



May 12, 2021

Consolidated Financial Results for the First Three Months of the Fiscal Year Ending December 31, 2021 (under IFRS)

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 Listing: Tokyo Stock Exchange
 Securities code: 4597
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Scheduled date to file quarterly securities report: May 12, 2021

Scheduled date to commence dividend payments: —

Preparation of supplementary material on quarterly financial results: None

Holding of quarterly financial results presentation meeting: None

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

1. Consolidated financial results for the first three months of the fiscal year ending December 31, 2021 (from January 1, 2021 to March 31, 2021)

(1) Consolidated operating results (cumulative)

(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	%
Three months ended								
March 31, 2021	91	(41.1)	(642)	—	(650)	—	(656)	—
March 31, 2020	156	154.5	(534)	—	(537)	—	(531)	—

	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
Three months ended						
March 31, 2021	(656)	—	(648)	—	(5.22)	(5.22)
March 31, 2020	(531)	—	(532)	—	(4.57)	(4.57)

(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
As of	Millions of yen	Millions of yen	Millions of yen	%	Yen
March 31, 2021	5,063	3,913	3,913	77.3	30.23
December 31, 2020	5,775	3,652	3,652	63.2	29.78

2. Cash dividends

	Annual cash dividends per share				
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended December 31, 2020	—	0.00	—	0.00	0.00
Fiscal year ending December 31, 2021	—				
Fiscal year ending December 31, 2021 (Forecast)		0.00	—	0.00	0.00

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

3. Consolidated earnings forecasts for the fiscal year ending December 31, 2021
(from January 1, 2021 to December 31, 2021)

(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, 2021	1,600	252.4	(2,800)	—	(2,800)	—	(2,800)	—	(2,800)	—	(21.62)
	~	~	~	~	~	~	~	~	~	~	~
	2,600	472.6	(1,800)	—	(1,800)	—	(1,800)	—	(1,800)	—	(13.90)

Note: Revisions to the consolidated earnings forecasts most recently announced: None

*** 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 March 31, 2021	129,926,210 shares
As of December 31, 2020	123,081,210 shares

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

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

3) Average number of shares during the period (cumulative from the beginning of the fiscal year)

For the three months ended March 31, 2021	125,694,543 shares
For the three months ended March 31, 2020	116,406,015 shares

* Quarterly consolidated financial results reports are not subject to quarterly review procedures by the Company's independent auditor.

*** Proper use of earnings forecasts, and other special matters**

The forward-looking statements, including earnings forecasts, contained in these materials are based on information currently available to the Company and on certain assumptions deemed to be reasonable. Actual business and other results may differ from the statements herein due to various factors.

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1. Qualitative information regarding results for the first three months

(1) Explanation of operating results

1) Overview of results

Operating results

	(Millions of yen)		
	Three months ended March 31, 2020	Three months ended March 31, 2021	Year-on-year
Revenue	156	91	(64)
Gross profit	112	50	(62)
Operating profit (loss)	(534)	(642)	(107)
Profit (loss)	(531)	(656)	(124)

The Group intends to focus business operations on expanding its oncology development pipeline, which consists of two products that have already been launched and two in the later stage of development. Under this goal, the Group primarily engaged in the following business activities in the three months ended March 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.

[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. As of the submission date of this document, we are preparing to file for approval to the regulatory authorities in the first half of the fiscal year ending December 31, 2021.

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 the submission date of this document, the Company is continuing the trial with the minimum target number of patients with the aim of bringing the product to market.

[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 have determined to conduct 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 three months ended March 31, 2021, was as follows.

[Revenue, Gross profit]

During the three months ended March 31, 2021, revenue totaled 91 million yen. Revenue mainly came from the sales of pipeline products of Sancuso® (SP-01) and episil® (SP-03). In addition, gross profit amounted to 50 million yen.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Three months ended March 31, 2020	Three months ended March 31, 2021	Year-on-year
R&D expenses	255	258	2
SG&A expenses	391	434	43
Total	647	692	45
(Breakdown)			
Personnel expenses	158	190	32
Outsourcing expenses	302	336	34
Depreciation and amortization of intangible assets	124	123	(0)
Other	62	41	(20)

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

R&D expenses amounted to 258 million yen. This amount is mainly attributable to expenses incurred for a multinational phase II clinical study (pivotal study) of SP-02 and a multinational phase III clinical study of SP-05. SG&A expenses amounted to 434 million yen, up 43 million yen year on year.

The Company incurred an operating loss of 642 million yen.

The Company incurred an overall loss of 656 million yen.

[Capitalized costs included in intangible assets and amortization of intangible assets]

The Group posted a 541 thousand yen increase in intangible assets attributable to development costs and in-licensing expenses recognized as assets among pipeline investment outlays. In the three months ended March 31, 2021, pipeline investment amounted to 258 million yen. This figure includes the 541 thousand yen in intangible assets derived from capitalization of such outlays and 258 million yen in R&D expenses. However, amortization of intangible assets related to the pipeline product Sancuso® (SP-01) and episil® (SP-03), leading to amortization of 109 million yen during the three months under review. As a result, the balance of intangible assets was 2,247 million yen as of March 31, 2021.

2) Cash flows

	(Millions of yen)		
	Three months ended March 31, 2020	Three months ended March 31, 2021	Year-on-year
Net cash provided by (used in) operating activities	(751)	(650)	100
Net cash provided by (used in) investing activities	(4)	(3)	1
Net cash provided by (used in) financing activities	(11)	(99)	(88)

[Cash flows from operating activities]

Net cash used in operating activities amounted to 650 million yen (compared with 751 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 650 million yen.

[Cash flows from investing activities]

Net cash used in investing activities amounted to 3 million yen (compared with 4 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 1 million yen in outflows related to capitalized development investment.

[Cash flows from financing activities]

Net cash used in financing activities amounted to 99 million yen (compared with 11 million yen used in 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 910 million yen in proceeds from issuance of new shares by the exercise of warrants.

3) R&D activities

R&D expenses amounted to 258 million yen. In addition, the Company recorded a 541 thousand 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 258 million yen.

Summaries regarding progress achieved with pipeline products—those in the clinical study or later phase—are as follows.

	As of January 1, 2021	Three months ended March 31, 2021	As of today
SP-01 Sancuso® China	Ongoing sale	Ongoing sale	Ongoing sale
SP-02 darinaparsin Japan etc.	Preparing for NDA filing	Preparing for NDA filing	Preparing for NDA filing
SP-03 episil® Japan	Ongoing sale	Ongoing sale	Ongoing sale
SP-03 episil® China	Ongoing sale	Ongoing sale	Ongoing sale
SP-03 episil® Korea	Ongoing sale	Ongoing sale	Ongoing sale

SP-05 arfollitoxin 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
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Details regarding progress achieved with pipeline products are please refer to today's news release, entitled "Business Overview of Pipeline Products".

(2) Explanation of financial position

As of March 31, 2021, total assets amounted to 5,063 million yen, down 712 million yen from the previous year-end. Current assets were 2,609 million yen, including 2,226 million yen in cash and cash equivalents. Non-current assets came to 2,453 million yen. This figure includes 2,247 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 1,149 million yen, down 973 million yen from the previous year-end. Current liabilities were 1,055 million yen, including 958 million yen in trade and other payables. Non-current liabilities amounted to 93 million yen, mainly due to 71 million yen in lease liabilities 10 million yen in deferred tax liabilities.

Total equity equaled 3,913 million yen, up 261 million yen from the previous year-end. The increase was mainly attributable to 910 million yen in proceeds from issuance of new shares. The decrease was mainly attributable to the overall loss of 656 million yen.

As of today, the overdraft and committed credit line with domestic banks total 3.5 billion yen. The entire amount is unused.

(3) Explanation of consolidated earnings forecasts and other forward-looking statements

The consolidated earnings forecasts for the fiscal year ending December 31, 2021 (announced on February 12, 2021) reflect the impact of the COVID-19 pandemic to some extent, and the Company has made no change to its forecasts as of the date this document was published. However, if the spread of the virus continues longer than anticipated, we cannot deny the possibility that it could have a stronger impact on product sales, out-licensing its pipeline products, development (primarily clinical development), and other elements of our business than initially estimated. We will promptly disclose any potential impact on our earnings forecasts as soon as the Company becomes clear.

2. Condensed quarterly consolidated financial statements and significant notes thereto

(1) Condensed consolidated statement of financial position

(Millions of yen)

	As of December 31, 2020	As of March 31, 2021
Assets		
Current assets		
Cash and cash equivalents	2,964	2,226
Trade and other receivables	173	210
Inventories	4	35
Other current assets	126	136
Total current assets	3,269	2,609
Non-current assets		
Property, plant and equipment	43	41
Light-of-use asset	59	117
Intangible assets	2,356	2,247
Other non-current assets	46	47
Total non-current assets	2,506	2,453
Total assets	5,775	5,063
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	987	958
Bonds payable	1,000	—
Lease liabilities	39	45
Other current liabilities	52	51
Total current liabilities	2,079	1,055
Non-current liabilities		
Deferred tax liabilities	11	10
Lease liabilities	21	71
Other non-current liabilities	10	10
Total non-current liabilities	43	93
Total liabilities	2,123	1,149
Equity		
Share capital	1,402	1,861
Capital surplus	5,043	5,499
Retained earnings	(2,726)	(3,382)
Treasury stock	(70)	(70)
Other components of equity	2	6
Total equity	3,652	3,913
Total liabilities and equity	5,775	5,063

(2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Three months ended March 31, 2020	Three months ended March 31, 2021
Revenue	156	91
Cost of sales	43	41
Gross profit	112	50
Research and development expenses	255	258
Selling, general and administrative expenses	391	434
Operating profit (loss)	(534)	(642)
Finance income	3	0
Finance costs	6	8
Other costs	0	—
Profit (loss) before tax	(537)	(650)
Income taxes	(6)	5
Profit (loss)	(531)	(656)
Profit (loss) attributable to:		
Owners of parent	(531)	(656)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(4.57)	(5.22)
Diluted earnings (loss) per share [yen]	(4.57)	(5.22)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Three months ended March 31, 2020	Three months ended March 31, 2021
Profit (loss)	(531)	(656)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(1)	7
Subtotal	(1)	7
Total other comprehensive income	(1)	7
Comprehensive income	(532)	(648)
Comprehensive income attributable to:		
Owners of parent	(532)	(648)

(4) Condensed consolidated statement of changes in equity

(Millions of yen)

	Other components of equity							
	Share capital	Capital surplus	Retained earnings	Treasury shares	Exchange differences on translation of foreign operations	Share acquisition rights	Total Other component of equity	Total equity
Balance at January 1, 2020	960	4,630	1,400	(70)	(4)	—	(4)	6,917
Comprehensive income								
Profit (loss)	—	—	(531)	—	—	—	—	(531)
Other comprehensive income	—	—	—	—	(1)	—	(1)	(1)
Total comprehensive income	—	—	(531)	—	(1)	—	(1)	(532)
Transactions with owners								
Exercise of share acquisition rights	0	0	—	—	—	—	—	0
Total transactions with owners	0	0	—	—	—	—	—	0
Balance at March 31, 2020	961	4,630	869	(70)	(5)	—	(5)	6,385
Balance at January 1, 2021	1,402	5,043	(2,726)	(70)	(6)	9	2	3,652
Comprehensive income								
Profit (loss)	—	—	(656)	—	—	—	—	(656)
Other comprehensive income	—	—	—	—	7	—	7	7
Total comprehensive income	—	—	(656)	—	7	—	7	(648)
Transactions with owners								
Exercise of share acquisition rights	458	455	—	—	—	(4)	(4)	910
Total transactions with owners	458	455	—	—	—	(4)	(4)	910
Balance at March 31, 2021	1,861	5,499	(3,382)	(70)	0	5	6	3,913

(5) Condensed consolidated statement of cash flows

(Millions of yen)

	Three months ended March 31, 2020	Three months ended March 31, 2021
Cash flows from operating activities		
Profit (loss) before tax	(537)	(650)
Depreciation and amortization	124	123
Finance income	(3)	(0)
Finance costs	6	8
Decrease (increase) in trade and other receivables	(90)	(36)
Decrease (increase) in inventories	1	(30)
Increase (decrease) in trade and other payables	(213)	(44)
Other	(38)	(17)
Subtotal	(751)	(648)
Interest received	0	0
Interest paid	(0)	(0)
Income taxes paid	—	(1)
Net cash provided by (used in) operating activities	(751)	(650)
Cash flows from investing activities		
Purchase of property, plant and equipment	(1)	(0)
Purchase of intangible assets	(2)	(1)
Other	0	(1)
Net cash provided by (used in) investing activities	(4)	(3)
Cash flows from financing activities		
Redemption of bonds	—	(1,000)
Proceeds from issuance of new shares	0	910
Repayment of lease liabilities	(11)	(9)
Net cash provided by (used in) financing activities	(11)	(99)
Net increase (decrease) in cash and cash equivalents	(766)	(753)
Cash and cash equivalents at beginning of period	4,116	2,964
Effect of exchange rate changes on cash and cash equivalents	(5)	15
Cash and cash equivalents at end of period	3,344	2,226

(6) Notes to condensed quarterly consolidated financial statements

(Notes on premise of going concern)

No items to report.

(Change in Accounting Policies)

The significant accounting policies adopted for the Group's condensed quarterly consolidated financial statements are the same as those for the consolidated financial statements for the previous year.