**English Translation:** 

This is a translation of the original release in Japanese. In the event of any discrepancy, the original release in Japanese shall prevail.

# Non-consolidated Financial Results for the Fiscal Year Ended July 31, 2022 [Japanese GAAP]

September 8, 2022

Company name: StemRIM Inc.

Stock exchange listing: Tokyo Stock Exchange

Stock code: 4599

URL: https://stemrim.com

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Scheduled date of filling annual securities report:

Scheduled date of commencing dividend payments:

Supplementary briefing materials on financial results:

None
Explanatory meeting on financial results:

None

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

# 1. Financial Results for the Fiscal Year Ended July 31, 2022 (August 1,2021 to July 31, 2022)

#### (1) Operating results

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

	Operating re	venue	Operating income		Ordinary income		Net income	
Fiscal Year ended	Million yen	%	Million yen	%	Million yen	%	Million yen	%
July 31, 2022	22	(98.4)	(1,980)	_	(1,972)	_	(1,948)	
July 31, 2021	1,400	(33.3)	(593)	_	(583)	_	(582)	

	Earnings per share	Earnings per share	Ratio of return on	Ratio of ordinary	Ratio of operating
	basic	diluted	equity	income to total assets	income to revenue
Fiscal Year ended	Yen	Yen	%	%	%
July 31, 2022	(32.92)	_	(20.7)	(19.2)	(8,620.7)
July 31, 2021	(10.02)		(5.5)	(5.3)	(42.4)

(Reference) Equity in earnings (losses) of affiliates: Fiscal year ended July 31, 2022: — million yen

Fiscal year ended July 31, 2021: — million yen

Note: Diluted net income per share is not stated because of a net loss per share.

# (2) Financial position

	Total assets	Net assets	Equity ratio	Net assets per share
	Million yen	Million yen	%	Yen
As of July 31, 2022	9,597	9,404	88.7	143.32
As of July 31, 2021	10,909	10,696	94.4	174.98

(Reference) Equity capital: As of July 31, 2022 8,513 Million yen
As of July 31, 2021 10,298 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, 2022	(1,404)	(0)	112	8,880
July 31, 2021	(519)	(92)	109	10,172

#### 2. Payment of Dividends

		Annual dividends					Dividend	Ratio of
	End Q1	End Q2	End Q3	Year-end	Total	(Annual)	payout ratio	dividends to net assets
Fiscal year ended	Yen	Yen	Yen	Yen	Yen	Million yen	%	%
July 31, 2021	_	0.00	_	0.00	0.00	_	_	_
July 31, 2022	_	0.00	_	0.00	0.00		_	_
July 31, 2023(forecast)	_	0.00		0.00	0.00		_	

Note: Revisions to the forecast of cash dividends most recently announced: None

3. Financial Forecasts for the Fiscal Year Ending July 31, 2023 (August 1, 2022 to July 31, 2023)

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. Hence, the Company have not provided a forecast for the fiscal year ending July 31, 2023. 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, 2023. 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 outflow for the fiscal year ending July 31, 2023, is expected to be as follows

- Forecast cash R&D expenses in the range of 1,200 million yen to 1,600 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) Application of specific accounting for preparing the 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. : Yes

(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)

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As of July 31, 2022	59,405,400 shares
As of July 31, 2021	58,851,600 shares

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

As of July 31, 2022	— shares
As of July 31, 2021	— shares

(c) Average number of shares during the period

Fiscal Year ended July 31, 2022	59,188,863 shares
Fiscal Year ended July 31, 2021	58,107,792 shares

<sup>\*</sup> 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.

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# 1. Overview of Financial Results for the Period under Review

# (1) Explanation of operating results

During the fiscal year ended July 31, 2022 (August 1, 2021, to July 31, 2022), we continued to make progress in the research and development of "Regeneration-Inducing Medicine" called Redasemtide (a peptide medicine created from HMGB1) for multiple ongoing clinical trials and the launch of new trials.

In the regenerative medicine industry, which is the business domain of our company, social expectations and interest in regenerative medicine technology has been increasing, as the foundation for promoting the industrialization of regenerative medicine has been laid by the Act on Securing Safety of Regenerative Medicine and the revised Pharmaceutical Affairs Law enacted in November 2014, with continued approvals of several new regenerative medicine products. The market scale of regenerative medicine is expected to increase significantly, from 95 billion yen in Japan in 2020 to 2.5 trillion yen in 2050, and from 1 trillion yen worldwide in 2020 to 38 trillion yen in 2050. This shows a tremendous need for new medical treatments for diseases that are difficult to treat with conventional drugs or medical care. Under these circumstances, we believe that it is our social mission to deliver "Regeneration-Inducing Medicine" which realizes in vivo regeneration therapy by recruitment of patient's own mesenchymal stem cells (MSCs) without utilizing in vitro cultured cells, to patients around the world suffering from various diseases including Epidermolysis Bullosa (EB) and other intractable diseases.

In the current fiscal year, the progresses of research and development on Redasemtide for each target disease are, as follows.

PJ1-01 (for Dystrophic Epidermolysis Bullosa (DEB)): An additional investigator-initiated clinical trial (Additional Phase II study) in patients with DEB was started in July 2022. The investigator-initiated clinical trial and follow-up study (Phase II) in patients with DEB was completed in March 2020. The results of these data analyses showed 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) as a result of Redasemtide treatment in all patients (9 patients) in this study. At the last observation point (28 weeks 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. In addition, since the efficacy was shown at the observation point after the end of the follow-up study (52 weeks after the end of administration), long-term effect of Redasemtide on DEB was also confirmed. Furthermore, since no adverse events of concern were observed in the secondary evaluation (safety evaluation), both the safety and efficacy of Redasemtide in patients with DEB were confirmed in this study. DEB is a rare intractable disease with 400 patients in Japan, and there is currently no effective treatment. In addition, it is difficult to plan a large-scale Phase III study. Therefore, Shionogi & Co., Ltd., the licensee of Redasemtide, has been in discussions with Pharmaceuticals and Medical Devices Agency (PMDA) to file an application for approval of the drug based on the results of the Phase II and follow-up study. Although the results of this study showed that there were significant cases of efficacy, it was concluded that further efficacy cases need to be accumulated. Therefore, additional study will be needed to confirm the reproducibility of the study results.

PJ1-02 (for Cerebral Infarction): Shionogi & Co., Ltd. announced that the primary endpoint of the Phase II study was achieved in December 2021. This was a placebo-controlled, double-blind, randomized, controlled study to evaluate the efficacy and safety of Redasemtide in patients who have had a cerebral infarction between 4.5 hours and 24 hours after the onset of cerebral infarction and were unable to undergo vascular recanalization (thrombolysis or thrombus retrieval). The modified Rankin Scale (mRS: a scale to evaluate the severity of cerebrovascular disorders such as cerebral hemorrhage and cerebral infarction) after 90 days of drug administration was evaluated as the primary endpoint, and the results confirmed the achievement of the primary endpoint and confirmed the efficacy of Redasemtide in patients with acute cerebral infarction. In terms of safety, a secondary endpoint, the incidence of adverse events was similar in the Redasemtide and placebo groups, confirming that the drug was well tolerated. In the treatment of acute cerebral infarction, thrombolytic therapy is available up to 4.5 hours after onset, and mechanical thrombus retrieval therapy is available up to 8 hours after onset. Redasemtide treatment options, which are less time-consuming than conventional angiolytic and mechanical thrombus retrieval therapies, are expected to meet these unmet medical needs. Based on the positive results of the Phase II study, Shionogi & Co., Ltd. plans to proceed with preparations for the transition to global Phase III study.

PJI-03 (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. Currently, preparations are underway at Osaka University for phase II study. The results were reported at international conferences such as American Heart Association (AHA) Scientific Sessions 2018. At the 18th Annual Meeting of the Japanese Society for Regenerative Medicine in March 2019, we reported successful observation of 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.

PJ1-04 (for Osteoarthritis of the Knee): An investigator-initiated clinical trial (Phase II study) for patients with

osteoarthritis of the knee has been underway at Hirosaki University since November 2020, and patient enrollment was completed in December 2021. Data analysis and evaluation will be conducted after a 4 week-treatment period and a 48 weeks follow-up period. 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 desired 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.

PJ1-05 (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, and patient enrollment completed in June 2022. Data analysis and evaluation will be conducted after a 6 months follow-up period. 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 mice, and may become a new treatment option for patients with chronic liver disease and cirrhosis accompanied by fibrosis.

As for the projects to discover "new Regeneration-Inducing Medicine" other than Redasemtide, we have identified several new candidate compounds with remarkable activities through the multifaceted development of screening methods with continuing active R&D.

PJ5 (stem cell gene therapy) that we are developing in joint research with Osaka University is based on our own development technology that collects MSCs from the skin of patients with EB in a minimally invasive manner using a lentiviral vector. It is a radical EB treatment technology that efficiently introduces VII collagen genes into MSCs derived from the patient's skin and returns them to the patient's skin to enable a continuous supply of type VII collagen. EB model skin tissue was prepared using patient-derived MSCs, and blisters were artificially formed by the aspiration method. We have confirmed that blisters do not form in skin tissue. In addition to pluripotency, MSCs have immunoregulatory functions and therapeutic effects on various diseases. A cure for the disease can be expected.

Compared to transplantation of transgenic cells via epidermal sheets or intradermal administration, stem cell gene therapy, which is less burdensome for patients and shows high and long-lasting efficacy, is expected to be a curative treatment for DEB, for which no effective curative therapy currently exists.

From April 2022, we will participate as a joint research company in the 2022 "Research Project for Practical Use of Intractable Diseases" implemented by the Japan Agency for Medical Research and Development (AMED). In this AMED-approved research, we will realize a radical treatment for DEB by utilizing the abundant data and knowledge accumulated by our company in stem cell gene therapy research.

Under these circumstances, for the fiscal year ended July 31, 2022, operating revenue was 22,976 thousand yen (operating revenue of 1,400,000 thousand yen for the previous fiscal year). This was due to the receipt of an upfront payment from Shionogi & Co., Ltd. for the licensing of research data related to the development of "Regeneration-Inducing Medicine."

R&D expenses was 1,421,286 thousand yen for the current fiscal year ended July 31, 2022, a decrease of 102,511 thousand yen from the previous fiscal year. Other selling, general and administrative expenses was 582,377 thousand yen for the fiscal year ended July 31, 2022, an increase of 112,445 thousand yen from the previous fiscal year. The decrease in R&D expenses was mainly due to the decrease in purchase of research equipment and construction costs of facilities following the opening of the animal experiment facility in the previous fiscal year. The increase in selling, general and administrative expenses was mainly due to an increase in share-based compensation expenses. As a result, the Company recorded 2,003,663 thousand yen in operating expenses for the fiscal year ended July 31, 2022, an increase of 9,933 thousand yen from the previous fiscal year. Operating loss was 1,980,687 thousand yen (operating loss of 593,279 thousand yen in the previous fiscal year).

Non-operating income was 8,502 thousand yen for the current fiscal year, a decrease of 4,276 thousand yen from the previous fiscal year. Non-operating expenses was 140 thousand yen for the current fiscal year, a decrease of 2,736 thousand yen from the previous fiscal year. The main components of non-operating income were 8,000 thousand yen in business consignment income, 273 thousand yen in subsidy income. The main component of non-operating expenses were 140 thousand yen of interest expenses. As a result, ordinary loss was 1,972,325 thousand yen (ordinary income of 583,827 thousand yen for the previous fiscal year).

Extraordinary income was 26,100 thousand yen. The main component of extraordinary income was gain on reversal of share acquisition rights. Net loss before taxes was 1,946,224 thousand yen (net income before taxes of 576,043 thousand yen in the previous year). Income taxes for the current fiscal year was 2,082 thousand yen. As a result, net

loss for the current fiscal year was 1,948,307 thousand yen (net loss of 582,448 thousand yen for the previous fiscal year).

As the Company operates in a single segment of the "Regeneration-Inducing 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 were 9,262,992 thousand yen, a decrease of 1,234,502 thousand yen from the end of the previous fiscal year. This was mainly due to a decrease of 1,292,031 thousand yen in cash and cash deposits. Total non-current assets were 334,380 thousand yen, a decrease of 77,403 thousand yen from the end of the previous fiscal year. This was mainly due to a decrease of 28,262 thousand yen in investments and other assets. As a result, total assets were 9,597,373 thousand yen, a decrease of 1,311,905 thousand yen from the previous fiscal year.

#### Liabilities

Total current liabilities at the end of the fiscal year under review were 71,830 thousand yen, a decrease of 15,794 thousand yen from the end of the previous fiscal year. This was mainly due to a decrease of 17,815 thousand yen in accounts payable-other. Total non-current liabilities were 120,598 thousand yen, a decrease of 4,414 thousand yen from the end of the previous fiscal year. This was mainly due to a decrease of 3,141 thousand yen in lease obligations. As a result, total liabilities were 192,429 thousand yen, a decrease of 20,209 thousand yen from the previous fiscal year.

# Net assets

Total net assets at the end of the fiscal year under review were 9,404,943 thousand yen, a decrease of 1,291,696 thousand yen from the end of the previous fiscal year. This was mainly due to the recording of 1,948,307 thousand yen in net loss, an increase of 492,985 thousand yen in stock acquisition rights, and an increase of 81,828 thousand yen in capital stock and capital surplus because of the exercise of stock acquisition rights and issuance of new shares through restricted stock compensation. The capital stock decreased by 37,936 thousand yen and the capital reserve increased by 37,936 thousand yen as a result of the capital reduction in December 2021. As a result, capital stock was 76,315 thousand yen, capital surplus was 10,620,172 thousand yen, and retained earnings -2,182,994 thousand yen.

# (3) Explanation of cash flows

Cash and cash equivalents at the fiscal year under review were 8,880,191 thousand yen, a decrease of 1,292,031 thousand yen from the end of the previous fiscal year.

# Cash flows from operating activities

Net cash used in operating activities was 1,404,565 thousand yen (inflow of 519,649 thousand yen in the previous fiscal year). The negative cash flow was mainly due to the recording of 1,946,224 thousand yen in loss before income taxes, recording of 555,732 thousand in stock-based compensation expenses, and an increase of 66,226 thousand yen in accrued consumption tax.

# Cash flows from investing activities

Net cash used in investing activities was 330 thousand yen (outflow of 92,715 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 112,859 thousand yen (inflow of 109,317 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) Financial forecasts for the fiscal year ending July 31, 2023

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, 2023. 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, 2023. 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, 2023, is expected to be as follows

- •Forecast cash R&D expenses in the range of 1,200 million yen to 1,600 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, 2021	As of July 31, 2022
Assets		
Current assets		
Cash and deposits	10,172,222	8,880,191
Supplies	12,111	4,348
Prepaid expenses	269,644	270,412
Other	43,516	108,040
Total current assets	10,497,494	9,262,992
Non-current assets		
Property, plant, and equipment		
Buildings, Net	309,003	266,526
Vehicles, Net	857	0
Tools, furniture and fixtures, Net	13,261	7,849
Total property, plant, and equipment	323,122	274,375
Intangible assets		
Software	1,249	855
Total intangible assets	1,249	855
Investments and other assets		
Long-term prepaid expenses	77,823	49,563
Leasehold and guarantee deposits	9,588	9,586
Total investments and other assets	87,412	59,149
Total non-current assets	411,784	334,380
Total assets	10,909,279	9,597,373

		(Thousands of yen)
	As of July 31, 2021	As of July 31, 2022
Liabilities		
Current liabilities		
Accounts payable-other	49,333	31,517
Accrued expenses	27,677	29,634
Income taxes payable	3,628	3,629
Lease obligations	3,060	3,141
Deposits received	3,925	3,907
Total current liabilities	87,625	71,830
Non-current liabilities		
Lease obligations	3,673	531
Asset retirement obligations	107,858	108,032
Deferred tax liabilities	13,481	12,034
Total non-current liabilities	125,013	120,598
Total liabilities	212,638	192,429
Net assets		
Shareholders' equity		
Capital stock	32,424	76,315
Capital surplus		
Legal capital surplus	10,500,407	10,620,172
Total capital surplus	10,500,407	10,620,172
Retained earning		
Other retained earnings		
Retained earnings brought forward	(234,686)	(2,182,994)
Total retained earnings	(234,686)	(2,182,994)
Treasury shares		(31)
Total shareholders' equity	10,298,145	8,513,462
Stock acquisition rights	398,495	891,481
Total net assets	10,696,640	9,404,943
Total liabilities and net assets	10,909,279	9,597,373

# (2) Statements of Income

		(Thousands of yen)
	For the fiscal Year ended July 31, 2021	For the fiscal Year ended July 31, 2022
Operating revenue	1,400,000	22,976
Operating expenses		
Research and development expenses	1,523,797	1,421,286
Other selling, general and administrative expenses	469,932	582,377
Total operating expenses	1,993,729	2,003,663
Operating loss	(593,729)	(1,980,687)
Non-operating income		
Interest and dividend income	8	0
Subsidy income	12,723	273
Foreign exchange gains	27	5
Business consignment income	_	8,000
Miscellaneous income	20	222
Total non-operating income	12,778	8,502
Non-operating expenses		
Interest expenses	219	140
Loss on removal	2,657	_
Miscellaneous loss	0	_
Total non-operating expenses	2,877	140
Ordinary loss	(583,827)	(1,972,325)
Extraordinary income		
Gain on reversal of share acquisition rights	7,784	26,100
Total extraordinary income	7,784	26,100
Loss before income taxes	(576,043)	(1,946,224)
Income taxes – current	3,630	3,529
Income taxes – deferred	2,774	(1,446)
Total income taxes	6,404	2,082
Net loss	(582,448)	(1,948,307)

(3) Statements of Changes in Equity
For the fiscal year ended July 31, 2021 (From August 1, 2020 to July 31, 2021)

(Thousands of yen)

			3 /
	Shareholders' equity		
		Capital	surplus
	Capital stock	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			
	Retained earnings	brought forward		C41 - A :-: 4:	Total net assets
	Other retained earnings	Total retained	Total shareholders' equity	Stock Acquisition Rights	
	Retained earnings brought forward	earnings	equity		
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

For the fiscal year ended July 31, 2021 (From August 1, 2021 to July 31, 2022)

(Thousands of yen)

	Shareholders' equity		
		Capital	surplus
	Capital stock	Legal capital surplus	Total capital surplus
Balance at the beginning of current period	32,424	10,500,407	10,500,407
Changes of items during period			
Issuance of new shares	81,828	81,828	81,828
Capital reduction	(37,936)	37,936	37,936
Net loss			
Net changes of items other than shareholders' equity			
Total changes of items during period	43,891	119,765	119,765
Balance at the end of current period	76,315	10,620,172	10,620,172

	Shareholders' equity					
	Retained earnings	brought forward			Stock	
	Other retained earnings Retained earnings brought forward	Total retained earnings	Treasury shares	Total shareholders' equity	Acquisition Rights	Total net assets
Balance at the beginning of current period	(234,686)	(234,686)		10,298,145	398,495	10,696,640
Changes of items during period						
Issuance of new shares				163,656		163,656
Capital reduction				_		_
Net loss	(1,948,307)	(1,948,307)		(1,948,307)		(1,948,307)
Acquisition of treasury shares			(31)	(31)		(31)
Net changes of items other than shareholders' equity					492,985	492,985
Total changes of items during period	(1,948,307)	(1,948,307)	(31)	(1,784,682)	492,985	(1,291,696)
Balance at the end of current period	(2,182,994)	(2,182,994)	(31)	8,513,462	891,481	9,404,943

# (4) Statements of Cash Flows

	For the fiscal year ended July 31, 2021	(Thousands of year For the fiscal year ended July 31, 2022
Cash flows from operating activities	5 diy 5 1, 2021	5 diy 51, 2022
Income (loss) before income taxes	(576,043)	(1,946,224
Depreciation	43,596	49,473
Interest and dividend income	(8)	(0
Subsidy income	(12,723)	(273
Business consignment income	—	(8,000
Interest expenses	219	140
Foreign exchange losses (gains)	(27)	(5
Share issuance expenses	<u> </u>	<u> </u>
Gain on reversal of share acquisition rights	(7,784)	(26,100
Share-based compensation expenses	324,519	555,732
Listing-related costs	_	_
Decrease (increase) in supplies	5,935	7,763
Decrease (increase) in prepaid expenses	(2,702)	38,551
Decrease (increase) in consumption taxes refund receivable	(37,260)	(66,226
Increase (decrease) in accounts payable - other	(203,623)	(17,815
Increase (decrease) in accrued expenses	8,484	1,950
Increase (decrease) of accrued consumption tax	(61,245)	_
Other	(10,210)	1,85
Subtotal	(528,873)	(1,409,17)
Interest and dividends received	8	(
Subsidy income received	12,723	273
Business consignment income received	_	8,000
Interest expenses paid	(219)	(140
Income taxes paid	(3,289)	(3,529
Income taxes refund	1	
Net cash provided by (used in) operating activities	(519,649)	(1,404,565
Cash flows from investing activities		·
Purchase of property, plant, and equipment	(89,054)	(332
Purchase of intangible assets	(530)	` <u> </u>
Payments of leasehold and guarantee deposits	(4,839)	_
Proceeds from refund of leasehold and guarantee deposits	1,708	2
Net cash provided by (used in) investing activities	(92,715)	(330
Cash flows from financing activities		·
Repayment of lease obligations	(2,980)	(3,060
Proceeds from issuance of shares	112,298	115,95
Payments for purchase of treasury shares	_	(31
Net cash provided by (used in) financing activities	109,317	112,859
Effect of exchange rate change on cash and cash equivalents	27	,
Net increase (decrease) in cash and cash equivalents	(503,020)	(1,292,031
Cash and cash equivalents at beginning of period	10,675,242	10,172,222
Cash and cash equivalents at end of period	10,172,222	8,880,191

# (3) Notes to the Financial Statements

(Notes regarding going concern assumption)

### (Changes in accounting policies)

(Application of the Accounting Standard for Revenue Recognition, etc.)

From the beginning of the first quarter of the fiscal year ending July 31, 2022, the Company has applied the "Accounting Standard for Revenue Recognition" (ASBJ Statement No. 29, March 31, 2020), etc., and recognizes revenue at the amounts expected to be received in exchange for promised goods or services, at the point when the control of such goods or services is transferred to customers. The Company has adopted the "Accounting Standard for Revenue Recognition" (ASBJ Statement No.84) in accordance with the transitional treatment. There is no effect on the beginning balance of retained earnings brought forward and profit and loss for the current fiscal year.

### (Application of the Accounting Standard for Fair Value Measurement, etc.)

From the beginning of the first quarter of the fiscal year ending July 31, 2022, the Company has applied the "Accounting Standard for Fair Value Measurement" (ASBJ Statement No. 30, July 4, 2019), etc. In accordance with the transitional treatment prescribed in Paragraph 19 of the Accounting Standard for Fair Value Measurement and Paragraph 44-2 of the "Accounting Standard for Financial Instruments" (ASBJ Statement No. 10, July 4, 2019), the new accounting policies prescribed by the Accounting Standard for Fair Value Measurement, etc. will be applied prospectively. There is no effect of the new standards on the financial statements.

# (Additional information)

The Company makes accounting estimates, such as impairment accounting for fixed assets, based on information available at the time the financial statements are prepared. The Company has determined that the impact of the spread of the COVID-19 infection on the Company is limited at this time and will not have a significant effect on the estimates for the current fiscal year.

### (Information broken down by revenue from contracts with customers)

The Company's business is a single segment of the Regeneration-Inducing Medicine business, and operating revenues broken down by major goods and services are as follows.

(Thousands of yen)

	For the fiscal year ended July 31, 2022
Lump-sum payment	_
Milestone income	_
Royalty income	_
Collaborative research income	_
Other lump-sum payments	22,976
Revenue from contracts with customers	22,976
Other income	_
Net income from external customers	22,976

#### (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, 2021	For the fiscal year ended July 31, 2022	
Net assets per share	174.98 yen	· · · · · · · · · · · · · · · · · · ·	
Earnings (loss) per share	(10.02) yen	(32.92) yen	

# Notes:

1. Diluted net income per share is not stated because of a net loss per share.

2. 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, 2021	For the fiscal year ended July 31, 2022
Net income (loss) (thousands of yen)	(582,448)	(1,948,307)
Amount not attributable to shareholders of capital stock (thousands of yen)	_	_
Net income (loss) related to common stock (thousands of yen)	(582,448)	(1,948,307)
Average number of shares during the period (shares)	58,107,792	59,188,863
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)	22 series stock acquisition rights (Total number of stock acquisition rights to shares: 5,818,800)

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

	As of July 31, 2021	As of July 31, 202
Total net assets (thousands of yen)	10,696,640	9,404,943
Amounts deducted from total net assets (thousands of yen)	398,495	891,481
[Amounts attributed to stock acquisition rights in total net assets]	[398,495]	[891,481]
Amounts of net assets related to common stock at the end of the period (thousands of yen)	10,298,145	8,513,462
Number of common stocks at the end of the period used for the calculation of net assets per share (shares)	58,851,600	59,402,400

# (Significant Subsequent Events)

(Issuance of stock acquisition rights as stock options)

The Board of Directors of the Company resolved on August 18, 2022 to issue stock acquisition rights as stock options approved at the Annual General Meeting of Shareholders held on October 27, 2021. The purpose of this issue is to contribute to the enhancement of the Company's corporate value by increasing the Company's morale and willingness to contribute to the advancement of the Company's research and development.

Name	The 11th stock options (b).
Allotment date	August 19, 2022
Classification and number of	Executive Officer 2
grantees	Employee 1
Total number of stock options	1,300 units
Amount to be paid upon issuance	None
of stock acquisition rights	
Type and number of shares	130,000 shares of common stock
Exercise price	894 yen per share
Capital incorporation	The amount of increase in capital stock in the event of the issuance of
	shares upon the exercise of these equity warrants shall be half of the
	maximum amount of increase in capital stock, etc., as calculated in
	accordance with Article 17, Paragraph 1 of the Corporate Calculation
	Regulations. Any fraction of less than one yen resulting from the
	calculation shall be rounded up to the nearest one yen. The amount of
	capital reserve to be increased shall be the amount obtained by subtracting
	the amount of stated capital as provided in the preceding paragraph.
Conditions for exercising stock	A person who has been allotted the Stock Options is required to have the
acquisition rights	status of any of the directors, corporate auditors, employees or outside
	collaborators of the Company or its subsidiaries when exercising the
	rights.

	In the event of the death of the holder of stock acquisition rights, his/her heirs may not exercise the rights. However, if an application is filed by the heir and approved by the Board of Directors, the heir may exercise the stock acquisition rights.
	Part of each stock acquisition right cannot be exercised.
Exercise period	From August 20, 2024 to August 18, 2032

Name	The 11th stock options (c).
Allotment date	September 5, 2022
Classification and number of	External collaborators 2
grantees	
Total number of stock options	1,200 units
Amount to be paid upon issuance	None
of stock acquisition rights	
Type and number of shares	120,000 shares of common stock
Exercise price	1,062 yen per share
Capital incorporation	The amount of increase in capital stock in the event of the issuance of shares upon the exercise of these equity warrants shall be half of the maximum amount of increase in capital stock, etc., as calculated in accordance with Article 17, Paragraph 1 of the Corporate Calculation Regulations. Any fraction of less than one yen resulting from the calculation shall be rounded up to the nearest one yen. The amount of capital reserve to be increased shall be the amount obtained by subtracting the amount of stated capital as provided in the preceding paragraph.
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. In the event of the death of the holder of stock acquisition rights, his/her heirs may not exercise the rights. However, if an application is filed by the heir and approved by the Board of Directors, the heir may exercise the stock acquisition rights.  Part of each stock acquisition right cannot be exercised.
Exercise period	From September 6, 2024 to September 5, 2031

Name	The 12th stock options
Allotment date	August 19, 2022
Classification and number of	Directors 4
grantees	
Total number of stock options	860 units
Amount to be paid upon issuance	None
of stock acquisition rights	
Type and number of shares	86,000 shares of common stock
Exercise price	894 yen per share
Capital incorporation	The amount of increase in capital stock in the event of the issuance of shares
	upon the exercise of these equity warrants shall be half of the maximum
	amount of increase in capital stock, etc., as calculated in accordance with
	Article 17, Paragraph 1 of the Corporate Calculation Regulations. Any
	fraction of less than one yen resulting from the calculation shall be rounded
	up to the nearest one yen. The amount of capital reserve to be increased
	shall be the amount obtained by subtracting the amount of stated capital as
	provided in the preceding paragraph.
Conditions for exercising stock	A person who has been allotted the Stock Options is required to have the
acquisition rights	status of any of the directors, corporate auditors, employees or outside
	collaborators of the Company or its subsidiaries when exercising the rights.
	In the event of the death of the holder of stock acquisition rights, his/her
	heirs may not exercise the rights. However, if an application is filed by the
	heir and approved by the Board of Directors, the heir may exercise the stock
	acquisition rights.
	Part of each stock acquisition right cannot be exercised.
Exercise period	From August 20, 2024 to August 18, 2032