

Outline of Consolidated Financial Results for the Year Ended March 31, 2023(IFRS)

May 11, 2023

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

Listing stock exchange: Tokyo

Code No.: 4516

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

Representative: Toru Nakai, President and Representative Director

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Scheduled date of annual general meeting of shareholders: June 29, 2023

Scheduled date to commence dividend payments: June 30, 2023

Scheduled date to file annual securities report: June 30, 2023

Preparation of supplementary material on financial results: Yes

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

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

1. Consolidated Results for the Year Ended March 31, 2023 (April 1, 2022 to March 31, 2023)

(1) Operating results

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
Year ended March 31, 2023	144,175	4.9	30,049	(8.8)	30,489	(8.4)	22,819	(8.7)	22,812	(8.7)	22,861	(5.7)
Year ended March 31, 2022	137,484	12.8	32,948	21.1	33,301	20.6	24,998	27.8	24,986	27.9	24,241	6.4

	Earnings per share (¥)		Return on equity attributable to owners of parent	Profit before tax to total assets	Operating profit to revenue
	Basic	Diluted			
Year ended March 31, 2023	338.70	—	12.1%	13.3%	20.8%
Year ended March 31, 2022	370.97	—	14.5%	15.7%	24.0%

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	Equity attributable to owners of parent per share (¥)
As of March 31, 2023	237,451	195,933	195,625	82.4%	2,904.49
As of March 31, 2022	219,943	180,886	180,585	82.1%	2,681.18

(3) Cash flows

(¥ million)

	Cash flows from operating activities	Cash flows from investing activities	Cash flows from financing activities	Cash and cash equivalents at year-end
Year ended March 31, 2023	26,170	(17,631)	(9,605)	60,047
Year ended March 31, 2022	21,316	(10,037)	(8,407)	60,566

2. Dividends

	Annual dividends per share (¥)			Total dividends (full term) (¥ million)	Payout ratio (consolidated)	Dividends as a percentage of net assets (consolidated)
	2 nd quarter	Year-end	Annual			
Year ended March 31, 2022	51.00	59.00	110.00	7,408	29.7%	4.3%
Year ended March 31, 2023	57.00	57.00	114.00	7,678	33.7%	4.1%
Year ending March 31, 2024 (forecast)	60.00	60.00	120.00		32.3%	

3. Business Forecast for the Year Ending March 31, 2024 (April 1, 2023 to March 31, 2024)

(¥ million)

	Revenue		Operating profit		Profit before tax		Net income attributable to owners of the parent		Basic earnings per share (¥)
		%		%		%		%	
First-half period	71,500	0.5	16,000	(16.5)	16,200	(16.5)	12,400	(18.5)	184.10
Full term	145,000	0.5	32,000	6.5	32,500	6.6	25,000	9.6	371.18

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 March 31, 2023: 70,251,484 shares

As of March 31, 2022: 70,251,484 shares

Number of shares of treasury stock

As of March 31, 2023: 2,898,610 shares

As of March 31, 2022: 2,898,434 shares

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

As of March 31, 2023: 67,352,967 shares

As of March 31, 2022: 67,353,219 shares

Note:

This summary of financial results is exempt from the audit 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, 2022	As of March 31, 2023
Assets		
Current assets		
Cash and cash equivalents	60,566	60,047
Trade and other receivables	43,178	44,686
Inventories	38,066	36,358
Other financial assets	5,174	11,554
Other current assets	2,738	5,225
Total current assets	149,724	157,873
Non-current assets		
Property, plant and equipment	28,304	32,215
Intangible assets	14,050	17,155
Right-of-use assets	2,753	2,779
Other financial assets	22,294	22,308
Deferred tax assets	901	3,241
Other non-current assets	1,915	1,877
Total non-current assets	70,219	79,578
Total assets	219,943	237,451

(Millions of yen)

	As of March 31, 2022	As of March 31, 2023
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	21,022	20,538
Other financial liabilities	374	314
Lease liabilities	1,494	1,516
Income taxes payable	3,123	6,131
Other current liabilities	6,014	6,682
Total current liabilities	32,029	35,183
Non-current liabilities		
Other financial liabilities	237	232
Lease liabilities	1,219	1,148
Retirement benefit liability	5,506	4,895
Other non-current liabilities	64	57
Total non-current liabilities	7,027	6,334
Total liabilities	39,057	41,518
Equity		
Share capital	5,174	5,174
Capital surplus	4,445	4,445
Retained earnings	165,303	180,433
Treasury shares	(2,478)	(2,480)
Other components of equity	8,140	8,052
Total equity attributable to owners of parent	180,585	195,625
Non-controlling interests	300	307
Total equity	180,886	195,933
Total liabilities and equity	219,943	237,451

(2) Consolidated Statements of Income

(Millions of yen)

	Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023
Revenue	137,484	144,175
Cost of sales	50,191	55,980
Gross profit	87,293	88,195
Selling, general and administrative expenses	32,173	34,812
Research and development expenses	22,863	24,135
Other income	1,573	1,908
Other expenses	882	1,106
Operating profit	32,948	30,049
Finance income	472	575
Finance costs	119	136
Profit before tax	33,301	30,489
Income tax expense	8,303	7,669
Profit	24,998	22,819
Profit attributable to		
Owners of parent	24,986	22,812
Non-controlling interests	12	7
Profit	24,998	22,819
Earnings per share		
Basic earnings per share	370.97	338.70

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023
Profit	24,998	22,819
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(547)	516
Remeasurements of defined benefit plans	(49)	(111)
Total of items that will not be reclassified to profit or loss	(596)	404
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(160)	(362)
Total of items that may be reclassified to profit or loss	(160)	(362)
Other comprehensive income, net of tax	(756)	41
Comprehensive income	24,241	22,861
Comprehensive income attributable to		
Owners of parent	24,229	22,854
Non-controlling interests	12	7
Comprehensive income	24,241	22,861

(3) Consolidated Statements of Changes in Net Assets
Fiscal year ended March 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	146,796	(2,476)	(93)	9,315
Profit	-	-	24,986	-	-	-
Other comprehensive income	-	-	-	-	(160)	(547)
Total	-	-	24,986	-	(160)	(547)
Purchase of treasury shares	-	-	-	(2)	-	-
Dividends of surplus	-	-	(6,802)	-	-	-
Transfer from other components of equity to retained earnings	-	-	324	-	-	(373)
Total transactions with owners	-	-	(6,478)	(2)	-	(373)
Balance at end of period	5,174	4,445	165,303	(2,478)	(253)	8,394

	Equity attributable to owners of parent				
	Other components of equity		Total	Non-controlling interests	Total
	Remeasurements of defined benefit plans	Total			
Balance at beginning of period	-	9,221	163,161	288	163,449
Profit	-	-	24,986	12	24,998
Other comprehensive income	(49)	(756)	(756)	-	(756)
Total	(49)	(756)	24,229	12	24,241
Purchase of treasury shares	-	-	(2)	-	(2)
Dividends of surplus	-	-	(6,802)	-	(6,802)
Transfer from other components of equity to retained earnings	49	(324)	-	-	-
Total transactions with owners	49	(324)	(6,804)	-	(6,804)
Balance at end of period	-	8,140	180,585	300	180,886

	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	-	-	22,812	-	-	-
Other comprehensive income	-	-	-	-	(362)	516
Total	-	-	22,812	-	(362)	516
Purchase of treasury shares	-	0	-	(1)	-	-
Dividends of surplus	-	-	(7,812)	-	-	-
Transfer from other components of equity to retained earnings	-	-	129	-	-	(241)
Total transactions with owners	-	0	(7,683)	(1)	-	(241)
Balance at end of period	5,174	4,445	180,433	(2,480)	(616)	8,669

	Equity attributable to owners of parent				
	Other components of equity		Total	Non-controlling interests	Total
	Remeasurements of defined benefit plans	Total			
Balance at beginning of period	-	8,140	180,585	300	180,886
Profit	-	-	22,812	7	22,819
Other comprehensive income	(111)	41	41	-	41
Total	(111)	41	22,854	7	22,861
Purchase of treasury shares	-	-	(1)	-	(1)
Dividends of surplus	-	-	(7,812)	-	(7,812)
Transfer from other components of equity to retained earnings	111	(129)	-	-	-
Total transactions with owners	111	(129)	(7,814)	-	(7,814)
Balance at end of period	-	8,052	195,625	307	195,933

(4) Consolidated Statements of Cash Flows

(Millions of yen)

	Fiscal year ended March 31, 2022	Fiscal year ended March 31, 2023
Cash flows from operating activities		
Profit before tax	33,301	30,489
Depreciation and amortization	4,588	5,041
Interest and dividend income	(472)	(575)
Interest expenses	55	50
Foreign exchange loss (gain)	(5)	(1,165)
Loss (gain) on sale of fixed assets	(1)	(1)
Loss on retirement of fixed assets	333	87
Decrease (increase) in trade and other receivables	(2,885)	(1,425)
Decrease (increase) in inventories	(2,425)	1,782
Increase (decrease) in trade and other payables	2,723	81
Increase (decrease) in retirement benefit liability	(679)	(771)
Other	(2,354)	(779)
Subtotal	32,178	32,815
Interest and dividends received	473	575
Interest paid	(30)	(50)
Income taxes paid	(11,305)	(7,169)
Net cash provided by (used in) operating activities	21,316	26,170
Cash flows from investing activities		
Payments into time deposits	(1,114)	(1,162)
Proceeds from withdrawal of time deposits	654	1,102
Purchase of property, plant and equipment	(3,137)	(5,660)
Proceeds from sale of property, plant and equipment	1	1
Purchase of intangible assets	(5,806)	(6,068)
Purchase of investments	(3,402)	(11,918)
Proceeds from sale and redemption of investments	2,765	6,064
Other	2	9
Net cash provided by (used in) investing activities	(10,037)	(17,631)
Cash flows from financing activities		
Repayments of lease liabilities	(1,605)	(1,794)
Purchase of treasury shares	(2)	(1)
Dividends paid	(6,799)	(7,809)
Other	-	0
Net cash provided by (used in) financing activities	(8,407)	(9,605)
Effect of exchange rate changes on cash and cash equivalents	(188)	547
Net increase (decrease) in cash and cash equivalents	2,683	(518)
Cash and cash equivalents at beginning of period	57,883	60,566
Cash and cash equivalents at end of period	60,566	60,047

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	145,000
Operating profit	17,079	20,644	21,668	27,702	32,948	30,049	32,000
Profit before tax	17,451	21,540	22,442	27,608	33,301	30,489	32,500
Profit attributable to owners of parent	12,953	16,302	16,866	19,540	24,986	22,812	25,000

(¥ million)

Brand name	Active Ingredient	Indications	Launch Date	Sales 2021 (IFRS)	Sales 2022 (IFRS)	Sales 2023 (IFRS) (estimated)	
						Apr-Sep	Annual
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	18,338	15,951	5,700	10,500
Viltepso	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	7,750	14,341	8,500	18,300
(Japan)				(4,059)	(4,139)	(2,200)	(4,800)
(U.S.)				(3,691)	(10,201)	(6,300)	(13,500)
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	8,400	10,543	6,400	14,000
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	6,770	5,358	2,250	4,300
Gazyva	obinutuzumab	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	Aug-2018/ Dec-2022	5,300	4,904	2,300	4,900
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,532	2,938	1,150	2,500
Zalutia	tadalafil	urinary disorder caused by benign prostatic hyperplasia	Apr-2014	4,106	2,826	1,050	2,000
Adcirca	tadalafil	pulmonary arterial hypertension	Dec-2009	4,563	2,649	1,100	2,100
Erizas	dexamethasone cipeclate	allergic rhinitis	Dec-2009	2,330	2,640	900	2,500
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	2,128	2,524	1,400	3,000
Profit in co-promotion				8,934	9,520	4,600	9,300
Revenues from the licensing of industrial property rights				33,207	30,714	17,200	35,000
Pharmaceuticals				120,650	121,988	60,500	123,500
Functional Food				16,834	22,187	11,000	21,500
Revenue				137,484	144,175	71,500	145,000

Appendix:
R&D Pipeline List

<Domestic>

As of May 11, 2023

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
Phase III	ZX008 (fenfluramine hydrochloride)	intractable disease · orphan disease	Lennox-Gastaut syndrome	Licensed - in from 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 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
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
Phase I/II	NS-87 (daunorubicin / cytarabine)	hematologic malignancies	secondary acute myeloid leukemia	Licensed - in from Jazz Pharmaceuticals plc	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-229	inflammatory diseases	inflammatory diseases	Nippon Shinyaku	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

<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 (ligratinib)	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 I/II	NS-050/NCNP-03	intractable disease · orphan disease	Duchenne muscular dystrophy	Co - development: National Center of Neurology and Psychiatry	Nippon Shinyaku