Consolidated Financial Results for the Fiscal Year Ended March 31, 2022 (IFRS)

May 13, 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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Executive Vice President, Head of

Administrative Division

Scheduled date of annual shareholders' meeting:

June 30, 2022

Scheduled date of commencement of dividend payment:

Scheduled date of filing of annual securities report: June 30, 2022

Presentation of supplementary materials on financial results:

Yes
Holding of financial presentation meeting:

Yes

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

1. Consolidated Financial Results for the Fiscal Year Ended March 31, 2022 (From April 1, 2021 to March 31, 2022)

(1) Consolidated Results of Operations

(Percentage figures represent changes from the previous fiscal year)

	Revenue	Core operating profit	Operating profit	Profit before tax	Profit	Profit attributable to owners of parent
Fiscal year ended March 31, 2022	¥179,060 million (-4.9%)	-¥16,776 million (-%)	-¥110,051 million (-%)	-¥107,842 million (-%)	-¥105,652 million (-%)	-¥104,984 million (-%)
Fiscal year ended March 31, 2021	¥188,218 million (-1.0%)	¥977 million (-87.8%)	¥107 million (-96.3%)	¥1,068 million (-85.6%)	-¥4,273 million (-%)	-¥4,179 million (-%)

	Total comprehensive income	Basic earnings per share	Diluted earnings per share	Return on equity	Rate of profit before tax to total assets	Ratio of operating profit to revenue
Fiscal year ended March 31, 2022	-¥102,352 million (-%)	-¥1,554.37	-¥1,554.37	-168.6%	-34.6%	-61.5%
Fiscal year ended March 31, 2021	-¥2,579 million (-%)	-¥65.28	-¥65.28	-3.7%	0.3%	0.1%

(Reference)

Share of profit (loss) of investments accounted for using equity method

Fiscal year ended March 31, 2022 203 million yen

Fiscal year ended March 31, 2021 432 million yen

(Note)

Core operating profit is calculated by deducting gains and losses caused by extraordinary factors (extraordinary items) from operating profit, and extraordinary factors are also excluded from revenue.

(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
Fiscal year ended March 31, 2022	¥260,559 million	¥13,773 million	¥13,394 million	5.1%	¥190.17
Fiscal year ended March 31, 2021	¥363,572 million	¥112,435 million	¥111,167 million	30.6%	¥1,733.58

(3) Consolidated Cash Flows

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at end of period
Fiscal year ended March 31, 2022	-¥24,248 million	-¥9,315 million	¥19,677 million	¥15,305 million
Fiscal year ended March 31, 2021	¥5,006 million	-¥29,334 million	¥10,867 million	¥29,142 million

2. Dividends

		Annual o	dividends j	per share				Ratio of
	First quarter	Second quarter	Third quarter	Year- end	Total	Total amount of cash dividends (annual)	Payout ratio (consolidated)	dividends to equity attributable to owners of parent (consolidated)
Fiscal year ended March 31, 2021	¥-	¥15.00	¥-	¥10.00	¥25.00	¥1,605 million	-%	1.4%
Fiscal year ended March 31, 2022	¥-	¥0.00	¥-	¥0.00	¥0.00	¥-	-%	-%
Fiscal year ending March 31, 2023 (forecast)	¥-	¥0.00	¥-	¥0.00	¥0.00		-%	

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. In the course of the procedure, we plan to proceed 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 fiscal year 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 March 31, 2022 71,382,652 shares As of March 31, 2021 65,162,652 shares

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

As of March 31, 2022 948,131 shares As of March 31, 2021 1,036,650 shares

(iii) Average number of shares during the period:

Fiscal year ended March 31, 2022 67,541,284 shares Fiscal year ended March 31, 2021 64,023,932 shares

(Note)

Number of treasury shares as of the end of the period includes shares held by the Employee Shareholding Incentive Plan.

- * Financial results reports are exempt from audit 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, May 13, 2022.

Attachment-Contents

1. Overview of Operating Results, etc.	2
(1) Overview of Operating Results for the Current Fiscal Year	2
(2) Overview of Financial Position for the Current Fiscal Year	
(3) Cash Flows	5
(4) Prospects for the Future	6
(5) Significant matters regarding the premise of going concern	6
2. Basic Stance Regarding the Selection of Accounting Standards	7
3. Consolidated Financial Statements and Primary Notes	8
(1) Consolidated Statement of Financial Position	8
(2) Consolidated Statement of Income and Consolidated Statement of Comprehensive	
Income	10
(Consolidated Statement of Income)	10
(Consolidated Statement of Comprehensive Income)	
(3) Consolidated Statement of Changes in Equity	12
(4) Consolidated Statement of Cash Flows	16
(5) Notes to Consolidated Financial Statements	18
(Notes on premise of going concern)	
(Reporting entity)	19
(Basis of preparation)	19
(Segment information, etc.)	
(Per share information)	26
(Significant subsequent events)	26

- 1. Overview of Operating Results, etc.
- (1) Overview of Operating Results for the Current Fiscal Year

(Operating Results for the Current Fiscal Year)

Although the Japanese economy is showing some signs of recovery in the current fiscal year, the outlook for the economy remains uncertain due to the spread of COVID-19, the situation in Ukraine, and rising of resource prices .

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 drug price revisions.

We are working to improve and strengthen the manufacturing and quality control system companywide and are resuming shipments of products manufactured at the Toyama Plant 1 after ensuring their quality. However, due to the stringent quality checks and other measures, the number of items that have resumed shipping is far below the initial expectations. Furthermore, due primarily to the recording of impairment losses on property, plant and equipment, intangible assets, goodwill, etc., we recorded net loss for the current fiscal year as in the previous fiscal year.

Under these circumstances, as stated in the press release "Notice of Formal Application and Acceptance of Business Turnaround ADR" dated May 13, 2022, we decided to engage in a business turnaround based on the specified certified dispute resolution procedure (the "Business Turnaround ADR") under the Act on Strengthening Industrial Competitiveness and have submitted a formal application for the Business Turnaround ADR procedure. We thereby aim to revitalize and continue our business in the future and to drastically improve our financial position.

A. Results by segment

(in millions of yen)	Nichi-Iko Group			Sagent Group		
	Fiscal year ended March 31, 2021	Fiscal year ended March 31, 2022	Change	Fiscal year ended March 31, 2021	Fiscal year ended March 31, 2022	Change
Revenue	152,481	139,027	-13,453	36,289	40,056	+3,767
Core operating profit	2,995	-14,017	-17,012	-2,017	-2,759	-741

- (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 resume production and release of products manufactured at Toyama Plant 1 and to expand the types and volume of resumed items, 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 Nichi-Iko Group during the current fiscal year showed revenue of 139,027 million yen (a decrease of 13,453 million yen year-on-year) and segment loss of 14,017 million yen (segment profit of 2,995 million yen in the previous year), a significant decrease in both sales and profit, due to a drop in drug prices as a result of the drug price revision, decrease in sales of Elmed products caused by stoppage of production and shipments by manufacturing subcontractor, Kobayashi Kako Co., Ltd., and the effect of delays in resuming release of products manufactured at Toyama Plant 1, despite contribution made by sales of products from Gifu Plant (approximately 32,700 million yen).

(ii) Sagent Group

In Sagent Group, efforts are being made in the in-house manufacturing and production capacity expansion projects, with the aim of being more cost competitive and enhancing stable supply capability. Furthermore, the Company is proceeding with efforts aimed at licensing out products developed by Sagent to the Japanese and Southeast Asian markets.

Meanwhile, with regard to biosimilar and orphan drugs being developed with the aim of launching in the U.S. market, it is certain that the approval application will be delayed more than planned, and it has been decided to reconsider the entire future development plan.

Results in Sagent Group during the current fiscal year showed revenue of 40,056 million yen (an increase of 3,767 million yen year-on-year) and segment loss of 2,759 million yen (an increase in loss of 741 million yen year-on-year) due mainly to the suspension of plant operation amid a review of production facilities at SterRx and the decline in unit sales prices of mainstay products, despite continued strong performance of products related to COVID-19 and growth in sales in the Canadian market.

B. Group Results

(in millions of yen)	Fiscal year ended March 31, 2021	Fiscal year ended March 31, 2022	Change
Revenue	188,218	179,060	-9,158
Core operating profit	977	-16,776	-17,754
Operating profit	107	-110,051	-110,158
Profit before tax	1,068	-107,842	-108,911
Profit attributable to owners of parent	-4,179	-104,984	-100,804
Diluted earnings per share	-¥65.28	-¥1,554.37	-¥1,489.09

^{*} 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 decreased by 9,158 million yen year-on-year due to decrease in revenue in Nichi-Iko Group despite increase in Sagent Group.

Core operating profit decreased by 17,754 million yen year-on-year due to decreases in earnings in both Nichi-Iko Group and Sagent Group.

Operating profit decreased by 110,158 million yen year-on-year due mainly to the recording of one-time expenses, including impairment loss on fixed assets including goodwill (32,480 million yen for Nichi-Iko Group and 26,900 million yen for Sagent Group), impairment loss on development costs, etc., including biosimilars and orphan drugs (16,508 million yen for Nichi-Iko Group and 8,241 million yen for Sagent Group), and inventory valuation loss due to revision of the

future manufacturing resumption schedule for products manufactured at Toyama Plant 1 (7,389 million yen for Nichi-Iko Group).

Profit before tax was down 108,911 million yen year-on-year mainly due to the reasons stated for operating profit and the recording of foreign exchange gains due to the depreciation of the yen.

Profit attributable to owners of parent decreased by 100,804 million yen year-on-year due mainly to the reasons stated for operating profit and the reversal of deferred tax liabilities due to the impairment of development costs mentioned above.

(Impact from COVID-19)

The Group is continuing its endeavor to prevent the spread of COVID-19 by implementing measures such as working from home, staggered working hours and dispersing of work areas per each department, in addition to implementing workplace vaccinations at the Toyama headquarters, Toyama Plant 1 and the Gifu Plant.

With regard to the impact on results, although there were some negative impacts on sales due to restraint on examinations, selective surgeries, restrictions on business activities, and shortages in the supply of materials for certain products, 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.

(2) Overview of Financial Position for the Current Fiscal Year

Assets on a consolidated basis at the end of the current fiscal year decreased by 103,013 million yen from the previous fiscal year-end to 260,559 million yen. This was mainly attributable to the following factors:

	Increase (decrease) (in millions of yen)	Main factors
Cash and cash equivalents	-13,837	Payments for inventories purchased in the previous fiscal year
Goodwill	-27,181	Recording of Sagent's goodwill impairment loss, etc.
Property, plant and equipment	-29,654	Recording of impairment loss due to decline in profitability, etc.
Intangible assets	-17,348	Recording of impairment loss due to decline in profitability, etc.

Liabilities on a consolidated basis at the end of the current fiscal year decreased by 4,351 million yen from the previous fiscal year-end to 246,785 million yen. This was mainly attributable to the following factors:

	Increase (decrease) (in millions of yen)	Main factors
Trade and other payables	-17,236	Payments for inventories purchased in the previous fiscal year
Borrowings	+13,497	Procurement of working capital
Other financial liabilities	+4,693	Increase in lease liabilities
Deferred tax liabilities	-4,551	Reversal of deferred tax liabilities due to recording of impairment loss in development costs, etc.

Equity on a consolidated basis at the end of the current fiscal year decreased by 98,662 million yen from the previous fiscal year-end to 13,773 million yen. This was mainly attributable to the following factors:

	Increase (decrease) (in millions of yen)	Main factors
Share capital	+2,615	Issuance of new shares by third-party allotment
Capital surplus	+2,615	Issuance of new shares by third-party allotment
Retained earnings	-106,479	Recording of net loss, etc.
Other components of equity	+3,332	Exchange differences, etc. on translation of foreign operations due to yen depreciation

(3) Cash Flows

At the end of the current fiscal year, cash and cash equivalents on a consolidated basis decreased by 13,837 million yen from the previous fiscal year-end to 15,305 million yen.

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

Net cash provided by operating activities on a consolidated basis for the current fiscal year amounted to expenditure over income of 24,248 million yen. This was mainly attributable to the following factors:

Details	Increase (decrease) (in millions of yen)
Recording of profit before tax	-107,842
Recording of impairment loss	+84,130
Recording of depreciation and amortization	+12,653
Decrease in trade and other receivables	+5,525
Decrease in trade and other payables	-16,710

Net cash provided by investing activities on a consolidated basis for the current fiscal year amounted to expenditure over income of 9,315 million yen. This was mainly attributable to the following factors:

Details	Increase (decrease) (in millions of yen)
Purchase of property, plant and equipment	-3,481
Purchase of intangible assets	-12,332
Proceeds from sale of investments accounted for using equity method	+2,500
Proceeds from collection of deposits	+3,290

Net cash provided by financing activities on a consolidated basis for the current fiscal year amounted to income over expenditure of 19,677 million yen. This was mainly attributable to the following factors:

Details	Increase (decrease) (in millions of yen)
Net increase in borrowings	+12,176
Proceeds from issuance of common shares	+5,207
Proceeds from sale and leaseback transactions	+5,641
Repayments of lease liabilities	-2,338

(4) Prospects for the Future

Regarding the outlook for the future, while advancing discussion with all financial institutions during the Business Turnaround ADR announced on May 13, 2022, we will ask the Japan Association of Turnaround Professionals for investigation, guidance and advice from a neutral standpoint, formulate a draft business rehabilitation plan, and attempt to have the draft plan approved by all financial institutions. Details of the proposed plan will be announced as soon as they are finalized.

(5) Significant matters regarding the premise of going concern

• Statement to the effect that a significant event or situation exists and the contents thereof

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 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 current 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.

As a result of the above, large operating losses have occurred and operating cash flow expenditures have been exceeded, and we are therefore in a situation in which material uncertainties have arisen regarding entity's ability to continue as a going concern.

• Countermeasures to resolve or improve the event or situation

(Business side)

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 end of the current fiscal year, including reducing costs by improving the efficiency of plant operations through optimization of manufacturing plants in Japan and overseas.

(Financial side)

On the financial side, financial institutions and others have agreed on matters related to financial covenants and on extending the benefits of long-term loans that are due for repayment in March 2022. In addition, a formal application for a Business Turnaround ADR was submitted on May 13, 2022 and was accepted on the same date. Going forward, we will proceed with discussions with the relevant companies in the Business Turnaround ADR, including pre-DIP financing to facilitate smooth business operations. With regard to further funding, we have received proposals from sponsor candidates at this stage, and we are in consultation with them.

· Statement of the fact that material uncertainty is recognized and the reason therefor

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)

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.

2. Basic Stance Regarding the Selection of Accounting Standards

Aiming at improved international comparability of financial information in capital markets, the Group has applied International Financial Reporting Standards (IFRS).

3. Consolidated Financial Statements and Primary Notes

(1) Consolidated Statement of Financial Position

		(in millions of yen)
	Fiscal year ended March 31, 2021 (as of March 31, 2021)	Fiscal year ended March 31, 2022 (as of March 31, 2022)
Assets		
Current assets		
Cash and cash equivalents	29,142	15,305
Trade and other receivables	42,882	38,605
Inventories	96,110	95,745
Income taxes receivable	55	-
Other financial assets	3,715	425
Other current assets	3,195	5,309
Total current assets	175,102	155,391
Non-current assets		
Property, plant and equipment	68,943	39,289
Goodwill	45,661	18,479
Intangible assets	56,957	39,609
Investments accounted for using equity method	2,202	68
Other financial assets	11,635	7,465
Deferred tax assets	12	9
Other non-current assets	3,058	246
Total non-current assets	188,469	105,167
Total assets	363,572	260,559

		(in millions of yen)
	Fiscal year ended March 31, 2021 (as of March 31, 2021)	Fiscal year ended March 31, 2022 (as of March 31, 2022)
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	65,359	48,123
Borrowings	63,113	85,529
Other financial liabilities	1,615	2,095
Income taxes payable	937	480
Refund liabilities	2,712	2,349
Contract liabilities	127	209
Other current liabilities	9,707	8,683
Total current liabilities	143,574	147,471
Non-current liabilities		
Borrowings	86,021	77,102
Other financial liabilities	4,182	8,396
Retirement benefit liability	960	1,190
Provisions	83	79
Refund liabilities	98	58
Contract liabilities	631	1,363
Deferred tax liabilities	14,711	10,160
Other non-current liabilities	874	964
Total non-current liabilities	107,562	99,314
Total liabilities	251,136	246,785
Equity		
Share capital	23,360	25,975
Capital surplus	21,896	24,511
Other equity instruments	9,918	9,918
Treasury shares	(2,267)	(2,124)
Retained earnings	50,822	(55,657)
Other components of equity	7,437	10,770
Total equity attributable to owners of parent	111,167	13,394
Non-controlling interests	1,268	379
Total equity	112,435	13,773
Total liabilities and equity	363,572	260,559
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(2) Consolidated Statement of Income and Consolidated Statement of Comprehensive Income

(Consolidated Statement of Income)

_		(in millions of yen)
	Previous fiscal year (from April 1, 2020 to March 31, 2021)	Current fiscal year (from April 1, 2021 to March 31, 2022)
Revenue	188,218	179,060
Cost of sales	166,973	175,094
Gross profit	21,245	3,965
Selling, general and administrative expenses	27,029	27,879
Research and development expenses	4,335	4,248
Other operating income	12,962	1,768
Other operating expenses	2,734	83,656
Operating profit	107	(110,051)
Finance income	1,330	3,133
Finance costs	801	1,128
Share of profit (loss) of investments accounted for using equity method	432	203
Profit before tax	1,068	(107,842)
Income tax expense	5,342	(2,190)
Profit (loss)	(4,273)	(105,652)
Profit attributable to:		
Owners of parent	(4,179)	(104,984)
Non-controlling interests	(93)	(668)
Profit (loss)	(4,273)	(105,652)
Earnings per share		
Basic earnings (loss) per share (Yen)	(65.28)	(1,554.37)
Diluted earnings (loss) per share (Yen)	(65.28)	(1,554.37)

(Consolidated Statement of Comprehensive Income)

(Consolidated Statement of Comprehensive meonic)		(in millions of yen)
	Previous fiscal year (from April 1, 2020 to March 31, 2021)	Current fiscal year (from April 1, 2021 to March 31, 2022)
Profit (loss)	(4,273)	(105,652)
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(565)	(1,808)
Remeasurements of defined benefit plans	53	(132)
Share of other comprehensive income of investments accounted for using equity method	(0)	-
Total of items that will not be reclassified to profit or loss	(512)	(1,940)
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	2,206	5,241
Total of items that may be reclassified to profit or loss	2,206	5,241
Other comprehensive income (net of tax)	1,693	3,300
Comprehensive income	(2,579)	(102,352)
Comprehensive income attributable to:		
Owners of parent	(2,504)	(101,737)
Non-controlling interests	(75)	(614)
Comprehensive income	(2,579)	(102,352)
·		-

(3) Consolidated Statement of Changes in Equity

Previous Fiscal Year (from April 1, 2020 to March 31, 2021)

(in millions of yen)

				(in millio	ns of yen)	
Equity attributable to owners of parent						
						nponents 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 comprehensi ve income
23,360	21,896	9,918	(2,562)	57,365	4,339	1,235
				(4,179)		
					2,187	(565)
-	-	-	-	(4,179)	2,187	(565)
				(440)		
			(0)			
	(85)		289			
	86			(86)		
	(1)		6			
				29		
				(1,919)		
				53		
-	-	-	295	(2,363)	-	-
23,360	21,896	9,918	(2,267)	50,822	6,526	669
	capital 23,360	capital surplus 23,360 21,896 (85) 86 (1)	Share capital surplus Other equity instruments 23,360 21,896 9,918 (85) (85) 86 (1)	Share capital surplus Other equity instruments Shares 23,360 21,896 9,918 (2,562) (0) (85) 289 86 (1) 6	Share capital Capital surplus Other equity instruments Treasury shares Retained earnings 23,360 21,896 9,918 (2,562) 57,365 (4,179) - - - - (4,179) (440) (0) (440) (85) 289 (86) (1) 6 (1,919) (1) 53 (2,363)	Share capital Capital surplus Other equity instruments Treasury shares Retained capital Exchange differences on translation of forcign operations 23,360

Equity attributable to owners of parent

	Other co	Other components of equity			Non-	
	Remeasure- ments of defined benefit plans	Others	Total	Total	controlling interests	Total equity
Balance as of April 1, 2020	-	274	5,848	115,826	1,343	117,170
Loss			-	(4,179)	(93)	(4,273)
Other comprehensive income	53		1,675	1,675	18	1,693
Total comprehensive income	53	-	1,675	(2,504)	(75)	(2,579)
Distributions to owners of other equity instruments			-	(440)		(440)
Purchase of treasury shares			-	(0)		(0)
Disposal of treasury shares			-	204		204
Transfer of loss on disposal of treasury shares			-	-		-
Exercise of share acquisition rights		(4)	(4)	0		0
Forfeiture of share acquisition rights		(29)	(29)	-		-
Dividends (Note)			-	(1,919)		(1,919)
Transfer from other components of equity	(53)		(53)	-		-
Total transactions with owners	(53)	(34)	(87)	(2,155)	-	(2,155)
Balance as of March 31, 2021		240	7,437	111,167	1,268	112,435

(Note)

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

(in millions of yen)

Equity	y attributable t	o owners	of parent
Lquit	, attiioataoic t	O O WILLIAM	or purcin

<u>_</u>			Equity attito	utable to own	ers or parent		
						Other compo	onents of equity
	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, 2021	23,360	21,896	9,918	(2,267)	50,822	6,526	669
Loss					(104,984)		
Other comprehensive income						5,187	(1,808)
Total comprehensive income	-	-	-	-	(104,984)	5,187	(1,808)
Issuance of new shares	2,615	2,615					
Direct issuance expenses due to issuance of new shares		(23)					
Distributions to owners of other equity instruments					(439)		
Purchase of treasury shares				(0)			
Disposal of treasury shares		(58)		133			
Transfer of loss on disposal of treasury shares		58			(58)		
Exercise of share acquisition rights		(3)		8			
Forfeiture of share acquisition rights					39		
Dividends (Note)					(641)		
Equity transactions with non-controlling interests and other		(236)					
Transfer to capital surplus from retained earnings		263			(263)		
Transfer from other components of equity					(131)		(1)
Total transactions with owners	2,615	2,615	-	142	(1,495)	-	(1)
Balance as of March 31, 2022	25,975	24,511	9,918	(2,124)	(55,657)	11,714	(1,139)

Equity attributable to owners of parent

	Other components of equity		quity		Non-	
	Remeasure- ments of defined benefit plans	Others	Total	Total	controlling interests	Total equity
Balance as of April 1, 2021	-	240	7,437	111,167	1,268	112,435
Loss			-	(104,984)	(668)	(105,652)
Other comprehensive income	(132)		3,246	3,246	53	3,300
Total comprehensive income	(132)	-	3,246	(101,737)	(614)	(102,352)
Issuance of new shares			-	5,231		5,231
Direct issuance expenses due to issuance of new shares			-	(23)		(23)
Distributions to owners of other equity instruments			-	(439)		(439)
Purchase of treasury shares			-	(0)		(0)
Disposal of treasury shares			-	74		74
Transfer of loss on disposal of treasury shares			-	-		-
Exercise of share acquisition rights		(5)	(5)	0		0
Forfeiture of share acquisition rights		(39)	(39)	-		-
Dividends (Note)			-	(641)		(641)
Equity transactions with non-controlling interests and other			-	(236)	(274)	(510)
Transfer to capital surplus from retained earnings			-	-		-
Transfer from other components of equity	132		131			
Total transactions with owners	132	(44)	86	3,964	(274)	3,690
Balance as of March 31, 2022	-	195	10,770	13,394	379	13,773

(Note)

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

(4) Consolidated Statement of Cash Flows

		(in millions of yen)
	Previous fiscal year (from April 1, 2020 to March 31, 2021)	Current fiscal year (from April 1, 2021 to March 31, 2022)
Net cash provided by (used in) operating activities		
Profit (loss) before tax	1,068	(107,842)
Depreciation and amortization	13,217	12,653
Impairment loss	5,950	84,130
Increase (decrease) in allowance for doubtful receivables	(8)	928
Loss (gain) on sales and retirement of property, plant and equipment and intangible assets	31	161
Interest and dividend income	(124)	(227)
Interest expenses	543	714
Foreign exchange losses (gains)	(755)	(2,146)
Gain on discounted purchases	(12,275)	-
Share of loss (profit) of investments accounted for using equity method	(432)	(203)
Loss (gain) on sale of investments in associates	-	(363)
Decrease (increase) in trade and other receivables	(2,769)	5,525
Decrease (increase) in inventories	(1,739)	2,019
Increase (decrease) in trade and other payables	3,783	(16,710)
Increase (decrease) in contract liabilities	(105)	813
Increase (decrease) in refund liabilities	(650)	(402)
Increase (decrease) in deposits received	102	(941)
Other	(484)	952
Subtotal	5,351	(20,938)
Dividends received	81	92
Interest received	15	2
Interest paid	(535)	(725)
Income taxes paid	(423)	(2,833)
Income taxes refund	518	154
Net cash provided by (used in) operating activities	5,006	(24,248)

_	(in millions of ye		
	Previous fiscal year (from April 1, 2020 to March 31, 2021)	Current fiscal year (from April 1, 2021 to March 31, 2022)	
Cash flows from investing activities			
Purchase of property, plant and equipment	(6,360)	(3,481)	
Proceeds from sale of property, plant and equipment	-	950	
Purchase of intangible assets	(12,767)	(12,332)	
Proceeds from sale of investments accounted for using equity method	-	2,500	
Collection of loans receivable	255	-	
Proceeds from collection of deposits	-	3,290	
Payments of deposits	(3,290)	-	
Payments for acquisition of subsidiaries	(7,039)	(108)	
Other	(130)	(133)	
Net cash provided by (used in) investing activities	(29,334)	(9,315)	
Cash flows from financing activities			
Net increase (decrease) in short-term borrowings	15,394	6,265	
Proceeds from long-term borrowings	9,200	15,100	
Repayments of long-term borrowings	(9,479)	(9,189)	
Proceeds from issuance of common shares	-	5,207	
Proceeds from sale and leaseback transactions	-	5,641	
Proceeds from sale of treasury shares	204	74	
Repayments of lease liabilities	(2,093)	(2,338)	
Dividends paid	(1,918)	(644)	
Distributions to owners of other equity instruments	(440)	(439)	
Other	(0)	(0)	
Net cash provided by (used in) financing activities	10,867	19,677	
Effect of exchange rate changes on cash and cash equivalents	(341)	49	
Net increase (decrease) in cash and cash equivalents	(13,801)	(13,837)	
Cash and cash equivalents at beginning of period	42,944	29,142	
Cash and cash equivalents at end of period	29,142	15,305	

(5) Notes to Consolidated Financial Statements

(Notes on premise of going concern)

Since April 2021, the Group has gradually resumed production and release Toyama Plant 1 while conducting stringent quality control checks such as FMEA, 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 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 current 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.

As a result of the above, large operating losses have occurred and operating cash flow expenditures have been exceeded, and we are therefore in a situation in which material uncertainties have arisen regarding entity's ability to continue as a 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 end of 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, financial institutions and others have agreed on matters related to financial covenants and on extending the benefits of long-term loans that are due for repayment in March 2022. In addition, a formal application for a Business Turnaround ADR was submitted on May 13, 2022 and was accepted on the same date. Going forward, we will proceed with discussions with the relevant companies in the Business Turnaround ADR, including pre-DIP financing to facilitate smooth business operations. With regard to further funding, we have received proposals from sponsor candidates at this stage, and we are in consultation with them.

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 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 consolidated financial statements.

(Reporting entity)

Nichi-Iko Pharmaceutical Co., Ltd. (hereinafter referred to as the "Company") is a company incorporated in Japan. The consolidated financial statements of the Company and its subsidiaries (hereinafter referred to as "the Group") with the fiscal closing date at March 31, 2022 are composed of the Company, its subsidiaries and ownership interests in its associates.

The Group is mainly engaged in the manufacture and sale of pharmaceuticals.

(Basis of preparation)

1 Compliance with IFRS

Pursuant to the provision of Article 93 of the Ordinance on Terminology, Forms, and Preparation Methods of Consolidated Financial Statements (Ordinance of the Ministry of Finance No. 28 of 1976; hereinafter referred to as "Ordinance on Consolidated Financial Statements"), the consolidated financial statements of the Group have been prepared in compliance with IFRS since the Group qualifies as a "Specified Company under Designated International Accounting Standards" prescribed in Article 1-2 of the Ordinance on Consolidated Financial Statements.

2 Basis of measurement

The consolidated financial statements have been prepared on a historical cost basis except for financial instruments, etc. measured at fair value or liabilities and assets pertaining to defined benefit plans calculated by deducting the fair value of plan assets from the present value of net defined benefit liability.

3 Presentation currency

The consolidated financial statements of the Group are presented in Japanese yen, which is the Company's functional currency, and figures are rounded down to the nearest million yen.

4 Accounting judgments, estimates and assumptions

In preparing consolidated financial statements, the management is obligated to make judgments, estimates and assumptions that may affect the application of accounting policies and the reported amounts of assets, liabilities, revenue and expenses. Actual results may differ from these estimates.

The main accounting judgments, estimates and assumptions are as follows.

Accounting judgments

Recognition of intangible assets arising from development

Estimates and assumptions

- Significant assumptions used in the sales plans for Infliximab BS
- Significant assumptions used for calculation of discounted cash flows in impairment test of property, plant and equipment, goodwill and intangible assets
- Recoverability of deferred tax assets

• Actuarial assumptions

(Segment information, etc.)

(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.

Previous Fiscal Year (from April 1, 2020 to March 31, 2021)

(in millions of ven)

(iii iiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii					
	Reportable segment				
	Nichi-Iko Group	Sagent Group	Total	Adjustment	Consolidated
Revenue					
External revenue	152,481	36,289	188,770	-	188,770
Inter-segment revenue	-	ı	1	1	-
Total	152,481	36,289	188,770	-	188,770
Segment profit (loss) (Core operating profit)	2,995	(2,017)	977		977
(Note)	2,993	(2,017)	711	-	711

(Note)

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

Current Fiscal Year (from April 1, 2021 to March 31, 2022)

(in millions of yen)

	Re	Reportable segment			
	Nichi-Iko Group	Sagent Group	Total	Adjustment	Consolidated
Revenue		-			
External revenue	139,027	40,056	179,084	-	179,084
Inter-segment revenue	-	18	18	(18)	-
Total	139,027	40,074	179,102	(18)	179,084
Segment profit (loss)					
(Core operating profit)	(14,017)	(2,759)	(16,776)	-	(16,776)
(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 consolidated financial statements has been adjusted as follows.

(in millions of yen)

		` '
	Previous fiscal year (from April 1, 2020 to March 31, 2021)	Current fiscal year (from April 1, 2021 to March 31, 2022)
Total revenue	188,770	179,084
Provisions for returns in voluntary recall	552	24
Revenue on consolidated financial statements	188,218	179,060

(in millions of yen)

<u></u>	1	(III IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII
	Previous fiscal year (from April 1, 2020 to March 31, 2021)	Current fiscal year (from April 1, 2021 to March 31, 2022)
Total segment profit (loss)	977	(16,776)
Integration-related expenses	196	25
Impairment loss on development costs	5,950	24,750
Goodwill impairment loss	-	30,337
Impairment loss on fixed assets	-	29,042
Loss on valuation of Infliximab	3,585	280
Voluntary recall expenses	2,158	351
Loss on valuation of inventory (Note 1)	1,253	7,389
Plant downtime loss (Note 2)	-	1,097
Gain on discounted purchases	(12,275)	-
Operating profit (loss)	107	(110,051)
Finance income	1,330	3,133
Finance costs	801	1,128
Share of profit (loss) of investments accounted for using equity method	432	203
Profit (loss) before tax on consolidated financial statements	1,068	(107,842)

(*Note 1*)

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

(*Note 2*)

Fixed costs incurred during the suspension of plant operations due to the review of the production facilities of the Sagent Group's SterRx were recorded.

(2) Information about products and services

Revenue from each product and service is as follows.

Previous Fiscal Year (from April 1, 2020 to March 31, 2021)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Treatments for blood and body fluid	27,217	-	27,217
Treatments for circulatory system	28,932	-	28,932
Antibiotics	8,400	8,972	17,372
Treatments for paramedics	-	15,950	15,950
Treatments for nervous system	18,397	-	18,397
Treatments for digestive system	16,063	-	16,063
Treatments for allergies	14,341	-	14,341
Chemotherapeutics	2,429	10,322	12,752
Other	36,698	1,045	37,743
Total	152,481	36,289	188,770

(Note)

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

Current Fiscal Year (from April 1, 2021 to March 31, 2022)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Treatments for blood and body fluid	21,693	-	21,693
Treatments for circulatory system	21,634	-	21,634
Antibiotics	8,829	10,952	19,782
Treatments for paramedics	-	16,846	16,846
Treatments for nervous system	15,613	-	15,613
Treatments for digestive system	14,599	-	14,599
Treatments for allergies	12,026	-	12,026
Chemotherapeutics	2,463	9,468	11,931
Other	42,167	2,788	44,956
Total	139,027	40,056	179,084

(Note)

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

Previous Fiscal Year (from April 1, 2020 to March 31, 2021)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Sales of merchandise and products	152,364	36,289	188,654
License agreement on sales of products, etc.	116	-	116
Total	152,481	36,289	188,770

(Note)

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

Current Fiscal Year (from April 1, 2021 to March 31, 2022)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Sales of merchandise and products	138,909	40,056	178,966
License agreement on sales of products, etc.	118	-	118
Total	139,027	40,056	179,084

(Note)

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

(3) Information by geographical area

(i) Revenue

Revenue by geographical area is shown below.

Previous Fiscal Year (from April 1, 2020 to March 31, 2021)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Japan	152,284	-	152,284
United States	-	31,647	31,647
Other	196	4,642	4,838
Total	152,481	36,289	188,770

(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.

Current Fiscal Year (from April 1, 2021 to March 31, 2022)

(in millions of yen)

			())
	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Japan	138,648	-	138,648
United States	-	33,991	33,991
Other	379	6,065	6,444
Total	139,027	40,056	179,084

(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.
- (ii) Non-current assets

The breakdown of the carrying amount of non-current assets (excluding financial assets and deferred tax assets) by geographical area is shown below.

(in millions of yen)

	Fiscal year ended March 31, 2021 (as of March 31, 2021)	Fiscal year ended March 31, 2022 (as of March 31, 2022)
Japan	95,501	39,979
United States	71,915	42,627
Canada	14,066	15,078
Others	5	6
Total	181,488	97,693

(4) Information about major customers

Revenue to external customers accounting for 10% or more of revenue is shown below.

(in millions of yen)

Name of customer	Related segment	Previous fiscal year (from April 1, 2020 to March 31, 2021)	Current fiscal year (from April 1, 2021 to March 31, 2022)
Mediceo Corporation	Nichi-Iko Group	39,831	28,480
Takeda Pharmaceutical Company Limited	Nichi-Iko Group	2,421	18,898
Alfresa Corporation	Nichi-Iko Group	26,186	18,428

(Per share information)

The basis for the calculation of basic earnings per share attributed to owners of parent and diluted earnings per share is as follows:

(in millions of yen)

	Previous fiscal year (from April 1, 2020	Current fiscal year (from April 1, 2021
	to March 31, 2021)	to March 31, 2022)
Profit (loss) attributable to owners of parent		
Profit attributable to owners of parent (in millions of yen)	(4,179)	(104,984)
Profit not attributable to common shareholders of parent (in millions of yen)	-	-
Profit used in calculation of earnings per share (in millions of yen)	(4,179)	(104,984)
Weighted average number of shares of common stock (shares)	64,023,932	67,541,284
Dilutive effect of stock options (shares)	-	-
After adjustment for the impact of dilutive effect (shares)	64,023,932	67,541,284
Earnings per share (loss)		
Basic earnings per share (Yen)	(65.28)	(1,554.37)
Diluted earnings per share (Yen)	(65.28)	(1,554.37)

As stock options have a negative dilutive effect in the previous and current fiscal years, this is not included in the calculation of the diluted loss per share.

(Significant subsequent events)

On May 13, 2022, the Company submitted a formal application for the Business Turnaround ADR to the Japanese Association of Turnaround Professionals (an association that has been certified as a certified dispute resolution business operator by the Minister of Justice and has been accredited as a specified certified dispute resolution business operator by the Minister of Economy, Trade and Industry), and it was accepted on the same date. For details, etc. on the Business Turnaround ADR, please see "1. Overview of Operating Results, etc. (5) Significant matters regarding the premise of going concern," and "3. Consolidated Financial Statements and Primary Notes (5) Notes to Consolidated Financial Statements (Notes on premise of going concern)."