(English Translation)

Consolidated Financial Results for the Second Quarter of the Fiscal Year Ending March 31, 2019 (IFRS)

November 9, 2018

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: Noboru Inasaka, Board of Executive Director, Head of Administrative Division Tel: 076-432-2121

Scheduled date of filing of quarterly report: November 12, 2018
Scheduled date of commencement of dividend payment: December 11, 2018
Presentation of supplementary materials on quarterly financial results: Yes
Holding of quarterly financial presentation meeting: Yes

(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, 2019 (From April 1, 2018 to September 30, 2018)

(1) Consolidated Results of Operations (cumulative)

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

	Revenue	Operating profit	Profit before tax	Profit	Profit attributable to owners of parent	Total comprehen-sive income
Second quarter of fiscal year ending March 31, 2019	¥82,346 million (-0.9%)	¥4,720 million (75.1%)	¥5,727 million (119.1%)	¥4,620 million (88.8%)	¥4,620 million (88.8%)	¥10,342 million (130.8%)
Second quarter of fiscal year ended March 31, 2018	¥83,060 million (-%)	¥2,695 million (-%)	¥2,613 million (-%)	¥2,446 million (-%)	¥2,446 million (-%)	¥4,480 million (-%)

	Basic earnings per share	Diluted earnings per share
Second quarter of fiscal year ending March 31, 2019	¥80.93	¥79.79
Second quarter of fiscal year ended March 31, 2018	¥43.45	¥43.38

(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, 2019	¥281,722 million	¥100,646 million	¥100,646 million	35.7%	¥1,700.96
Fiscal year ended March 31, 2018	¥278,364 million	¥87,542 million	¥87,542 million	31.4%	¥1,550.65

2. Dividends

	Annual dividends per share				
	First quarter	Second quarter	Third quarter	Year-end	Total
Fiscal year ended March 31, 2018	¥-	¥15.00	¥-	¥15.00	¥30.00
Fiscal year ending March 31, 2019	¥-	¥15.00			
Fiscal year ending March 31, 2019 (forecast)			¥-	¥15.00	¥30.00

(Note)
Revisions to recently announced dividends forecast: None

3. Forecast of Consolidated Financial Results for the Fiscal Year Ending March 31, 2019 (From April 1, 2018 to March 31, 2019)

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

	Revenue	Operating profit	Profit attributable to owners of parent	Basic earnings per share
Annual	¥170,000 million (3.2%)	¥9,500 million (-7.8%)	¥7,000 million (-13.3%)	¥118.99

(Note)
Revisions to recently announced forecast of financial results: None
For details, please refer to "Notice Concerning Revisions of Forecast of Consolidated Financial Results for the Fiscal Year Ending March 31, 2019" announced on Wednesday, November 7, 2018 and "(3) Explanation of Forecast of Consolidated Financial Results and Other Forward-looking Statements" in "1. Qualitative Information on Financial Results for the Quarter under Review" on page 4 of the Attachment.

***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:	Yes
(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, 2018	60,662,652 shares
As of March 31, 2018	60,662,652 shares

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

As of September 30, 2018	1,492,505 shares
As of March 31, 2018	4,207,195 shares

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

Second quarter of fiscal year ending March 31, 2019	57,088,597 shares
Second quarter of fiscal year ended March 31, 2018	56,313,303 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, November 9, 2018.

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

The Group (the Company and the Company's subsidiaries and associates) has applied International Financial Reporting Standards (IFRS) in place of previous Japan GAAP, effective from the previous fiscal year (from April 1, 2017 to March 31, 2018).

(1) Explanation on Operating Results

In the cumulative second quarter under review, although there was still a concern over the impact that intensifying trade friction between the United States and China starting in the United States has on the global economy and the rate of growth in Japan temporarily slowed due to the typhoon that hit western Japan and the earthquake that occurred in Hokkaido, the domestic economy is continuing a trend of gradual recovery that continues to be supported by steady corporate earnings and improvements in the employment and income environment.

In the generic drug industry, although the usage rate of generic drugs steadily increased with the aim of "an 80% usage rate of generic drugs by September 2020" in the Cabinet decision made in June 2017, the speed of growth has slowed and the earning environment has become increasingly harsh due to a significant price revision in April 2018 lowering prices by 7.48% on a drug cost basis.

Under such circumstances, during the second quarter that is the midpoint of the final year of the 7th Medium-term Business Plan "Obelisk," which positions the three years from April 2016 as a period for launch to new business fields from the preparatory stage to embark on entering global markets, the Company steadily implemented the basic policies of "Expansion," "Production" and "Development" set forth under the plan.

In "Expansion," the Company launched Minodronic Acid Tablets 50mg "Nichi-Iko" taking into consideration the prevention of accidental ingestion by children and Iluamix Combination Tablets HD "Nichi-Iko" that adopted individual packaging boxes with a cut-off label indicating a GS-1 data bar that can be used to manage the remaining medicine in June 2018, and obtained marketing approval of 5 products with 9 strengths such as Mirtazapine Tablets 15mg/30mg "Nichi-Iko" and Toaraset Combination Tablets "Nichi-Iko" in August 2018.

In "Production," Quality Operation Division was newly established in October 2018 to provide stable supply with premium quality and conform with global quality, establishing a structure strengthening response capability to the forthcoming FDA inspections and providing independence to compliance with GMP standards.

In "Development," an agreement was concluded in June 2018 with Lupin Limited (headquarters: Mumbai, India) and its Japanese subsidiary Kyowa Pharmaceutical Industry Co., Ltd. (headquarters: Kita-ku, Osaka; President and Representative Director Ray Tsunoda) for Etanercept BS, which is the second biosimilar handled by Nichi-Iko. This will make it possible to provide more treatment options especially to rheumatoid arthritis patients. Furthermore, in July 2018, a business alliance was formed with Sunward Pharmaceutical Pte Ltd. (Singapore), which has sales and manufacturing bases in both Malaysia and Singapore, with the aim of entering these markets.

The accumulation of the above efforts has also been made as the Company steadily works to become a global top 10 company.

As a result, the cumulative second quarter showed revenue of 82,346 million yen (0.9% decrease year-on-year), operating profit of 4,720 million yen (75.1% increase year-on-year), and profit

attributable to owners of parent of 4,620 million yen (88.8% increase year-on-year) with revenue remaining almost the same, but despite price revisions putting pressure on profit, profit increasing due to decreases in selling, general and administrative expenses, etc. as a result of a rebound from recognition of impairment loss in the previous fiscal year and an increase in profit in affiliates accounted for by the equity method.

(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 increased by 3,357 million yen from the previous fiscal year-end to 281,722 million yen. This was mainly attributable to investments accounted for using equity method increasing by 4,439 million yen, and intangible assets increasing by 4,389 million yen, cash and cash equivalents increasing by 4,077 million yen, other financial assets increasing by 1,342 million yen, trade and other receivables decreasing by 6,253 million yen and inventories decreasing by 5,773 million yen.

Liabilities on a consolidated basis decreased by 9,746 million yen from the previous fiscal year-end to 181,075 million yen. This was mainly attributable to borrowings increasing by 1,755 million yen, trade and other payables decreasing by 11,134 million yen, and income taxes payable decreasing by 1,108 million yen.

Equity on a consolidated basis increased by 13,103 million yen from the previous fiscal year-end to 100,646 million yen. This was mainly attributable to treasury shares decreasing by 6,043 million yen and other components of equity increasing by 5,760 million yen.

(ii) Cash Flows

At the end of the second quarter of the current fiscal year, cash and cash equivalents on a consolidated basis increased by 4,077 million yen from the previous fiscal year-end to 22,606 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 provided by operating activities during the cumulative second quarter of the current fiscal year amounted to income over expenditure by 12,064 million yen. The main outflows included trade and other payables decreasing by 7,933 million yen. In terms of inflows, there were trade and other receivables decreasing by 5,859 million yen, inventories decreasing by 6,556 million yen, profit before tax of 5,727 million yen, and depreciation and amortization of 4,601 million yen.

(Cash flows from investing activities)

Net cash used in investing activities during the cumulative second quarter of the current fiscal year amounted to expenditure over income by 11,785 million yen. This was due to outflows such as expenditure of 3,400 million yen arising due to the purchase of investments accounted for using equity method as a result of the acquisition of 20% of the shares issued by Elmed Eisai Co., Ltd., 5,066 million yen in purchase of property, plant and equipment, and 3,853 million yen in purchase of intangible assets.

(Cash flows from financing activities)

Net cash used in financing activities during the cumulative second quarter of the current fiscal year amounted to income over expenditure by 3,927 million yen. The main outflow was 3,918 million yen in repayments of long-term borrowings, while the main inflows were 4,031 million yen in proceeds from disposal of treasury shares and 5,000 million yen in proceeds from long-term borrowings.

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

With regard to the forecast of financial results for the fiscal year ending March 31, 2019, the forecast has been changed as stated in the “Notice Concerning Revisions of Forecast of Consolidated Financial Results” announced on November 7, 2018.

The forecast of financial results was made based on information available to the Company at this point, and actual business and other results may differ from the forecast values provided in these materials as a result of various factors in the future.

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, 2018 (as of March 31, 2018)	Second quarter of fiscal year ending March 31, 2019 (as of September 30, 2018)
Assets		
Current assets		
Cash and cash equivalents	18,529	22,606
Trade and other receivables	32,087	25,833
Inventories	74,321	68,548
Income taxes receivable	–	57
Other financial assets	974	425
Other current assets	2,365	2,441
Total current assets	128,278	119,913
Non-current assets		
Property, plant and equipment	54,045	53,541
Goodwill	38,536	41,107
Intangible assets	45,735	50,124
Investments accounted for using equity method	6,380	10,819
Other financial assets	3,962	5,853
Deferred tax assets	1,326	278
Other non-current assets	99	83
Total non-current assets	150,086	161,809
Total assets	278,364	281,722

(in millions of yen)

	Fiscal year ended March 31, 2018 (as of March 31, 2018)	Second quarter of fiscal year ending March 31, 2019 (as of September 30, 2018)
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	50,686	39,552
Borrowings	35,499	37,584
Other financial liabilities	994	989
Income taxes payable	1,676	567
Provisions	2,928	–
Refund liabilities	–	2,583
Contract liabilities	–	82
Other current liabilities	5,608	6,489
Total current liabilities	97,394	87,849
Non-current liabilities		
Borrowings	85,625	85,295
Other financial liabilities	2,232	1,942
Retirement benefit liability	465	474
Provisions	56	57
Refund liabilities	–	96
Contract liabilities	–	581
Deferred tax liabilities	2,823	2,947
Other non-current liabilities	2,224	1,831
Total non-current liabilities	93,427	93,226
Total liabilities	190,821	181,075
Equity		
Share capital	19,976	19,976
Capital surplus	18,827	18,511
Treasury shares	(9,046)	(3,002)
Retained earnings	51,912	53,527
Other components of equity	5,872	11,633
Total equity attributable to owners of parent	87,542	100,646
Non-controlling interests	0	0
Total equity	87,542	100,646
Total liabilities and equity	278,364	281,722

(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, 2017 to September 30, 2017)	Second quarter of current fiscal year (from April 1, 2018 to September 30, 2018)
Revenue	83,060	82,346
Cost of sales	64,202	64,166
Gross profit	18,858	18,179
Selling, general and administrative expenses	11,813	11,615
Research and development expenses	1,977	1,915
Other operating income	657	273
Other operating expenses	3,029	202
Operating profit	2,695	4,720
Finance income	148	484
Finance costs	433	474
Share of profit (loss) of investments accounted for using equity method	204	997
Profit before tax	2,613	5,727
Income tax expense	167	1,107
Profit	2,446	4,620
Profit attributable to:		
Owners of parent	2,446	4,620
Non-controlling interests	(0)	(0)
Profit	2,446	4,620
Earnings per share		
Basic earnings per share (Yen)	43.45	80.93
Diluted earnings per share (Yen)	43.38	79.79

(Condensed Quarterly Consolidated Statement of Comprehensive Income)

(in millions of yen)

	Second quarter of previous fiscal year (from April 1, 2017 to September 30, 2017)	Second quarter of current fiscal year (from April 1, 2018 to September 30, 2018)
Profit	2,446	4,620
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	831	665
Share of other comprehensive income of investments accounted for using equity method	96	(109)
Total of items that will not be reclassified to profit or loss	928	555
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	1,147	5,070
Share of other comprehensive income of investments accounted for using equity method	(40)	96
Total of items that may be reclassified to profit or loss	1,106	5,167
Other comprehensive income (net of tax)	2,034	5,722
Comprehensive income	4,480	10,342
Comprehensive income attributable to:		
Owners of parent	4,480	10,343
Non-controlling interests	(0)	(0)
Comprehensive income	4,480	10,342

(3) Condensed Quarterly Consolidated Statement of Changes in Equity

Second Quarter of Previous Fiscal Year (from April 1, 2017 to September 30, 2017)

(in millions of yen)

	Equity attributable to owners of parent					
					Other components of equity	
	Share capital	Capital surplus	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, 2017	19,976	18,845	(9,401)	45,050	7,267	1,200
Profit (loss)				2,446		
Other comprehensive income					1,106	927
Total comprehensive income	-	-	-	2,446	1,106	927
Purchase of treasury shares			(0)			
Disposal of treasury shares (including disposal by exercise of share acquisition rights)		(25)	235			
Dividends				(843)		
Share-based payment transactions						
Transfer from other components of equity				0		
Total transactions with owners	-	(25)	234	(843)	-	-
Balance as of September 30, 2017	19,976	18,819	(9,166)	46,652	8,373	2,128

	Equity attributable to owners of parent					
	Other components of equity			Total	Non-controlling interests	Total
	Remeasure-ments of defined benefit plans	Other	Total			
Balance as of April 1, 2017	-	234	8,701	83,171	0	83,171
Profit (loss)				2,446	(0)	2,446
Other comprehensive income	0		2,034	2,034	0	2,034
Total comprehensive income	0	-	2,034	4,480	(0)	4,480
Purchase of treasury shares				(0)		(0)
Disposal of treasury shares (including disposal by exercise of share acquisition rights)		(101)	(101)	108		108
Dividends				(843)		(843)
Share-based payment transactions		117	117	117		117
Transfer from other components of equity	(0)		(0)	-		-
Total transactions with owners	(0)	15	15	(618)	-	(618)
Balance as of September 30, 2017	-	249	10,751	87,033	0	87,034

Second Quarter of Current Fiscal Year (from April 1, 2018 to September 30, 2018)

(in millions of yen)

	Equity attributable to owners of parent					
					Other components of equity	
	Share capital	Capital surplus	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, 2018	19,976	18,827	(9,046)	51,912	3,448	2,165
Changes in accounting policies				(480)		
Restated balance	19,976	18,827	(9,046)	51,431	3,448	2,165
Profit (loss)				4,620		
Other comprehensive income					5,167	565
Total comprehensive income	-	-	-	4,620	5,167	565
Purchase of treasury shares			(0)			
Disposal of treasury shares (including disposal by exercise of share acquisition rights)		(1,996)	6,044			
Transfer of loss on disposal of treasury shares		1,681		(1,681)		
Forfeiture of share acquisition rights				13		
Dividends				(846)		
Share-based payment transactions						
Transfer from other components of equity				(10)		
Total transactions with owners	-	(315)	6,043	(2,524)	-	-
Balance as of September 30, 2018	19,976	18,511	(3,002)	53,527	8,615	2,731

	Equity attributable to owners of parent				Non-controlling interests	Total
	Other components of equity			Total		
	Remeasure-ments of defined benefit plans	Other	Total			
Balance as of April 1, 2018	-	258	5,872	87,542	0	87,542
Changes in accounting policies				(480)		(480)
Restated balance	-	258	5,872	87,062	0	87,062
Profit (loss)				4,620	(0)	4,620
Other comprehensive income	(10)		5,722	5,722	(0)	5,722
Total comprehensive income	(10)	-	5,722	10,343	(0)	10,342
Purchase of treasury shares				(0)		(0)
Disposal of treasury shares (including disposal by exercise of share acquisition rights)		(3)	(3)	4,043		4,043
Transfer of loss on disposal of treasury shares				-		-
Forfeiture of share acquisition rights		(13)	(13)	-		-
Dividends				(846)		(846)
Share-based payment transactions		44	44	44		44
Transfer from other components of equity	10		10	-		-
Total transactions with owners	10	27	37	3,240	-	3,240
Balance as of September 30, 2018	-	285	11,633	100,646	0	100,646

(Note)

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

(4) Condensed Quarterly Consolidated Statement of Cash Flows

(in millions of yen)

	Second quarter of previous fiscal year (from April 1, 2017 to September 30, 2017)	Second quarter of current fiscal year (from April 1, 2018 to September 30, 2018)
Cash flows from operating activities		
Profit before tax	2,613	5,727
Depreciation and amortization	4,176	4,601
Impairment loss	5,729	111
Interest and dividend income	(55)	(40)
Interest expenses	324	345
Share of loss (profit) of investments accounted for using equity method	(204)	(997)
Decrease (increase) in trade and other receivables	(2,075)	5,859
Decrease (increase) in inventories	(2,054)	6,556
Increase (decrease) in trade and other payables	(1,376)	(7,933)
Increase (decrease) in provisions	406	(506)
Other	1,505	(108)
Subtotal	8,989	13,615
Dividends received	69	59
Interest received	1	16
Interest paid	(315)	(340)
Income taxes paid	(300)	(1,294)
Income taxes refund	764	7
Net cash provided by (used in) operating activities	9,208	12,064
Cash flows from investing activities		
Purchase of property, plant and equipment	(5,547)	(5,066)
Purchase of intangible assets	(2,324)	(3,853)
Purchase of investments	(3)	(994)
Purchase of investments accounted for using equity method	(1,665)	(3,400)
Collection of loans receivable	49	598
Proceeds from reversal of international interests	–	999
Other	14	(68)
Net cash provided by (used in) investing activities	(9,477)	(11,785)

(in millions of yen)

	Second quarter of previous fiscal year (from April 1, 2017 to September 30, 2017)	Second quarter of current fiscal year (from April 1, 2018 to September 30, 2018)
Cash flows from financing activities		
Net increase (decrease) in short-term borrowings	1,896	91
Proceeds from long-term borrowings	5,189	5,000
Repayments of long-term borrowings	(3,928)	(3,918)
Proceeds from disposal of treasury shares	107	4,031
Repayments of finance lease obligations	(522)	(469)
Dividends paid	(842)	(847)
Other	0	40
Net cash provided by (used in) financing activities	1,901	3,927
Effect of exchange rate changes on cash and cash equivalents	160	(128)
Net increase (decrease) in cash and cash equivalents	1,793	4,077
Cash and cash equivalents at beginning of period	12,457	18,529
Cash and cash equivalents at end of period	14,250	22,606

(5) Notes to Condensed Quarterly Consolidated Financial Statements

(Notes on premise of going concern)

Not applicable.

(Changes in accounting policies)

The significant accounting policies applied to the Condensed Quarterly Consolidated Financial Statements are the same as the accounting policies applied to the consolidated financial statements for the previous fiscal year with the exception of the changes in the accounting policies listed below. Income tax expense for the cumulative second quarter of the current fiscal year is calculated based on the estimated annual effective tax rate.

The following standards are applied from the first quarter of the current fiscal year.

The Group has adopted IFRS 15 “Revenue from Contracts with Customers” (issued in May 2014) and “Clarifications to IFRS 15” (issued in April 2016) (hereinafter, “IFRS 15” collectively), from the first quarter of the current fiscal year.

In the application of IFRS 15, the Group has adopted the method where the cumulative effect of applying this standard is recognized at the date of initial application, which is allowed as the transition approach.

With the application of IFRS 15, the Group recognizes revenue based on the following five steps approach.

Step 1: Identify the contract(s) with a customer

Step 2: Identify the performance obligations in the contract

Step 3: Determine the transaction price

Step 4: Allocate the transaction price to the performance obligations in the contract

Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation

With the application of this standard, for revenue from intellectual property that had previously been recognized as one-time revenue at the time of receipt, the consideration received is recorded as contract liabilities and recognized as revenue over a fixed period as performance obligations related to license agreements are fulfilled. Furthermore, the allowance for sales returns and allowance for rebates previously represented in provisions have been represented as refund liabilities, and the advances received previously represented as included in other current liabilities are represented as contract liabilities.

As a result, compared to if the previous accounting standards are applied, primarily retained earnings decreased by 480 million yen, provisions decreased by 2,928 million yen, refund liabilities increased by 2,928 million yen and contract liabilities increased by 691 million yen at the beginning of the first quarter of the current fiscal year.

In the condensed quarterly consolidated statement of income for the cumulative second quarter of the current fiscal year, compared to if the previous accounting standards are applied, the impact on revenue, operating profit and profit was minor.

Furthermore, in the condensed quarterly consolidated statement of financial position as of the end of the second quarter of the current fiscal year, compared to if the previous accounting standards are applied, primarily retained earnings decreased by 481 million yen, provisions decreased by 2,679 million yen, refund liabilities increased by 2,679 million yen and contract liabilities increased by 664 million yen.

Assets recognized from costs to obtain or fulfill contracts with customers

During the cumulative second quarter of the current fiscal year, the amount of assets recognized from costs to obtain or fulfill contracts with customers was not significant.