

Outline of Consolidated Financial Results for the Second Quarter Ended September 30, 2022 (IFRS)

November 10, 2022

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, 2022

Scheduled start of payment: December 5, 2022

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 September 30, 2022 (April 1, 2022 to September 30, 2022)

(1) Operating results

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
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)
Second quarter ended September 30, 2021	71,533	—	21,808	—	22,006	—	16,527	—	16,519	—	15,837	—
Earnings per share (¥)												
	Basic		Diluted									
Second quarter ended September 30, 2022	226.01		—									
Second quarter ended September 30, 2021	245.27		—									

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, 2022	225,374	191,503	191,197	84.8%
As of March 31, 2022	219,943	180,886	180,585	82.1%

2. Dividends

	Annual dividends per share (¥)				
	1 st quarter	2 nd quarter	3 rd quarter	Year-end	Annual
Year ended March 31, 2022	—	51.00	—	59.00	110.00
Year ending March 31, 2023	—	57.00	—	—	—
Year ending March 31, 2023 (forecast)	—	—	—	57.00	114.00

3. Business Forecast for the Year Ending March 31, 2023 (April 1, 2022 to March 31, 2023)

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit attributable to owners of parent		Basic earnings per share (¥)
		%		%		%		%	
Full term	141,000	2.6	30,000	(8.9)	30,400	(8.7)	24,000	(4.0)	356.33

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, 2022: 70,251,484 shares

As of March 31, 2022: 70,251,484 shares

Number of shares of treasury stock

As of September 30, 2022: 2,898,520 shares

As of March 31, 2022: 2,898,434 shares

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

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

As of September 30, 2021: 67,353,287 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.

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, 2022	As of September 30, 2022
Assets		
Current assets		
Cash and cash equivalents	60,566	63,449
Trade and other receivables	43,178	44,614
Inventories	38,066	36,349
Other financial assets	5,174	6,435
Other current assets	2,738	4,490
Total current assets	149,724	155,339
Non-current assets		
Property, plant and equipment	28,304	30,070
Intangible assets	14,050	12,727
Right-of-use assets	2,753	2,516
Other financial assets	22,294	21,929
Deferred tax assets	901	904
Other non-current assets	1,915	1,886
Total non-current assets	70,219	70,035
Total assets	219,943	225,374

(Millions of yen)

	As of March 31, 2022	As of September 30, 2022
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	21,022	15,129
Other financial liabilities	374	352
Lease liabilities	1,494	1,338
Income taxes payable	3,123	3,964
Other current liabilities	6,014	6,580
Total current liabilities	32,029	27,365
Non-current liabilities		
Other financial liabilities	237	232
Lease liabilities	1,219	1,040
Retirement benefit liability	5,506	5,174
Other non-current liabilities	64	57
Total non-current liabilities	7,027	6,504
Total liabilities	39,057	33,870
Equity		
Share capital	5,174	5,174
Capital surplus	4,445	4,445
Retained earnings	165,303	176,568
Treasury shares	(2,478)	(2,479)
Other components of equity	8,140	7,488
Total equity attributable to owners of parent	180,585	191,197
Non-controlling interests	300	306
Total equity	180,886	191,503
Total liabilities and equity	219,943	225,374

(2) Consolidated Statements of Income

(Millions of yen)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Revenue	71,533	71,136
Cost of sales	24,254	27,991
Gross profit	47,278	43,144
Selling, general and administrative expenses	15,381	16,284
Research and development expenses	10,117	9,691
Other income	369	2,805
Other expenses	340	813
Operating profit	21,808	19,161
Finance income	246	297
Finance costs	48	60
Profit before tax	22,006	19,398
Income tax expense	5,479	4,170
Profit	16,527	15,228
Profit attributable to		
Owners of parent	16,519	15,222
Non-controlling interests	7	5
Profit	16,527	15,228
Earnings per share		
Basic earnings per share	245.27	226.01

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Profit	16,527	15,228
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(674)	(230)
Total of items that will not be reclassified to profit or loss	(674)	(230)
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(15)	(406)
Total of items that may be reclassified to profit or loss	(15)	(406)
Total other comprehensive income	(690)	(636)
Comprehensive income	15,837	14,591
Comprehensive income attributable to		
Owners of parent	15,829	14,585
Non-controlling interests	7	5
Comprehensive income	15,837	14,591

(3) Consolidated Statements of Changes in Net Assets
For the three-month period ended September 30, 2021

(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	146,796	(2,476)	(93)	9,315
Profit	-	-	16,519	-	-	-
Other comprehensive income	-	-	-	-	(15)	(674)
Comprehensive income	-	-	16,519	-	(15)	(674)
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(3,367)	-	-	-
Transfer from other components of equity to retained earnings	-	-	367	-	-	(367)
Total transactions with owners	-	-	(2,999)	(0)	-	(367)
Balance at end of period	5,174	4,445	160,315	(2,476)	(108)	8,272

	Equity attributable to owners of parent			
	Other components of equity	Total	Non-controlling interests	Total
	Total			
Balance at beginning of period	9,221	163,161	288	163,449
Profit	-	16,519	7	16,527
Other comprehensive income	(690)	(690)	-	(690)
Comprehensive income	(690)	15,829	7	15,837
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(3,367)	-	(3,367)
Transfer from other components of equity to retained earnings	(367)	-	-	-
Total transactions with owners	(367)	(3,367)	-	(3,367)
Balance at end of period	8,163	175,622	295	175,918

For the three-month period ended September 30, 2022

(Millions of yen)

	Equity attributable to owners of parent					Other components of equity	
	Share capital	Capital surplus	Retained earnings	Treasury shares	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

(4) Consolidated Statements of Cash Flows

(Millions of yen)

	Six months ended September 30, 2021	Six months ended September 30, 2022
Cash flows from operating activities		
Profit before tax	22,006	19,398
Depreciation and amortization	2,264	2,388
Interest and dividend income	(246)	(297)
Interest expenses	22	21
Foreign exchange loss (gain)	(0)	(1,463)
Decrease (increase) in trade and other receivables	303	(1,187)
Decrease (increase) in inventories	(188)	1,890
Increase (decrease) in trade and other payables	(1,484)	(4,631)
Increase (decrease) in retirement benefit liability	(351)	(332)
Other	(1,725)	(14)
Subtotal	20,600	15,772
Interest and dividends received	246	297
Interest paid	(10)	(21)
Income taxes paid	(6,723)	(3,231)
Net cash provided by (used in) operating activities	14,113	12,817
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	(1,272)	(3,037)
Purchase of intangible assets	(1,792)	(1,488)
Purchase of investments	(0)	(5,551)
Proceeds from sale and redemption of investments	1,157	4,223
Other	2	1
Net cash provided by (used in) investing activities	(1,935)	(5,882)
Cash flows from financing activities		
Repayments of lease liabilities	(795)	(939)
Purchase of treasury shares	(0)	(0)
Dividends paid	(3,365)	(3,971)
Net cash provided by (used in) financing activities	(4,161)	(4,911)
Effect of exchange rate changes on cash and cash equivalents	(15)	859
Net increase (decrease) in cash and cash equivalents	7,999	2,883
Cash and cash equivalents at beginning of period	57,883	60,566
Cash and cash equivalents at end of period	65,883	63,449

Appendix:
Leading Products

Performance (consolidated)

(¥ million)

	2016 (JGAAP)	2017 (JGAAP)	2018 (JGAAP)	2019 (JGAAP)	2020 (IFRS)	2021 (IFRS)	2022 (IFRS) (estimated)
Revenue	98,781	101,448	114,716	116,637	121,859	137,484	141,000
Operating profit	15,280	17,079	20,644	21,668	27,702	32,948	30,000
Profit before tax	16,244	17,451	21,540	22,442	27,608	33,301	30,400
Profit attributable to owners of parent	11,749	12,953	16,302	16,866	19,540	24,986	24,000

(¥ million)

Brand name	Active Ingredient	Indications	Launch Date	Sales 2020 (IFRS)	Sales 2021 (IFRS)	Sales 2022	
						Apr.-Sep.	Annual (estimated)
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	15,350	18,338	9,139	14,600
Viltepso	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	2,387	7,750	6,856	14,700
(Japan)				(1,953)	(4,059)	(2,090)	(4,500)
(U.S.)				(434)	(3,691)	(4,765)	(10,200)
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	6,804	8,400	4,921	10,300
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	6,906	6,770	2,997	5,500
Gazyva	obinutuzumab	CD20-positive follicular lymphoma	Aug-2018	5,312	5,300	2,618	5,400
Zalutia	tadalafil	urinary disorder caused by benign prostatic hyperplasia	Apr-2014	6,743	4,106	1,470	2,700
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,677	2,532	1,439	2,850
Adcirca	tadalafil	pulmonary arterial hypertension	Dec-2009	5,474	4,563	1,392	2,500
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	1,970	2,128	1,259	2,900
Erizas	dexamethasone cipeclate	allergic rhinitis	Dec-2009	2,444	2,330	674	2,400
Profit in co-promotion				8,442	8,934	5,005	9,500
Revenues from the licensing of industrial property rights				24,338	33,207	14,469	30,200
Pharmaceuticals				106,478	120,650	60,499	119,500
Functional Food				15,380	16,834	10,637	21,500
Revenue				121,859	137,484	71,136	141,000

Appendix:
R&D Pipeline List

< Domestic >

As of November 10, 2022

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
Preparation for launch	NS-32 (ferric derisomaltose)	gynecology	iron deficiency anemia	Licensed - in from Pharmacosmos A/S	Nippon Shinyaku
Preparation for launch	ZX008 (fenfluramine hydrochloride)	intractable disease ・ orphan disease	Dravet syndrome	Licensed - in from UCB S.A. (former : Zogenix, Inc.)	UCB S.A. (former : Zogenix, Inc.)
Phase III	ZX008 (fenfluramine hydrochloride)	intractable disease ・ orphan disease	Lennox-Gastaut syndrome	Licensed - in from UCB S.A. (former : Zogenix, Inc.)	UCB S.A. (former : Zogenix, Inc.)
Phase III	GA101 (obinutuzumab)	inflammatory diseases	lupus nephritis	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 I/II	NS-87 (daunorubicin / cytarabine)	hematologic malignancies	secondary acute myeloid leukemia	Licensed - in from Jazz Pharmaceuticals plc	Nippon Shinyaku
Phase I/II	NS-401 (tagraxofusp)	hematologic malignancies	blastic plasmacytoid dendritic cell neoplasm	Licensed - in from The Menarini Group	Nippon Shinyaku
Phase I	NS-229	inflammatory diseases	inflammatory diseases	Nippon Shinyaku	Nippon Shinyaku
Phase I	NS-917 (radgocitabine)	hematologic malignancies	relapsed/refractory acute myeloid leukemia	Licensed - in from Delta-Fly Pharma, Inc.	Nippon Shinyaku
Preparation for Phase I	NS-161	inflammatory diseases	inflammatory diseases	Nippon Shinyaku	Nippon Shinyaku
Preparation for Phase I	NS-025	urological diseases	urological diseases	Nippon Shinyaku	Nippon Shinyaku

< Overseas >

Stage	Code No. (Generic name)	Therapeutic field	Indications	Origin	Development
U.S. 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.
Preparation for Phase II	NS-018 (ilginatinib)	hematologic malignancies	myelofibrosis	Nippon Shinyaku	Nippon Shinyaku