

Outline of Consolidated Financial Results for the First Quarter Ended June 30, 2023(IFRS)

August 10, 2023

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

Listing stock exchange: Tokyo

Code No.: 4516

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

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Scheduled date for submission of quarterly Securities Report: August 14, 2023

Scheduled start of payment: —

Supplementary material: Yes

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

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

1. Consolidated Results for the Year Ended June 30, 2023 (April 1, 2023 to June 30, 2023)

(1) Operating results

(¥ million)

	Revenue		Operating profit		Profit before tax		Profit		Profit attributable to owners of parent		Comprehensive income	
		%		%		%		%		%		%
Three months ended June 30, 2023	37,012	3.9	11,163	8.6	11,440	8.8	8,751	6.0	8,749	6.1	10,705	28.7
Three months ended June 30, 2022	35,619	(13.1)	10,276	(37.9)	10,514	(37.3)	8,253	(34.5)	8,249	(34.5)	8,315	(27.1)

Earnings per share (¥)

	Basic	Diluted
Three months ended June 30, 2023	129.91	—
Three months ended June 30, 2022	122.48	—

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 June 30, 2023	237,408	202,799	202,489	85.3%
As of March 31, 2023	237,451	195,933	195,625	82.4%

2. Dividends

Annual dividends per share (¥)

	1 st quarter	2 nd quarter	3 rd quarter	Year-end	Annual
Year ended March 31, 2023	—	57.00	—	57.00	114.00
Year ending March 31, 2024	—	—	—	—	—
Year ending March 31, 2024 (forecast)	—	60.00	—	60.00	120.00

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 June 30, 2023: 70,251,484 shares

As of March 31, 2023: 70,251,484 shares

Number of shares of treasury stock

As of June 30, 2023: 2,898,645 shares

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

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

As of June 30, 2023: 67,352,866 shares

As of June 30, 2022: 67,353,034 shares

Note:

This summary of quarterly financial results is exempt from the quarterly 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 quarterly review of financial statements based on the Financial Instruments and Exchange Law.

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, 2023	As of June 30, 2023
Assets		
Current assets		
Cash and cash equivalents	60,047	55,251
Trade and other receivables	44,686	45,752
Inventories	36,358	35,518
Other financial assets	11,554	11,568
Other current assets	5,225	6,680
Total current assets	157,873	154,771
Non-current assets		
Property, plant and equipment	32,215	31,272
Intangible assets	17,155	18,205
Right-of-use assets	2,779	2,482
Other financial assets	22,308	25,119
Deferred tax assets	3,241	2,776
Other non-current assets	1,877	2,780
Total non-current assets	79,578	82,636
Total assets	237,451	237,408

(Millions of yen)

	As of March 31, 2023	As of June 30, 2023
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	20,538	16,361
Other financial liabilities	314	338
Lease liabilities	1,516	1,410
Income taxes payable	6,131	2,283
Other current liabilities	6,682	8,262
Total current liabilities	35,183	28,655
Non-current liabilities		
Other financial liabilities	232	232
Lease liabilities	1,148	971
Retirement benefit liability	4,895	4,691
Other non-current liabilities	57	57
Total non-current liabilities	6,334	5,953
Total liabilities	41,518	34,609
Equity		
Share capital	5,174	5,174
Capital surplus	4,445	4,445
Retained earnings	180,433	185,344
Treasury shares	(2,480)	(2,480)
Other components of equity	8,052	10,006
Total equity attributable to owners of parent	195,625	202,489
Non-controlling interests	307	309
Total equity	195,933	202,799
Total liabilities and equity	237,451	237,408

(2) Consolidated Statements of Income

(Millions of yen)

	Three months ended June 30, 2022	Three months ended June 30, 2023
Revenue	35,619	37,012
Cost of sales	13,928	12,962
Gross profit	21,690	24,050
Selling, general and administrative expenses	8,200	8,418
Research and development expenses	4,738	5,911
Other income	1,652	1,572
Other expenses	128	129
Operating profit	10,276	11,163
Finance income	266	298
Finance costs	28	21
Profit before tax	10,514	11,440
Income tax expense	2,260	2,688
Profit	8,253	8,751
Profit attributable to		
Owners of parent	8,249	8,749
Non-controlling interests	4	2
Profit	8,253	8,751
Earnings per share		
Basic earnings per share	122.48	129.91

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Three months ended June 30, 2022	Three months ended June 30, 2023
Profit	8,253	8,751
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	319	1,955
Total of items that will not be reclassified to profit or loss	319	1,955
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	(258)	(2)
Total of items that may be reclassified to profit or loss	(258)	(2)
Total other comprehensive income	61	1,953
Comprehensive income	8,315	10,705
Comprehensive income attributable to		
Owners of parent	8,310	10,703
Non-controlling interests	4	2
Comprehensive income	8,315	10,705

(3) Consolidated Statements of Changes in Net Assets
For the three-month period ended June 30,2022

(Millions of yen)

	Equity attributable to owners of parent					
					Other components of equity	
	Share capital	Capital surplus	Retained earnings	Treasury shares	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	-	-	8,249	-	-	-
Other comprehensive income	-	-	-	-	(258)	319
Comprehensive income	-	-	8,249	-	(258)	319
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(3,973)	-	-	-
Total transactions with owners	-	-	(3,973)	(0)	-	-
Balance at end of period	5,174	4,445	169,579	(2,479)	(512)	8,714

	Equity attributable to owners of parent			
	Other components of equity	Total	Non-controlling interests	Total
	Total			
Balance at beginning of period	8,140	180,585	300	180,886
Profit	-	8,249	4	8,253
Other comprehensive income	61	61	-	61
Comprehensive income	61	8,310	4	8,315
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(3,973)	-	(3,973)
Total transactions with owners	-	(3,974)	-	(3,974)
Balance at end of period	8,202	184,922	305	185,227

For the three-month period ended June 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	-	-	8,749	-	-	-
Other comprehensive income	-	-	-	-	(2)	1,955
Comprehensive income	-	-	8,749	-	(2)	1,955
Purchase of treasury shares	-	-	-	(0)	-	-
Dividends of surplus	-	-	(3,839)	-	-	-
Total transactions with owners	-	-	(3,839)	(0)	-	-
Balance at end of period	5,174	4,445	185,344	(2,480)	(619)	10,625

	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	-	8,749	2	8,751
Other comprehensive income	1,953	1,953	-	1,953
Comprehensive income	1,953	10,703	2	10,705
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(3,839)	-	(3,839)
Total transactions with owners	-	(3,839)	-	(3,839)
Balance at end of period	10,006	202,489	309	202,799

(4) Consolidated Statements of Cash Flows

(Millions of yen)

	Three months ended June 30, 2022	Three months ended June 30, 2023
Cash flows from operating activities		
Profit before tax	10,514	11,440
Depreciation and amortization	1,221	1,236
Interest and dividend income	(266)	(298)
Interest expenses	15	5
Foreign exchange loss (gain)	(720)	(940)
Loss (gain) on sale of fixed assets	15	31
Decrease (increase) in trade and other receivables	(2,392)	(899)
Decrease (increase) in inventories	1,508	948
Increase (decrease) in trade and other payables	(4,750)	(4,425)
Increase (decrease) in retirement benefit liability	(175)	(204)
Other	2,096	270
Subtotal	7,065	7,165
Interest and dividends received	266	296
Interest paid	(8)	(5)
Income taxes paid	(3,451)	(6,930)
Net cash provided by (used in) operating activities	3,872	526
Cash flows from investing activities		
Payments into time deposits	(45)	(45)
Proceeds from withdrawal of time deposits	30	30
Purchase of property, plant and equipment	(860)	(1,661)
Purchase of intangible assets	(1,243)	(385)
Purchase of investments	(1,850)	(0)
Proceeds from sale and redemption of investments	2,400	—
Other	1	1
Net cash provided by (used in) investing activities	(1,566)	(2,060)
Cash flows from financing activities		
Repayments of lease liabilities	(535)	(422)
Purchase of treasury shares	(0)	(0)
Dividends paid	(3,753)	(3,625)
Net cash provided by (used in) financing activities	(4,289)	(4,047)
Effect of exchange rate changes on cash and cash equivalents	331	786
Net increase (decrease) in cash and cash equivalents	(1,651)	(4,795)
Cash and cash equivalents at beginning of period	60,566	60,047
Cash and cash equivalents at end of period	58,915	55,251

Appendix:
Leading Products

August 10, 2023

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	27,202	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)		
						Apr-Jun	Apr-Sep (estimated)	Annual (estimated)
Viltepso				7,750	14,341	4,165	8,500	18,300
(Japan)	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	(4,059)	(4,139)	(1,051)	(2,200)	(4,800)
(U.S.)				(3,691)	(10,201)	(3,113)	(6,300)	(13,500)
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	8,400	10,543	3,255	6,400	14,000
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	18,338	15,951	2,871	5,700	10,500
Gazyva	obinutuzumab	CD20-positive follicular lymphoma/ CD20-positive chronic lymphocytic leukemia	Aug-2018/ Dec-2022	5,300	4,904	1,220	2,300	4,900
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	6,770	5,358	1,104	2,250	4,300
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,532	2,938	654	1,150	2,500
Adcirca	tadalafil	pulmonary arterial hypertension	Dec-2009	4,563	2,649	631	1,100	2,100
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	2,128	2,524	631	1,400	3,000
Zalutia	tadalafil	urinary disorder caused by benign prostatic hyperplasia	Apr-2014	4,106	2,826	614	1,050	2,000
Erizas	dexamethasone cipeclate	allergic rhinitis	Dec-2009	2,330	2,640	334	900	2,500
Profit in co-promotion				8,934	9,520	2,310	4,600	9,300
Revenues from the licensing of industrial property rights				33,207	30,714	9,104	17,200	35,000
Pharmaceuticals				120,650	121,988	30,870	60,500	123,500
Functional Food				16,834	22,187	6,142	11,000	21,500
Revenue				137,484	144,175	37,012	71,500	145,000

**Appendix:
R&D Pipeline List**

<Domestic>

As of August 10, 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
NDA filing	NS-87 (daunorubicin / cytarabine)	hematologic malignancies	high-risk acute myeloid leukemia	Licensed - in from Jazz Pharmaceuticals plc	Nippon Shinyaku
NDA filing	ZX008 (fenfluramine hydrochloride)	intractable disease · orphan disease	Lennox-Gastaut syndrome	Distribution partnership: UCB S.A. (former : Zogenix, Inc.)	UCB S.A. (former : Zogenix, Inc.)
Phase III	ZX008 (fenfluramine hydrochloride)	intractable disease · orphan disease	CDKL5 deficiency disorder	Distribution partnership: 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
Phase II	NS-580	urological diseases	chronic prostatitis / chronic pelvic pain syndrome	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 II	NS-229	intractable disease · orphan disease	eosinophilic granulomatosis with polyangiitis	Nippon Shinyaku	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-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 (ilginateinib)	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 II	NS-229	intractable disease · orphan disease	eosinophilic granulomatosis with polyangiitis	Nippon Shinyaku	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