

Outline of Consolidated Financial Results for the First Quarter Ended June 30, 2025(IFRS)

August 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

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 Year Ended June 30, 2025 (April 1, 2025 to June 30, 2025)

(1) Operating results

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
Three months ended June 30, 2025	39,546	1.1	10,081	(9.0)	10,504	(7.9)	8,256	(19.6)	8,255	(19.6)	8,648	(22.1)
Three months ended June 30, 2024	39,131	5.7	11,078	(0.8)	11,411	(0.3)	10,270	17.3	10,264	17.3	11,104	3.7
Earnings per share (¥)												
	Basic		Diluted									
Three months ended June 30, 2025	122.52		122.52									
Three months ended June 30, 2024	152.40		—									

(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 June 30, 2025	289,625	251,834	251,521	86.8%
As of March 31, 2025	283,637	247,340	247,028	87.1%

2. Dividends

	Annual dividends per share (¥)				
	1 st quarter	2 nd quarter	3 rd quarter	Year-end	Annual
Year ended March 31, 2025	—	62.00	—	62.00	124.00
Year ending March 31, 2026	—				
Year ending March 31, 2026 (forecast)		62.00	—	62.00	124.00

3. Business Forecast for the Year Ending March 31, 2026 (April 1, 2025 to March 31, 2026)

(¥ million)

	Revenue		Operating profit		Profit before tax		Net income attributable to owners of the parent		Basic earnings per share (¥)
		%		%		%		%	
First-half period	81,500	2.7	16,000	(10.5)	16,300	(10.4)	12,800	(21.8)	189.97
Full term	166,000	3.6	30,000	(15.4)	30,600	(15.3)	24,000	(26.3)	356.20

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 June 30, 2025: 70,251,484 shares

As of March 31, 2025: 70,251,484 shares

Number of shares of treasury stock

As of June 30, 2025: 2,872,839 shares

As of March 31, 2025: 2,872,839 shares

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

As of June 30, 2025: 67,378,645 shares

As of June 30, 2024: 67,352,713 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.

※This document has been translated from the Japanese original for reference purposes only. In the event of any discrepancy between this translated document and the Japanese original, the original shall prevail.

5. Consolidated Financial Statement

(1) Consolidated Balance Sheet

(Millions of yen)

	As of March 31, 2025	As of June 30, 2025
Assets		
Current assets		
Cash and cash equivalents	55,241	58,277
Trade and other receivables	42,292	42,452
Inventories	42,500	45,700
Other financial assets	3,244	3,654
Other current assets	6,461	7,583
Total current assets	149,740	157,667
Non-current assets		
Property, plant and equipment	34,531	34,391
Intangible assets	48,315	47,749
Right-of-use assets	2,781	2,474
Other financial assets	39,492	37,512
Deferred tax assets	5,597	6,642
Other non-current assets	3,177	3,186
Total non-current assets	133,897	131,957
Total assets	283,637	289,625

(Millions of yen)

	As of March 31, 2025	As of June 30, 2025
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	16,857	18,192
Other financial liabilities	305	299
Lease liabilities	1,348	1,224
Income taxes payable	4,705	3,451
Other current liabilities	7,100	8,796
Total current liabilities	30,316	31,964
Non-current liabilities		
Other financial liabilities	233	233
Lease liabilities	1,374	1,197
Retirement benefit liability	4,313	4,336
Other non-current liabilities	59	59
Total non-current liabilities	5,980	5,826
Total liabilities	36,297	37,791
Equity		
Share capital	5,174	5,174
Capital surplus	4,491	4,514
Retained earnings	222,640	228,538
Treasury shares	(2,459)	(2,459)
Other components of equity	17,181	15,754
Total equity attributable to owners of parent	247,028	251,521
Non-controlling interests	312	312
Total equity	247,340	251,834
Total liabilities and equity	283,637	289,625

(2) Consolidated Statements of Income

(Millions of yen)

	Three months ended June 30, 2024	Three months ended June 30, 2025
Revenue	39,131	39,546
Cost of sales	12,636	12,655
Gross profit	26,494	26,890
Selling, general and administrative expenses	9,221	9,995
Research and development expenses	7,497	6,189
Other income	1,507	169
Other expenses	204	794
Operating profit	11,078	10,081
Finance income	363	468
Finance costs	31	46
Profit before tax	11,411	10,504
Income tax expense	1,141	2,247
Profit	10,270	8,256
Profit attributable to		
Owners of parent	10,264	8,255
Non-controlling interests	5	0
Profit	10,270	8,256
Earnings per share		
Basic earnings per share	152.40	122.52
Diluted earnings per share	-	122.52

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Three months ended June 30, 2024	Three months ended June 30, 2025
Profit	10,270	8,256
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	1,051	592
Total of items that will not be reclassified to profit or loss	1,051	592
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(216)	(200)
Total of items that may be reclassified to profit or loss	(216)	(200)
Total other comprehensive income	834	392
Comprehensive income	11,104	8,648
Comprehensive income attributable to		
Owners of parent	11,099	8,647
Non-controlling interests	5	0
Comprehensive income	11,104	8,648

(3) Consolidated Statements of Changes in Net Assets
Fiscal year ended June 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	-	-	10,264	-	-	-
Other comprehensive income	-	-	-	-	(216)	1,051
Comprehensive income	-	-	10,264	-	(216)	1,051
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(4,175)	-	-	-
Total transactions with owners	-	-	(4,175)	(0)	-	-
Balance at end of period	5,174	4,445	204,348	(2,481)	(704)	16,364

	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	-	10,264	5	10,270
Other comprehensive income	834	834	-	834
Comprehensive income	834	11,099	5	11,104
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(4,175)	-	(4,175)
Total transactions with owners	-	(4,176)	-	(4,176)
Balance at end of period	15,659	227,147	315	227,462

(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	4,491	222,640	(2,459)	(1,136)	18,318
Profit	-	-	8,255	-	-	-
Other comprehensive income	-	-	-	-	(200)	592
Comprehensive income	-	-	8,255	-	(200)	592
Purchase of treasury shares	-	-	-	-	-	-
Dividends of surplus	-	-	(4,177)	-	-	-
Share-based payment transactions	-	22	-	-	-	-
Transfer from other components of equity to retained earnings	-	-	1,819	-	-	(1,819)
Total transactions with owners	-	22	(2,357)	-	-	(1,819)
Balance at end of period	5,174	4,514	228,538	(2,459)	(1,337)	17,091

	Equity attributable to owners of parent			
	Other components of equity	Total	Non-controlling interests	Total
	Total			
Balance at beginning of period	17,181	247,028	312	247,340
Profit	-	8,255	0	8,256
Other comprehensive income	392	392	-	392
Comprehensive income	392	8,647	0	8,648
Purchase of treasury shares	-	-	-	-
Dividends of surplus	-	(4,177)	-	(4,177)
Share-based payment transactions	-	22	-	22
Transfer from other components of equity to retained earnings	(1,819)	-	-	-
Total transactions with owners	(1,819)	(4,154)	-	(4,154)
Balance at end of period	15,754	251,521	312	251,834

(4) Consolidated Statements of Cash Flow

(Millions of yen)

	Three months ended June 30, 2024	Three months ended June 30, 2025
Cash flows from operating activities		
Profit before tax	11,411	10,504
Depreciation and amortization	1,464	1,592
Interest and dividend income	(363)	(468)
Interest expenses	13	22
Foreign exchange loss (gain)	(792)	191
Loss (gain) on sale of fixed assets	95	(0)
Decrease (increase) in trade and other receivables	(922)	(293)
Decrease (increase) in inventories	1,797	(3,226)
Increase (decrease) in trade and other payables	(3,388)	2,098
Increase (decrease) in retirement benefit liability	(96)	22
Other	1,677	712
Subtotal	10,896	11,155
Interest and dividends received	364	469
Interest paid	(13)	(22)
Income taxes paid	(4,243)	(4,803)
Net cash provided by (used in) operating activities	7,004	6,798
Cash flows from investing activities		
Payments into time deposits	(645)	(1,025)
Proceeds from withdrawal of time deposits	630	610
Purchase of property, plant and equipment	(957)	(876)
Purchase of intangible assets	(5,817)	(636)
Purchase of investments	(0)	(97)
Proceeds from sale and redemption of investments	-	2,933
Other	1	0
Net cash provided by (used in) investing activities	(6,788)	908
Cash flows from financing activities		
Repayments of lease liabilities	(410)	(365)
Purchase of treasury shares	(0)	-
Dividends paid	(3,918)	(3,920)
Net cash provided by (used in) financing activities	(4,328)	(4,286)
Effect of exchange rate changes on cash and cash equivalents	492	(385)
Net increase (decrease) in cash and cash equivalents	(3,621)	3,036
Cash and cash equivalents at beginning of period	58,094	55,241
Cash and cash equivalents at end of period	54,472	58,277

Performance (consolidated)

(¥ million)

	FY2019 (JGAAP)	FY2020 (IFRS)	FY2021 (IFRS)	FY2022 (IFRS)	FY2023 (IFRS)	FY2024 (IFRS)	FY2025 (IFRS) (estimated)
Revenue	116,637	121,859	137,484	144,175	148,255	160,232	166,000
Operating profit	21,668	27,202	32,948	30,049	33,295	35,450	30,000
Profit before tax	22,442	27,608	33,301	30,489	33,616	36,135	30,600
Profit attributable to owners of parent	16,866	19,540	24,986	22,812	25,851	32,558	24,000

(¥ million)

Brand name	Active Ingredients	Indications	Launch Date	Sales FY2023 (IFRS)	Sales FY2024 (IFRS)	Sales FY2025 (IFRS)		
						Apr-Jun	Apr-Sep (estimated)	Annual (estimated)
Viltepso				17,530	21,782	5,194	10,800	21,500
(Japan)	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	(4,407)	(4,664)	(1,198)	(2,400)	(4,800)
(U.S.)				(13,123)	(17,117)	(3,995)	(8,400)	(16,700)
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	12,918	14,971	4,375	8,300	16,800
Vyxeos	daunorubicin / cytarabine	high-risk acute myeloid leukemia	May-2024	-	5,139	1,447	3,500	7,300
Gazyva	obinutuzumab	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	Aug-2018/ Dec-2022	4,695	4,821	1,180	2,600	5,200
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	10,383	5,109	1,022	1,700	3,100
Fintepla	fenfluramine hydrochloride	seizures associated with Dravet syndrome/ seizures associated with Lennox-Gastaut syndrome	Apr-2014	377	2,067	887	1,700	4,000
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	2,221	2,364	650	1,200	2,500
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	3,927	2,728	571	1,000	2,000
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,499	2,425	557	1,250	2,500
CAP-1002 (U.S.)	deramiciel	Duchenne muscular dystrophy cardiomyopathy	Filed	-	-	-	-	-
Profit in co-promotion				8,658	9,170	2,517	4,700	9,600
Revenues from the licensing of industrial property rights				40,304	45,585	11,511	22,800	47,500
Pharmaceuticals				125,105	138,654	34,163	71,000	143,000
Functional Food				23,150	21,577	5,382	10,500	23,000
Revenue				148,255	160,232	39,546	81,500	166,000

Nippon Shinyaku: R&D Pipeline List

<Japan>

August 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.
Filed	NS-401 (tagraxofusp)	hematologic malignancies	blastic plasmacytoid dendritic cell neoplasm	In-licensed from The Menarini Group	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-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.
Filed	CAP-1002 (deramiocel)	intractable and rare diseases	Duchenne muscular dystrophy cardiomyopathy	Partnered with Capricor Therapeutics, Inc.	Capricor Therapeutics, Inc.
Filed	RGX-121 (clemidsogene lanaparvovec)	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	In-licensed from Atsena Therapeutics, Inc.	Atsena Therapeutics, Inc.
Phase I/II	RGX-111	intractable and rare diseases	Mucopolysaccharidosis Type I	Partnered with REGENXBIO Inc.	REGENXBIO Inc.