

Outline of Consolidated Financial Results for the Six Months Ended September 30, 2024 (IFRS)

November 13, 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: November 14, 2024

Scheduled start of payment: December 5, 2024

Supplementary material: Yes

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

Listing stock exchange: Tokyo

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

Tel. +81-75-321-9116

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

1. Consolidated Results for the Six months Ended September 30, 2024 (April 1, 2024 to September 30, 2024)

(1) Operating results

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
Six months ended September 30, 2024	79,332	8.2	17,867	(14.4)	18,198	(13.9)	16,378	1.2	16,373	1.2	18,872	(4.1)
Six months 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
Earnings per share (¥)												
	Basic		Diluted									
Six months ended September 30, 2024	243.09		243.07									
Six months ended September 30, 2023	240.17		—									

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, 2024	268,542	235,252	234,936	87.5%
As of March 31, 2024	263,404	220,534	220,224	83.6%

2. Dividends

	Annual dividends per share (¥)				
	1 st quarter	2 nd quarter	3 rd quarter	Year-end	Annual
Year ended March 31, 2024	—	62.00	—	62.00	124.00
Year ending March 31, 2025	—	62.00			
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	157,000	5.9	33,000	(0.9)	33,600	(0.0)	30,000	16.0	445.24

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, 2024: 70,251,484 shares

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

Number of shares of treasury stock

As of September 30, 2024: 2,872,676 shares

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

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

As of September 30, 2024: 67,352,653 shares

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

Note:

This summary of semi-annual financial results is exempt from the 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 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, 2024	As of September 30, 2024
Assets		
Current assets		
Cash and cash equivalents	58,094	56,387
Trade and other receivables	47,237	43,071
Inventories	39,111	42,805
Other financial assets	10,609	9,633
Other current assets	9,232	7,929
Total current assets	164,285	159,826
Non-current assets		
Property, plant and equipment	33,582	34,094
Intangible assets	25,120	29,079
Right-of-use assets	2,971	2,615
Other financial assets	32,862	39,823
Deferred tax assets	1,766	274
Other non-current assets	2,817	2,829
Total non-current assets	99,119	108,716
Total assets	263,404	268,542

(Millions of yen)

	As of March 31, 2024	As of September 30, 2024
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	24,706	17,628
Other financial liabilities	372	286
Lease liabilities	1,720	1,317
Income taxes payable	3,594	1,556
Other current liabilities	6,941	6,923
Total current liabilities	37,336	27,712
Non-current liabilities		
Other financial liabilities	232	233
Lease liabilities	1,152	1,234
Retirement benefit liability	4,090	4,050
Other non-current liabilities	58	58
Total non-current liabilities	5,533	5,578
Total liabilities	42,870	33,290
Equity		
Share capital	5,174	5,174
Capital surplus	4,445	4,445
Retained earnings	198,260	210,457
Treasury shares	(2,480)	(2,459)
Other components of equity	14,825	17,318
Total equity attributable to owners of parent	220,224	234,936
Non-controlling interests	310	315
Total equity	220,534	235,252
Total liabilities and equity	263,404	268,542

(2) Consolidated Statements of Income

(Millions of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Revenue	73,314	79,332
Cost of sales	25,320	24,935
Gross profit	47,994	54,396
Selling, general and administrative expenses	16,952	18,031
Research and development expenses	12,517	16,732
Other income	2,596	455
Other expenses	242	2,219
Operating profit	20,878	17,867
Finance income	326	396
Finance costs	57	65
Profit before tax	21,146	18,198
Income tax expense	4,969	1,819
Profit	16,176	16,378
Profit attributable to		
Owners of parent	16,176	16,373
Non-controlling interests	0	5
Profit	16,176	16,378
Earnings per share		
Basic earnings per share	240.17	243.09
Diluted earnings per share	-	243.07

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Profit	16,176	16,378
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	3,418	3,394
Total of items that will not be reclassified to profit or loss	3,418	3,394
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	85	(900)
Total of items that may be reclassified to profit or loss	85	(900)
Total other comprehensive income	3,503	2,493
Comprehensive income	19,680	18,872
Comprehensive income attributable to		
Owners of parent	19,679	18,866
Non-controlling interests	0	5
Comprehensive income	19,680	18,872

(3) Consolidated Statements of Changes in Net Assets
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)	-	-	-
Share-based payment transactions	-	-	-	-	-	-
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)
Share-based payment transactions	-	-	-	-
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

For the six-month period ended September 30,2024

(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	-	-	16,373	-	-	-
Other comprehensive income	-	-	-	-	(900)	3,394
Comprehensive income	-	-	16,373	-	(900)	3,394
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(4,175)	-	-	-
Share-based payment transactions	-	0	-	22	-	-
Transfer from other components of equity to retained earnings	-	-	-	-	-	-
Total transactions with owners	-	0	(4,175)	21	-	-
Balance at end of period	5,174	4,445	210,457	(2,459)	(1,389)	18,707

	Equity attributable to owners of parent			
	Other components of equity	Total	Non-controlling interests	Total
	Total			
Balance at beginning of period	14,825	220,224	310	220,534
Profit	-	16,373	5	16,378
Other comprehensive income	2,493	2,493	-	2,493
Comprehensive income	2,493	18,866	5	18,872
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(4,175)	-	(4,175)
Share-based payment transactions	-	22	-	22
Transfer from other components of equity to retained earnings	-	-	-	-
Total transactions with owners	-	(4,153)	-	(4,153)
Balance at end of period	17,318	234,936	315	235,252

(4) Consolidated Statements of Cash Flow

(Millions of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Cash flows from operating activities		
Profit before tax	21,146	18,198
Depreciation and amortization	2,462	2,980
Interest and dividend income	(326)	(396)
Interest expenses	24	29
Foreign exchange loss (gain)	(1,378)	160
Loss (gain) on sale and retirement of fixed assets	50	109
Decrease (increase) in trade and other receivables	(3,737)	3,909
Decrease (increase) in inventories	2,101	(3,781)
Increase (decrease) in trade and other payables	(2,485)	(1,558)
Increase (decrease) in retirement benefit liability	(397)	(39)
Other	(2,852)	1,604
Subtotal	14,606	21,217
Interest and dividends received	324	399
Interest paid	(24)	(29)
Income taxes paid	(6,967)	(3,855)
Net cash provided by (used in) operating activities	7,938	17,732
Cash flows from investing activities		
Payments into time deposits	(60)	(860)
Proceeds from withdrawal of time deposits	30	830
Purchase of property, plant and equipment	(2,169)	(1,458)
Purchase of intangible assets	(1,751)	(10,739)
Purchase of investments	(2,500)	(3,614)
Proceeds from sale and redemption of investments	4,752	2,500
Other	4	3
Net cash provided by (used in) investing activities	(1,693)	(13,340)
Cash flows from financing activities		
Repayments of lease liabilities	(846)	(823)
Purchase of treasury shares	(0)	(0)
Dividends paid	(3,837)	(4,172)
Net cash provided by (used in) financing activities	(4,685)	(4,996)
Effect of exchange rate changes on cash and cash equivalents	1,248	(1,102)
Net increase (decrease) in cash and cash equivalents	2,807	(1,706)
Cash and cash equivalents at beginning of period	60,047	58,094
Cash and cash equivalents at end of period	62,855	56,387

Performance (consolidated)

(¥ million)

	2018 (JGAAP)	2019 (JGAAP)	2020 (IFRS)	2021 (IFRS)	2022 (IFRS)	2023 (IFRS)	2024 (IFRS) (estimated)
Revenue	114,716	116,637	121,859	137,484	144,175	148,255	157,000
Operating profit	20,644	21,668	27,202	32,948	30,049	33,295	33,000
Profit before tax	21,540	22,442	27,608	33,301	30,489	33,616	33,600
Profit attributable to owners of parent	16,302	16,866	19,540	24,986	22,812	25,851	30,000

(¥ million)

Brand name	Active Ingredient	Indications	Launch Date	Sales 2022 (IFRS)	Sales 2023 (IFRS)	Sales 2024	
						Apr.-Sep.	Annual (estimated)
Viltepso	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	14,341	17,530	11,002	21,400
(Japan)				(4,139)	(4,407)	(2,319)	(4,600)
(U.S.)				(10,201)	(13,123)	(8,682)	(16,800)
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	10,543	12,918	7,474	15,000
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	15,951	10,383	2,757	4,800
Gazyva	obinutuzumab	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	Aug-2018/ Dec-2022	4,904	4,695	2,452	4,800
Vyxeos	daunorubicin / cytarabine	high-risk acute myeloid leukemia	May-2024	-	-	2,236	4,600
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	5,358	3,927	1,470	2,700
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	2,524	2,221	1,277	2,400
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,938	2,499	1,219	2,400
Zalutia	tadalafil	urinary disorder caused by benign prostatic hyperplasia	Apr-2014	2,826	2,256	903	1,600
Adcirca	tadalafil	pulmonary arterial hypertension	Dec-2009	2,649	2,255	893	1,600
Erizas	dexamethasone cipeclilate	allergic rhinitis	Dec-2009	2,640	2,284	511	2,000
Profit in co-promotion				9,520	8,658	4,700	9,400
Revenues from the licensing of industrial property rights				30,714	40,304	22,655	44,100
Pharmaceuticals				121,988	125,105	68,496	135,500
Functional Food				22,187	23,150	10,836	21,500
Revenue				144,175	148,255	79,332	157,000

Nippon Shinyaku: R&D Pipeline List

< Domestic >

November 13, 2024

Stage	Code No. (Generic name)	Therapeutic field	Indications	Origin	Development
Launch Phase III	NS-065/NCNP-01 (viltolarsen)	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Preparation for launch	ACT-064992D (macitentan/tadalafil)	cardiovascular	pulmonary arterial hypertension	Janssen Pharmaceutical K.K.	Janssen Pharmaceutical K.K.
NDA filing	NS-304 (selexipag)	intractable diseases・orphan diseases	pediatric pulmonary arterial hypertension	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.
Phase III	ZX008 (fenfluramine hydrochloride)	intractable diseases・orphan diseases	CDKL5 deficiency disorder	Distribution partnership: UCB S.A. (former : Zogenix, Inc.)	UCB S.A. (former : Zogenix, Inc.)
Phase III	GA101 (obinutuzumab)	intractable diseases・orphan diseases	lupus nephritis	Licensed - in from Chugai Pharmaceutical Co., Ltd.	Co - development: Chugai Pharmaceutical Co., Ltd.
Phase III	GA101 (obinutuzumab)	intractable diseases・orphan diseases	pediatric nephrotic syndrome	Licensed - in from Chugai Pharmaceutical Co., Ltd.	Co - development: Chugai Pharmaceutical Co., Ltd.
Phase III	GA101 (obinutuzumab)	intractable diseases・orphan diseases	extra renal lupus	Licensed - in from Chugai Pharmaceutical Co., Ltd.	Co - development: Chugai Pharmaceutical Co., Ltd.
Phase III	LY3527277 (pirtobrutinib)	hematologic malignancies	mantle cell lymphoma	Alliance agreement in Japan: Eli Lilly Japan K.K.	Eli Lilly Japan K.K.
Phase III	LY3527277 (pirtobrutinib)	hematologic malignancies	chronic lymphocytic leukemia	Alliance agreement in Japan: 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 diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase II	NS-229	intractable diseases・orphan 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	Licensed - in from The Menarini Group	Nippon Shinyaku Co., Ltd.
Phase I/II	NS-050/NCNP-03	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase I	NS-917 (radgocitabine)	hematologic malignancies	relapsed/refractory acute myeloid leukemia	Licensed - in 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
US Launch Phase III	NS-065/NCNP-01 (viltolarsen)	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Rolling submission	CAP-1002 (deramiciel)	intractable diseases・orphan diseases	Duchenne muscular dystrophy cardiomyopathy	Partnership: Capricor Therapeutics, Inc.	Capricor Therapeutics, Inc.
Phase III	CAP-1002 (deramiciel)	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Partnership: Capricor Therapeutics, Inc.	Capricor Therapeutics, Inc.
Phase II	NS-089/NCNP-02 (brogidirsen)	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.
Phase II	NS-229	intractable diseases・orphan diseases	eosinophilic granulomatosis with polyangiitis	Nippon Shinyaku Co., Ltd.	Nippon Shinyaku Co., Ltd.
Phase I/II	NS-050/NCNP-03	intractable diseases・orphan diseases	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku Co., Ltd.