

Non-consolidated Financial Results for the Fiscal Year Ended July 31, 2021 [Japanese GAAP]

September 9, 2021

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 Stock exchange listing: Tokyo Stock Exchange
 Stock code: 4599
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 Scheduled date of filing annual 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, 2021 (August 1, 2020 to July 31, 2021)

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

	Operating revenue		Operating income		Ordinary income		Net income	
	Million yen	%	Million yen	%	Million yen	%	Million yen	%
Fiscal year ended July 31, 2021	1,400	(33.3)	(593)	—	(583)	—	(582)	—
July 31, 2020	2,100	—	415	—	361	—	347	—

	Earnings per share - basic	Earnings per share - diluted	Ratio of return on equity	Ratio of ordinary income to total assets	Ratio of operating income to revenue
Fiscal year ended	Yen	Yen	%	%	%
July 31, 2021	(10.02)	—	(5.5)	(5.3)	(42.4)
July 31, 2020	6.44	5.74	5.2	5.2	19.8

(Reference) Equity in earnings (losses) of affiliates: Fiscal year ended July 31, 2021: — million yen

Fiscal year ended July 31, 2020: — million yen

Notes:

- Diluted net income per share for the fiscal year ended July 31, 2021, 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.

(2) Financial position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of July 31, 2021	10,909	10,696	94.4	174.98
As of July 31, 2020	11,281	10,850	95.5	189.62

(Reference) Equity capital: As of July 31, 2021 10,298 million yen

As of July 31, 2020 10,768 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
Fiscal year ended	Million yen	Million yen	Million yen	Million yen
July 31, 2021	(519)	(92)	109	10,172
July 31, 2020	575	(153)	7,757	10,675

2. Payment of Dividends

	Annual dividends					Total dividends (Annual)	Dividend payout ratio	Ratio of dividends to net assets
	End Q1	End Q2	End Q3	Year-end	Total			
Fiscal year ended	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
July 31, 2020	—	0.00	—	0.00	0.00	—	—	—
July 31, 2021	—	0.00	—	0.00	0.00	—	—	—
July 31, 2022(forecast)	—	0.00	—	0.00	0.00	—	—	—

3. Financial Forecasts for the Fiscal Year Ending July 31, 2022 (August 1, 2021 to July 31, 2022)

The majority of the Company's current operating revenue comes from milestone revenues associated with the progress of development, and these revenues are highly dependent on the development strategies and schedules of our business partners. Therefore, it is difficult to predict when the Company will receive milestone revenues, and the amount of business revenue for each fiscal year may fluctuate significantly. Therefore, as it is difficult to calculate a reasonable forecast at this time, we have not provided a forecast for the fiscal year ending July 31, 2022. We will continue to research and develop of the Regeneration-Inducing Medicine Redasemtide (a peptide medicine created from HMGB1; development code: PJ1) in the fiscal year ending July 31, 2022. In addition, the Company expects to continue to progress the development of Regeneration-Inducing Medicine candidate that follows Redasemtide for the clinical trials and negotiations for licensing out.

The cash balance for the fiscal year ending July 31, 2022, is expected to be as follows

- Forecast cash R&D expenses in the range of 1,200 million yen to 1,500 million yen.
- Forecast cash other selling, general and administrative expenses in the range of 230 million yen to 300 million yen.
- There is a possibility that upfront payments related to new partnerships.
- There is a possibility that milestone payments from existing partners for out-licensed pipelines.

The Company has secured sufficient funds for research and development activities through 2026.

*Notes

(1) 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, 2021	58,851,600 shares
As of July 31, 2020	56,789,400 shares

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

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

(c) Average number of shares during the period

Fiscal year ended July 31, 2021	58,107,792 shares
Fiscal year ended July 31, 2020	54,007,263 shares

* These financial results reports are outside the scope of audit procedures 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. Overview of 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 fiscal year ended July 31, 2021 (August 1, 2020, to July 31, 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 1,400 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). Clinical trials had already started for osteoarthritis of the knee at Hiroasaki University and liver cirrhosis at Niigata University.

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 an 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 been in progress at Shionogi & Co., Ltd., the licensee of this drug. In July 2021, we reached and completed our target of 150 patient inclusion. We plan to conduct data analysis and evaluation after the follow-up period of the patients enrolled in the trial is over.

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 March 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.

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. We are developing a therapeutic drug for Pulmonary Fibrosis (including COVID-19 pneumonia) with Redasemtide. In a mouse model of pulmonary fibrosis, administration of Redasemtide statistically significantly suppressed the amount of hydroxyproline, an indicator of collagen in the lung, by up to 70%, and histopathological evaluation confirmed a decrease in the fibrosis score. In addition, the results of transcutaneous arterial oxygen saturation (SpO₂) measurements showed an improvement in pulmonary function, which is important in clinical practice. In the LPS-induced acute inflammatory pneumonia model, the amounts of cytokines and the number of inflammatory cells in the lung tended to decrease after treatment with Redasemtide. These results suggest the efficacy of Redasemtide against acute hyperinflammation of COVID-19. In addition, in the parabiosis mouse model, mesenchymal stem cells induced by Redasemtide differentiated into Ace2-positive type 2 alveolar epithelium in the injured lung and contributed to the regeneration of alveolar function.

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.

Under these circumstances, for the fiscal year ended July 31, 2021, operating revenue was 1,400,000 thousand yen (operating revenue of 2,100,000 thousand yen for the previous fiscal year). This due to an agreement with Shionogi & Co., Ltd. to expand the indication of Redasemtide for three new diseases.

R&D expenses was 1,523,797 thousand yen for the current fiscal year ended July 31, 2021, an increase of 167,150 thousand yen from the previous fiscal year. Other selling, general and administrative expenses was 469,932 thousand yen for the fiscal year ended July 31, 2021, an increase of 142,292 thousand yen from the previous fiscal year. The increase in R&D expenses was mainly due to the introduction of research equipment in conjunction with the expansion of the animal experiment facility at the head office, and the purchase of research reagents and other items in line with the active promotion of research and development activities. As a result, the Company recorded 1,993,729 thousand yen in operating expenses for the fiscal year ended July 31, 2021, an increase of 309,443 thousand yen from the previous fiscal year. Operating loss is 593,729 thousand yen (operating income of 415,713 thousand yen in the previous fiscal year).

Non-operating income was 12,778 thousand yen for the current fiscal year, a decrease of 302 thousand yen from the previous fiscal year. Non-operating expenses was 2,877 thousand yen for the current fiscal year, a decrease of 64,887 thousand yen from the previous fiscal year. The main component of non-operating income was 12,723 thousand yen in subsidy income, which was adopted by the Japan Agency for Medical Research and Development (AMED) for “Development of therapeutic drug for new coronavirus infections (COVID-19) (3rd round of public offering)”. The main components of non-operating expenses was 2,657 thousand yen of removal expenses related to the construction of the animal experiment facility at the head office, and interest expenses of 219 thousand yen. As a result, ordinary loss was 583,827 thousand yen (ordinary income of 361,030 thousand yen for the previous fiscal year).

Extraordinary income was 7,784 thousand yen. Net loss before taxes was 576,043 thousand yen (net income before taxes of 361,030 thousand yen in the previous year). Income taxes for the current fiscal year was 6,404 thousand yen. As a result, net loss for the current fiscal year was 582,448 thousand yen (net income of 347,761 thousand yen for the previous fiscal year).

As the Company operates in a single segment of the regenerative medicine business, the disclosure of business results by segment has been omitted.

(2) Explanation of financial position

Assets

Total current assets at the end of the fiscal year under review was 10,497,494 thousand yen, a decrease of 469,216 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 503,020 thousand yen in cash and deposits. Total non-current assets were 411,784 thousand yen, an increase of 97,080 thousand yen from the end of the previous fiscal year, mainly due to an increase of 94,115 thousand yen in property, plant, and equipment and 2,819 thousand yen in investments and other assets.

Liabilities

Total current liabilities at the end of the fiscal year under review was 87,625 thousand yen, a decrease of 266,904 thousand yen from the end of the previous fiscal year, mainly due to a decrease of 203,623 thousand yen in accounts payable-other. Total non-current liabilities were 125,013 thousand yen, an increase 48,182 thousand yen from the end of the previous fiscal year, mainly due to an increase of 2,774 thousand yen in asset retirement obligations.

Net assets

Total net assets at the end of the fiscal year under review was 10,696,640 thousand yen, a decrease of 153,414 thousand yen from the end of the previous fiscal year, mainly due to the recording of 582,448 thousand yen in net loss, an increase of 316,734 thousand yen in stock acquisition rights, and an increase of 56,419 thousand yen in capital stock and capital surplus as a result of the exercise of stock acquisition rights. As a result of the capital reduction in December 2020, capital stock decreased by 73,013 thousand yen and capital surplus increased by 73,013 thousand yen. Therefore, the capital stock was 32,424 thousand yen, capital surplus was 10,500,407 thousand yen, and retained earnings was (234,686) thousand yen.

(3) Explanation of cash flows

Cash and cash equivalents at the fiscal year under review were 10,172,222 thousand yen, a decrease of 503,020 thousand yen from the end of the previous fiscal year.

Cash flows from operating activities

Net cash used in operating activities was 519,649 thousand yen (inflow of 575,413 thousand yen in the previous fiscal year). The negative cash flow was mainly due to the recording of 576,043 thousand yen in loss before income taxes, recording of 324,519 thousand in stock-based compensation expenses, and a decrease of 203,623 thousand yen in accounts payable-other.

Cash flows from investing activities

Net cash used in investing activities was 92,715 thousand yen (outflow of 153,711 thousand yen in the previous fiscal year). This is due to the acquisition of fixed assets.

Cash flows from financing activities

Net cash provided by financing activities was 109,317 thousand yen (inflow of 7,757,140 thousand yen in the previous fiscal year). This is due to the issuance of shares as a result of the exercise of stock acquisition rights.

(4) Outlook for the Fiscal Year Ending July 31, 2022.

The majority of the Company's current operating revenue comes from milestone revenues associated with the progress of development, and these revenues are highly dependent on the development strategies and schedules of our business partners. Therefore, it is difficult to predict when the Company will receive milestone revenues, and the amount of business revenue for each fiscal year may fluctuate significantly. Therefore, as it is difficult to calculate a reasonable forecast at this time, we have not provided a forecast for the fiscal year ending July 31, 2022. We will continue to research and develop of the Regeneration-Inducing Medicine Redasemtide (a peptide medicine created from HMGB1; development code: PJ1) in the fiscal year ending July 31, 2022. In addition, the Company expects to continue to progress the development of Regeneration-Inducing Medicine candidate that follows Redasemtide for the clinical trials and negotiations for licensing out.

The cash balance for the fiscal year ending July 31, 2022, is expected to be as follows

- Forecast cash R&D expenses in the range of 1,200 million yen to 1,500 million yen.
- Forecast cash other selling, general and administrative expenses in the range of 230 million yen to 300 million yen.
- There is a possibility that upfront payments related to new partnerships.
- There is a possibility that milestone payments from existing partners for out-licensed pipelines.

The Company has secured sufficient funds for research and development activities through 2026.

2. 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 and Primary Notes

(1) Balance Sheets

(Thousands of yen)

	As of July 31, 2020	As of July 31, 2021
Assets		
Current assets		
Cash and deposits	10,675,242	10,172,222
Supplies	18,047	12,111
Prepaid expenses	266,630	269,644
Other	6,790	43,516
Total current assets	10,966,711	10,497,494
Non-current assets		
Property, plant, and equipment		
Buildings, Net	207,748	309,003
Vehicles, Net	—	857
Tools, furniture and fixtures, Net	21,257	13,261
Total property, plant, and equipment	229,006	323,122
Intangible assets		
Software	1,104	1,249
Total intangible assets	1,104	1,249
Investments and other assets		
Long-term prepaid expenses	78,135	77,823
Leasehold and guarantee deposits	6,457	9,588
Total investments and other assets	84,592	87,412
Total non-current assets	314,704	411,784
Total assets	11,281,415	10,909,279

(Thousands of yen)

	As of July 31, 2020	As of July 31, 2021
Liabilities		
Current liabilities		
Accounts payable-other	252,956	49,333
Accrued expenses	19,192	27,677
Income taxes payable	3,286	3,628
Lease obligations	2,980	3,060
Deposits received	14,867	3,925
Other	61,245	—
Total current liabilities	354,529	87,625
Non-current liabilities		
Lease obligations	6,733	3,673
Asset retirement obligations	59,390	107,858
Deferred tax liabilities	10,707	13,481
Total non-current liabilities	76,830	125,013
Total liabilities	431,360	212,638
Net assets		
Shareholders' equity		
Capital stock	49,288	32,424
Capital surplus		
Legal capital surplus	10,371,245	10,500,407
Total capital surplus	10,371,245	10,500,407
Retained earnings		
Other retained earnings		
Retained earnings brought forward	347,761	(234,686)
Total retained earnings	347,761	(234,686)
Total shareholders' equity	10,768,294	10,298,145
Stock acquisition rights	81,760	398,495
Total net assets	10,850,054	10,696,640
Total liabilities and net assets	11,281,415	10,909,279

(2) Statements of Income

(Thousands of yen)

	For the fiscal year ended July 31, 2020	For the fiscal year ended July 31, 2021
Operating revenue	2,100,000	1,400,000
Operating expenses		
Research and development expenses	1,356,646	1,523,797
Other selling, general and administrative expenses	327,640	469,932
Total operating expenses	1,684,286	1,993,729
Operating income (loss)	415,713	(593,729)
Non-operating income		
Interest and dividend income	12	8
Subsidy income	13,049	12,723
Foreign exchange gains	—	27
Miscellaneous income	18	20
Total non-operating income	13,080	12,778
Non-operating expenses		
Interest expenses	296	219
Share issuance costs	55,221	—
Listing related costs	9,363	—
Foreign exchange loss	22	—
Loss on removal	—	2,657
Miscellaneous loss	2,860	0
Total non-operating expenses	67,764	2,877
Ordinary income (loss)	361,030	(583,827)
Extraordinary income		
Gain on reversal of share acquisition rights	—	7,784
Total extraordinary income	—	7,784
Income (loss) before income taxes	361,030	(576,043)
Income taxes – current	3,288	3,630
Income taxes – deferred	9,980	2,774
Total income taxes	13,268	6,404
Net income (loss)	347,761	(582,448)

(3) Statements of Changes in Equity

For the fiscal year ended July 31, 2020 (From August 1, 2019 to 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 income				
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		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 income	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

For the fiscal year ended July 31, 2021 (From August 1, 2020 to July 31, 2021)

(Thousands of yen)

	Shareholders' equity		
	Capital stock	Capital surplus	
		Legal capital surplus	Total capital surplus
Balance at the beginning of current period	49,288	10,371,245	10,371,245
Changes of items during period			
Issuance of new shares	56,149	56,149	56,149
Capital reduction	(73,013)	73,013	73,013
Net loss			
Net changes of items other than shareholders' equity			
Total changes of items during period	(16,863)	129,162	129,162
Balance at the end of current period	32,424	10,500,407	10,500,407

	Shareholders' equity			Stock Acquisition Rights	Total net assets
	Retained earnings brought forward	Total retained earnings	Total shareholders' equity		
	Other retained earnings				
	Retained earnings brought forward				
Balance at the beginning of current period	347,761	347,761	10,768,294	81,760	10,850,054
Changes of items during period					
Issuance of new shares			112,298		112,298
Capital reduction			—		—
Net loss	(582,448)	(582,448)	(582,448)		(582,448)
Net changes of items other than shareholders' equity				316,734	316,734
Total changes of items during period	(582,448)	(582,448)	(470,149)	316,734	(153,414)
Balance at the end of current period	(234,686)	(234,686)	10,298,145	398,495	10,696,640

(4) Statements of Cash Flows

(Thousands of yen)

	For the fiscal year ended July 31, 2020	For the fiscal year ended July 31, 2021
Cash flows from operating activities		
Income (loss) before income taxes	361,030	(576,043)
Depreciation	7,730	43,596
Interest and dividend income	(12)	(8)
Subsidy income	(13,049)	(12,723)
Interest expenses	296	219
Foreign exchange losses (gains)	22	(27)
Share issuance expenses	55,221	—
Gain on reversal of share acquisition rights	—	(7,784)
Share-based compensation expenses	81,760	324,519
Listing-related costs	9,363	—
Decrease (increase) in supplies	(5,398)	5,935
Decrease (increase) in prepaid expenses	(233,412)	(2,702)
Decrease (increase) in consumption taxes refund receivable	41,848	(37,260)
Increase (decrease) in accounts payable - other	197,746	(203,623)
Increase (decrease) in accrued expenses	3,237	8,484
Increase (decrease) of accrued consumption tax	61,245	(61,245)
Other	5,043	(10,210)
Subtotal	572,672	(528,873)
Interest and dividends received	12	8
Subsidy income received	22,545	12,723
Interest expenses paid	(296)	(219)
Income taxes paid	(19,522)	(3,289)
Income taxes refund	2	1
Net cash provided by (used in) operating activities	575,413	(519,649)
Cash flows from investing activities		
Purchase of property, plant, and equipment	(152,973)	(89,054)
Purchase of intangible assets	—	(530)
Payments of leasehold and guarantee deposits	(1,243)	(4,839)
Proceeds from refund of leasehold and guarantee deposits	505	1,708
Net cash provided by (used in) investing activities	(153,711)	(92,715)
Cash flows from financing activities		
Repayment of lease obligations	(2,903)	(2,980)
Proceeds from issuance of shares	7,769,407	112,298
Payments of listing related costs	(9,363)	—
Net cash provided by (used in) financing activities	7,757,140	109,317
Effect of exchange rate change on cash and cash equivalents	(22)	27
Net increase (decrease) in cash and cash equivalents	8,178,820	(503,020)
Cash and cash equivalents at beginning of period	2,496,422	10,675,242
Cash and cash equivalents at end of period	10,675,242	10,172,222

(5) Notes to the Financial Statements

(Notes regarding going concern assumption)

None

(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)

	For the fiscal year ended July 31, 2020	For the fiscal year ended July 31, 2021
Net assets per share	189.62 yen	174.98 yen
Earnings (loss) per share	6.44 yen	(10.02) yen
Diluted net income per share	5.74 yen	— yen

Notes:

1. Diluted net income per share for the fiscal Year ended July 31, 2021 is not stated because of a net loss per share.
2. 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.
3. Net income (loss) per share and diluted net income per share are calculated based on the following basis:

	For the fiscal year ended July 31, 2020	For the fiscal year ended July 31, 2021
Net income (loss) per share		
Net income (loss) (thousands of yen)	347,761	(582,448)
Amount not attributable to shareholders of capital stock (thousands of yen)	—	—
Net income (loss) related to common stock (thousands of yen)	347,761	(582,448)
Average number of shares during the period (shares)	54,007,263	58,107,792
Diluted net income per share		
Net income attributable to owners of parent (thousands of yen)	—	—
Increase of common stock (shares)	6,628,460	—
[Stock acquisition rights (shares)]	[6,628,460]	[—]
Dilutive shares not included in the calculation since there was no dilutive effect.	—	22 series stock acquisition rights (Total number of stock acquisition rights to shares: 6,034,600)

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

	As of July 31, 2020	As of July 31, 2021
Total net assets (thousands of yen)	10,850,054	10,696,640
Amounts deducted from total net assets (thousands of yen)	81,760	398,495
[Amounts attributed to stock acquisition rights in total net assets]	[81,760]	[398,495]
Amounts of net assets related to common stock at the end of the period (thousands of yen)	10,768,294	10,298,145
Number of common stocks at the end of the period used for the calculation of net assets per share (shares)	56,789,400	58,851,600