

Outline of Consolidated Financial Results for the Second Quarter Ended September 30, 2023 (IFRS)

November 13, 2023

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 date for submission of quarterly Securities Report: November 14, 2023

Scheduled start of payment: December 5, 2023

Supplementary material: Yes

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

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 September 30, 2023 (April 1, 2023 to September 30, 2023)

(1) Operating results

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
Second quarter ended September 30, 2023	73,314	3.1	20,878	9.0	21,146	9.0	16,176	6.2	16,176	6.3	19,680	34.9
Second quarter ended September 30, 2022	71,136	(0.6)	19,161	(12.1)	19,398	(11.9)	15,228	(7.9)	15,222	(7.9)	14,591	(7.9)

Earnings per share (¥)

	Basic	Diluted
Second quarter ended September 30, 2023	240.17	—
Second quarter ended September 30, 2022	226.01	—

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 September 30, 2023	249,499	211,774	211,466	84.8%
As of March 31, 2023	237,451	195,933	195,625	82.4%

2. Dividends

Annual dividends per share (¥)

	1 st quarter	2 nd quarter	3 rd quarter	Year-end	Annual
Year ended March 31, 2023	—	57.00	—	57.00	114.00
Year ending March 31, 2024	—	62.00	—	—	—
Year ending March 31, 2024 (forecast)	—	—	—	62.00	124.00

3. Business Forecast for the Year Ending March 31, 2024 (April 1, 2023 to March 31, 2024)

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit attributable to owners of parent		Basic earnings per share (¥)
		%		%		%		%	
Full term	147,000	2.0	33,500	11.5	34,000	11.5	26,000	14.0	386.03

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 September 30, 2023: 70,251,484 shares

As of March 31, 2023: 70,251,484 shares

Number of shares of treasury stock

As of September 30, 2023: 2,898,706 shares

As of March 31, 2023: 2,898,610 shares

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

As of September 30, 2023: 67,352,840 shares

As of September 30, 2022: 67,353,007 shares

Note:

This summary of quarterly financial results is exempt from the quarterly review procedures under the Financial Instruments and Exchange Act. At the time of disclosure, published figures in this financial release have not been completed to a quarterly review of financial statements based on the Financial Instruments and Exchange Law.

The above forecasts are based on data available as of the date of release of this document as well as assumptions based on uncertain factors, which might have a material effect on the Company's performance in the future. 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, 2023	As of September 30, 2023
Assets		
Current assets		
Cash and cash equivalents	60,047	62,855
Trade and other receivables	44,686	48,725
Inventories	36,358	34,455
Other financial assets	11,554	9,581
Other current assets	5,225	7,841
Total current assets	157,873	163,459
Non-current assets		
Property, plant and equipment	32,215	32,803
Intangible assets	17,155	18,070
Right-of-use assets	2,779	2,285
Other financial assets	22,308	28,451
Deferred tax assets	3,241	1,629
Other non-current assets	1,877	2,800
Total non-current assets	79,578	86,040
Total assets	237,451	249,499

(Millions of yen)

	As of March 31, 2023	As of September 30, 2023
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	20,538	19,911
Other financial liabilities	314	391
Lease liabilities	1,516	1,361
Income taxes payable	6,131	4,021
Other current liabilities	6,682	6,422
Total current liabilities	35,183	32,109
Non-current liabilities		
Other financial liabilities	232	232
Lease liabilities	1,148	827
Retirement benefit liability	4,895	4,497
Other non-current liabilities	57	58
Total non-current liabilities	6,334	5,616
Total liabilities	41,518	37,725
Equity		
Share capital	5,174	5,174
Capital surplus	4,445	4,445
Retained earnings	180,433	192,806
Treasury shares	(2,480)	(2,480)
Other components of equity	8,052	11,520
Total equity attributable to owners of parent	195,625	211,466
Non-controlling interests	307	308
Total equity	195,933	211,774
Total liabilities and equity	237,451	249,499

(2) Consolidated Statements of Income

(Millions of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Revenue	71,136	73,314
Cost of sales	27,991	25,320
Gross profit	43,144	47,994
Selling, general and administrative expenses	16,284	16,952
Research and development expenses	9,691	12,517
Other income	2,805	2,596
Other expenses	813	242
Operating profit	19,161	20,878
Finance income	297	326
Finance costs	60	57
Profit before tax	19,398	21,146
Income tax expense	4,170	4,969
Profit	15,228	16,176
Profit attributable to		
Owners of parent	15,222	16,176
Non-controlling interests	5	0
Profit	15,228	16,176
Earnings per share		
Basic earnings per share	226.01	240.17

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Profit	15,228	16,176
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(230)	3,418
Total of items that will not be reclassified to profit or loss	(230)	3,418
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(406)	85
Total of items that may be reclassified to profit or loss	(406)	85
Total other comprehensive income	(636)	3,503
Comprehensive income	14,591	19,680
Comprehensive income attributable to		
Owners of parent	14,585	19,679
Non-controlling interests	5	0
Comprehensive income	14,591	19,680

(3) Consolidated Statements of Changes in Net Assets
For the six-month period ended September 30,2022

(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	165,303	(2,478)	(253)	8,394
Profit	-	-	15,222	-	-	-
Other comprehensive income	-	-	-	-	(406)	(230)
Comprehensive income	-	-	15,222	-	(406)	(230)
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(3,973)	-	-	-
Transfer from other components of equity to retained earnings	-	-	15	-	-	(15)
Total transactions with owners	-	-	(3,957)	(0)	-	(15)
Balance at end of period	5,174	4,445	176,568	(2,479)	(659)	8,148

	Equity attributable to owners of parent			
	Other components of equity	Total	Non-controlling interests	Total
	Total			
Balance at beginning of period	8,140	180,585	300	180,886
Profit	-	15,222	5	15,228
Other comprehensive income	(636)	(636)	-	(636)
Comprehensive income	(636)	14,585	5	14,591
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(3,973)	-	(3,973)
Transfer from other components of equity to retained earnings	(15)	-	-	-
Total transactions with owners	(15)	(3,974)	-	(3,974)
Balance at end of period	7,488	191,197	306	191,503

For the six-month period ended September 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	-	-	16,176	-	-	-
Other comprehensive income	-	-	-	-	85	3,418
Comprehensive income	-	-	16,176	-	85	3,418
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(3,839)	-	-	-
Transfer from other components of equity to retained earnings	-	-	36	-	-	(36)
Total transactions with owners	-	-	(3,803)	(0)	-	(36)
Balance at end of period	5,174	4,445	192,806	(2,480)	(531)	12,051

	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	-	16,176	0	16,176
Other comprehensive income	3,503	3,503	-	3,503
Comprehensive income	3,503	19,679	0	19,680
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(3,839)	-	(3,839)
Transfer from other components of equity to retained earnings	(36)	-	-	-
Total transactions with owners	(36)	(3,839)	-	(3,839)
Balance at end of period	11,520	211,466	308	211,774

(4) Consolidated Statements of Cash Flow

(Millions of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Cash flows from operating activities		
Profit before tax	19,398	21,146
Depreciation and amortization	2,388	2,462
Interest and dividend income	(297)	(326)
Interest expenses	21	24
Foreign exchange loss (gain)	(1,463)	(1,378)
Loss (gain) on sale and retirement of fixed assets	30	50
Decrease (increase) in trade and other receivables	(1,187)	(3,737)
Decrease (increase) in inventories	1,890	2,101
Increase (decrease) in trade and other payables	(4,631)	(2,485)
Increase (decrease) in retirement benefit liability	(332)	(397)
Other	(45)	(2,852)
Subtotal	15,772	14,606
Interest and dividends received	297	324
Interest paid	(21)	(24)
Income taxes paid	(3,231)	(6,967)
Net cash provided by (used in) operating activities	12,817	7,938
Cash flows from investing activities		
Payments into time deposits	(60)	(60)
Proceeds from withdrawal of time deposits	30	30
Purchase of property, plant and equipment	(3,037)	(2,169)
Purchase of intangible assets	(1,488)	(1,751)
Purchase of investments	(5,551)	(2,500)
Proceeds from sale and redemption of investments	4,223	4,752
Other	1	4
Net cash provided by (used in) investing activities	(5,882)	(1,693)
Cash flows from financing activities		
Repayments of lease liabilities	(939)	(846)
Purchase of treasury shares	(0)	(0)
Dividends paid	(3,971)	(3,837)
Net cash provided by (used in) financing activities	(4,911)	(4,685)
Effect of exchange rate changes on cash and cash equivalents	859	1,248
Net increase (decrease) in cash and cash equivalents	2,883	2,807
Cash and cash equivalents at beginning of period	60,566	60,047
Cash and cash equivalents at end of period	63,449	62,855

Performance (consolidated)

(¥ million)

	2017 (JGAAP)	2018 (JGAAP)	2019 (JGAAP)	2020 (IFRS)	2021 (IFRS)	2022 (IFRS)	2023 (IFRS) (estimated)
Revenue	101,448	114,716	116,637	121,859	137,484	144,175	147,000
Operating profit	17,079	20,644	21,668	27,202	32,948	30,049	33,500
Profit before tax	17,451	21,540	22,442	27,608	33,301	30,489	34,000
Profit attributable to owners of parent	12,953	16,302	16,866	19,540	24,986	22,812	26,000

(¥ million)

Brand name	Active Ingredient	Indications	Launch Date	Sales 2021 (IFRS)	Sales 2022 (IFRS)	Sales 2023	
						Apr.-Sep.	Annual (estimated)
Viltepso	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	7,750	14,341	8,358	18,300
(Japan)				(4,059)	(4,139)	(2,188)	(4,800)
(U.S.)				(3,691)	(10,201)	(6,169)	(13,500)
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	8,400	10,543	6,465	14,000
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	18,338	15,951	5,526	10,200
Gazyva	obinutuzumab	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	Aug-2018/ Dec-2022	5,300	4,904	2,439	4,900
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	6,770	5,358	2,080	3,900
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,532	2,938	1,250	2,500
Adcirca	tadalafil	pulmonary arterial hypertension	Dec-2009	4,563	2,649	1,190	2,100
Zalutia	tadalafil	urinary disorder caused by benign prostatic hyperplasia	Apr-2014	4,106	2,826	1,161	2,200
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	2,128	2,524	1,099	2,300
Erizas	dexamethasone cipeclate	allergic rhinitis	Dec-2009	2,330	2,640	584	2,200
Profit in co-promotion				8,934	9,520	4,404	8,800
Revenues from the licensing of industrial property rights				33,207	30,714	18,580	38,000
Pharmaceuticals				120,650	121,988	60,988	125,000
Functional Food				16,834	22,187	12,325	22,000
Revenue				137,484	144,175	73,314	147,000

Nippon Shinyaku : R&D Pipeline List

<Domestic>

November 13, 2023

Stage	Code No. (Generic name)	Therapeutic field	Indications	Origin	Development
Launch Phase III	NS-065/NCNP-01 (viltolarsen)	intractable disease・orphan disease	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku
NDA filing	NS-87 (daunorubicin / cytarabine)	hematologic malignancies	high-risk acute myeloid leukemia	Licensed - in from Jazz Pharmaceuticals plc	Nippon Shinyaku
NDA filing	ZX008 (fenfluramine hydrochloride)	intractable disease・orphan disease	Lennox-Gastaut syndrome	Distribution partnership: UCB S.A. (former : Zogenix, Inc.)	UCB S.A. (former : Zogenix, Inc.)
Phase III	ZX008 (fenfluramine hydrochloride)	intractable disease・orphan disease	CDKL5 deficiency disorder	Distribution partnership: UCB S.A. (former : Zogenix, Inc.)	UCB S.A. (former : Zogenix, Inc.)
Phase III	GA101 (obinutuzumab)	intractable disease・orphan disease	lupus nephritis	Licensed - in from Chugai Pharmaceutical Co., Ltd.	Co - development: Chugai Pharmaceutical Co., Ltd.
Phase III	GA101 (obinutuzumab)	intractable disease・orphan disease	pediatric nephrotic syndrome	Licensed - in from Chugai Pharmaceutical Co., Ltd.	Co - development: Chugai Pharmaceutical Co., Ltd.
Phase III	GA101 (obinutuzumab)	intractable disease・orphan disease	extra renal lupus	Licensed - in from Chugai Pharmaceutical Co., Ltd.	Co - development: Chugai Pharmaceutical Co., Ltd.
Phase II	NS-304 (selexipag)	cardiovascular	arteriosclerosis obliterans	Nippon Shinyaku	Nippon Shinyaku
Phase II	NS-304 (selexipag)	intractable disease・orphan disease	pediatric pulmonary arterial hypertension	Nippon Shinyaku	Co - development: Janssen Pharmaceutical K.K.
Phase II	NS-580	gynecology	endometriosis	Nippon Shinyaku	Nippon Shinyaku
Phase II	NS-580	urological diseases	chronic prostatitis/chronic pelvic pain syndrome	Nippon Shinyaku	Nippon Shinyaku
Preparation for Phase II	NS-089/NCNP-02 (brogidirsen)	intractable disease・orphan disease	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku
Preparation for Phase II	NS-229	intractable disease・orphan disease	Eosinophilic granulomatosis with polyangiitis	Nippon Shinyaku	Nippon Shinyaku
Phase I/II	NS-401 (tagraxofusp)	hematologic malignancies	blastic plasmacytoid dendritic cell neoplasm	Licensed - in from The Menarini Group	Nippon Shinyaku
Preparation for Phase I/II	NS-050/NCNP-03	intractable disease・orphan disease	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku
Phase I	NS-917 (radgocitabine)	hematologic malignancies	relapsed/refractory acute myeloid leukemia	Licensed - in from Delta-Fly Pharma, Inc.	Nippon Shinyaku
Phase I	NS-161	inflammatory diseases	inflammatory diseases	Nippon Shinyaku	Nippon Shinyaku
Phase I	NS-025	urological diseases	urological diseases	Nippon Shinyaku	Nippon Shinyaku
Phase I	NS-863	cardiovascular	cardiovascular diseases	Nippon Shinyaku	Nippon Shinyaku

<Overseas>

Stage	Code No. (Generic name)	Therapeutic field	Indications	Origin	Development
US Launch Phase III	NS-065/NCNP-01 (viltolarsen)	intractable disease・orphan disease	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku
Phase III	CAP-1002	intractable disease・orphan disease	Duchenne muscular dystrophy	Partnership: Capricor Therapeutics, Inc.	Capricor Therapeutics, Inc.
Phase II	NS-018 (ilginatinib)	hematologic malignancies	myelofibrosis	Nippon Shinyaku	Nippon Shinyaku
Preparation for Phase II	NS-089/NCNP-02 (brogidirsen)	intractable disease・orphan disease	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku
Preparation for Phase II	NS-229	intractable disease・orphan disease	Eosinophilic granulomatosis with polyangiitis	Nippon Shinyaku	Nippon Shinyaku
Preparation for Phase I/II	NS-050/NCNP-03	intractable disease・orphan disease	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku