

Outline of Consolidated Financial Results for the First Quarter Ended June 30, 2022(IFRS)

August 9, 2022

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: August 12, 2022

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, 2022 (April 1, 2022 to June 30, 2022)

(1) Operating results

(¥ million)

	Revenue	Operating profit	Profit before tax	Profit	Profit attributable to owners of parent	Comprehensive income
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)
Three months ended June 30, 2021	40,968 —	16,559 —	16,770 —	12,594 —	12,589 —	11,412 —
	Earnings per share (¥)					
	Basic	Diluted				
Three months ended June 30, 2022	122.48	—				
Three months ended June 30, 2021	186.91	—				

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, 2022	219,684	185,227	184,922	84.2%
As of March 31, 2022	219,943	180,886	180,585	82.1%

2. Dividends

	Annual dividends per share (¥)				
	1 st quarter	2 nd quarter	3 rd quarter	Year-end	Annual
Year ended March 31, 2022	—	51.00	—	59.00	110.00
Year ending March 31, 2023	—				
Year ending March 31, 2023 (forecast)		56.00	—	56.00	112.00

3. Business Forecast for the Year Ending March 31, 2023 (April 1, 2022 to March 31, 2023)

(¥ million)

	Revenue	Operating profit	Profit before tax	Net income attributable to owners of the parent	Basic earnings per share (¥)
First-half period	67,000 —	14,500 —	14,700 —	11,300 —	167.77
Full term	134,000 (2.5)	27,000 (18.1)	27,500 (17.4)	21,500 (14.0)	319.21

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, 2022: 70,251,484 shares

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

Number of shares of treasury stock

As of June 30, 2022: 2,898,500 shares

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

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

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

As of June 30, 2021: 67,353,291 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, 2022	As of June 30, 2022
Assets		
Current assets		
Cash and cash equivalents	60,566	58,915
Trade and other receivables	43,178	45,724
Inventories	38,066	36,662
Other financial assets	5,174	4,530
Other current assets	2,738	3,452
Total current assets	149,724	149,284
Non-current assets		
Property, plant and equipment	28,304	28,541
Intangible assets	14,050	13,525
Right-of-use assets	2,753	2,760
Other financial assets	22,294	22,768
Deferred tax assets	901	934
Other non-current assets	1,915	1,867
Total non-current assets	70,219	70,399
Total assets	219,943	219,684

(Millions of yen)

	As of March 31, 2022	As of June 30, 2022
Liabilities and equity		
Liabilities		
Current liabilities		
Trade and other payables	21,022	15,200
Other financial liabilities	374	398
Lease liabilities	1,494	1,395
Income taxes payable	3,123	2,106
Other current liabilities	6,014	8,516
Total current liabilities	32,029	27,616
Non-current liabilities		
Other financial liabilities	237	232
Lease liabilities	1,219	1,200
Retirement benefit liability	5,506	5,338
Other non-current liabilities	64	67
Total non-current liabilities	7,027	6,839
Total liabilities	39,057	34,456
Equity		
Share capital	5,174	5,174
Capital surplus	4,445	4,445
Retained earnings	165,303	169,579
Treasury shares	(2,478)	(2,479)
Other components of equity	8,140	8,202
Total equity attributable to owners of parent	180,585	184,922
Non-controlling interests	300	305
Total equity	180,886	185,227
Total liabilities and equity	219,943	219,684

(2) Consolidated Statements of Income

(Millions of yen)

	Three months ended June 30, 2021	Three months ended June 30, 2022
Revenue	40,968	35,619
Cost of sales	12,898	13,928
Gross profit	28,069	21,690
Selling, general and administrative expenses	7,681	8,200
Research and development expenses	3,737	4,738
Other income	135	1,652
Other expenses	226	128
Operating profit	16,559	10,276
Finance income	234	266
Finance costs	23	28
Profit before tax	16,770	10,514
Income tax expense	4,175	2,260
Profit	12,594	8,253
Profit attributable to		
Owners of parent	12,589	8,249
Non-controlling interests	5	4
Profit	12,594	8,253
Earnings per share		
Basic earnings per share	186.91	122.48

(Consolidated Statements of Comprehensive Income)

(Millions of yen)

	Three months ended June 30, 2021	Three months ended June 30, 2022
Profit	12,594	8,253
Other comprehensive income		
Items that will not be reclassified to profit or loss		
Financial assets measured at fair value through other comprehensive income	(1,206)	319
Total of items that will not be reclassified to profit or loss	(1,206)	319
Items that may be reclassified to profit or loss		
Exchange differences on translation of foreign operations	24	(258)
Total of items that may be reclassified to profit or loss	24	(258)
Total other comprehensive income	(1,182)	61
Comprehensive income	11,412	8,315
Comprehensive income attributable to		
Owners of parent	11,407	8,310
Non-controlling interests	5	4
Comprehensive income	11,412	8,315

(3) Consolidated Statements of Changes in Net Assets
For the three-month period ended June 30, 2021

(Millions of yen)

	Equity attributable to owners of parent					Other components of equity	
	Share capital	Capital surplus	Retained earnings	Treasury shares	Exchange difference s 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	-	-	12,589	-	-		-
Other comprehensive income	-	-	-	-	24		(1,206)
Comprehensive income	-	-	12,589	-	24		(1,206)
Purchase of treasury shares	-	-	-	(0)	-		-
Dividends of surplus	-	-	(3,367)	-	-		-
Total transactions with owners	-	-	(3,367)	(0)	-		-
Balance at end of period	5,174	4,445	156,017	(2,476)	(68)		8,108

	Equity attributable to owners of parent			
	Other components of equity	Total	Non-controlling interests	Total
	Total			
Balance at beginning of period	9,221	163,161	288	163,449
Profit	-	12,589	5	12,594
Other comprehensive income	(1,182)	(1,182)	-	(1,182)
Comprehensive income	(1,182)	11,407	5	11,412
Purchase of treasury shares	-	(0)	-	(0)
Dividends of surplus	-	(3,367)	-	(3,367)
Total transactions with owners	-	(3,367)	-	(3,367)
Balance at end of period	8,039	171,200	293	171,494

For the three-month period ended June 30, 2022

(Millions of yen)

	Equity attributable to owners of parent					
	Share capital	Capital surplus	Retained earnings	Treasury shares	Other components of equity	
					Exchange difference s 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- controllin g 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

(4) Consolidated Statements of Cash Flows

	Three months ended June 30, 2021	Three months ended June 30, 2022
Cash flows from operating activities		
Profit before tax	16,770	10,514
Depreciation and amortization	1,119	1,221
Interest and dividend income	(234)	(266)
Interest expenses	14	15
Foreign exchange loss (gain)	0	(720)
Loss (gain) on sale of fixed assets	11	15
Decrease (increase) in trade and other receivables	(1,839)	(2,392)
Decrease (increase) in inventories	(198)	1,508
Increase (decrease) in trade and other payables	(1,738)	(4,750)
Increase (decrease) in retirement benefit liability	(164)	(175)
Other	177	2,096
Subtotal	13,917	7,065
Interest and dividends received	234	266
Interest paid	(7)	(8)
Income taxes paid	(6,746)	(3,451)
Net cash provided by (used in) operating activities	7,397	3,872
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	(551)	(860)
Purchase of intangible assets	(1,670)	(1,243)
Purchase of investments	(0)	(1,850)
Proceeds from sale and redemption of investments	—	2,400
Other	2	1
Net cash provided by (used in) investing activities	(2,234)	(1,566)
Cash flows from financing activities		
Repayments of lease liabilities	(396)	(535)
Purchase of treasury shares	(0)	(0)
Dividends paid	(3,161)	(3,753)
Net cash provided by (used in) financing activities	(3,557)	(4,289)
Effect of exchange rate changes on cash and cash equivalents	25	331
Net increase (decrease) in cash and cash equivalents	1,630	(1,651)
Cash and cash equivalents at beginning of period	57,883	60,566
Cash and cash equivalents at end of period	59,513	58,915

Appendix :
Leading Products

Performance (consolidated)

(¥ million)

	2016 (JGAAP)	2017 (JGAAP)	2018 (JGAAP)	2019 (JGAAP)	2020 (IFRS)	2021 (IFRS)	2022 (IFRS) (estimated)
Revenue	98,781	101,448	114,716	116,637	121,859	137,484	134,000
Operating profit	15,280	17,079	20,644	21,668	27,702	32,948	27,000
Profit before tax	16,244	17,451	21,540	22,442	27,608	33,301	27,500
Profit attributable to owners of parent	11,749	12,953	16,302	16,866	19,540	24,986	21,500

(¥ million)

Brand name	Active Ingredient	Indications	Launch Date	Sales 2020 (IFRS)	Sales 2021 (IFRS)	Sales 2022 (IFRS)		
						Apr-Jun	Apr-Sep (estimated)	Annual (estimated)
Vidaza	azacitidine	myelodysplastic syndrome/ acute myeloid leukemia	Mar-2011/ Mar-2021	15,350	18,338	4,800	7,800	12,400
Viltepso	viltolarsen	Duchenne muscular dystrophy	Japan May-2020 U.S. Aug-2020	2,387	7,750	3,193	5,900	13,000
(Japan)				(1,953)	(4,059)	(1,054)	(2,200)	(4,750)
(U.S.)				(434)	(3,691)	(2,139)	(3,700)	(8,250)
Upravi	selexipag	pulmonary arterial hypertension/ chronic thromboembolic pulmonary hypertension	Nov-2016/ Aug-2021	6,804	8,400	2,367	4,500	9,800
Tramal, Onetram	tramadol hydrochloride	cancer pain, chronic pain	Sep-2010	6,906	6,770	1,674	2,700	5,000
Gazyva	obinutuzumab	CD20-positive follicular lymphoma	Aug-2018	5,312	5,300	1,333	2,700	5,800
Zalutia	tadalafil	urinary disorder caused by benign prostatic hyperplasia	Apr-2014	6,743	4,106	771	1,300	2,300
Cialis	tadalafil	erectile dysfunction	Jul-2009	2,677	2,532	754	1,250	2,600
Adcirca	tadalafil	pulmonary arterial hypertension	Dec-2009	5,474	4,563	742	1,400	2,500
Defitelio	defibrotide sodium	sinusoidal obstruction syndrome	Sep-2019	1,970	2,128	594	1,000	2,300
Erizas	dexamethasone cipeclate	allergic rhinitis	Dec-2009	2,444	2,330	385	700	2,400
Profit in co-promotion				8,442	8,934	2,603	4,600	9,500
Revenues from the licensing of industrial property rights				24,338	33,207	6,903	14,600	29,800
Pharmaceuticals				106,478	120,650	30,407	57,400	115,000
Functional Food				15,380	16,834	5,211	9,600	19,000
Revenue				121,859	137,484	35,619	67,000	134,000

**Appendix :
R&D Pipeline List**

<Domestic>

As of August 9, 2022

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
Preparation for launch	NS-32 (ferric derisomaltose)	gynecology	iron deficiency anemia	Licensed - in from Pharmacosmos A/S	Nippon Shinyaku
NDA filing	ZX008 (fenfluramine hydrochloride)	intractable disease ・ orphan disease	Dravet syndrome	Licensed - in from UCB S.A. (former : Zogenix, Inc.)	UCB S.A. (former : Zogenix, Inc.)
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)	inflammatory diseases	lupus nephritis	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 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
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

<Overseas>

Stage	Code No. (Generic name)	Therapeutic field	Indications	Origin	Development
U.S. 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.
Preparation for Phase II	NS-018 (ilgatinib)	hematologic malignancies	myelofibrosis	Nippon Shinyaku	Nippon Shinyaku