

# Outline of Consolidated Financial Results for the Third Quarter Ended December 31, 2024 (IFRS)

February 7, 2025

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 December 31, 2024 (April 1, 2024 to December 31, 2024)

### (1) Operating results

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
Third quarter ended December 31, 2024	121,320	7.6	32,752	7.6	33,438	8.0	28,556	19.0	28,552	19.0	35,557	29.8
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

#### Earnings per share (¥)

	Basic	Diluted
Third quarter ended December 31, 2024	423.93	423.84
Third quarter ended December 31, 2023	356.37	—

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, 2024	284,459	247,782	247,469	87.0%
As of March 31, 2024	263,404	220,534	220,224	83.6%

## 2. Dividends

### Annual dividends per share (¥)

	1 <sup>st</sup> quarter	2 <sup>nd</sup> quarter	3 <sup>rd</sup> quarter	Year-end	Annual
Year ended March 31, 2024	—	62.00	—	62.00	124.00
Year ending March 31, 2025	—	62.00	—	62.00	124.00
Year ending March 31, 2025 (forecast)	—	—	—	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		Profit attributable to owners of parent		Basic earnings per share (¥)
		%		%		%		%	
Full term	160,000	7.9	36,000	8.1	36,600	8.9	31,500	21.9	467.51

#### 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, 2024: 70,251,484 shares

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

Number of shares of treasury stock

As of December 31, 2024: 2,872,786 shares

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

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

As of December 31, 2024: 67,352,595 shares

As of December 31, 2023: 67,352,821 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 December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	58,094	55,421
Trade and other receivables	47,237	50,532
Inventories	39,111	44,501
Other financial assets	10,609	4,656
Other current assets	9,232	7,248
Total current assets	164,285	162,359
Non-current assets		
Property, plant and equipment	33,582	34,189
Intangible assets	25,120	32,690
Right-of-use assets	2,971	2,508
Other financial assets	32,862	44,578
Deferred tax assets	1,766	4,944
Other non-current assets	2,817	3,188
Total non-current assets	99,119	122,099
Total assets	263,404	284,459

(Millions of yen)

	As of March 31, 2024	As of December 31, 2024
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	24,706	16,781
Other financial liabilities	372	1,055
Lease liabilities	1,720	1,219
Income taxes payable	3,594	4,231
Other current liabilities	6,941	5,831
Total current liabilities	37,336	29,119
Non-current liabilities		
Other financial liabilities	232	233
Lease liabilities	1,152	1,235
Retirement benefit liability	4,090	4,074
Deferred tax liabilities	—	1,953
Other non-current liabilities	58	59
Total non-current liabilities	5,533	7,556
Total liabilities	42,870	36,676
Equity		
Share capital	5,174	5,174
Capital surplus	4,445	4,468
Retained earnings	198,260	218,803
Treasury shares	(2,480)	(2,459)
Other components of equity	14,825	21,482
Total equity attributable to owners of parent	220,224	247,469
Non-controlling interests	310	313
Total equity	220,534	247,782
Total liabilities and equity	263,404	284,459

## (2) Consolidated Statements of Income

(Millions of yen)

	Nine months ended December 31, 2023	Nine months ended December 31, 2024
Revenue	112,728	121,320
Cost of sales	38,613	38,810
Gross profit	74,114	82,509
Selling, general and administrative expenses	25,741	27,562
Research and development expenses	19,500	23,547
Other income	1,887	1,725
Other expenses	309	371
Operating profit	30,450	32,752
Finance income	611	774
Finance costs	89	89
Profit before tax	30,973	33,438
Income tax expense	6,968	4,881
Profit	24,004	28,556
Profit attributable to		
Owners of parent	24,002	28,552
Non-controlling interests	1	3
Profit	24,004	28,556
Earnings per share		
Basic earnings per share	356.37	423.93
Diluted earnings (loss) per share	-	423.84

## (Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Nine months ended December 31, 2023	Nine months ended December 31, 2024
Profit	24,004	28,556
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	3,355	7,196
Total of items that will not be reclassified to profit or loss	3,355	7,196
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	39	(195)
Total of items that may be reclassified to profit or loss	39	(195)
Total other comprehensive income	3,394	7,001
Comprehensive income	27,398	35,557
Comprehensive income attributable to		
Owners of parent	27,397	35,554
Non-controlling interests	1	3
Comprehensive income	27,398	35,557

(3) Consolidated Statements of Changes in Net Assets  
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

For the nine-month period ended December 31,2024

(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	-	-	28,552	-	-	-
Other comprehensive income	-	-	-	-	(195)	7,196
Comprehensive income	-	-	28,552	-	(195)	7,196
Purchase of treasury shares	-	-	-	(1)	-	-
Dividends of surplus	-	-	(8,353)	-	-	-
Share-based payment transactions	-	22	-	22	-	-
Transfer from other components of equity to retained earnings	-	-	343	-	-	(343)
Total transactions with owners	-	22	(8,009)	21	-	(343)
Balance at end of period	5,174	4,468	218,803	(2,459)	(683)	22,166

	Equity attributable to owners of parent			
	Other components of equity		Non- controlling interests	Total
	Total	Total		
Balance at beginning of period	14,825	220,224	310	220,534
Profit	-	28,552	3	28,556
Other comprehensive income	7,001	7,001	-	7,001
Comprehensive income	7,001	35,554	3	35,557
Purchase of treasury shares	-	(1)	-	(1)
Dividends of surplus	-	(8,353)	-	(8,353)
Share-based payment transactions	-	45	-	45
Transfer from other components of equity to retained earnings	(343)	-	-	-
Total transactions with owners	(343)	(8,309)	-	(8,309)
Balance at end of period	21,482	247,469	313	247,782



## (4) Consolidated Statements of Cash Flow

(Millions of yen)

	Nine months ended December 31, 2023	Nine months ended December 31, 2024
Cash flows from operating activities		
Profit before tax	30,973	33,438
Depreciation and amortization	3,695	4,521
Interest and dividend income	(611)	(774)
Interest expenses	31	37
Foreign exchange loss (gain)	(894)	(926)
Loss (gain) on sale and retirement of fixed assets	61	7
Decrease (increase) in trade and other receivables	(2,673)	(3,119)
Decrease (increase) in inventories	(2,433)	(5,317)
Increase (decrease) in trade and other payables	(3,713)	(3,733)
Increase (decrease) in retirement benefit liability	(617)	(15)
Other	(4,506)	898
Subtotal	19,311	25,015
Interest and dividends received	616	775
Interest paid	(31)	(37)
Income taxes paid	(11,769)	(8,628)
Net cash provided by (used in) operating activities	8,126	17,125
Cash flows from investing activities		
Payments into time deposits	(85)	(1,075)
Proceeds from withdrawal of time deposits	40	1,030
Purchase of property, plant and equipment	(2,635)	(2,857)
Purchase of intangible assets	(1,833)	(13,109)
Purchase of investments	(6,997)	(4,615)
Proceeds from sale and redemption of investments	8,850	9,209
Other	6	4
Net cash provided by (used in) investing activities	(2,654)	(11,413)
Cash flows from financing activities		
Repayments of lease liabilities	(1,260)	(1,157)
Purchase of treasury shares	(0)	(1)
Dividends paid	(7,785)	(8,090)
Net cash provided by (used in) financing activities	(9,046)	(9,248)
Effect of exchange rate changes on cash and cash equivalents	849	863
Net increase (decrease) in cash and cash equivalents	(2,724)	(2,672)
Cash and cash equivalents at beginning of period	60,047	58,094
Cash and cash equivalents at end of period	57,323	55,421

## Nippon Shinyaku: Leading Products

Financial performance (consolidated)

(¥ million)

	FY2018 (JGAAP)	FY2019 (JGAAP)	FY2020 (IFRS)	FY2021 (IFRS)	FY2022 (IFRS)	FY2023 (IFRS)	FY2024 (IFRS) (estimated)
Revenue	114,716	116,637	121,859	137,484	144,175	148,255	160,000
Operating profit	20,644	21,668	27,202	32,948	30,049	33,295	36,000
Profit before tax	21,540	22,442	27,608	33,301	30,489	33,616	36,600
Profit attributable to owners of parent	16,302	16,866	19,540	24,986	22,812	25,851	31,500

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(¥ million)

Brand name	Active ingredient	Indications	Launch date	Sales FY2022 (IFRS)	Sales FY2023 (IFRS)	Sales FY2024 (IFRS)	
						Apr-Dec	Full-year (estimated)
Viltepso	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	14,341	17,530	16,389	21,850
(Japan)				(4,139)	(4,407)	(3,527)	(4,600)
(U.S.)				(10,201)	(13,123)	(12,861)	(17,250)
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	10,543	12,918	11,623	15,200
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	15,951	10,383	4,111	5,100
Gazyva	obinutuzumab	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	Aug-2018/ Dec-2022	4,904	4,695	3,805	4,900
Vyxeos	daunorubicin / cytarabine	high-risk acute myeloid leukemia	May-24	-	-	3,737	4,900
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	5,358	3,927	2,179	2,700
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	2,524	2,221	2,090	2,400
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,938	2,499	1,932	2,400
Adcirca	tadalafil	pulmonary arterial hypertension	Dec-2009	2,649	2,255	1,302	1,600
Zalutia	tadalafil	urinary disorder caused by benign prostatic hyperplasia	Apr-2014	2,826	2,256	1,235	1,600
Erizas	dexamethasone cipeccilate	allergic rhinitis	Dec-2009	2,640	2,284	916	2,000
Profit in co-promotion				9,520	8,658	7,132	9,100
Revenues from the licensing of industrial property rights				30,714	40,304	34,071	45,650
Pharmaceuticals				121,988	125,105	104,560	138,500
Functional Food				22,187	23,150	16,759	21,500
Revenue				144,175	148,255	121,320	160,000

# **Nippon Shinyaku: R&D Pipeline List**

## **<Japan>**

February 07, 2025

Stage	Code No. (Generic name)	Therapeutic field	Indications	Origin	Development
Launch Phase III	NS-065/NCNP-01 (viltolarsen)	intractable and rare diseases	Duchenne muscular dystrophy	Co-development with National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Preparing for launch	NS-304 (selexipag)	intractable and rare diseases	pediatric pulmonary arterial hypertension	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.
Phase III	ZX008 (fenfluramine hydrochloride)	intractable and rare diseases	CDKL5 deficiency disorder	Distribution partnership with UCB S.A. (formerly known as Zogenix, Inc.)	UCB S.A. (formerly known as Zogenix, Inc.)
Phase III	GA101 (obinutuzumab)	intractable and rare diseases	lupus nephritis	In-licensed from Chugai Pharmaceutical Co., Ltd.	Co-development with Chugai Pharmaceutical Co., Ltd.
Phase III	GA101 (obinutuzumab)	intractable and rare diseases	pediatric nephrotic syndrome	In-licensed from Chugai Pharmaceutical Co., Ltd.	Co-development with Chugai Pharmaceutical Co., Ltd.
Phase III	GA101 (obinutuzumab)	intractable and rare diseases	extra renal lupus	In-licensed from Chugai Pharmaceutical Co., Ltd.	Co-development with Chugai Pharmaceutical Co., Ltd.
Phase III	LY3527727 (pirtobrutinib)	hematologic malignancies	mantle cell lymphoma	Alliance agreement in Japan with Eli Lilly Japan K.K.	Eli Lilly Japan K.K.
Phase III	LY3527727 (pirtobrutinib)	hematologic malignancies	chronic lymphocytic leukemia	Alliance agreement in Japan with 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 and rare diseases	Duchenne muscular dystrophy	Co-development with National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase II	NS-229	intractable and rare 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	In-licensed from The Menarini Group	Nippon Shinyaku Co., Ltd.
Phase I/II	NS-050/NCNP-03	intractable and rare diseases	Duchenne muscular dystrophy	Co-development with National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase I	NS-917 (radgocitabine)	hematologic malignancies	relapsed/refractory acute myeloid leukemia	In-licensed 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
U.S. Launch Phase III	NS-065/NCNP-01 (viltolarsen)	intractable and rare diseases	Duchenne muscular dystrophy	Co-development with National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
BLA filing	CAP-1002 (deramiocel)	intractable and rare diseases	Duchenne muscular dystrophy cardiomyopathy	Partnered with Capricor Therapeutics, Inc.	Capricor Therapeutics, Inc.
Rolling Submission	RGX-121 (clemidsogene lanaparovec)	intractable and rare diseases	Mucopolysaccharidosis Type II	Partnered with REGENXBIO Inc.	REGENXBIO Inc.
Phase III	CAP-1002 (deramiocel)	intractable and rare diseases	Duchenne muscular dystrophy	Partnered with Capricor Therapeutics, Inc.	Capricor Therapeutics, Inc.
Phase II	NS-089/NCNP-02 (brogidirsen)	intractable and rare diseases	Duchenne muscular dystrophy	Co-development with National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase II	NS-229	intractable and rare diseases	eosinophilic granulomatosis with polyangiitis	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.
Phase I/II	NS-050/NCNP-03	intractable and rare diseases	Duchenne muscular dystrophy	Co-development with National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase I/II	ATSN-101	intractable and rare diseases	GUCY2D-associated Leber congenital amaurosis	Partnered with Atsena Therapeutics, Inc.	Atsena Therapeutics, Inc.
Phase I/II	RGX-111	intractable and rare diseases	Mucopolysaccharidosis Type I	Partnered with REGENXBIO Inc.	REGENXBIO Inc.