

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.**

Code No.: 4516

Representative: Toru Nakai, President and Representative Director

Contact: Hideyuki Fujii, Department Manager and Finance & Accounting Dept.

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)

Listing stock exchange: Tokyo

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

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* 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 |

(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 | 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 (ilginatinib) | 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 |