

Outline of Consolidated Financial Results for the First Quarter Ended June 30, 2024(IFRS)

August 7, 2024

Name of the listed company: **NIPPON SHINYAKU CO., LTD.**

Code No.: 4516

Representative: Toru Nakai, President and Representative Director

Contact: Hideyuki Fujii, Department Manager and Finance & Accounting Dept.

Scheduled start of payment: —

Supplementary material: Yes

Financial result meeting: Yes (for institutional investors and securities analysts on conference call)

Listing stock exchange: Tokyo

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* All amounts are rounded down to the nearest million yen.

1. Consolidated Results for the Year Ended June 30, 2024 (April 1, 2024 to June 30, 2024)

(1) Operating results

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
Three months ended June 30, 2024	39,131	5.7	11,078	(0.8)	11,411	(0.3)	10,270	17.3	10,264	17.3	11,104	3.7
Three months ended June 30, 2023	37,012	3.9	11,163	8.6	11,440	8.8	8,751	6.0	8,749	6.1	10,705	28.7

Earnings per share (¥)

	Basic	Diluted
Three months ended June 30, 2024	152.40	—
Three months ended June 30, 2023	129.91	—

Note: Equity-method investments: not applicable

(2) Financial position

(¥ million)

	Total assets	Total equity	Total equity attributable to owners of parent	Ratio of equity attributable to owners of parent to total assets
As of June 30, 2024	265,828	227,462	227,147	85.4%
As of March 31, 2024	263,404	220,534	220,224	83.6%

2. Dividends

Annual dividends per share (¥)

	1 st quarter	2 nd quarter	3 rd quarter	Year-end	Annual
Year ended March 31, 2024	—	62.00	—	62.00	124.00
Year ending March 31, 2025	—	—	—	—	—
Year ending March 31, 2025 (forecast)	—	62.00	—	62.00	124.00

3. Business Forecast for the Year Ending March 31, 2025 (April 1, 2024 to March 31, 2025)

(¥ million)

	Revenue		Operating profit		Profit before tax		Net income attributable to owners of the parent		Basic earnings per share (¥)
		%		%		%		%	
First-half period	75,800	3.4	15,000	(28.2)	15,200	(28.1)	13,500	(16.5)	200.44
Full term	154,000	3.9	32,000	(3.9)	32,500	(3.3)	29,000	12.2	430.57

4. Others

(1) Changes in the scope of consolidation

Inclusion: None

Exclusion: None

Note: Changes in specified subsidiaries involved changes in the scope of consolidation

(2) Changes in accounting policies and accounting estimates, and restatement

1. Changes in accounting policies arising from revision of accounting standards: None

2. Changes in arising from other factors: None

3. Changes in accounting estimates: None

(3) Number of shares outstanding (ordinary shares)

Number of shares outstanding (including treasury stock)

As of June 30, 2024: 70,251,484 shares

As of March 31, 2024: 70,251,484 shares

Number of shares of treasury stock

As of June 30, 2024: 2,898,786 shares

As of March 31, 2024: 2,898,726 shares

Average number of shares outstanding (total for the consolidated period)

As of June 30, 2024: 67,352,713 shares

As of June 30, 2023: 67,352,866 shares

※Review of the attached condensed interim consolidated financial statements by certified public accountants or an audit firm: Yes (voluntary)

※Explanation of appropriate use of earnings forecasts and other special notes (Cautionary statement regarding forward-looking statements, etc.)

This financial release contains certain statements about the future, which are based information available and deemed reasonable to Nippon Shinyaku at the time of announcement, and are not the commitments made by Nippon Shinyaku.

Readers are advised that actual results may differ substantially from the above forecasts due to various unforeseeable factors.

5. Consolidated Financial Statement

(1) Consolidated Balance Sheet

(Millions of yen)

	As of March 31, 2024	As of June 30, 2024
Assets		
Current assets		
Cash and cash equivalents	58,094	54,472
Trade and other receivables	47,237	48,357
Inventories	39,111	37,428
Other financial assets	10,609	10,630
Other current assets	9,232	9,084
Total current assets	164,285	159,973
Non-current assets		
Property, plant and equipment	33,582	34,324
Intangible assets	25,120	29,436
Right-of-use assets	2,971	2,701
Other financial assets	32,862	34,878
Deferred tax assets	1,766	1,709
Other non-current assets	2,817	2,804
Total non-current assets	99,119	105,854
Total assets	263,404	265,828

(Millions of yen)

	As of March 31, 2024	As of June 30, 2024
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	24,706	21,649
Other financial liabilities	372	269
Lease liabilities	1,720	1,385
Income taxes payable	3,594	896
Other current liabilities	6,941	8,626
Total current liabilities	37,336	32,826
Non-current liabilities		
Other financial liabilities	232	248
Lease liabilities	1,152	1,238
Retirement benefit liability	4,090	3,993
Other non-current liabilities	58	58
Total non-current liabilities	5,533	5,539
Total liabilities	42,870	38,365
Equity		
Share capital	5,174	5,174
Capital surplus	4,445	4,445
Retained earnings	198,260	204,348
Treasury shares	△2,480	△2,481
Other components of equity	14,825	15,659
Total equity attributable to owners of parent	220,224	227,147
Non-controlling interests	310	315
Total equity	220,534	227,462
Total liabilities and equity	263,404	265,828

(2) Consolidated Statements of Income

(Millions of yen)

	Three months ended June 30, 2023	Three months ended June 30, 2024
Revenue	37,012	39,131
Cost of sales	12,962	12,636
Gross profit	24,050	26,494
Selling, general and administrative expenses	8,418	9,221
Research and development expenses	5,911	7,497
Other income	1,572	1,507
Other expenses	129	204
Operating profit	11,163	11,078
Finance income	298	363
Finance costs	21	31
Profit before tax	11,440	11,411
Income tax expense	2,688	1,141
Profit	8,751	10,270
Profit attributable to		
Owners of parent	8,749	10,264
Non-controlling interests	2	5
Profit	8,751	10,270
Earnings per share		
Basic earnings per share	129.91	152.40

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Three months ended June 30, 2023	Three months ended June 30, 2024
Profit	8,751	10,270
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	1,955	1,051
Total of items that will not be reclassified to profit or loss	1,955	1,051
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(2)	(216)
Total of items that may be reclassified to profit or loss	(2)	(216)
Total other comprehensive income	1,953	834
Comprehensive income	10,705	11,104
Comprehensive income attributable to		
Owners of parent	10,703	11,099
Non-controlling interests	2	5
Comprehensive income	10,705	11,104

(3) Consolidated Statements of Changes in Net Assets
For the three-month period ended June 30,2023

(Millions of yen)

	Equity attributable to owners of parent					
	Share capital	Capital surplus	Retained earnings	Treasury shares	Other components of equity	
					Exchange differences on translation of foreign operations	Financial assets measured at fair value through other comprehensive income
Balance at beginning of period	5,174	4,445	180,433	(2,480)	(616)	8,669
Profit	-	-	8,749	-	-	-
Other comprehensive income	-	-	-	-	(2)	1,955
Comprehensive income	-	-	8,749	-	(2)	1,955
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(3,839)	-	-	-
Total transactions with owners	-	-	(3,839)	(0)	-	-
Balance at end of period	5,174	4,445	185,344	(2,480)	(619)	10,625

	Equity attributable to owners of parent			
	Other components of equity	Total	Non-controlling interests	Total
	Total			
Balance at beginning of period	8,052	195,625	307	195,933
Profit	-	8,749	2	8,751
Other comprehensive income	1,953	1,953	-	1,953
Comprehensive income	1,953	10,703	2	10,705
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(3,839)	-	(3,839)
Total transactions with owners	-	(3,839)	-	(3,839)
Balance at end of period	10,006	202,489	309	202,799

For the three-month period ended June 30,2024

(Millions of yen)

	Equity attributable to owners of parent					
	Share capital	Capital surplus	Retained earnings	Treasury shares	Other components of equity	
					Exchange differences on translation of foreign operations	Financial assets measured at fair value through other comprehensive income
Balance at beginning of period	5,174	4,445	198,260	(2,480)	(488)	15,313
Profit	-	-	10,264	-	-	-
Other comprehensive income	-	-	-	-	(216)	1,051
Comprehensive income	-	-	10,264	-	(216)	1,051
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(4,175)	-	-	-
Total transactions with owners	-	-	(4,175)	(0)	-	-
Balance at end of period	5,174	4,445	204,348	(2,481)	(704)	16,364

	Equity attributable to owners of parent			
	Other components of equity	Total	Non-controlling interests	Total
	Total			
Balance at beginning of period	14,825	220,224	310	220,534
Profit	-	10,264	5	10,270
Other comprehensive income	834	834	-	834
Comprehensive income	834	11,099	5	11,104
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(4,175)	-	(4,175)
Total transactions with owners	-	(4,176)	-	(4,176)
Balance at end of period	15,659	227,147	315	227,462

(4) Consolidated Statements of Cash Flow

(Millions of yen)

	Three months ended June 30, 2023	Three months ended June 30, 2024
Cash flows from operating activities		
Profit before tax	11,440	11,411
Depreciation and amortization	1,236	1,464
Interest and dividend income	(298)	(363)
Interest expenses	5	13
Foreign exchange loss (gain)	(940)	(792)
Loss (gain) on sale of fixed assets	31	95
Decrease (increase) in trade and other receivables	(899)	(922)
Decrease (increase) in inventories	948	1,797
Increase (decrease) in trade and other payables	(4,425)	(3,388)
Increase (decrease) in retirement benefit liability	(204)	(96)
Other	270	1,677
Subtotal	7,165	10,896
Interest and dividends received	296	364
Interest paid	(5)	(13)
Income taxes paid	(6,930)	(4,243)
Net cash provided by (used in) operating activities	526	7,004
Cash flows from investing activities		
Payments into time deposits	(45)	(645)
Proceeds from withdrawal of time deposits	30	630
Purchase of property, plant and equipment	(1,661)	(957)
Purchase of intangible assets	(385)	(5,817)
Purchase of investments	(0)	(0)
Other	1	1
Net cash provided by (used in) investing activities	(2,060)	(6,788)
Cash flows from financing activities		
Repayments of lease liabilities	(422)	(410)
Purchase of treasury shares	(0)	(0)
Dividends paid	(3,625)	(3,918)
Net cash provided by (used in) financing activities	(4,047)	(4,328)
Effect of exchange rate changes on cash and cash equivalents	786	492
Net increase (decrease) in cash and cash equivalents	(4,795)	(3,621)
Cash and cash equivalents at beginning of period	60,047	58,094
Cash and cash equivalents at end of period	55,251	54,472

Performance (consolidated)

(¥ million)

	2018 (JGAAP)	2019 (JGAAP)	2020 (IFRS)	2021 (IFRS)	2022 (IFRS)	2023 (IFRS)	2024 (IFRS) (estimated)
Revenue	114,716	116,637	121,859	137,484	144,175	148,255	154,000
Operating profit	20,644	21,668	27,202	32,948	30,049	33,295	32,000
Profit before tax	21,540	22,442	27,608	33,301	30,489	33,616	32,500
Profit attributable to owners of parent	16,302	16,866	19,540	24,986	22,812	25,851	29,000

(¥ million)

Brand name	Active Ingredient	Indications	Launch Date	Sales 2022 (IFRS)	Sales 2023 (IFRS)	Sales 2024 (IFRS)		
						Apr-Jun	Apr-Sep (estimated)	Annual (estimated)
Viltepso				14,341	17,530	5,450	10,300	20,600
(Japan)	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	(4,139)	(4,407)	1,175	2,300	4,600
(U.S.)				(10,201)	(13,123)	4,275	8,000	16,000
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	10,543	12,918	3,855	7,600	15,400
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	15,951	10,383	1,462	2,600	4,800
Gazyva	obinutuzumab	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	Aug-2018/ Dec-2022	4,904	4,695	1,254	2,500	5,100
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	5,358	3,927	778	1,400	2,700
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	2,524	2,221	709	1,100	2,300
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,938	2,499	647	1,400	2,700
Zalutia	tadalafil	urinary disorder caused by benign prostatic hyperplasia	Apr-2014	2,826	2,256	493	850	1,600
Adcirca	tadalafil	pulmonary arterial hypertension	Dec-2009	2,649	2,255	480	900	1,700
Erizas	dexamethasone cipeclate	allergic rhinitis	Dec-2009	2,640	2,284	281	700	2,100
Profit in co-promotion				9,520	8,658	2,461	4,550	9,100
Revenues from the licensing of industrial property rights				30,714	40,304	10,779	21,000	42,100
Pharmaceuticals				121,988	125,105	33,738	65,300	132,500
Functional Food				22,187	23,150	5,393	10,500	21,500
Revenue				144,175	148,255	39,131	75,800	154,000

Nippon Shinyaku: R&D Pipeline List

< Domestic >

August 7, 2024

Stage	Code No. (Generic name)	Therapeutic field	Indications	Origin	Development
Launch Phase III	NS-065/NCNP-01 (viltolarsen)	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Preparation for launch	LY3527727 (pirtobrutinib)	hematologic malignancies	patients with relapsed or refractory mantle cell lymphoma who are resistant or intolerant to other BTK inhibitors	Alliance agreement in Japan: Eli Lilly Japan K.K.	Eli Lilly Japan K.K.
NDA filing	NS-304 (selexipag)	intractable diseases・orphan diseases	pediatric pulmonary arterial hypertension	Nippon Shinyaku Co., Ltd.	Co - development: Janssen Pharmaceutical K.K.
Phase III	ZX008 (fenfluramine hydrochloride)	intractable diseases・orphan diseases	CDKL5 deficiency disorder	Distribution partnership: UCB S.A. (former : Zogenix, Inc.)	UCB S.A. (former : Zogenix, Inc.)
Phase III	GA101 (obinutuzumab)	intractable diseases・orphan diseases	lupus nephritis	Licensed - in from Chugai Pharmaceutical Co., Ltd.	Co - development: Chugai Pharmaceutical Co., Ltd.
Phase III	GA101 (obinutuzumab)	intractable diseases・orphan diseases	pediatric nephrotic syndrome	Licensed - in from Chugai Pharmaceutical Co., Ltd.	Co - development: Chugai Pharmaceutical Co., Ltd.
Phase III	GA101 (obinutuzumab)	intractable diseases・orphan diseases	extra renal lupus	Licensed - in from Chugai Pharmaceutical Co., Ltd.	Co - development: Chugai Pharmaceutical Co., Ltd.
Phase III	LY3527727 (pirtobrutinib)	hematologic malignancies	mantle cell lymphoma	Alliance agreement in Japan: Eli Lilly Japan K.K.	Eli Lilly Japan K.K.
Phase III	LY3527727 (pirtobrutinib)	hematologic malignancies	chronic lymphocytic leukemia	Alliance agreement in Japan: Eli Lilly Japan K.K.	Eli Lilly Japan K.K.
Phase II	NS-304 (selexipag)	cardiovascular	arteriosclerosis obliterans	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.
Phase II	NS-580	gynecology	endometriosis	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.
Phase II	NS-580	urological diseases	chronic prostatitis / chronic pelvic pain syndrome	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.
Phase II	NS-089/NCNP-02 (brogidirsen)	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase II	NS-229	intractable diseases・orphan diseases	eosinophilic granulomatosis with polyangiitis	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.
Phase I/II	NS-401 (tagraxofusp)	hematologic malignancies	blastic plasmacytoid dendritic cell neoplasm	Licensed - in from The Menarini Group	Nippon Shinyaku Co., Ltd.
Preparation for Phase I/II	NS-050/NCNP-03	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase I	NS-917 (radgocitabine)	hematologic malignancies	relapsed/refractory acute myeloid leukemia	Licensed - in from Delta-Fly Pharma, Inc.	Nippon Shinyaku Co., Ltd.
Phase I	NS-025	urological diseases	urological diseases	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.
Phase I	NS-863	cardiovascular	cardiovascular diseases	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.

< Overseas >

Stage	Code No. (Generic name)	Therapeutic field	Indications	Origin	Development
US Launch Phase III	NS-065/NCNP-01 (viltolarsen)	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase III	CAP-1002 (deramiciel)	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Partnership: Capricor Therapeutics, Inc.	Capricor Therapeutics, Inc.
Phase II	NS-089/NCNP-02 (brogidirsen)	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase II	NS-229	intractable diseases・orphan diseases	eosinophilic granulomatosis with polyangiitis	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.
Preparation for Phase I/II	NS-050/NCNP-03	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.