

Outline of Consolidated Financial Results for the Third Quarter Ended December 31, 2022 (IFRS)

February 10, 2023

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

Listing stock exchange: Tokyo

Code No.: 4516

URL <https://www.nippon-shinyaku.co.jp/>

Representative: Toru Nakai, President and Representative Director

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

Tel. +81-75-321-9116

Scheduled date for submission of quarterly Securities Report: February 14, 2023

Scheduled start of payment: —

Supplementary material: Yes

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

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

1. Consolidated Results for the Year Ended December 31, 2022 (April 1, 2022 to December 31, 2022)

(1) Operating results

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
Third quarter ended December 31, 2022	109,919	3.4	27,987	(7.8)	28,422	(7.5)	22,681	(1.7)	22,674	(1.7)	22,895	3.7
Third quarter ended December 31, 2021	106,292	—	30,353	—	30,722	—	23,072	—	23,062	—	22,077	—

Earnings per share (¥)

	Basic	Diluted
Third quarter ended December 31, 2022	336.65	—
Third quarter ended December 31, 2021	342.41	—

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 December 31, 2022	231,876	195,968	195,660	84.4%
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	(3.9)	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 December 31, 2022: 70,251,484 shares

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

Number of shares of treasury stock

As of December 31, 2022: 2,898,549 shares

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

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

As of December 31, 2022: 67,352,988 shares

As of December 31, 2021: 67,353,253 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 December 31, 2022
Assets		
Current assets		
Cash and cash equivalents	60,566	54,919
Trade and other receivables	43,178	51,607
Inventories	38,066	37,357
Other financial assets	5,174	9,517
Other current assets	2,738	5,026
Total current assets	149,724	158,427
Non-current assets		
Property, plant and equipment	28,304	31,160
Intangible assets	14,050	15,592
Right-of-use assets	2,753	2,228
Other financial assets	22,294	22,435
Deferred tax assets	901	147
Other non-current assets	1,915	1,884
Total non-current assets	70,219	73,448
Total assets	219,943	231,876

(Millions of yen)

	As of March 31,2022	As of December 31, 2022
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	21,022	20,517
Other financial liabilities	374	1,156
Lease liabilities	1,494	1,237
Income taxes payable	3,123	1,217
Other current liabilities	6,014	5,612
Total current liabilities	32,029	29,740
Non-current liabilities		
Other financial liabilities	237	232
Lease liabilities	1,219	873
Retirement benefit liability	5,506	5,003
Other non-current liabilities	64	57
Total non-current liabilities	7,027	6,167
Total liabilities	39,057	35,908
Equity		
Share capital	5,174	5,174
Capital surplus	4,445	4,445
Retained earnings	165,303	180,406
Treasury shares	(2,478)	(2,479)
Other components of equity	8,140	8,114
Total equity attributable to owners of parent	180,585	195,660
Non-controlling interests	300	307
Total equity	180,886	195,968
Total liabilities and equity	219,943	231,876

(2) Consolidated Statements of Income

(Millions of yen)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022
Revenue	106,292	109,919
Cost of sales	37,520	42,556
Gross profit	68,771	67,363
Selling, general and administrative expenses	23,239	24,791
Research and development expenses	15,541	15,135
Other income	871	1,492
Other expenses	509	941
Operating profit	30,353	27,987
Finance income	452	533
Finance costs	82	98
Profit before tax	30,722	28,422
Income tax expense	7,650	5,741
Profit	23,072	22,681
Profit attributable to		
Owners of parent	23,062	22,674
Non-controlling interests	10	7
Profit	23,072	22,681
Earnings per share		
Basic earnings per share	342.41	336.65

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022
Profit	23,072	22,681
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(921)	566
Total of items that will not be reclassified to profit or loss	(921)	566
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(73)	(352)
Total of items that may be reclassified to profit or loss	(73)	(352)
Total other comprehensive income	(995)	214
Comprehensive income	<u>22,077</u>	<u>22,895</u>
Comprehensive income attributable to		
Owners of parent	22,066	22,888
Non-controlling interests	10	7
Comprehensive income	<u>22,077</u>	<u>22,895</u>

(3) Consolidated Statements of Changes in Net Assets
For the nine-month period ended December 31,2021

(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	146,796	(2,476)	(93)	9,315
Profit	-	-	23,062	-	-	-
Other comprehensive income	-	-	-	-	(73)	(921)
Comprehensive income	-	-	23,062	-	(73)	(921)
Purchase of treasury shares	-	-	-	(1)	-	-
Dividends of surplus	-	-	(6,802)	-	-	-
Transfer from other components of equity to retained earnings	-	-	367	-	-	(367)
Total transactions with owners	-	-	(6,434)	(1)	-	(367)
Balance at end of period	5,174	4,445	163,423	(2,477)	(166)	8,025

	Equity attributable to owners of parent			Total
	Other components of equity	Total	Non-controlling interests	
	Total			
Balance at beginning of period	9,221	163,161	288	163,449
Profit	-	23,062	10	23,072
Other comprehensive income	(995)	(995)	-	(995)
Comprehensive income	(995)	22,066	10	22,077
Purchase of treasury shares	-	(1)	-	(1)
Dividends of surplus	-	(6,802)	-	(6,802)
Transfer from other components of equity to retained earnings	(367)	-	-	-
Total transactions with owners	(367)	(6,804)	-	(6,804)
Balance at end of period	7,858	178,424	298	178,723

For the nine-month period ended December 31,2022

(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	-	-	22,674	-	-	-
Other comprehensive income	-	-	-	-	(352)	566
Comprehensive income	-	-	22,674	-	(352)	566
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(7,812)	-	-	-
Transfer from other components of equity to retained earnings	-	-	241	-	-	(241)
Total transactions with owners	-	-	(7,571)	(0)	-	(241)
Balance at end of period	5,174	4,445	180,406	(2,479)	(606)	8,720

	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	-	22,674	7	22,681
Other comprehensive income	214	214	-	214
Comprehensive income	214	22,888	7	22,895
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(7,812)	-	(7,812)
Transfer from other components of equity to retained earnings	(241)	-	-	-
Total transactions with owners	(241)	(7,813)	-	(7,813)
Balance at end of period	8,114	195,660	307	195,968

(4) Consolidated Statements of Cash Flows

(Millions of yen)

	Nine months ended December 31, 2021	Nine months ended December 31, 2022
Cash flows from operating activities		
Profit before tax	30,722	28,422
Depreciation and amortization	3,424	3,679
Interest and dividend income	(452)	(533)
Interest expenses	40	31
Foreign exchange loss (gain)	(2)	(457)
Decrease (increase) in trade and other receivables	(9,228)	(8,363)
Decrease (increase) in inventories	(2,187)	776
Increase (decrease) in trade and other payables	315	(2,814)
Increase (decrease) in retirement benefit liability	(521)	(502)
Other	(2,127)	(979)
Subtotal	19,984	19,258
Interest and dividends received	451	533
Interest paid	(21)	(31)
Income taxes paid	(11,295)	(7,142)
Net cash provided by (used in) operating activities	9,119	12,618
Cash flows from investing activities		
Payments into time deposits	(385)	(85)
Proceeds from withdrawal of time deposits	40	40
Purchase of property, plant and equipment	(2,010)	(4,354)
Purchase of intangible assets	(2,348)	(1,176)
Purchase of investments	(501)	(9,449)
Proceeds from sale and redemption of investments	1,657	5,594
Other	1	8
Net cash provided by (used in) investing activities	(3,545)	(9,421)
Cash flows from financing activities		
Repayments of lease liabilities	(1,183)	(1,322)
Purchase of treasury shares	(1)	(0)
Dividends paid	(6,605)	(7,599)
Net cash provided by (used in) financing activities	(7,790)	(8,922)
Effect of exchange rate changes on cash and cash equivalents	(68)	78
Net increase (decrease) in cash and cash equivalents	(2,285)	(5,647)
Cash and cash equivalents at beginning of period	57,883	60,566
Cash and cash equivalents at end of period	55,597	54,919

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	27,202	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 (IFRS)	
						Apr-Dec	Annual (estimated)
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	15,350	18,338	13,047	14,600
Viltepso	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	2,387	7,750	10,717	14,700
(Japan)				(1,953)	(4,059)	(3,188)	(4,500)
(U.S.)				(434)	(3,691)	(7,528)	(10,200)
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	6,804	8,400	7,984	10,300
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	6,906	6,770	4,349	5,500
Gazyva	obinutuzumab	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	Aug-2018/ Dec-2022	5,312	5,300	3,918	5,400
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,677	2,532	2,287	2,850
Zalutia	tadalafil	urinary disorder caused by benign prostatic hyperplasia	Apr-2014	6,743	4,106	2,233	2,700
Adcirca	tadalafil	pulmonary arterial hypertension	Dec-2009	5,474	4,563	2,117	2,500
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	1,970	2,128	2,041	2,900
Erizas	dexamethasone cipeccilate	allergic rhinitis	Dec-2009	2,444	2,330	1,146	2,400
Profit in co-promotion				8,442	8,934	7,634	9,500
Revenues from the licensing of industrial property rights				24,338	33,207	22,607	30,200
Pharmaceuticals				106,478	120,650	93,095	119,500
Functional Food				15,380	16,834	16,824	21,500
Revenue				121,859	137,484	109,919	141,000

Appendix:
R&D Pipeline List

< Domestic >

As of February 10, 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
Preparation for launch	NS-32 (ferric derisomaltose)	gynecology	iron deficiency anemia	Licensed - in from Pharmacosmos A/S	Nippon Shinyaku
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
Phase I	NS-161	inflammatory diseases	inflammatory diseases	Nippon Shinyaku	Nippon Shinyaku
Phase I	NS-025	urological diseases	urological 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 (ilglatinib)	hematologic malignancies	myelofibrosis	Nippon Shinyaku	Nippon Shinyaku