

Outline of Consolidated Financial Results for the Third Quarter Ended December 31, 2023 (IFRS)

February 9, 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 date for submission of quarterly Securities Report: February 14, 2024

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 December 31, 2023 (April 1, 2023 to December 31, 2023)

(1) Operating results												(¥ million)
	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
Third quarter ended December 31, 2023	112,728	2.6	30,450	8.8	30,973	9.0	24,004	5.8	24,002	5.9	27,398	19.7
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
Earnings per share (¥)												
	Basic		Diluted									
Third quarter ended December 31, 2023	356.37		—									
Third quarter ended December 31, 2022	336.65		—									

Note: Equity-method investments: not applicable

(2) Financial position					(¥ million)
	Total assets		Total equity		Ratio of equity attributable to owners of parent to total assets
As of December 31, 2023	247,830		215,316		86.8%
As of March 31, 2023	237,451		195,933		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	—	62.00	124.00
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 December 31, 2023: 70,251,484 shares

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

Number of shares of treasury stock

As of December 31, 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 December 31, 2023: 67,352,821 shares

As of December 31, 2022: 67,352,988 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 December 31, 2023
Assets		
Current assets		
Cash and cash equivalents	60,047	57,323
Trade and other receivables	44,686	47,507
Inventories	36,358	38,848
Other financial assets	11,554	8,491
Other current assets	5,225	8,730
Total current assets	157,873	160,901
Non-current assets		
Property, plant and equipment	32,215	33,203
Intangible assets	17,155	19,322
Right-of-use assets	2,779	2,127
Other financial assets	22,308	28,346
Deferred tax assets	3,241	1,134
Other non-current assets	1,877	2,795
Total non-current assets	79,578	86,928
Total assets	237,451	247,830

(Millions of yen)

	As of March 31, 2023	As of December 31, 2023
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	20,538	19,089
Other financial liabilities	314	1,143
Lease liabilities	1,516	1,297
Income taxes payable	6,131	696
Other current liabilities	6,682	4,966
Total current liabilities	35,183	27,193
Non-current liabilities		
Other financial liabilities	232	232
Lease liabilities	1,148	751
Retirement benefit liability	4,895	4,277
Other non-current liabilities	57	58
Total non-current liabilities	6,334	5,319
Total liabilities	41,518	32,513
Equity		
Share capital	5,174	5,174
Capital surplus	4,445	4,445
Retained earnings	180,433	196,457
Treasury shares	(2,480)	(2,480)
Other components of equity	8,052	11,411
Total equity attributable to owners of parent	195,625	215,007
Non-controlling interests	307	309
Total equity	195,933	215,316
Total liabilities and equity	237,451	247,830

(2) Consolidated Statements of Income

(Millions of yen)

	Nine months ended December 31, 2022	Nine months ended December 31, 2023
Revenue	109,919	112,728
Cost of sales	42,556	38,613
Gross profit	67,363	74,114
Selling, general and administrative expenses	24,791	25,741
Research and development expenses	15,135	19,500
Other income	1,492	1,887
Other expenses	941	309
Operating profit	27,987	30,450
Finance income	533	611
Finance costs	98	89
Profit before tax	28,422	30,973
Income tax expense	5,741	6,968
Profit	22,681	24,004
Profit attributable to		
Owners of parent	22,674	24,002
Non-controlling interests	7	1
Profit	22,681	24,004
Earnings per share		
Basic earnings per share	336.65	356.37

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Nine months ended December 31, 2022	Nine months ended December 31, 2023
Profit	22,681	24,004
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	566	3,355
Total of items that will not be reclassified to profit or loss	566	3,355
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(352)	39
Total of items that may be reclassified to profit or loss	(352)	39
Total other comprehensive income	214	3,394
Comprehensive income	22,895	27,398
Comprehensive income attributable to		
Owners of parent	22,888	27,397
Non-controlling interests	7	1
Comprehensive income	22,895	27,398

(3) Consolidated Statements of Changes in Net Assets
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

For the nine-month period ended December 31, 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	-	-	24,002	-	-	-
Other comprehensive income	-	-	-	-	39	3,355
Comprehensive income	-	-	24,002	-	39	3,355
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(8,014)	-	-	-
Transfer from other components of equity to retained earnings	-	-	36	-	-	(36)
Total transactions with owners	-	-	(7,978)	(0)	-	(36)
Balance at end of period	5,174	4,445	196,457	(2,480)	(577)	11,988

	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	-	24,002	1	24,004
Other comprehensive income	3,394	3,394	-	3,394
Comprehensive income	3,394	27,397	1	27,398
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(8,014)	-	(8,014)
Transfer from other components of equity to retained earnings	(36)	-	-	-
Total transactions with owners	(36)	(8,015)	-	(8,015)
Balance at end of period	11,411	215,007	309	215,316

(4) Consolidated Statements of Cash Flow

(Millions of yen)

	Nine months ended December 31, 2022	Nine months ended December 31, 2023
Cash flows from operating activities		
Profit before tax	28,422	30,973
Depreciation and amortization	3,679	3,695
Interest and dividend income	(533)	(611)
Interest expenses	31	31
Foreign exchange loss (gain)	(457)	(894)
Loss (gain) on sale and retirement of fixed assets	43	61
Decrease (increase) in trade and other receivables	(8,363)	(2,673)
Decrease (increase) in inventories	776	(2,433)
Increase (decrease) in trade and other payables	(2,814)	(3,713)
Increase (decrease) in retirement benefit liability	(502)	(617)
Other	(1,023)	(4,506)
Subtotal	19,258	19,311
Interest and dividends received	533	616
Interest paid	(31)	(31)
Income taxes paid	(7,142)	(11,769)
Net cash provided by (used in) operating activities	12,618	8,126
Cash flows from investing activities		
Payments into time deposits	(85)	(85)
Proceeds from withdrawal of time deposits	40	40
Purchase of property, plant and equipment	(4,354)	(2,635)
Purchase of intangible assets	(1,176)	(1,833)
Purchase of investments	(9,449)	(6,997)
Proceeds from sale and redemption of investments	5,594	8,850
Other	8	6
Net cash provided by (used in) investing activities	(9,421)	(2,654)
Cash flows from financing activities		
Repayments of lease liabilities	(1,322)	(1,260)
Purchase of treasury shares	(0)	(0)
Dividends paid	(7,599)	(7,785)
Net cash provided by (used in) financing activities	(8,922)	(9,046)
Effect of exchange rate changes on cash and cash equivalents	78	849
Net increase (decrease) in cash and cash equivalents	(5,647)	(2,724)
Cash and cash equivalents at beginning of period	60,566	60,047
Cash and cash equivalents at end of period	54,919	57,323

Nippon Shinyaku:Leading Products

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

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(¥ million)

Brand name	Active Ingredient	Indications	Launch Date	Sales 2021 (IFRS)	Sales 2022 (IFRS)	Sales 2023(IFRS)	
						Apr-Dec	Annual (estimated)
Viltepso				7,750	14,341	13,225	18,300
(Japan)	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	(4,059)	(4,139)	(3,332)	(4,800)
(U.S.)				(3,691)	(10,201)	(9,892)	(13,500)
Uptravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	8,400	10,543	10,024	14,000
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	18,338	15,951	8,329	10,200
Gazyva	obinutuzumab	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	Aug-2018/ Dec-2022	5,300	4,904	3,692	4,900
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	6,770	5,358	3,142	3,900
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,532	2,938	1,946	2,500
Adcirca	tadalafil	pulmonary arterial hypertension	Dec-2009	4,563	2,649	1,791	2,100
Zalutia	tadalafil	urinary disorder caused by benign prostatic hyperplasia	Apr-2014	4,106	2,826	1,788	2,200
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	2,128	2,524	1,712	2,300
Erizas	dexamethasone cipeclate	allergic rhinitis	Dec-2009	2,330	2,640	1,038	2,200
Profit in co-promotion				8,934	9,520	6,703	8,800
Revenues from the licensing of industrial property rights				33,207	30,714	28,897	38,000
Pharmaceuticals				120,650	121,988	94,606	125,000
Functional Food				16,834	22,187	18,121	22,000
Revenue				137,484	144,175	112,728	147,000

Nippon Shinyaku: R&D Pipeline List

< Domestic >

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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