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February 9, 2022

Consolidated Financial Results for the Fiscal Year Ended December 31, 2021 (under IFRS)

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 Listing: Tokyo Stock Exchange
 Securities code: 4597
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Scheduled date of ordinary general meeting of shareholders: March 24, 2022
 Scheduled date to commence dividend payments: –
 Scheduled date to file annual securities report: March 24, 2022
 Preparation of supplementary material on financial results: Yes
 Holding of financial results presentation meeting: Yes (for institutional investors and analysts)

(Millions of yen with fractional amounts discarded, unless otherwise noted)

1. Consolidated financial results for the fiscal year ended December 31, 2021 (from January 1, 2021 to December 31, 2021)

(1) Consolidated operating results

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Profit before tax		Profit	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
Fiscal year ended								
December 31, 2021	559	23.1	(2,419)	–	(2,442)	–	(2,478)	–
December 31, 2020	454	(65.4)	(4,116)	–	(4,159)	–	(4,127)	–

	Profit attributable to owners of parent		Total comprehensive income		Basic earnings per share	Diluted earnings per share
	Millions of yen	%	Millions of yen	%	Yen	Yen
Fiscal year ended						
December 31, 2021	(2,478)	–	(2,461)	–	(19.04)	(19.04)
December 31, 2020	(4,127)	–	(4,129)	–	(35.16)	(35.16)

	Ratio of profit to equity attributable to owners of parent	Ratio of profit before tax to total assets	Ratio of operating profit to revenue
	%	%	%
Fiscal year ended			
December 31, 2021	(79.4)	(54.8)	(432.9)
December 31, 2020	(78.1)	(60.6)	(906.5)

(2) Consolidated financial position

	Total assets	Total equity	Equity attributable to owners of parent	Ratio of equity attributable to owners of parent to total assets	Equity attributable to owners of parent per share
	Millions of yen	Millions of yen	Millions of yen	%	Yen
As of					
December 31, 2021	3,144	2,587	2,587	82.3	19.38
December 31, 2020	5,775	3,652	3,652	63.2	29.78

(3) Consolidated cash flows

	Net cash provided by (used in) operating activities	Net cash provided by (used in) investing activities	Net cash provided by (used in) financing activities	Cash and cash equivalents at end of period
	Millions of yen	Millions of yen	Millions of yen	Millions of yen
Fiscal year ended				
December 31, 2021	(2,473)	(164)	361	714
December 31, 2020	(2,789)	(171)	1,829	2,964

2. Cash dividends

	Annual cash dividends per share					Total cash dividends (Annual)	Dividend payout ratio (Consolidated)	Ratio of dividends to equity attributable to owners of parent (Consolidated)
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total			
	Yen	Yen	Yen	Yen	Yen	Millions of yen	%	%
Fiscal year ended December 31, 2020	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ended December 31, 2021	–	0.00	–	0.00	0.00	–	–	–
Fiscal year ending December 31, 2022 (Forecast)	–	0.00	–	0.00	0.00		–	

3. Consolidated earnings forecasts for the fiscal year ending December 31, 2022 (from January 1, 2022 to December 31, 2022)

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Basic earnings per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Fiscal year ending December 31, 2022	2,300	311.4	(1,100)	–	(1,100)	–	(1,200)	–	(1,200)	–	(8.99)
	~	~	~	~	~	~	~	~	~	~	~
	3,800	579.8	150	–	150	–	50	–	50	–	0.37

* Notes

(1) Changes in significant subsidiaries during the period (changes in specified subsidiaries resulting in the change in scope of consolidation): None

(2) Changes in accounting policies and changes in accounting estimates

1) Changes in accounting policies required by IFRS: None

2) Changes in accounting policies due to other reasons: None

3) Changes in accounting estimates: None

(3) Number of issued shares (ordinary shares)

1) Total number of issued shares at the end of the period (including treasury shares)

As of December 31, 2021	133,946,210 shares
As of December 31, 2020	123,081,210 shares

2) Number of treasury shares at the end of the period

As of December 31, 2021	440,010 shares
As of December 31, 2020	440,000 shares

3) Average number of shares during the period

Fiscal year ended December 31, 2021	130,149,265 shares
Fiscal year ended December 31, 2020	117,379,177 shares

(Reference) Summary of Non-consolidated Results**1. Non-Consolidated financial results for the fiscal year ended December 31, 2021 (from January 1, 2021 to December 31, 2021)****(1) Non-Consolidated operating results**

(Percentages indicate year-on-year changes.)

Fiscal year ended	Net sales		Operating income		Ordinary income		Net income	
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
December 31, 2021	559	23.1	(2,206)	–	(2,228)	–	(2,232)	–
December 31, 2020	454	(65.4)	(3,035)	–	(3,090)	–	(3,091)	–

Fiscal year ended	Net income per share	Diluted net income per share
	Yen	Yen
December 31, 2021	(17.15)	(17.15)
December 31, 2020	(26.34)	(26.34)

(2) Non-Consolidated Financial Position

Fiscal year ended	Total assets	Net assets	Shareholders' equity ratio	Net assets per share
	Millions of yen	Millions of yen	%	yen
December 31, 2021	922	443	47.7	3.30
December 31, 2020	3,286	1,267	38.3	10.33

(Reference) Shareholders' equity: Fiscal year ended December 31, 2021: 439 millions of yen
: Fiscal year ended December 31, 2020: 1,257 millions of yen

The difference between operating results in the fiscal year under review and the preceding fiscal year is attributable to reasons stated in the section titled (1) Overview of operating results for the fiscal year ended December 31, 2021 under 1. Overview of operating results on page 2 of the Attached Material.

* Consolidated financial results reports are not subject to audit procedures by the Company's independent auditor.

* Proper use of earnings forecasts, and other special matters

For the Group's consolidated earnings forecasts contained in these materials, disclosure is made with a range because it is difficult to estimate specific figures.

The forecasts are based on judgments and assumptions derived from information available to the Company as of the date of disclosure of these materials, and actual results may differ from such forecasts due to various factors. For the suppositions that form the assumptions for earnings forecasts and cautions concerning the use thereof, please refer to the section of "(3) Future outlook" on page 5 of the attached material.

The Company plans to hold a financial results presentation meeting for institutional investors and analysts on Tuesday, February 15, 2022.

The materials used at this meeting shall be posted on the Company's website promptly after the meeting is held.

[Attached Material]

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1. Overview of operating results

(1) Overview of operating results for the fiscal year ended December 31, 2021

1) Overview of results

Operating results

	Fiscal year ended December 31, 2020	Fiscal year ended December 31, 2021	Year-on-year
Revenue	454	559	104
Gross profit	244	373	128
Operating profit (loss)	(4,116)	(2,419)	(1,696)
Profit (loss)	(4,127)	(2,478)	(1,648)

(Millions of yen)

The Group intends to focus business operations on expanding its oncology development pipeline, which consists of two products that have already been launched and three in the later stage of development.

Under this goal, the Group primarily engaged in the following business activities in the fiscal year ended December 31, 2021.

[Launched products (development completed)]

SP-01 (Chemotherapy-induced nausea and vomiting)

SP-03 (Oral mucositis/stomatitis caused by chemotherapy and radiotherapy)

The COVID-19 pandemic significantly restrained marketing activities of the Group's and sales partners' medical representatives (MRs), including their access to medical sites. This in turn had an impact on the prescription and delivery volumes of Sancuso® (SP-01) and episil® (SP-03), which were mainly sold in China. However, delivery volumes (which approximate prescription volumes) of SP-01 and SP-03 in the three Chinese cities (Beijing, Shanghai, and Guangzhou) in which the Company sells its products increased by 102% and 90% year on year, respectively. These increases indicate that the investment in sales activities conducted by the Company since the launch of the two products in 2019 has begun to generate results.

[Pipeline products in the clinical study and later phase]

SP-02 (Relapsed or Refractory Peripheral T-cell Lymphoma)

In 2020, the Company achieved the primary endpoint (antitumor effect) in the Global Phase II clinical trial (pivotal study) of our pipeline product SP-02. In June 2021, we filed a New Drug Application (NDA) for the drug with the regulatory authority in Japan. Additionally, in October 2021, we concluded a license agreement with Nippon Kayaku Co., Ltd. regarding the commercialization of SP-02 in Japan.

SP-05 (Increase in antitumor efficacy of fluorouracil)

Based on the interim analysis of the global Phase III clinical trial of SP-05, a pivotal study before filing for regulatory approval, the target number of patients enrolled in the study should be 440, the minimum number specified in the trial protocol. As of this document's date of submission, the Company is executing the final stages of this clinical trial with the goal of completing associated clinical development and confirming top-line data in the first half of the fiscal year ending December 31, 2022.

[Pipeline products in the non-clinical study phase]

SP-04 (Chemotherapy-induced peripheral neuropathy)

Based on the results of the Phase III clinical trial of SP-04 targeting oxaliplatin-induced peripheral

neuropathy, the Company has decided to park the development of the pipeline product for this indication; instead, we are conducting additional animal studies to investigate the product's potential in treating taxane-induced peripheral neuropathy.

As indicated above, we have focused on achieving progress in terms of both our products and pipeline products. On the financial front, however, we continue making up-front investments, as product sales have just entered the initial stages. Given these circumstances, our financial performance during the fiscal year ended December 31, 2021, was as follows.

[Revenue, gross profit]

In the fiscal year ended December 31, 2021, revenue totaled 559 million yen, mainly owed to sales of pipeline products Sancuso® (SP-01) and episil® (SP-03) as well as upfront payments for out-licensing SP-02. In addition, gross profit amounted to 373 million yen.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Fiscal year ended December 31, 2020	Fiscal year ended December 31, 2021	Year-on-year
R&D expenses	1,928	845	(1,082)
SG&A expenses	2,432	1,948	(484)
Total	4,361	2,793	(1,567)
(Breakdown)			
Personnel expenses	685	882	197
Outsourcing expenses / Subcontract expenses	2,196	1,159	(1,036)
Depreciation and amortization of intangible assets	1,296	495	(801)
Other	182	256	73

[R&D expenses, SG&A expenses, Operating profit (loss), Profit (loss)]

R&D expenses amounted to 845 million yen. This amount is mainly attributable to expenses incurred for a multinational phase II clinical study (pivotal study) and the submission cost of New Drug Application for SP-02 and a multinational phase III clinical study of SP-05. SG&A expenses amounted to 1,948 million yen, down 484 million yen year on year.

The Company incurred an operating loss of 2,419 million yen.

The Company incurred an overall loss of 2,478 million yen.

[Capitalized costs included in intangible assets]

The Group posted a 161 million yen increase in intangible assets attributable to development costs and in-licensing expenses recognized as assets among pipeline investment outlays. In the fiscal year ended December 31, 2021, pipeline investment amounted to 1,007 million yen. This figure includes the 161 million yen in intangible assets derived from capitalization of such outlays and 845 million yen in R&D expenses.

Amortization expenses of intangible assets related to the pipeline product Sancuso® (SP-01) and episil® (SP-03) were 438 million yen. As a result, the balance of intangible assets was 2,079 million yen as of December 31, 2021.

2) Cash flows

(Millions of yen)

	Fiscal year ended December 31, 2020	Fiscal year ended December 31, 2021	Year-on-year
Net cash provided by (used in) operating activities	(2,789)	(2,473)	316
Net cash provided by (used in) investing activities	(171)	(164)	7
Net cash provided by (used in) financing activities	1,829	361	(1,468)

[Cash flows from operating activities]

Net cash used in operating activities amounted to 2,473 million yen (compared with 2,789 million yen in net cash used in these activities in the corresponding period of the previous fiscal year), which was mainly attributable to loss before tax of 2,442 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 164 million yen (down from 171 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 161 million yen in outflows related to capitalized development investment, primarily for the in-licensing of the new pipeline product SP-05.

[Cash flows from financing activities]

Net cash provided by financing activities amounted to 361 million yen (down from 1,829 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 1,000 million yen from redemption of bonds and 1,403 million yen in proceeds from issuance of new shares by the exercise of warrants.

3) Research and development activities

R&D expenses amounted to 845 million yen. In addition, the Company recorded a 161 million yen increase in intangible assets attributable to development costs, which have been recognized as assets from among pipeline investment outlays. Meanwhile, total pipeline investment amounted to 1,007 million yen.

Summaries regarding progress achieved with pipeline products are as follows.

	As of January 1, 2021	Fiscal year ended December 31, 2021	As of today
SP-01 Sancuso® China	Ongoing sale	Ongoing sale	Ongoing sale
SP-02 darinaparsin Japan etc.	Preparing for NDA filing	Application for approval filed (in June 2021)	Application for approval filed (in June 2021)
SP-03 episil® Japan China Korea	Ongoing sale	Ongoing sale	Ongoing sale
SP-05 arfollitoxorin Japan	Global Phase III clinical study in progress. Preparing for an interim analysis of data obtained from 330 patients Patient enrollment reached 440	Global Phase III clinical study in progress. Determined to continue the study with the minimum target number of patients based on interim analysis	Global Phase III clinical study in progress. Completion of patient enrollment

Details regarding progress achieved with pipeline products are please refer to today's news release, entitled "Business Overview of Pipeline Products".

(2) Overview of financial position for the fiscal year ended December 31, 2021

As of December 31, 2021, total assets amounted to 3,144 million yen, down 2,631 million yen from the previous year-end. Current assets were 894 million yen, including 714 million yen in cash and cash equivalents. Non-current assets came to 2,249 million yen. This figure includes 2,079 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 556 million yen, down 1566 million yen from the previous year-end. Current liabilities were 489 million yen, including 386 million yen in trade and other payables. Non-current liabilities amounted to 67 million yen, mainly due to 37 million yen in lease liabilities 18 million yen in deferred tax liabilities.

Total equity equaled 2,587 million yen, down 1,064 million yen from the previous year-end. The increase was mainly attributable to 1,403 million yen in proceeds from issuance of new shares. The decrease was mainly attributable to the overall loss of 2,478 million yen.

(3) Future outlook

On the premise of the following business progress, we forecast that for the fiscal year ending December 31, 2021, revenue would range between 2.3 billion to 3.8 billion yen, while operating profit (loss) and profit (loss) before tax would range between a loss of 1.1 billion yen to a profit of 150 million yen, and bottom-line profit (loss) would range between a loss of 1.2 billion yen to a profit of 50 million yen.

1) Key assumptions behind the revenue forecast (2.3 billion yen to 3.8 billion yen)

We expect to generate 1.1 billion yen in revenue from product sales of episil®(SP-03 (Japan)), which launched in the fiscal year ended December 31, 2018; product sales of Sancuso®(SP-01 (China)) and episil®(SP-03 (China, Korea)), which launched from the fiscal year ended December 31, 2019; and product sales of SP-02 (Japan), which is scheduled for launch during the second half of the fiscal year ending December 31, 2022. However, as sales of these products are still in the sales expansion stage, we believe their market penetration will be limited relative to the potential size of the market. We have also factored in

to a certain degree the impact of the COVID-19 pandemic. Additionally, we anticipate that SP-02, SP-05, and other products will generate a range of 1.2 billion to 2.7 billion yen in revenue through milestone payments received in association with existing out-licensing agreements and upfront payments received in connection with new out-licensing agreements.

2) Key assumptions behind the operating expense forecast (3.4 billion yen to 3.65 billion yen)

We will incur cost of sales due to product sales of Sancuso®(SP-01), episil®(SP-03) and SP-02. For Sancuso®(SP-01) and episil®(SP-03), we will operate an in-house sales structure in China and invest in marketing activities, including post-marketing surveillance. We will incur amortization expenses on intangible assets of Sancuso®(SP-01),episil®(SP-03) and SP-02. We expect to incur operating expenses related to NDA filing for SP-02, Phase III clinical trial of SP-05, and development investment into new drug candidates.

Because the overall Group expects to continue making upfront investments as described above, we forecast an operating profit (loss) and profit (loss) before tax would range between a loss of 1.1 billion yen to a profit of 150 million yen, and bottom-line profit (loss) would range between a loss of 1.2 billion yen to a profit of 50 million yen.

Due to the impact of the COVID-19 pandemic and progress in the clinical trial of SP-05, the Group faces considerable uncertainty with respect to product sales, the possibility of out-licensing its pipeline products, and the scale of upfront payments if it does conclude an out-licensing agreement. It would therefore be difficult to specify individual revenue and expense amounts at this stage, so we have released the range-based projections as above with respect to our forecasts of consolidated performance for the fiscal year ending December 31, 2022.

2. Basic rationale for selecting the accounting standard

The Group adopted International Financial Reporting Standards (IFRS) from the fiscal year ended December 31, 2015, in order to improve international comparability and the convenience of financial information in capital markets.

3. Consolidated financial statements and significant notes thereto

(1) Consolidated statement of financial position

(Millions of yen)

	As of December 31, 2020	As of December 31, 2021
Assets		
Current assets		
Cash and cash equivalents	2,964	714
Trade and other receivables	173	126
Inventories	4	0
Other current assets	126	53
Total current assets	3,269	894
Non-current assets		
Property, plant and equipment	43	36
Light-of-use asset	59	84
Intangible assets	2,356	2,079
Other non-current assets	46	49
Total non-current assets	2,506	2,249
Total assets	5,775	3,144
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	987	386
Bonds payable	1,000	—
Lease liabilities	39	47
Other current liabilities	52	55
Total current liabilities	2,079	489
Non-current liabilities		
Deferred tax liabilities	11	18
Lease liabilities	21	37
Other non-current liabilities	10	10
Total non-current liabilities	43	67
Total liabilities	2,123	556
Equity		
Share capital	1,402	2,110
Capital surplus	5,043	5,738
Retained earnings	(2,726)	(5,204)
Treasury stock	(70)	(70)
Other components of equity	2	13
Total equity	3,652	2,587
Total liabilities and equity	5,775	3,144

(2) Consolidated statement of profit or loss

(Millions of yen)

	Fiscal year ended December 31, 2020	Fiscal year ended December 31, 2021
Revenue	454	559
Cost of sales	209	185
Gross profit	244	373
Research and development expenses	1,928	845
Selling, general and administrative expenses	2,432	1,948
Operating profit (loss)	(4,116)	(2,419)
Finance income	0	0
Finance costs	43	23
Other income	—	0
Other costs	0	—
Profit (loss) before tax	(4,159)	(2,442)
Income taxes	(32)	35
Profit (loss)	(4,127)	(2,478)
Profit (loss) attributable to:		
Owners of parent	(4,127)	(2,478)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(17.75)	(19.04)
Diluted earnings (loss) per share [yen]	(17.75)	(19.04)

(3) Consolidated statement of comprehensive income

(Millions of yen)

	Fiscal year ended December 31, 2020	Fiscal year ended December 31, 2021
Profit (loss)	(4,127)	(2,478)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(2)	17
Subtotal	(2)	17
Total other comprehensive income	(2)	17
Comprehensive income	(4,129)	(2,461)
Comprehensive income attributable to:		
Owners of parent	(4,129)	(2,461)

(4) Consolidated statement of changes in equity

(Millions of yen)

	Share capital	Capital surplus	Retained earnings	Treasury shares	Other components of equity			Total equity
					Exchange differences on translation of foreign operations	Share acquisition rights	Total Other components of equity	
Balance at January 1, 2020	960	4,630	1,400	(70)	(4)		(4)	6,917
Comprehensive income								
Profit (loss)	–	–	(4,127)	–	–	–	–	(4,127)
Other comprehensive income	–	–	–	–	(2)	–	(2)	(2)
Total comprehensive income	–	–	(4,127)	–	(2)	–	(2)	(4,129)
Transactions with owners								
Exercise of share acquisition rights	442	423	–	–	–	(3)	(3)	861
Issuance of share acquisition rights	–	–	–	–	–	13	13	13
Share-based payments	–	(10)	–	–	–	–	–	(10)
Total transactions with owners	442	413	–	–	–	9	9	865
Balance at December 31, 2020	1,402	5,043	(2,726)	(70)	(6)	9	2	3,652
Balance at January 1, 2021	1,402	5,043	(2,726)	(70)	(6)	9	2	3,652
Comprehensive income								
Profit (loss)	–	–	(2,478)	–	–	–	–	(2,478)
Other comprehensive income	–	–	–	–	17	–	17	17
Total comprehensive income	–	–	(2,478)	–	17	–	17	(2,461)
Transactions with owners								
Exercise of share acquisition rights	707	702	–	–	–	(6)	(6)	1,403
Acquisition of treasury shares	–	–	–	(0)	–	–	–	(0)
Share-based payments	–	(7)	–	–	–	–	–	(7)
Total transactions with owners	707	695	–	(0)	–	(6)	(6)	1,396
Balance at December 31, 2021	2,110	5,738	(5,204)	(70)	10	3	13	2,587

(5) Consolidated statement of cash flows

(Millions of yen)

	Fiscal year ended December 31, 2020	Fiscal year ended December 31, 2021
Cash flows from operating activities		
Profit (loss) before tax	(4,159)	(2,442)
Depreciation and amortization	496	495
Impairment losses	800	—
Finance income	(0)	(0)
Finance costs	43	23
Decrease (increase) in trade and other receivables	(160)	51
Decrease (increase) in inventories	(1)	4
Increase (decrease) in trade and other payables	225	(626)
Other	(18)	47
Subtotal	(2,774)	(2,448)
Interest received	0	0
Interest paid	(1)	(1)
Income taxes paid	(14)	(22)
Net cash provided by (used in) operating activities	(2,789)	(2,473)
Cash flows from investing activities		
Purchase of property, plant and equipment	(10)	(2)
Purchase of intangible assets	(161)	(161)
Other	(0)	—
Net cash provided by (used in) investing activities	(171)	(164)
Cash flows from financing activities		
Proceeds from issuance of bonds	2,500	—
Redemption of bonds	(1,500)	(1,000)
Proceeds from issuance of new shares	861	1,403
Proceeds from issuance of share acquisition rights	13	—
Repayment of lease liabilities	(45)	(41)
Acquisition of treasury shares	—	(0)
Net cash provided by (used in) financing activities	1,829	361
Net increase (decrease) in cash and cash equivalents	(1,131)	(2,275)
Cash and cash equivalents at beginning of period	4,116	2,964
Effect of exchange rate changes on cash and cash equivalents	(20)	25
Cash and cash equivalents at end of period	2,964	714

(6) Notes to consolidated financial statements

(Notes on premise of going concern)

No items to report.

(Change in Accounting Policies)

No items to report.

(Segment information)

Disclosure is omitted as the Group has a single reportable segment.

(Per share information)

The basis for calculating basic earnings (loss) per share is as follows.

	Fiscal year ended December 31, 2020	Fiscal year ended December 31, 2021
Profit (loss) attributable to ordinary equity holders of parent		
Profit (loss) attributable to owners of parent (Millions of yen)	(4,127)	(2,478)
Amount not attributable to ordinary equity holders of parent (Millions of yen)	—	—
Profit (loss) attributable to ordinary equity holders of parent (Millions of yen)	(4,127)	(2,478)
Average number of ordinary shares during the period (shares)	117,379,177	130,149,265

The figure for diluted earnings (loss) per share has been presented at an amount equal to that of basic earnings (loss) per share due to antidilutive effects of the share options with share acquisition rights.

(Significant subsequent events)

No items to report.