

(English Translation)

Consolidated Financial Results
for the Second Quarter of the Fiscal Year Ending March 31, 2023 (IFRS)

November 14, 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
Contact: Shuji Ishida Tel: 076-432-2121
Board Member, Executive Vice
President
Scheduled date of filing of quarterly report: November 14, 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 Second Quarter of the Fiscal Year Ending March 31, 2023 (From April 1, 2022 to September 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
Second quarter of fiscal year ending March 31, 2023	¥91,250 million (6.2%)	-¥8,238 million (-%)	-¥57,844 million (-%)	-¥54,882 million (-%)	-¥55,180 million (-%)	-¥54,817 million (-%)
Second quarter of fiscal year ended March 31, 2022	¥85,931 million (-4.1%)	-¥8,790 million (-%)	-¥14,026 million (-%)	-¥13,626 million (-%)	-¥14,760 million (-%)	-¥14,593 million (-%)

	Total comprehensive income	Basic earnings per share	Diluted earnings per share
Second quarter of fiscal year ending March 31, 2023	-¥49,179 million (-%)	-¥778.12	-¥778.12
Second quarter of fiscal year ended March 31, 2022	-¥14,006 million (-%)	-¥224.30	-¥224.30

(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
Second quarter of fiscal year ending March 31, 2023	¥246,558 million	-¥35,626 million	-¥35,682 million	-14.5%	-¥506.38
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	¥-	¥0.00			
Fiscal year ending March 31, 2023 (forecast)			¥-	¥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 September 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 September 30, 2022 916,293 shares

As of March 31, 2022 948,131 shares

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

Second quarter of fiscal year ending March 31, 2023 70,449,168 shares

Second quarter of fiscal year ended March 31, 2022 65,061,333 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 Monday, November 14, 2022.

Attachment – Contents

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

(1) Explanation on Operating Results

In the cumulative second quarter under review, the Japanese economy progressed toward normalization of economic activity as COVID-19 settled overall despite the expansion of the seventh wave, but the outlook is uncertain due to the prolongation of the Ukraine situation and the upward pressure on prices caused by the rapid devaluation of the yen.

In the generic drug industry, in addition to the NHI drug price revision at the start of the fiscal year, further enhancement of steps to address issues in quality and stable supply continues to be required, and there is also a strong need to strengthen profitability and also strengthen the safe, secure and stable production and supply system.

As stated in the press release entitled “Notice Regarding Recording of Impairment Loss” dated November 8, 2022 and the press release entitled “(Progress of Disclosed Matter) Notice Regarding Recording of Impairment Loss” dated November 14, 2022, the Company had liability in excess of assets at the end of the second quarter of the current fiscal year, but in addition to steadily taking steps aimed at improvement of performance, the Company is proceeding to hold discussions with relevant companies with the aim of formulating a business turnaround plan in an effort to achieve a business turnaround, continue business and improve the financial position under the business turnaround utilizing the specified certified dispute resolution procedure (the “Business Turnaround ADR”) under the Act on Strengthening Industrial Competitiveness, for which a formal application was filed in May 13, 2022.

A. Results by segment

(in millions of yen)	Nichi-Iko Group			Sagent Group		
	Second quarter of fiscal year ended March 31, 2022	Second quarter of fiscal year ending March 31, 2023	Change	Second quarter of fiscal year ended March 31, 2022	Second quarter of fiscal year ending March 31, 2023	Change
Revenue	65,614	69,548	+3,934	20,316	21,755	+1,438
Core operating profit	-8,137	-4,841	+3,296	-652	-3,397	-2,745

(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 quantity while ensuring quality at Toyama Plant 1, and although it is taking longer than originally expected to resume some shipments mainly due to the stringent quality checks and other measures, we are making company-wide efforts to expand these shipments as quickly as possible.

Results in the Nichi-Iko Group during the cumulative second quarter of the current fiscal year showed revenue of 69,548 million yen (an increase of 3,934 million yen year-on-year) and segment loss of 4,841 million yen, an improvement of 3,296 million yen year-on-year, due in part to an increase in sales volume and the effects of measures ensuring appropriate inventories and use of expenses despite a fall in sale prices caused by the drug price revision.

(ii) Sagent Group

In Sagent Group, as a result of impairment testing performed based on the decline in business conditions during the cumulative second quarter of the current fiscal year and future business operations in the US market, we recorded significant impairment loss of 47,417 million yen during the cumulative second quarter of the current fiscal year on fixed assets including goodwill held by Sagent Group.

Results in Sagent Group during the cumulative second quarter of the current fiscal year showed revenue of 21,755 million yen (an increase of 1,438 million yen year-on-year) due to a significant weakening of the yen, but a segment loss of 3,397 million yen (a deterioration of 2,745 million yen year-on-year) due mainly to the delay in resumption from suspension of plant operation amid the review of production facilities at SterRx, production volume being lower than anticipated at the Raleigh Plant and the delay of deliveries from manufacturing subcontractors.

B. Group Results

(in millions of yen)	Second quarter of fiscal year ended March 31, 2022	Second quarter of fiscal year ending March 31, 2023	Change
Revenue	85,931	91,250	+5,319
Core operating profit	- 8,790	-8,238	+551
Operating profit	-14,026	-57,844	-43,818
Profit before tax	-13,626	-54,882	-41,256
Profit attributable to owners of parent	-14,593	-54,817	-40,224
Diluted earnings per share	-¥224.30	-¥778.12	-¥553.82

(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 5,319 million yen year-on-year due mainly to an increase in the sales volume of the Nichi-Iko Group and the impact of the weak yen in the Sagent Group.

Core operating profit improved by 551 million yen year-on-year due to improvement in the Nichi-Iko Group despite a deterioration in the Sagent Group.

Operating profit deteriorated by 43,818 million yen due to the recording of impairment loss on fixed assets including goodwill in the Sagent Group, and the recording of 1,239 million yen in impairment loss on development costs and 823 million yen in business restructuring expenses in the Nichi-Iko Group.

Profit before tax deteriorated by 41,256 million yen year-on-year and profit attributable to owners of parent deteriorated by 40,224 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 second quarter of the current fiscal year decreased by 14,001 million yen from the previous fiscal year-end to 246,558 million yen. The main factors were as follows.

	Increase (decrease) (in millions of yen)	Main factors
Trade and other receivables	+31,732	Decrease in liquidation of receivables
Inventories	-8,618	Review of inventories to an appropriate level
Goodwill	-18,479	Recording of impairment loss
Intangible assets	-17,442	Recording of impairment loss

Liabilities on a consolidated basis at the end of the second quarter of the current fiscal year increased by 35,398 million yen from the previous fiscal year-end to 282,184 million yen. The main factors were as follows.

	Increase (decrease) (in millions of yen)	Main factors
Trade and other payables	-7,472	Decrease in trade payables associated with review of inventories to an appropriate level
Borrowings	+38,314	Procurement of working capital
Other financial liabilities	+5,549	Increase in lease liabilities

Equity on a consolidated basis at the end of the second quarter of the current fiscal year decreased by 49,400 million yen from the previous fiscal year-end to -35,626 million yen. The main factors were as follows.

	Increase (decrease) (in millions of yen)	Main factors
Retained earnings	-55,058	Recording of loss
Other components of equity	+5,909	Increase in exchange differences on translation of foreign operations due to yen depreciation and fair value adjustments of shareholdings

(ii) Consolidated Cash Flows

At the end of the second quarter of the current fiscal year, cash and cash equivalents on a consolidated basis decreased by 2,316 million yen from the previous fiscal year-end to 12,989 million yen.

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

(Cash flows from operating activities)

Net cash used in operating activities during the cumulative second quarter of the current fiscal year amounted to 34,624 million yen mainly due to a decrease in trade receivables caused by a decrease in liquidation of receivables. The main factors were as follows.

Details	Increase (decrease) (in millions of yen)
Recording of loss before tax	-54,882
Recording of impairment loss	48,702
Decrease in inventories	10,956
Increase in trade and other receivables	-31,230
Decrease in trade and other payables	-8,481

(Cash flows from investing activities)

Net cash used in investing activities during the cumulative second quarter of the current fiscal year amounted to 2,439 million yen. The main factors were as follows.

Details	Increase (decrease) (in millions of yen)
Purchase of property, plant and equipment	-1,843
Purchase of intangible assets	-1,957
Proceeds from settlement of contingent considerations	1,053

(Cash flows from financing activities)

Net cash provided by financing activities during the cumulative second quarter of the current fiscal year amounted to 34,099 million yen. The main factor was as follows.

Details	Increase (decrease) (in millions of yen)
Net increase in borrowings	35,724

(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)	Second quarter of fiscal year ending March 31, 2023 (as of September 30, 2022)
Assets		
Current assets		
Cash and cash equivalents	15,305	12,989
Trade and other receivables	38,605	70,338
Inventories	95,745	87,127
Other financial assets	425	355
Other current assets	5,309	4,031
Subtotal	155,391	174,841
Assets held for sale	-	2,283
Total current assets	155,391	177,124
Non-current assets		
Property, plant and equipment	39,289	35,894
Goodwill	18,479	-
Intangible assets	39,609	22,167
Investments accounted for using equity method	68	68
Other financial assets	7,465	11,067
Deferred tax assets	9	6
Other non-current assets	246	229
Total non-current assets	105,167	69,433
Total assets	260,559	246,558

	(in millions of yen)	
	Fiscal year ended March 31, 2022 (as of March 31, 2022)	Second quarter of fiscal year ending March 31, 2023 (as of September 30, 2022)
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	48,123	40,650
Borrowings	85,529	129,138
Other financial liabilities	2,095	2,629
Income taxes payable	480	1,241
Refund liabilities	2,349	2,311
Contract liabilities	209	213
Other current liabilities	8,683	6,372
Total current liabilities	147,471	182,556
Non-current liabilities		
Borrowings	77,102	71,808
Other financial liabilities	8,396	13,411
Retirement benefit liability	1,190	1,223
Provisions	79	61
Refund liabilities	58	59
Contract liabilities	1,363	1,283
Deferred tax liabilities	10,160	10,685
Other non-current liabilities	964	1,093
Total non-current liabilities	99,314	99,627
Total liabilities	246,785	282,184
Equity		
Share capital	25,975	25,975
Capital surplus	24,511	24,511
Other equity instruments	9,918	9,918
Treasury shares	(2,124)	(2,053)
Retained earnings	(55,657)	(110,715)
Other components of equity	10,770	16,679
Total equity attributable to owners of parent	13,394	(35,682)
Non-controlling interests	379	56
Total equity	13,773	(35,626)
Total liabilities and equity	260,559	246,558

(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)	
	Second quarter of previous fiscal year (from April 1, 2021 to September 30, 2021)	Second quarter of current fiscal year (from April 1, 2022 to September 30, 2022)
Revenue	85,931	91,250
Cost of sales	85,079	99,078
Gross profit (loss)	851	(7,828)
Selling, general and administrative expenses	13,483	13,729
Research and development expenses	1,819	2,226
Other operating income	751	467
Other operating expenses	327	34,528
Operating profit (loss)	(14,026)	(57,844)
Finance income	628	4,371
Finance costs	427	1,409
Share of profit (loss) of investments accounted for using equity method	199	-
Profit (loss) before tax	(13,626)	(54,882)
Income tax expense	1,134	297
Profit (loss)	(14,760)	(55,180)
Profit attributable to:		
Owners of parent	(14,593)	(54,817)
Non-controlling interests	(167)	(362)
Profit (loss)	(14,760)	(55,180)
Earnings per share		
Basic earnings (loss) per share (Yen)	(224.30)	(778.12)
Diluted earnings (loss) per share (Yen)	(224.30)	(778.12)

(Condensed Quarterly Consolidated Statement of Comprehensive Income)

(in millions of yen)

	Second quarter of previous fiscal year (from April 1, 2021 to September 30, 2021)	Second quarter of current fiscal year (from April 1, 2022 to September 30, 2022)
Profit (loss)	(14,760)	(55,180)
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	97	3,462
Total of items that will not be reclassified to profit or loss	97	3,462
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	656	2,538
Total of items that may be reclassified to profit or loss	656	2,538
Other comprehensive income (net of tax)	753	6,000
Comprehensive income	(14,006)	(49,179)
Comprehensive income attributable to:		
Owners of parent	(13,848)	(48,856)
Non-controlling interests	(158)	(322)
Comprehensive income	(14,006)	(49,179)

(3) Condensed Quarterly Consolidated Statement of Changes in Equity

Second Quarter of Previous Fiscal Year (from April 1, 2021 to September 30, 2021)

(in millions of yen)

	Equity attributable to owners of parent					Other components 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 comprehensive income
Balance as of April 1, 2021	23,360	21,896	9,918	(2,267)	50,822	6,526	669
Profit (loss)					(14,593)		
Other comprehensive income						648	97
Total comprehensive income	-	-	-	-	(14,593)	648	97
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					(220)		
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					1		(1)
Total transactions with owners	2,615	2,615	-	142	(1,143)	-	(1)
Balance as of September 30, 2021	25,975	24,511	9,918	(2,124)	35,084	7,174	765

	Equity attributable to owners of parent		Total	Non-controlling interests	Total
	Other components of equity				
	Others	Total			
Balance as of April 1, 2021	240	7,437	111,167	1,268	112,435
Profit (loss)		-	(14,593)	(167)	(14,760)
Other comprehensive income		745	745	8	753
Total comprehensive income	-	745	(13,848)	(158)	(14,006)
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		-	(220)		(220)
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		(1)	-		-
Total transactions with owners	(44)	(46)	4,183	(274)	3,909
Balance as of September 30, 2021	195	8,136	101,502	835	102,337

(Note)

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

Second Quarter of Current Fiscal Year (from April 1, 2022 to September 30, 2022)

(in millions of yen)

	Equity attributable to owners of parent					Other components 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 comprehensive income
Balance as of April 1, 2022	25,975	24,511	9,918	(2,124)	(55,657)	11,714	(1,139)
Profit (loss)					(54,817)		
Other comprehensive income						2,498	3,462
Total comprehensive income	-	-	-	-	(54,817)	2,498	3,462
Distributions to owners of other equity instruments					(220)		
Purchase of treasury shares				(0)			
Transfer of loss on disposal of treasury shares		20			(20)		
Exercise of share acquisition rights		(20)		71			
Total transactions with owners	-	-	-	71	(240)	-	-
Balance as of September 30, 2022	25,975	24,511	9,918	(2,053)	(110,715)	14,212	2,322

	Equity attributable to owners of parent			Non-controlling interests	Total
	Other components of equity		Total		
	Others	Total			
Balance as of April 1, 2022	195	10,770	13,394	379	13,773
Profit (loss)		-	(54,817)	(362)	(55,180)
Other comprehensive income		5,960	5,960	39	6,000
Total comprehensive income	-	5,960	(48,856)	(322)	(49,179)
Distributions to owners of other equity instruments		-	(220)		(220)
Purchase of treasury shares		-	(0)		(0)
Transfer of loss on disposal of treasury shares		-	-		-
Exercise of share acquisition rights	(51)	(51)	0		0
Total transactions with owners	(51)	(51)	(220)	-	(220)
Balance as of September 30, 2022	144	16,679	(35,682)	56	(35,626)

(4) Condensed Quarterly Consolidated Statement of Cash Flows

(in millions of yen)

	Second quarter of previous fiscal year (from April 1, 2021 to September 30, 2021)	Second quarter of current fiscal year (from April 1, 2022 to September 30, 2022)
Cash flows from operating activities		
Profit (loss) before tax	(13,626)	(54,882)
Depreciation and amortization	6,171	5,138
Impairment loss	212	48,702
Interest and dividend income	(144)	(136)
Interest expenses	301	928
Share of loss (profit) of investments accounted for using equity method	(199)	-
Loss (gain) on sale of investments in associates	(363)	-
Foreign exchange losses (gains)	6	(3,556)
Decrease (increase) in trade and other receivables	2,425	(31,230)
Decrease (increase) in inventories	(4,508)	10,956
Increase (decrease) in trade and other payables	(8,796)	(8,481)
Increase (decrease) in refund liabilities	(639)	(37)
Increase (decrease) in deposits received	(1,060)	(1,529)
Other	600	717
Subtotal	(19,619)	(33,411)
Dividends received	76	46
Interest received	1	1
Interest paid	(331)	(883)
Income taxes paid	(140)	(398)
Income taxes refund	154	20
Net cash provided by (used in) operating activities	(19,859)	(34,624)
Cash flows from investing activities		
Purchase of property, plant and equipment	(2,090)	(1,843)
Purchase of intangible assets	(7,937)	(1,957)
Proceeds from sale of investments accounted for using equity method	2,500	-
Proceeds from settlement of contingent considerations	-	1,053
Other	(152)	307
Net cash provided by (used in) investing activities	(7,680)	(2,439)

(in millions of yen)

	Second quarter of previous fiscal year (from April 1, 2021 to September 30, 2021)	Second quarter of current fiscal year (from April 1, 2022 to September 30, 2022)
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	5,669	35,836
Proceeds from long-term borrowings	14,170	-
Repayments of long-term borrowings	(5,276)	(112)
Proceeds from issuance of common shares	5,207	-
Proceeds from sale and leaseback transactions	5,641	-
Repayments of lease liabilities	(1,106)	(1,268)
Dividends paid	(641)	(2)
Distributions to owners of other equity instruments	(220)	(220)
Other	74	(133)
Net cash provided by (used in) financing activities	23,517	34,099
Effect of exchange rate changes on cash and cash equivalents	(154)	648
Net increase (decrease) in cash and cash equivalents	(4,177)	(2,316)
Cash and cash equivalents at beginning of period	29,142	15,305
Cash and cash equivalents at end of period	24,965	12,989

(5) Notes to Condensed Quarterly Consolidated Financial Statements

(Notes on premise of going concern)

Since April 2021, the Group has gradually resumed production and shipment 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 reorganizing 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 second quarter of the current fiscal year, operating loss was 57,844 million yen and loss attributable to owners of parent was 54,817 million yen due mainly to the fall in sale prices resulting from the drug price revisions, the recording of impairment on development costs for products that ceased to be developed, impairment of fixed assets including goodwill in the Sagent Group associated with the review of future business operations in the US market, delays in the resumption of product shipments manufactured at Toyama Plant 1, and the impact of the suspension of plant operation amid the review of production facilities at SterRx, resulting on liability in excess of assets totaling 35,626 million yen at the end of the second quarter of the current fiscal year.

As a result of the above, there have been ongoing operating losses and losses attributable to owners of parent leading to liability in excess of assets at the end of the second quarter of the current fiscal year, and there are events or circumstances causing significant doubts about the premise of going concern.

In order to resolve this situation, the 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.

Second Quarter of Previous Fiscal Year (from April 1, 2021 to September 30, 2021)

(in millions of yen)

	Reportable segments			Adjustment	Consolidated
	Nichi-Iko Group	Sagent Group	Total		
Revenue					
External revenue	65,614	20,316	85,930	-	85,930
Inter-segment revenue	-	18	18	(18)	-
Total	65,614	20,334	85,948	(18)	85,930
Segment profit (loss) (Core operating profit) (Note)	(8,137)	(652)	(8,790)	-	(8,790)

(Note)

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

Second Quarter of Current Fiscal Year (from April 1, 2022 to September 30, 2022)

(in millions of yen)

	Reportable segments			Adjustment	Consolidated
	Nichi-Iko Group	Sagent Group	Total		
Revenue					
External revenue	69,548	21,755	91,303	-	91,303
Inter-segment revenue	-	37	37	(37)	-
Total	69,548	21,792	91,340	(37)	91,303
Segment profit (loss) (Core operating profit) (Note)	(4,841)	(3,397)	(8,238)	-	(8,238)

(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)

	Second quarter of previous fiscal year (from April 1, 2021 to September 30, 2021)	Second quarter of current fiscal year (from April 1, 2022 to September 30, 2022)
Total revenue	85,930	91,303
Provisions for returns in voluntary recall	(1)	53
Revenue on condensed quarterly consolidated financial statements	85,931	91,250

(in millions of yen)

	Second quarter of previous fiscal year (from April 1, 2021 to September 30, 2021)	Second quarter of current fiscal year (from April 1, 2022 to September 30, 2022)
Segment profit (loss)	(8,790)	(8,238)
Impairment loss on development costs	212	19,134
Goodwill impairment loss	-	20,269
Impairment loss on fixed assets	-	9,297
Loss on valuation of Infiximab	-	219
(Reversal of) loss on valuation of inventory (Note)	4,837	(459)
Integration-related expenses	24	-
Voluntary recall expenses	161	292
Business restructuring expenses	-	851
Operating profit (loss)	(14,026)	(57,844)
Finance income	628	4,371
Finance costs	427	1,409
Share of profit (loss) of investments accounted for using equity method	199	-
Profit (loss) before tax	(13,626)	(54,882)

(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.

Second Quarter of Previous Fiscal Year (from April 1, 2021 to September 30, 2021)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Sales of merchandise and products			
Treatments for paramedics	-	9,658	9,658
Treatments for circulatory system	10,154	-	10,154
Antibiotics	4,202	5,544	9,746
Treatments for blood and body fluid	9,807	-	9,807
Treatments for nervous system	7,353	-	7,353
Treatments for digestive system	7,026	-	7,026
Treatments for external use	5,185	-	5,185
Other metabolic pharmaceuticals	4,880	-	4,880
Other	17,004	5,113	22,118
Total	65,614	20,316	85,930

(Note)

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

Second Quarter of Current Fiscal Year (from April 1, 2022 to September 30, 2022)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Sales of merchandise and products			
Treatments for paramedics	-	12,810	12,810
Treatments for circulatory system	11,250	-	11,250
Antibiotics	4,984	5,160	10,144
Treatments for blood and body fluid	9,624	-	9,624
Treatments for nervous system	8,638	-	8,638
Treatments for digestive system	7,252	-	7,252
Treatments for external use	5,379	-	5,379
Other metabolic pharmaceuticals	5,257	-	5,257
Other	17,160	3,784	20,944
Total	69,548	21,755	91,303

(Note)

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

Second Quarter of Previous Fiscal Year (from April 1, 2021 to September 30, 2021)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Sales of merchandise and products	65,554	20,316	85,870
License agreement on sales of products, etc.	59	-	59
Total	65,614	20,316	85,930

(Note)

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

Second Quarter of Current Fiscal Year (from April 1, 2022 to September 30, 2022)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Sales of merchandise and products	69,438	21,755	91,193
License agreement on sales of products, etc.	109	-	109
Total	69,548	21,755	91,303

(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.

Second Quarter of Previous Fiscal Year (from April 1, 2021 to September 30, 2021)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Japan	65,453	-	65,453
United States	-	17,189	17,189
Other	160	3,126	3,287
Total	65,614	20,316	85,930

(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.

Second Quarter of Current Fiscal Year (from April 1, 2022 to September 30, 2022)

(in millions of yen)

	Reportable segments		
	Nichi-Iko Group	Sagent Group	Total
Japan	69,371	-	69,371
United States	-	18,550	18,550
Other	176	3,204	3,380
Total	69,548	21,755	91,303

(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 shipment 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 reorganizing 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.

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