th stock options (g).
Allotment date	September 23, 2020
Classification and number of grantees	External collaborators 2
Total number of stock options	280 units
Type and number of shares	28,000 shares of common stock
Exercise price	974 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 September 24, 2022 to September 23, 2029