



November 13, 2020

## Consolidated Financial Results for the Nine Months of the Fiscal Year Ending December 31, 2020 (under IFRS)

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 Listing: Tokyo Stock Exchange  
 Securities code: 4597  
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Scheduled date to file quarterly securities report: November 13, 2020

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 nine months of the fiscal year ending December 31, 2020 (from January 1, 2020 to September 30, 2020)

#### (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	%
Nine months ended September 30, 2020	287	(1.3)	(1,902)	—	(1,928)	—	(1,937)	—
September 30, 2019	291	163.2	(1,585)	—	(1,621)	—	(1,672)	—

	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
Nine months ended September 30, 2020	(1,937)	—	(1,938)	—	(16.64)	(16.64)
September 30, 2019	(1,672)	—	(1,675)	—	(15.93)	(15.93)

#### (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 September 30, 2020	7,926	5,285	5,285	66.7	44.62
December 31, 2019	7,946	6,917	6,917	87.0	59.43

### 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, 2019	—	0.00	—	0.00	0.00
Fiscal year ending December 31, 2020	—	0.00	—		
Fiscal year ending December 31, 2020 (Forecast)				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, 2020 (from January 1, 2020 to December 31, 2020)

(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, 2020	500	(61.8)	(2,900)	–	(2,900)	–	(2,900)	–	(2,900)	–	(24.48)
	to	To	to	To	to	to	to	to	to	to	to
	2,000	52.6	(2,000)	–	(2,000)	–	(2,000)	–	(2,000)	–	(16.89)

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 September 30, 2020	118,886,210 shares
As of December 31, 2019	116,835,795 shares

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

As of September 30, 2020	440,000 shares
As of December 31, 2019	440,000 shares

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

For the Nine months ended September 30, 2020	116,447,636 shares
For the Nine months ended September 30, 2019	105,012,839 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 nine months

### (1) Explanation of operating results

#### 1) Overview of results

##### Operating results

	(Millions of yen)		
	Nine months ended September 30, 2019	Nine months ended September 30, 2020	Year-on-year
Revenue	291	287	(3)
Gross profit	243	186	(56)
Operating profit (loss)	(1,585)	(1,902)	(316)
Profit (loss)	(1,672)	(1,937)	(265)

The spread of the novel coronavirus disease (COVID-19) greatly hindered access to medical sites and other sales activities performed by Group medical representatives (MRs) responsible for promoting sales of Sancuso® (SP-01) and episil® (SP-03), which were launched in China during the previous fiscal year. However, the impact of the COVID-19 outbreak on the prescription and shipment volumes of the two products were within the scope of earnings projections released in February 2020. As of the submission date of this document, MRs are gradually resuming contact with hospitals and medical personnel in areas in China where the Company conducts sales activities on its own. Further, shipment of Sancuso® (SP-01) initially scheduled for September 2020 has been delayed to November 2020 due to circumstances of the contract manufacturer, but this is not expected to have an impact on the full-year earnings forecast announced in February.

Aside from products that have been successfully commercialized, three pipeline products reached the final stages of clinical development. In June 2020, we 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. Development of SP-04 was at the Global Phase III clinical trial stage, but we decided to suspend new patient enrollment and study drug administration in April 2020 and to bring this trial to a close after making an early cut-off of case data collection (data cut-off) in the third quarter of 2020. The decision was taken after a recommendation from the independent Data Safety Monitoring Board (DSMB) to stop the studies due to severe allergic reactions and hypersensitivity observed in a number of patients. As of the submission date of this document, we had made an early data cut-off with 590 patients enrolled in the study (out of a target of 700). Starting in the fourth quarter of the fiscal year ending December 31, 2020, we will conduct detailed and robust evaluations of the safety and effectiveness of SP-04 focusing on information acquired through the early closure of the trial, and formulate further plans for SP-04. For SP-05, our new pipeline product, we acquired exclusive rights to develop and market the product in Japan in August 2020, and took over the Global Phase III clinical trial in Japan.

On August 13, the Company's Board of Directors passed a resolution to raise funds through the issue of unsecured straight bonds (2,500 million yen, no interest, payments completed on August 31, 2020) and warrants (total expected proceeds: 5,500 million yen). The intended uses of the funds raised are as follows: in-licensing and development of SP-05; potential further development of SP-04, in case it becomes necessary to conduct additional clinical trials after the review of the Phase III study results, which are currently undergoing statistical analysis; development of SP-02 to expand its target indications beyond peripheral T-cell lymphoma; and development of new pipeline products. The Company will use the proceeds from the exercise of warrants to redeem the unsecured straight bonds, and any proceeds from the exercise of warrants after the bonds have been redeemed will be considered additional funds (besides the 2,500 million yen raised through the issuance of the bonds). As of the end of September 2020, the Company had already redeemed 250 million yen of the bonds, leaving the outstanding bond balance at 2,250 million yen.

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 nine months ended September 30, 2020 was as follows.

[Revenue, Gross profit]

During the nine months ended September 30, 2020, revenue totaled 287 million yen, down 3 million yen from the nine months of the preceding fiscal year. Revenue mainly came from the sales of pipeline products Sancuso®(SP-01) and episil®(SP-03), and the year-on-year decline in revenue was mainly due to the aforementioned delay in the shipment of some products initially scheduled for the third quarter to the fourth quarter of the fiscal year under review. In addition, gross profit amounted to 186 million yen, down 56 million yen from the first nine months of the preceding fiscal year due to changes in the sales mix.

Breakdown of R&D and SG&A expenses

	(Millions of yen)		
	Nine months ended September 30, 2019	Nine months ended September 30, 2020	Year-on-year
R&D expenses	716	1,003	286
SG&A expenses	1,113	1,085	(27)
Total	1,829	2,089	259
(Breakdown)			
Personnel expenses	412	458	45
Outsourcing expenses	900	1,117	217
Depreciation and amortization of intangible assets	348	372	23
Other	168	140	(28)

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

R&D expenses amounted to 1,003 million yen. This amount is mainly attributable to expenses incurred for the Phase II clinical study (pivotal study) of SP-02 and the Phase III clinical study (pivotal study) of SP-04. SG&A expenses amounted to 1,085 million yen, down 27 million yen year on year, as a result of delays in the booking of marketing and other expenses due to the COVID-19 outbreak. The Company incurred an operating loss of 1,902 million yen, calculated by subtracting R&D expenses and SG&A expenses from gross profit. The Company incurred an overall loss of 1,937million yen.

[Capitalization of costs as intangible assets and amortization of intangible assets]

The Group posted a 107 million yen increase in intangible assets attributable to development costs and in-licensing expenses recognized as assets among pipeline investment outlays. In the nine months ended September 30, 2020, pipeline investment amounted to 1,111 million yen. This figure includes the 107 million yen in intangible assets derived from capitalization of such outlays and 1,003 million yen in R&D expenses. However, amortization of intangible assets related to the pipeline product Sancuso® (SP-01) and episil® (SP-03) led to amortization expenses of 329 million yen during the nine months under review. As a result, the balance of intangible assets was 3,263 million yen as of September 30, 2020.

## 2) Cash flows

	(Millions of yen)		
	Nine months ended September 30, 2019	Nine months ended September 30, 2020	Year-on-year
Net cash provided by (used in) operating activities	(1,372)	(2,243)	(871)
Net cash provided by (used in) investing activities	(680)	(161)	519
Net cash provided by (used in) financing activities	(20)	2,521	2,542

### [Cash flows from operating activities]

Net cash used in operating activities amounted to 2,243 million yen (compared with 1,372 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 1,928 million yen.

### [Cash flows from investing activities]

Net cash used in investing activities amounted to 161 million yen (down from 680 million yen used in these activities in the corresponding period of the previous fiscal year), mainly attributable to 159 million yen in outflows related to the capitalization of 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 2,521 million yen (down from 2,542 million yen provided by these activities in the same period of the previous year). This figure was mainly attributable to 2,500 million yen in proceeds from the aforementioned issuance of bonds and 292 million yen in proceeds from issuance of new shares by the exercise of warrants.

## 3) R&D activities

R&D expenses amounted to 1,003 million yen. In addition, the Company recorded a 107 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 1,111 million yen.

Summaries regarding progress achieved with pipeline products are as follows.

	As of January 1, 2020	Nine months ended September 30, 2020	As of today
P-01 Sancuso® China	Ongoing sale	Ongoing sale	Ongoing sale
P-02 darinaparsin Japan etc.	Global Phase II clinical study (pivotal study, patient enrollment completed) in progress	Achieved primary endpoint (antitumor effect) in Global Phase II clinical study (pivotal study)	Preparing for approval filing
P-03 episil® Japan	Ongoing sale	Ongoing sale	Ongoing sale
P-03 episil® China	Ongoing sale	Ongoing sale	Ongoing sale

SP-04 PledOx® Japan etc.	Global Phase III clinical study (POLAR-A study, patient enrollment completed ) in progress	Suspended patient recruitment and the study drug administration in the Global Phase III clinical study; made an early data cut-off	Preparing for statistical analysis the Global Phase III study results (590 patients enrolled, out of the initial target of 700)
SP-05 arfollitoxin Japan	—	Acquired exclusive rights to develop and market the product in Japan; Global Phase III clinical study in progress	Global Phase III clinical study in progress

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

## (2) Explanation of financial position

As of September 30, 2020, total assets amounted to 7,926 million yen, down 20 million yen from the previous year-end. Current assets were 4,507 million yen, including 4,221 million yen in cash and cash equivalents. Non-current assets came to 3,418 million yen. This figure includes 3,263 million yen in intangible assets constituting the capitalized amount of development investment.

Total liabilities totaled 2,641 million yen, up 1,611 million yen from the previous year-end. Current liabilities were 2,542 million yen, including 192 million yen in trade and other payables and 2,250 million yen in bonds payable. Non-current liabilities amounted to 99 million yen, mainly due to 61 million yen in deferred tax liabilities.

Total equity equaled 5,285 million yen, down 1,632 million yen from the previous year-end. The decrease was mainly attributable to the overall loss of 1,937 million yen.

As of today, the overdraft and committed credit line with domestic banks totaled 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, 2020 (announced on February 13, 2020) reflect the impact of the novel coronavirus disease 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, 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, 2019	As of September 30, 2020
<b>Assets</b>		
Current assets		
Cash and cash equivalents	4,116	4,221
Trade and other receivables	10	92
Inventories	3	6
Other current assets	172	187
Total current assets	4,302	4,507
Non-current assets		
Property, plant and equipment	46	38
Light-of-use asset	66	70
Intangible assets	3,485	3,263
Other non-current assets	45	45
Total non-current assets	3,644	3,418
Total assets	7,946	7,926
<b>Liabilities and equity</b>		
<b>Liabilities</b>		
Current liabilities		
Trade and other payables	800	192
Bonds payable	—	2,250
Lease liabilities	41	44
Other current liabilities	84	55
Total current liabilities	925	2,542
Non-current liabilities		
Deferred tax liabilities	65	61
Lease liabilities	27	27
Other non-current liabilities	10	10
Total non-current liabilities	103	99
Total liabilities	1,029	2,641
<b>Equity</b>		
Share capital	960	1,115
Capital surplus	4,630	4,769
Retained earnings	1,400	(536)
Treasury stock	(70)	(70)
Other components of equity	(4)	6
Total equity	6,917	5,285
Total liabilities and equity	7,946	7,926



## (2) Condensed consolidated statement of profit or loss

(Millions of yen)

	Nine months ended September 30, 2019	Nine months ended September 30, 2020
Revenue	291	287
Cost of sales	47	100
Gross profit	243	186
Research and development expenses	716	1,003
Selling, general and administrative expenses	1,113	1,085
Operating profit (loss)	(1,585)	(1,902)
Finance income	0	0
Finance costs	35	27
Other income	0	–
Other costs	–	–
Profit (loss) before tax	(1,621)	(1,928)
Income taxes	51	8
Profit (loss)	(1,672)	(1,937)
Profit (loss) attributable to:		
Owners of parent	(1,672)	(1,937)
Earnings (loss) per share		
Basic earnings (loss) per share [yen]	(15.93)	(16.64)
Diluted earnings (loss) per share [yen]	(15.93)	(16.64)

(3) Condensed consolidated statement of comprehensive income

(Millions of yen)

	Nine months ended September 30, 2019	Nine months ended September 30, 2020
Profit (loss)	(1,672)	(1,937)
Other comprehensive income		
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(2)	(0)
Subtotal	(2)	(0)
Total other comprehensive income	(2)	(0)
Comprehensive income	(1,675)	(1,938)
Comprehensive income attributable to:		
Owners of parent	(1,534)	(1,938)

## (4) Condensed 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, 2019	7,632	7,483	(7,975)	(48)	(3)	—	(3)	7,087
Comprehensive income								
Profit (loss)	—	—	(1,672)	—	—	—	—	(1,672)
Other comprehensive income	—	—	—	—	(2)	—	(2)	(2)
Total comprehensive income	—	—	(1,672)	—	(2)	—	(2)	(1,675)
Transactions with owners								
Exercise of share acquisition rights	5	5	—	—	—	—	—	10
Capital reduction	(7,532)	(3,712)	11,244	—	—	—	—	—
Total transactions with owners	(7,526)	(3,706)	11,244	—	—	—	—	10
Balance at September 30, 2019	105	3,776	1,596	(48)	(6)	—	(6)	5,422
Balance at January 1, 2020	960	4,630	1,400	(70)	(4)		(4)	6,917
Comprehensive income								
Profit (loss)	—	—	(1,937)	—	—	—	—	(1,937)
Other comprehensive income	—	—	—	—	(0)	—	(0)	(0)
Total comprehensive income	—	—	(1,937)	—	(0)	—	(0)	(1,938)
Transactions with owners								
Exercise of share acquisition rights	154	139	—	—	—	(1)	(1)	292
Issuance of share acquisition rights	—	—	—	—	—	13	13	13
Total transactions with owners	154	139	—	—	—	12	12	306
Balance at September 30, 2020	1,115	4,769	(536)	(70)	(5)	12	6	5,285

## (5) Condensed consolidated statement of cash flows

(Millions of yen)

	Nine months ended September 30, 2019	Nine months ended September 30, 2020
Cash flows from operating activities		
Profit (loss) before tax	(1,621)	(1,928)
Depreciation and amortization	348	372
Finance income	(0)	(0)
Finance costs	35	27
Decrease (increase) in trade and other receivables	34	(79)
Decrease (increase) in inventories	5	(3)
Increase (decrease) in trade and other payables	(127)	(556)
Other	(47)	(60)
Subtotal	(1,371)	(2,228)
Interest received	0	0
Interest paid	(0)	(0)
Income taxes paid	—	(14)
Net cash provided by (used in) operating activities	(1,372)	(2,243)
Cash flows from investing activities		
Purchase of property, plant and equipment	(2)	(2)
Purchase of intangible assets	(679)	(159)
Other	0	(0)
Net cash provided by (used in) investing activities	(680)	(161)
Cash flows from financing activities		
Proceeds from issuance of bonds	—	2,500
Redemption of bonds	—	(250)
Proceeds from issuance of new shares	10	292
Proceeds from issuance of share acquisition rights	—	13
Repayment of lease liabilities	(31)	(34)
Net cash provided by (used in) financing activities	(20)	2,521
Net increase (decrease) in cash and cash equivalents	(2,073)	116
Cash and cash equivalents at beginning of period	4,046	4,116
Effect of exchange rate changes on cash and cash equivalents	(16)	(0)
Cash and cash equivalents at end of period	1,956	4,221

(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.