Consolidated Financial Resultsfor the First Quarter of the Fiscal Year Ending March 31, 2023 (IFRS)

August 12, 2022

Company name: Nichi-Iko Pharmaceutical Co., Ltd. Stock exchange listings:

Tokyo Stock Exchange

Securities code: 4541 (URL https://www.nichiiko.co.jp/)

Representative: Yuichi Tamura

President and CEO

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Board Member, Executive Vice

President

Scheduled date of filing of quarterly report: August 12, 2022

Scheduled date of commencement of dividend payment:

Presentation of supplementary materials on quarterly financial results:

Yes
Holding of quarterly financial presentation meeting:

No

(Note that all amounts have been rounded down to the nearest one million yen.)

1. Consolidated Financial Results for the First Quarter of the Fiscal Year Ending March 31, 2023 (From April 1, 2022 to June 30, 2022)

(1) Consolidated Results of Operations (cumulative)

(Percentage figures represent changes from the same period of the previous fiscal year)

	Revenue	Core operating profit	Operating profit	Profit before tax	Profit	Profit attributable to owners of parent
First quarter of fiscal year ending March 31, 2023	¥47,062 million (9.6%)	-¥5,117 million (-%)	-¥6,549 million (-%)	-¥4,200 million (-%)	-¥4,385 million (-%)	-¥4,200 million (-%)
First quarter of fiscal year ended March 31, 2022	¥42,943 million (-5.1%)	-¥3,945 million (-%)	-¥4,124 million (-%)	-¥3,611 million (-%)	-¥3,881 million (-%)	-¥3,777 million (-%)

	Total comprehensive income	Basic earnings per share	Diluted earnings per share
First quarter of fiscal year ending March 31, 2023	-¥1,214 million (-%)	-¥59.63	-¥59.63
First quarter of fiscal year ended March 31, 2022	-¥3,691 million (-%)	-¥58.90	-¥58.90

(Note)

Core operating profit is calculated by deducting gains and losses caused by extraordinary factors (extraordinary items) from operating profit.

(2) Consolidated Financial Position

	Total assets	Total equity	Equity attributable to owners of parent	Ratio of total equity attributable to owners of the parent to total assets	Equity attributable to owners of parent per share
First quarter of fiscal year ending March 31, 2023	¥266,215 million	¥12,449 million	¥12,221 million	4.6%	¥173.52
Fiscal year ended March 31, 2022	¥260,559 million	¥13,773 million	¥13,394 million	5.1%	¥190.17

2. Dividends

	Annual dividends per share					
	First quarter	Second quarter	Third quarter	Year-end	Total	
Fiscal year ended March 31, 2022	¥-	¥0.00	¥-	¥0.00	¥0.00	
Fiscal year ending March 31, 2023	¥-					
Fiscal year ending March 31, 2023 (forecast)		¥0.00	¥-	¥0.00	¥0.00	

(Note)

Revisions to recently announced dividends forecast: None

3. Forecast of Consolidated Financial Results for the Fiscal Year Ending March 31, 2023 (From April 1, 2022 to March 31, 2023)

On May 13, 2022, the Company formally applied for a specified certified dispute resolution procedure (the "Business Turnaround ADR") under the Act on Strengthening Industrial Competitiveness, and this was accepted on the same day. In the course of the procedure, we are proceeding with consultations with the relevant companies. Therefore, the consolidated earnings forecast for the fiscal year ending March 31, 2023 is yet to be determined.

*Notes

- (1) Changes in significant subsidiaries during the consolidated cumulative quarter under review (changes in specified subsidiaries resulting in change in scope of consolidation): No
- (2) Changes in accounting policies and changes in accounting estimates

(i) Changes in accounting policies required by IFRS: No

(ii) Changes in accounting policies due to other reasons: No

(iii) Changes in accounting estimates: No

- (3) Total number of issued shares (common stock)
 - (i) Total number of issued shares as of the end of the period (including treasury shares):

As of June 30, 2022 71,382,652 shares As of March 31, 2022 71,382,652 shares

(ii) Number of treasury shares as of the end of the period:

As of June 30, 2022 945,948 shares As of March 31, 2022 948,131 shares

(iii) Average number of shares during the period (cumulative quarter):

First quarter of fiscal year ending March 31, 2023 70,436,235 shares First quarter of fiscal year ended March 31, 2022 64,141,888 shares

- * Quarterly financial results reports are exempt from quarterly reviews conducted by certified public accountants or an audit corporation.
- * Explanation on the appropriate usage of forecast of financial results, and other specific matters

(Considerations on forward-looking statements)

The forward-looking statements including forecast of financial results contained in these materials are based on the information currently available to the Company and certain assumptions which are regarded as legitimate. As such, they do not constitute the Company's guarantee that such results would be achieved. Actual business and other results may differ substantially from the forecasts provided in these materials as a result of various factors.

(How to obtain supplementary materials for financial results)

Supplementary materials for financial results will be provided on the website of the Company on Friday, August 12, 2022.

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1. Qualitative Information on Financial Results for the Quarter under Review

(1) Explanation on Operating Results

In the cumulative first quarter under review, while the Japanese economy showed signs of recovery from the stagnation in economic activity associated with the novel coronavirus disease (COVID-19), uncertainty about the economic outlook remains due to the renewed spread of COVID-19. Furthermore, there are concerns that the Japanese economy will be affected by the rise in material and energy prices due to the impact of Russia's invasion of Ukraine and the rapid devaluation of the yen.

In the generic drug industry, further enhancement of steps to address issues in quality and stable supply is required, as well as strengthening of profitability in the face of the lower drug prices resulting from the NHI drug price revisions.

On May 13, 2022, the Company formally applied for a specified certified dispute resolution procedure (the "Business Turnaround ADR") under the Act on Strengthening Industrial Competitiveness, and is proceeding with consultations with the relevant companies to draft a business rehabilitation plan under the Business Turnaround ADR.

A. Results by segment

	Nichi-Iko Group			Sagent Group		
(in millions of yen)	First quarter of fiscal year ended March 31, 2022	First quarter of fiscal year ending March 31, 2023	Change	First quarter of fiscal year ended March 31, 2022	First quarter of fiscal year ending March 31, 2023	Change
Revenue	33,268	35,988	+2,720	9,690	11,099	+1,408
Core operating profit	-3,521	-3,409	+112	-423	-1,708	-1,284

(Notes)

- 1. The two segments are the "Nichi-Iko Group" and the "Sagent Group," with the "Sagent Group" being made up of Sagent Pharmaceuticals, Inc. and its consolidated subsidiaries, and the "Nichi-Iko Group" being made up of companies excluding the "Sagent Group."
- 2. The Group has adopted "core operating profit" as an indicator representing ordinary profitability, and has also adopted "core operating profit" for segment profit. "Core operating profit" is calculated by deducting gains and losses caused by extraordinary factors from operating profit, and extraordinary factors are also excluded from revenue.

(i) Nichi-Iko Group

In the Nichi-Iko Group, efforts are being made to improve and enhance manufacturing and quality control systems, in addition to increasing the production volume and shipment volume while ensuring quality at Toyama Plant 1, but due to the stringent quality checks and other measures, it is taking longer than originally expected to resume full shipments. We are making company-wide efforts to expand these shipments as quickly as possible.

Results in the Nichi-Iko Group during the cumulative first quarter of the current fiscal year showed revenue of 35,988 million yen (an increase of 2,720 million yen year-on-year) and segment loss of 3,409 million yen (an improvement of 112 million yen year-on-year) due to an increase in sales volume despite a fall in sale prices caused by the drug price revision and the impact of the delay in resumption of product shipments, manufactured at Toyama Plant 1.

(ii) Sagent Group

In Sagent Group, efforts are continuing to be made in the in-house production and production capacity expansion projects, with the aim of being more cost competitive and enhancing stable supply capability.

Results in Sagent Group during the cumulative first quarter of the current fiscal year showed revenue of 11,099 million yen (an increase of 1,408 million yen year-on-year) but a segment loss of 1,708 million yen (a deterioration of 1,284 million yen year-on-year) due mainly to the suspension of plant operation amid a review of production facilities at SterRx, production volume being lower than anticipated at the Raleigh Plant and the decline in unit sales prices of mainstay products.

B. Group Results

(in millions of yen)	First quarter of fiscal year ended March 31, 2022	First quarter of fiscal year ending March 31, 2023	Change
Revenue	42,943	47,062	+4,118
Core operating profit	-3,945	-5,117	-1,172
Operating profit	-4,124	-6,549	-2,424
Profit before tax	-3,611	-4,200	-588
Profit attributable to owners of parent	-3,777	-4,200	-422
Diluted earnings per share	-¥58.90	-¥59.63	-¥0.73

(Note)

The Group has adopted "core operating profit" as an indicator representing ordinary profitability. "Core operating profit" is calculated by deducting gains and losses caused by extraordinary factors from operating profit.

Revenue increased by 4,118 million yen year-on-year due mainly to an increase in the sales volume of the Nichi-Iko Group.

Core operating profit deteriorated by 1,172 million yen year-on-year due to an increase in losses in the Sagent Group.

Operating profit deteriorated by 2,424 million yen year-on-year due mainly to the recording of an impairment losses on development costs of 1,058 million yen for products that ceased to be developed.

Profit before tax deteriorated by 588 million yen year-on-year and profit attributable to owners of parent deteriorated by 422 million yen year-on-year due to factors such as the recording of foreign exchange gains resulting from the depreciation of the yen.

(Impact from COVID-19)

The Group is endeavoring to prevent the spread of COVID-19 among all employees through measures such as working at home, staggered working hours and dispersing of work areas per each department.

With regard to the impact on results, although there were some negative impacts on sales due to restraint on examinations, selective surgeries and restrictions on business activities, there were also

positive aspects such as increase in sales of products related to COVID-19. As such, there has been no significant impact on results to date.

(2) Explanation on Financial Position

(i) Assets, Liabilities and Equity

Assets on a consolidated basis at the end of the first quarter of the current fiscal year increased by 5,655 million yen from the previous fiscal year-end to 266,215 million yen. This was mainly attributable to the following factors:

	Increase (decrease) (in millions of yen)	Main factors
Cash and cash equivalents	-5,318	Payments for inventories purchased in the previous fiscal year
Trade and other receivables	+12,868	Decrease in liquidation of receivables
Inventories	-5,507	Review of volume of inventories held

Liabilities on a consolidated basis at the end of the first quarter of the current fiscal year increased by 6,979 million yen from the previous fiscal year-end to 253,765 million yen. This was mainly attributable to the following factors:

	Increase (decrease) (in millions of yen)	Main factors
Trade and other payables		Decrease in trade payables associated with review of volume of inventories held
Borrowings	+13,433	Procurement of working capital

Equity on a consolidated basis at the end of the first quarter of the current fiscal year decreased by 1,323 million yen from the previous fiscal year-end to 12,449 million yen. This was mainly attributable to the following factors:

	Increase (decrease) (in millions of yen)	Main factors
Retained earnings	-4,312	Recording of loss
Other components of equity	+3,134	Increase in exchange differences on translation of foreign operations due to yen depreciation

(ii) Consolidated Cash Flows

At the end of the first quarter of the current fiscal year, cash and cash equivalents on a consolidated basis decreased by 5,318 million yen from the previous fiscal year-end to 9,987 million yen.

Details of cash flows from each of the three activities for the cumulative first quarter of the current fiscal year are described below.

(Cash flows from operating activities)

Net cash used in operating activities during the cumulative first quarter of the current fiscal year amounted to 15,889 million yen. This was mainly attributable to the following factors:

Details	Increase (decrease) (in millions of yen)
Recording of loss before tax	-4,200
Recording of depreciation and amortization	2,459
Recording of foreign exchange gain	-2,784
Decrease in inventories	7,099
Increase in trade and other receivables	-13,947
Decrease in trade and other payables	-5,120

(Cash flows from investing activities)

Net cash used in investing activities during the cumulative first quarter of the current fiscal year amounted to 884 million yen. This was mainly attributable to the following factors:

Details	Increase (decrease) (in millions of yen)
Purchase of property, plant and equipment	-961
Purchase of intangible assets	-989
Proceeds from settlement of contingent considerations	1,053

(Cash flows from financing activities)

Net cash provided by financing activities during the cumulative first quarter of the current fiscal year amounted to 10,941 million yen. This was mainly attributable to the following factors:

Details	Increase (decrease) (in millions of yen)
Net increase in borrowings	11,782

(3) Explanation of Forecast of Consolidated Financial Results and Other Forward-looking Statements

On May 13, 2022, the Company formally applied for a specified certified dispute resolution procedure (the "Business Turnaround ADR") under the Act on Strengthening Industrial Competitiveness, and this was accepted on the same day. In the course of the procedure, we are proceeding with consultations with the relevant companies. Therefore, the consolidated earnings forecast for the fiscal year ending March 31, 2023 is yet to be determined.

2. Condensed Quarterly Consolidated Financial Statements and Primary Notes

(1) Condensed Quarterly Consolidated Statement of Financial Position

		(in millions of yen)
	Fiscal year ended March 31, 2022 (as of March 31, 2022)	First quarter of fiscal year ending March 31, 2023 (as of June 30, 2022)
Assets		
Current assets		
Cash and cash equivalents	15,305	9,987
Trade and other receivables	38,605	51,473
Inventories	95,745	90,238
Other financial assets	425	355
Other current assets	5,309	4,311
Total current assets	155,391	156,366
Non-current assets		
Property, plant and equipment	39,289	40,511
Goodwill	18,479	20,321
Intangible assets	39,609	41,505
Investments accounted for using equity method	68	68
Other financial assets	7,465	7,205
Deferred tax assets	9	9
Other non-current assets	246	227
Total non-current assets	105,167	109,848
Total assets	260,559	266,215

		(in millions of yen)
	Fiscal year ended March 31, 2022 (as of March 31, 2022)	First quarter of fiscal year ending March 31, 2023 (as of June 30, 2022)
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	48,123	43,210
Borrowings	85,529	101,771
Other financial liabilities	2,095	2,044
Income taxes payable	480	716
Refund liabilities	2,349	2,384
Contract liabilities	209	209
Other current liabilities	8,683	7,500
Total current liabilities	147,471	157,838
Non-current liabilities		
Borrowings	77,102	74,293
Other financial liabilities	8,396	8,154
Retirement benefit liability	1,190	1,219
Provisions	79	61
Refund liabilities	58	73
Contract liabilities	1,363	1,310
Deferred tax liabilities	10,160	9,713
Other non-current liabilities	964	1,100
Total non-current liabilities	99,314	95,927
Total liabilities	246,785	253,765
Equity		
Share capital	25,975	25,975
Capital surplus	24,511	24,511
Other equity instruments	9,918	9,918
Treasury shares	(2,124)	(2,119)
Retained earnings	(55,657)	(59,969)
Other components of equity	10,770	13,904
Total equity attributable to owners of parent	13,394	12,221
Non-controlling interests	379	227
Total equity	13,773	12,449
Total liabilities and equity	260,559	266,215

(2) Condensed Quarterly Consolidated Statement of Income and Condensed Quarterly Consolidated Statement of Comprehensive Income

(Condensed Quarterly Consolidated Statement of Income)

		(in millions of yen)
	First quarter of previous fiscal year (from April 1, 2021 to June 30, 2021)	First quarter of current fiscal year (from April 1, 2022 to June 30, 2022)
Revenue	42,943	47,062
Cost of sales	39,420	44,061
Gross profit	3,523	3,001
Selling, general and administrative expenses	6,879	6,867
Research and development expenses	790	1,715
Other operating income	95	229
Other operating expenses	73	1,197
Operating profit (loss)	(4,124)	(6,549)
Finance income	545	2,842
Finance costs	232	492
Share of profit (loss) of investments accounted for using equity method	201	-
Profit (loss) before tax	(3,611)	(4,200)
Income tax expense	270	185
Profit (loss)	(3,881)	(4,385)
Profit attributable to:		
Owners of parent	(3,777)	(4,200)
Non-controlling interests	(103)	(185)
Profit (loss)	(3,881)	(4,385)
Earnings per share		
Basic earnings (loss) per share (Yen)	(58.90)	(59.63)
Diluted earnings (loss) per share (Yen)	(58.90)	(59.63)

(Condensed Quarterly Consolidated Statement of Comprehensive Income)

		(in millions of yen)
	First quarter of previous fiscal year (from April 1, 2021 to June 30, 2021)	First quarter of current fiscal year (from April 1, 2022 to June 30, 2022)
Profit (loss)	(3,881)	(4,385)
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	73	(325)
Total of items that will not be reclassified to profit or loss	73	(325)
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	116	3,496
Total of items that may be reclassified to profit or loss	116	3,496
Other comprehensive income (net of tax)	189	3,171
Comprehensive income	(3,691)	(1,214)
Comprehensive income attributable to:		
Owners of parent	(3,586)	(1,062)
Non-controlling interests	(105)	(151)
Comprehensive income	(3,691)	(1,214)

Condensed Quarterly Consolidated Statement of Changes in Equity (3)

First Quarter of Previous Fiscal Year (from April 1, 2021 to June 30, 2021)

(in millions of yen)

						nponents of uity
Share capital	Capital surplus	Other equity instruments	Treasury shares	Retained earnings	Exchange differences on translation of foreign operations	Financial assets measured a fair value through other compreher sive incom

Equity attributable to owners of parent

	Share capital	Capital surplus	Other equity instruments	Treasury shares	Retained earnings	Exchange differences on translation of foreign operations	assets measured at fair value through other comprehen- sive income
Balance as of April 1, 2021	23,360	21,896	9,918	(2,267)	50,822	6,526	669
Profit (loss)					(3,777)		
Other comprehensive income						118	73
Total comprehensive income	-	-	-	-	(3,777)	118	73
Distributions to owners of other equity instruments					(109)		
Purchase of treasury shares				(0)			
Disposal of treasury shares		(21)		50			
Transfer of loss on disposal of treasury shares		21			(21)		
Exercise of share acquisition rights							
Dividends (Note)					(641)		
Transfer from other components of equity					1		(1)
Total transactions with owners	-	-	-	50	(771)	-	(1)
Balance as of June 30, 2021	23,360	21,896	9,918	(2,216)	46,272	6,645	741

_	Equity attribu	table to owner	NT		
	Other components of equity		Total	Non- controlling interests	Total
	Others	Total		merests	
Balance as of April 1, 2021	240	7,437	111,167	1,268	112,435
Profit (loss)			(3,777)	(103)	(3,881)
Other comprehensive income		191	191	(2)	189
Total comprehensive income	-	191	(3,586)	(105)	(3,691)
Distributions to owners of other equity instruments			(109)		(109)
Purchase of treasury shares			(0)		(0)
Disposal of treasury shares			28		28
Transfer of loss on disposal of treasury shares			-		-
Exercise of share acquisition rights			-		-
Dividends (Note)			(641)		(641)
Transfer from other components of equity		(1)	-		-
Total transactions with owners	-	(1)	(722)	-	(722)
Balance as of June 30, 2021	240	7,627	106,859	1,162	108,021

(Note)

The amount of dividends does not include the amount of dividends to the Employee Shareholding Incentive Plan.

(in millions of yen)

_	Equity attributable to owners of parent						
							ponents of uity
	Share capital	Capital surplus	Other equity instruments	Treasury shares	Retained earnings	Exchange differences on translation of foreign operations	Financial assets measured at fair value through other comprehen- sive income
Balance as of April 1, 2022	25,975	24,511	9,918	(2,124)	(55,657)	11,714	(1,139)
Profit (loss)					(4,200)		
Other comprehensive income						3,462	(325)
Total comprehensive income	-	-	-	-	(4,200)	3,462	(325)
Distributions to owners of other equity instruments					(109)		
Purchase of treasury shares				(0)			
Disposal of treasury shares							
Transfer of loss on disposal of treasury shares		2			(2)		
Exercise of share acquisition rights		(2)		5			
Dividends Transfer from other							
components of equity							
Total transactions with owners	-	-	-	5	(111)	-	-
Balance as of June 30, 2022	25,975	24,511	9,918	(2,119)	(59,969)	15,176	(1,465)

	Equity attributable to owners of parent				
	Other components of equity		Total	Non- controlling interests	Total
	Others	Total		merests	
Balance as of April 1, 2022	195	10,770	13,394	379	13,773
Profit (loss)			(4,200)	(185)	(4,385)
Other comprehensive income		3,137	3,137	34	3,171
Total comprehensive income	-	3,137	(1,062)	(151)	(1,214)
Distributions to owners of other equity instruments			(109)		(109)
Purchase of treasury shares			(0)		(0)
Disposal of treasury shares			-		-
Transfer of loss on disposal of treasury shares			-		-
Exercise of share acquisition rights	(3)	(3)	0		0
Dividends			-		-
Transfer from other components of equity			-		-
Total transactions with owners	(3)	(3)	(109)	-	(109)
Balance as of June 30, 2022	192	13,904	12,221	227	12,449

(4) Condensed Quarterly Consolidated Statement of Cash Flows

		(in millions of yen)
	First quarter of previous fiscal year (from April 1, 2021 to June 30, 2021)	First quarter of current fiscal year (from April 1, 2022 to June 30, 2022)
Cash flows from operating activities		_
Profit (loss) before tax	(3,611)	(4,200)
Depreciation and amortization	3,094	2,459
Impairment loss	-	1,155
Interest and dividend income	(92)	(48)
Interest expenses	155	272
Share of loss (profit) of investments accounted for using equity method	(201)	-
Loss (gain) on sale of investments in associates	(363)	-
Foreign exchange losses (gains)	(8)	(2,784)
Decrease (increase) in trade and other receivables	3,431	(13,947)
Decrease (increase) in inventories	(7,273)	7,099
Increase (decrease) in trade and other payables	(7,120)	(5,120)
Increase (decrease) in refund liabilities	(616)	49
Increase (decrease) in deposits received	(992)	(993)
Other	(789)	762
Subtotal	(14,387)	(15,294)
Dividends received	73	43
Interest received	0	1
Interest paid	(152)	(262)
Income taxes paid	(89)	(398)
Income taxes refund	57	20
Net cash provided by (used in) operating activities	(14,497)	(15,889)
Cash flows from investing activities		
Purchase of property, plant and equipment	(1,045)	(961)
Purchase of intangible assets	(2,478)	(989)
Proceeds from sale of investments accounted for using equity method	2,500	-
Proceeds from settlement of contingent considerations	-	1,053
Other	0	12
Net cash provided by (used in) investing activities	(1,024)	(884)

		(in millions of yen)
	First quarter of previous fiscal year (from April 1, 2021 to June 30, 2021)	First quarter of current fiscal year (from April 1, 2022 to June 30, 2022)
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	2,967	11,844
Proceeds from long-term borrowings	1,000	-
Repayments of long-term borrowings	(2,511)	(62)
Repayments of lease liabilities	(492)	(596)
Dividends paid	(594)	(0)
Distributions to owners of other equity instruments	(109)	(109)
Other	28	(133)
Net cash provided by (used in) financing activities	287	10,941
Effect of exchange rate changes on cash and cash equivalents	(204)	514
Net increase (decrease) in cash and cash equivalents	(15,439)	(5,318)
Cash and cash equivalents at beginning of period	29,142	15,305
Cash and cash equivalents at end of period	13,703	9,987

(5) Notes to Condensed Quarterly Consolidated Financial Statements

(Notes on premise of going concern)

Since April 2021, the Group has gradually resumed production and release while conducting stringent quality control checks such as FMEA (Note) at Toyama Plant 1, but the plant has not yet resumed shipments of some of the items scheduled for production. In addition, product sales have declined due to lower drug prices resulting from the drug price revisions and the stoppage of production and shipments at manufacturing subcontractors. In order to improve this situation, we have implemented various efforts in relation to products manufactured at Toyama Plant 1, the Group's main plant, with the aim of ensuring an appropriate production system and scale optimization. These efforts include identifying products that are expected to take more time than anticipated to resume manufacturing, integrating products into formulations with compounds of the same type and same effect, and organizing products for which improvement measures can be implemented. As a result, we recorded a valuation loss on raw materials and work in progress, etc. likely to be disposed of in the future. Furthermore, in the previous fiscal year we recorded an operating loss of 110,051 million yen and a loss attributable to owners of parent of 104,984 million yen. This was primarily due to factors such as the reconsideration of development investments that have been underway up to now and the resulting impairment of goodwill at overseas subsidiaries and impairment loss on domestic fixed assets due to the decline in earnings conditions in Japan.

In the cumulative first quarter of the current fiscal year, operating loss was 6,549 million yen and loss attributable to owners of parent was 4,200 million yen due mainly to the fall in sale prices resulting from the drug price revisions, the recording of impairment loss on development costs for products that ceased to be developed, delays in the resumption of product shipments, manufactured at Toyama Plant 1 and the impact of the suspension of plant operation amid a review of production facilities at SterRx.

As a result of the above, there have been ongoing operating losses and losses attributable to owners of parent, and there are events or circumstances causing significant doubts about the premise of going concern.

In order to resolve this situation, the Nichi-Iko Group will continue to gradually resume production and shipment of products manufactured at Toyama Plant 1, and continue its efforts to improve profitability by promoting initiatives aimed at optimization of the production system throughout the entire Group. In addition, we are taking steps to improve cash flow by reducing expenses, curbing logistics costs and thoroughly implementing inventory and purchasing management on a company-wide level. Furthermore, we are working to accelerate structural reforms with a view to recovering business performance after the current fiscal year, including reducing costs by improving the efficiency of plant operations through optimization of manufacturing plants in Japan and overseas.

On the financial side, on May 13, 2022 the Company submitted a formal application for a Business Turnaround ADR, which was accepted on the same day. In the first meeting of creditors held on May 26, 2022 consent for temporary suspension was obtained from all financial institutions, and approval was also received for the execution of financing based on the credit line established by Sumitomo Mitsui Banking Corporation, which is the Company's main bank. For this reason, the necessary financial arrangements have been made. We will continue with discussions with the relevant companies concerning sponsor selection in the Business Turnaround ADR.

In light of these circumstances, we are currently in the process of implementing response measures to resolve material doubts regarding the premise of going concern. We recognize that there are material uncertainties regarding the premise of going concern given that the Company's cash flow

may be impacted significantly depending on future business progress, discussions with the above financial institutions and related companies, etc., and the status of financing, etc.

Note that since the condensed quarterly consolidated financial statements are prepared based on the premise of going concern, the impact of such material uncertainties on the premise of going concern is not reflected in the condensed quarterly consolidated financial statements.

(Note)

FMEA (Failure Mode and Effect Analysis) is a technique for assessing the risks inherent in products and processes primarily in the product design phase and the process design phase, and eliminating or mitigating such risks as much as possible. It is also recommended as a risk evaluation method in ICHQ9, and is widely used in risk assessments of pharmaceutical companies.

(Segment information)

(1) Reportable segments

The Group's reportable segments are components of the business units of the Group for which discrete financial statements are available and evaluated regularly by the Board of Directors in determining the allocation of management resources and assessing the segment's performance.

The Company's pharmaceutical business is made up of two segments: the "Nichi-Iko Group "and the "Sagent Group." The "Sagent Group" is made up of Sagent Pharmaceuticals, Inc. and its consolidated subsidiaries. The "Nichi-Iko Group" is made up of companies excluding the "Sagent Group."

Revenue and segment profit of the reportable segments are as follows.

First Quarter of Previous Fiscal Year (from April 1, 2021 to June 30, 2021)

(in millions of yen)

	Re	portable segme	nts			
	Nichi-Iko Group	Sagent Group	Total	Adjustment	Consolidated	
Revenue						
External revenue	33,268	9,690	42,959	-	42,959	
Inter-segment revenue	-	18	18	(18)	-	
Total	33,268	9,709	42,977	(18)	42,959	
Segment profit (loss) (Core operating profit) (Note)	(3,521)	(423)	(3,945)	-	(3,945)	

(Note)

Core operating profit excludes profits and losses caused by extraordinary factors from operating profit, and extraordinary factors are also excluded from revenue.

First Quarter of Current Fiscal Year (from April 1, 2022 to June 30, 2022)

(in millions of yen)

(in immons of jen)					
	Re	portable segme	nts		
	Nichi-Iko Group	Sagent Group	Total	Adjustment	Consolidated
Revenue					
External revenue	35,988	11,099	47,088	-	47,088
Inter-segment revenue	-	37	37	(37)	1
Total	35,988	11,136	47,125	(37)	47,088
Segment profit (loss)					
(Core operating profit)	(3,409)	(1,708)	(5,117)	-	(5,117)
(Note)					

(Note)

Core operating profit excludes profits and losses caused by extraordinary factors from operating profit, and extraordinary factors are also excluded from revenue.

The difference between the total amounts for the reportable segments and the amount reported on the condensed quarterly consolidated financial statements has been adjusted as follows.

(in millions of yen)

	First quarter of previous fiscal year (from April 1, 2021 to June 30, 2021)	First quarter of current fiscal year (from April 1, 2022 to June 30, 2022)
Total revenue	42,959	47,088
Provisions for returns in voluntary recall	16	26
Revenue on condensed quarterly consolidated financial statements	42,943	47,062

(in millions of yen)

	First quarter of previous fiscal year (from April 1, 2021 to June 30, 2021)	First quarter of current fiscal year (from April 1, 2022 to June 30, 2022)
Segment profit (loss)	(3,945)	(5,117)
Impairment loss on development costs	(3,713)	1,155
Loss on valuation of Infliximab	_	219
Loss on valuation of inventory (Note)	-	(331)
Integration-related expenses	24	-
Voluntary recall expenses	154	109
Business restructuring expenses	-	278
Operating profit (loss)	(4,124)	(6,549)
Finance income	545	2,842
Finance costs	232	492
Share of profit (loss) of investments accounted for using equity method	201	-
Profit (loss) before tax	(3,611)	(4,200)

(Note)

We recorded a valuation loss on raw materials and work in progress likely to be disposed of and its gain on reversal in future at Toyama Plant 1.

(2) Information about products and services

Revenue from each product and service is as follows.

First Quarter of Previous Fiscal Year (from April 1, 2021 to June 30, 2021)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Sales of merchandise and products			
Treatments for paramedics	-	5,556	5,556
Treatments for circulatory system	5,092	-	5,092
Treatments for blood and body fluid	5,078	-	5,078
Antibiotics	2,004	2,501	4,505
Treatments for nervous system	3,610	-	3,610
Treatments for digestive system	3,824	-	3,824
Treatments for allergies	2,497	-	2,497
Treatments for external use	2,595	-	2,595
Other	8,566	1,633	10,199
Total	33,268	9,690	42,959

(Note)

In the same manner as "core operating profit," extraordinary factors are also excluded from revenue.

First Quarter of Current Fiscal Year (from April 1, 2022 to June 30, 2022)

(in millions of yen)

(in initions of year)				
		Reportable segments		
	Nichi-Iko Group	Sagent Group	Total	
Sales of merchandise and products				
Treatments for paramedics	-	6,592	6,592	
Treatments for circulatory system	5,906	-	5,906	
Treatments for blood and body fluid	5,055	-	5,055	
Antibiotics	2,311	2,545	4,856	
Treatments for nervous system	4,296	-	4,296	
Treatments for digestive system	3,913	-	3,913	
Treatments for allergies	2,815	-	2,815	
Treatments for external use	2,676	-	2,676	
Other	9,013	1,961	10,975	
Total	35,988	11,099	47,088	

(Note)

In the same manner as "core operating profit," extraordinary factors are also excluded from revenue.

First Quarter of Previous Fiscal Year (from April 1, 2021 to June 30, 2021)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Sales of merchandise and products	33,239	9,690	42,929
License agreement on sales of products, etc.	29	-	29
Total	33,268	9,690	42,959

(Note)

In the same manner as "core operating profit," extraordinary factors are also excluded from revenue.

First Quarter of Current Fiscal Year (from April 1, 2022 to June 30, 2022)

(in millions of yen)

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	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Sales of merchandise and products	35,936	11,099	47,035
License agreement on sales of products, etc.	52	-	52
Total	35,988	11,099	47,088

(Note)

In the same manner as "core operating profit," extraordinary factors are also excluded from revenue.

(3) Information by geographical area

Revenue by geographical area is shown below.

First Quarter of Previous Fiscal Year (from April 1, 2021 to June 30, 2021)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Japan	33,220	-	33,220
United States	-	7,749	7,749
Other	48	1,940	1,989
Total	33,268	9,690	42,959

(Notes)

- 1. Revenue is based on the location of the destination of sales.
- 2. In the same manner as "core operating profit," extraordinary factors are also excluded from revenue.

First Quarter of Current Fiscal Year (from April 1, 2022 to June 30, 2022)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Japan	35,889	-	35,889
United States	-	9,400	9,400
Other	99	1,698	1,797
Total	35,988	11,099	47,088

(Notes)

- 1. Revenue is based on the location of the destination of sales.
- 2. In the same manner as "core operating profit," extraordinary factors are also excluded from revenue.

3. Other

Significant matters regarding the premise of going concern

Since April 2021, the Group has gradually resumed production and release while conducting stringent quality control checks such as FMEA at Toyama Plant 1, but the plant has not yet resumed shipments of some of the items scheduled for production. In addition, product sales have declined due to lower drug prices resulting from the drug price revisions and the stoppage of production and shipments at manufacturing subcontractors. In order to improve this situation, we have implemented various efforts in relation to products manufactured at Toyama Plant 1, the Group's main plant, with the aim of ensuring an appropriate production system and scale optimization. These efforts include identifying products that are expected to take more time than anticipated to resume manufacturing, integrating products into formulations with compounds of the same type and same effect, and organizing products for which improvement measures can be implemented. As a result, we recorded a valuation loss on raw materials and work in progress, etc. likely to be disposed of in the future. Furthermore, in the previous fiscal year we recorded an operating loss of 110,051 million yen and a loss attributable to owners of parent of 104,984 million yen. This was primarily due to factors such as the reconsideration of development investments that have been underway up to now and the resulting impairment of goodwill at overseas subsidiaries and impairment loss on domestic fixed assets due to the decline in earnings conditions in Japan.

In the cumulative first quarter of the current fiscal year, operating loss was 6,549 million yen and loss attributable to owners of parent was 4,200 million yen due mainly to the fall in sale prices resulting from the drug price revisions, the recording of impairment loss on development costs for products that ceased to be developed, delays in the resumption of product shipments, manufactured at Toyama Plant 1 and the impact of the suspension of plant operation amid a review of production facilities at SterRx.

As a result of the above, there have been ongoing operating losses and losses attributable to owners of parent, and there are events or circumstances causing significant doubts about the premise of going concern.

In order to resolve this situation, the Nichi-Iko Group will continue to gradually resume production and shipment of products manufactured at Toyama Plant 1, and continue its efforts to improve profitability by promoting initiatives aimed at optimization of the production system throughout the entire Group. In addition, we are taking steps to improve cash flow by reducing expenses, curbing logistics costs and thoroughly implementing inventory and purchasing management on a company-wide level. Furthermore, we are working to accelerate structural reforms with a view to recovering business performance after the current fiscal year, including reducing costs by improving the efficiency of plant operations through optimization of manufacturing plants in Japan and overseas.

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In light of these circumstances, we are currently in the process of implementing response measures to resolve material doubts regarding the premise of going concern. We recognize that there are material uncertainties regarding the premise of going concern given that the Company's cash flow may be impacted significantly depending on future business progress, discussions with the above financial institutions and related companies, etc., and the status of financing, etc.