

Outline of Consolidated Financial Results for the Six Months Ended September 30, 2025 (IFRS)

November 14, 2025

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

Code No.: 4516

Representative: Toru Nakai, President and Representative Director

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Scheduled date for submission of quarterly Securities Report: November 14, 2025

Scheduled start of payment: December 5, 2025

Supplementary material: Yes

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

Listing stock exchange: Tokyo

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

1. Consolidated Results for the Six months Ended September 30, 2025 (April 1, 2025 to September 30, 2025)

(1) Operating results

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
Six months ended September 30, 2025	79,647	0.4	19,580	9.6	20,029	10.1	15,762	(3.8)	15,760	(3.7)	17,008	(9.9)
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)
Earnings per share (¥)												
	Basic		Diluted									
Six months ended September 30, 2025	233.88		233.88									
Six months ended September 30, 2024	243.09		243.07									

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, 2025	297,037	260,211	259,897	87.5%
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	—	62.00			
Year ending March 31, 2025 (forecast)			—	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		Profit attributable to owners of parent		Basic earnings per share (¥)
		%		%		%		%	
Full term	168,000	4.8	33,000	(6.9)	33,700	(6.7)	26,300	(19.2)	390.20

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 September 30, 2025: 70,251,484 shares

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

Number of shares of treasury stock

As of September 30, 2025: 2,850,535 shares

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

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

As of September 30, 2025: 67,354,740 shares

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

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 September 30, 2025
Assets		
Current assets		
Cash and cash equivalents	55,241	65,291
Trade and other receivables	42,292	42,967
Inventories	42,500	47,629
Other financial assets	3,244	3,167
Other current assets	6,461	6,097
Total current assets	149,740	165,153
Non-current assets		
Property, plant and equipment	34,531	34,811
Intangible assets	48,315	47,155
Right-of-use assets	2,781	2,556
Other financial assets	39,492	38,237
Deferred tax assets	5,597	5,964
Other non-current assets	3,177	3,158
Total non-current assets	133,897	131,884
Total assets	283,637	297,037

(Millions of yen)

	As of March 31, 2025	As of September 30, 2025
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	16,857	17,024
Other financial liabilities	305	240
Lease liabilities	1,348	1,370
Income taxes payable	4,705	4,971
Other current liabilities	7,100	7,419
Total current liabilities	30,316	31,027
Non-current liabilities		
Other financial liabilities	233	234
Lease liabilities	1,374	1,160
Retirement benefit liability	4,313	4,344
Other non-current liabilities	59	59
Total non-current liabilities	5,980	5,799
Total liabilities	36,297	36,826
Equity		
Share capital	5,174	5,174
Capital surplus	4,491	4,512
Retained earnings	222,640	236,209
Treasury shares	(2,459)	(2,440)
Other components of equity	17,181	16,441
Total equity attributable to owners of parent	247,028	259,897
Non-controlling interests	312	314
Total equity	247,340	260,211
Total liabilities and equity	283,637	297,037

(2) Consolidated Statements of Income

(Millions of yen)

	Six months ended September 30, 2024	Six months ended September 30, 2025
Revenue	79,332	79,647
Cost of sales	24,935	25,336
Gross profit	54,396	54,311
Selling, general and administrative expenses	18,031	20,357
Research and development expenses	16,732	14,637
Other income	455	521
Other expenses	2,219	258
Operating profit	17,867	19,580
Finance income	396	550
Finance costs	65	101
Profit before tax	18,198	20,029
Income tax expense	1,819	4,266
Profit	16,378	15,762
Profit attributable to		
Owners of parent	16,373	15,760
Non-controlling interests	5	2
Profit	16,378	15,762
Earnings per share		
Basic earnings per share	243.09	233.88
Diluted earnings per share	243.07	233.88

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Six months ended September 30, 2024	Six months ended September 30, 2025
Profit	16,378	15,762
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	3,394	1,272
Total of items that will not be reclassified to profit or loss	3,394	1,272
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(900)	(27)
Total of items that may be reclassified to profit or loss	(900)	(27)
Total other comprehensive income	2,493	1,245
Comprehensive income	18,872	17,008
Comprehensive income attributable to		
Owners of parent	18,866	17,006
Non-controlling interests	5	2
Comprehensive income	18,872	17,008

(3) Consolidated Statements of Changes in Net Assets
Fiscal year 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	-	-
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
Total transactions with owners	-	(4,153)	-	(4,153)
Balance at end of period	17,318	234,936	315	235,252

(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	-	-	15,760	-	-	-
Other comprehensive income	-	-	-	-	(27)	1,272
Comprehensive income	-	-	15,760	-	(27)	1,272
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(4,177)	-	-	-
Share-based payment transactions	-	21	-	19	-	-
Transfer from other components of equity to retained earnings	-	-	1,985	-	-	(1,985)
Total transactions with owners	-	21	(2,192)	18	-	(1,985)
Balance at end of period	5,174	4,512	236,209	(2,440)	(1,163)	17,605

	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	-	15,760	2	15,762
Other comprehensive income	1,245	1,245	-	1,245
Comprehensive income	1,245	17,006	2	17,008
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(4,177)	-	(4,177)
Share-based payment transactions	-	40	-	40
Transfer from other components of equity to retained earnings	(1,985)	-	-	-
Total transactions with owners	(1,985)	(4,137)	-	(4,137)
Balance at end of period	16,441	259,897	314	260,211

(4) Consolidated Statements of Cash Flow

(Millions of yen)

	Six months ended September 30, 2024	Six months ended September 30, 2025
Cash flows from operating activities		
Profit before tax	18,198	20,029
Depreciation and amortization	2,980	3,233
Interest and dividend income	(396)	(550)
Interest expenses	29	49
Foreign exchange loss (gain)	160	(251)
Loss (gain) on sale and retirement of fixed assets	109	19
Decrease (increase) in trade and other receivables	3,909	(697)
Decrease (increase) in inventories	(3,781)	(5,128)
Increase (decrease) in trade and other payables	(1,558)	967
Increase (decrease) in retirement benefit liability	(39)	31
Other	1,604	634
Subtotal	21,217	18,338
Interest and dividends received	399	550
Interest paid	(29)	(49)
Income taxes paid	(3,855)	(4,897)
Net cash provided by (used in) operating activities	17,732	13,942
Cash flows from investing activities		
Payments into time deposits	(860)	(1,460)
Proceeds from withdrawal of time deposits	830	1,030
Purchase of property, plant and equipment	(1,458)	(1,678)
Purchase of intangible assets	(10,739)	(698)
Purchase of investments	(3,614)	(97)
Proceeds from sale and redemption of investments	2,500	3,645
Other	3	2
Net cash provided by (used in) investing activities	(13,340)	743
Cash flows from financing activities		
Repayments of lease liabilities	(823)	(720)
Purchase of treasury shares	(0)	(0)
Dividends paid	(4,172)	(4,173)
Net cash provided by (used in) financing activities	(4,996)	(4,894)
Effect of exchange rate changes on cash and cash equivalents	(1,102)	259
Net increase (decrease) in cash and cash equivalents	(1,706)	10,050
Cash and cash equivalents at beginning of period	58,094	55,241
Cash and cash equivalents at end of period	56,387	65,291

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	168,000
Operating profit	21,668	27,202	32,948	30,049	33,295	35,450	33,000
Profit before tax	22,442	27,608	33,301	30,489	33,616	36,135	33,700
Profit attributable to owners of parent	16,866	19,540	24,986	22,812	25,851	32,558	26,300

(¥ million)

Brand name	Active Ingredient	Indications	Launch Date	Sales FY2023 (IFRS)	Sales FY2024 (IFRS)	Sales FY2025 (IFRS)	
						Apr.-Sep.	Annual (estimated)
Viltepso				17,530	21,782	10,349	21,100
(Japan)	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	(4,407)	(4,664)	(2,386)	(4,800)
(U.S.)				(13,123)	(17,117)	(7,963)	(16,300)
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	12,918	14,971	8,448	17,000
Vyxeos	daunorubicin / cytarabine	high-risk acute myeloid leukemia	May-2024	-	5,139	2,941	6,500
Gazyva	obinutuzumab	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	Aug-2018/ Dec-2022	4,695	4,821	2,451	5,000
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	10,383	5,109	1,818	3,200
Fintepla	fenfluramine hydrochloride	seizures associated with Dravet syndrome/ seizures associated with Lennox-Gastaut syndrome	Nov-2022	377	2,067	1,765	4,000
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	2,221	2,364	1,252	2,500
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	3,927	2,728	1,184	2,200
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,499	2,425	1,119	2,300
Erleada	apalutamide	prostate cancer	May-2019	-	-	-	6,300
CAP-1002 (U.S.)	deramiciel	Duchenne muscular dystrophy cardiomyopathy	Filed	-	-	-	-
Profit in co-promotion				8,658	9,170	4,792	9,200
Revenues from the licensing of industrial property rights				40,304	45,585	24,181	47,000
Pharmaceuticals				125,105	138,654	68,561	145,000
Functional Food				23,150	21,577	11,086	23,000
Revenue				148,255	160,232	79,647	168,000

Nippon Shinyaku: R&D Pipeline List

<Japan>

November 14, 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 (deramiciel)	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 (deramiciel)	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.