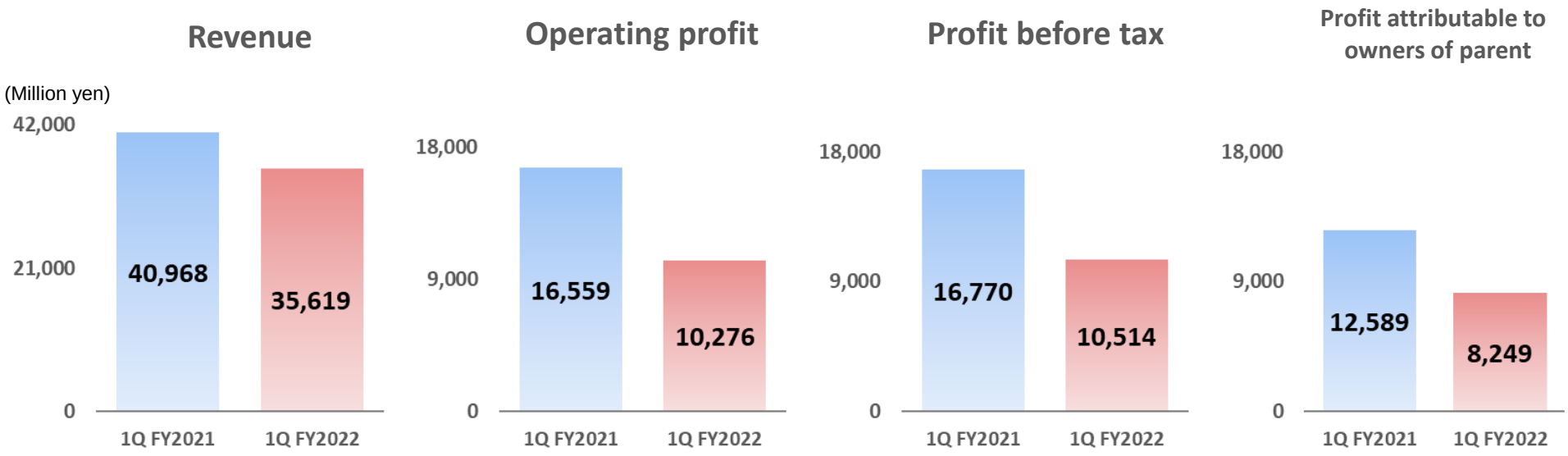
# Outline of Consolidated Financial Results for the 1st Quarter Ended June 30, 2022

**August 9, 2022**
**NIPPON SHINYAKU CO., LTD.**

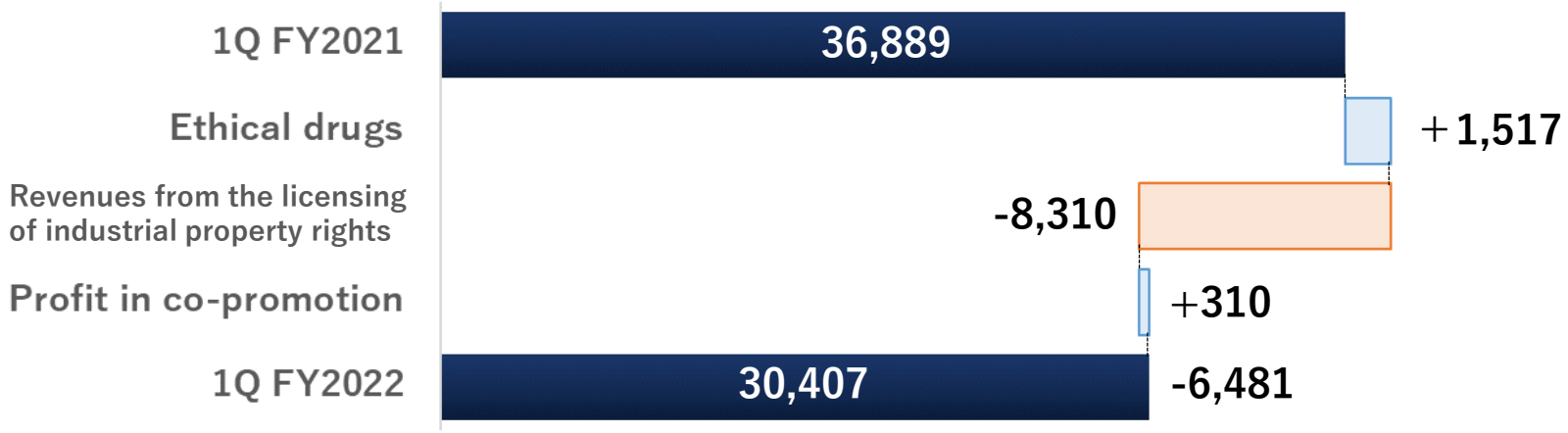
NIPPON SHINYAKU CO., LTD.

# 1Q FY2022 Summary

- **Revenue** : 35,619 million yen （- 13.1%）
- **Operating profit** : 10,276 million yen （- 37.9%）
- **Profit before tax** : 10,514 million yen （- 37.3%）
- **Profit attributable to owners of parent** : 8,249 million yen （- 34.5%）



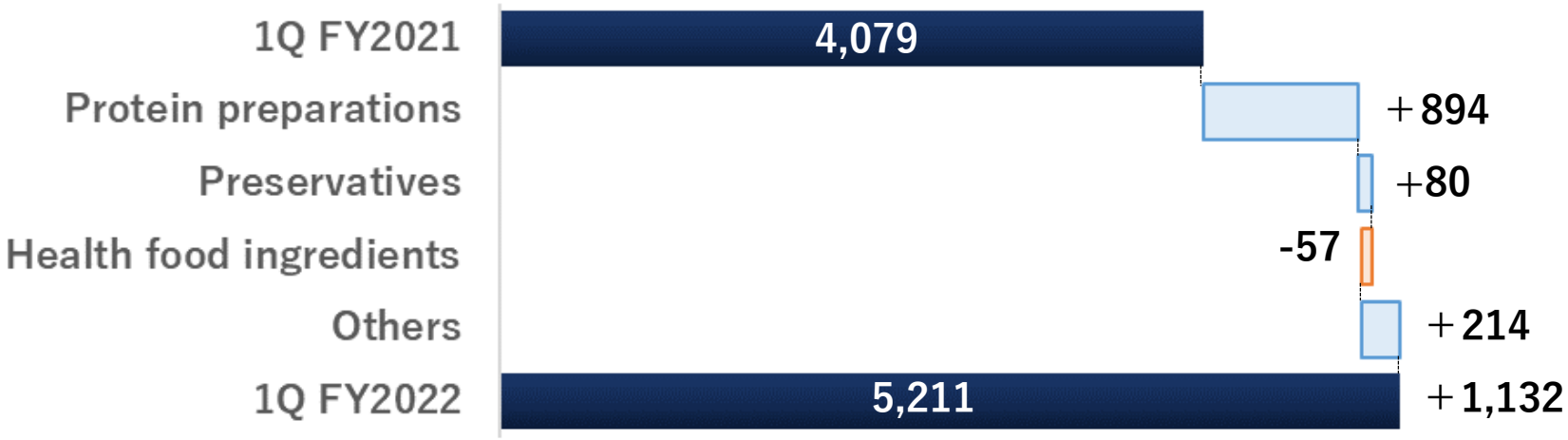
# Segmental Review - Pharmaceuticals -




| (Million yen) | 1Q FY2021 | | 1Q FY2022 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Results | Ratio | Amt | % |
| Ethical drugs | 19,382 | 52.6% | 20,900 | 68.7% | +1,517 | +7.8% |
| Revenues from the licensing of industrial property rights | 15,214 | 41.2% | 6,903 | 22.7% | -8,310 | -54.6% |
| Profit in co-promotion | 2,292 | 6.2% | 2,603 | 8.6% | +310 | +13.6% |
| Revenue | 36,889 | 100.0% | 30,407 | 100.0% | -6,481 | -17.6% |

Sales of Ethical drugs including “Viltepso” and “Uptravi”, revenues from the licensing of industrial property rights containing royalty revenue from Uptravi’s overseas sales grew.
However, due to price revision by MHLW and backlash from the loss of sales revenue from the priority review voucher booked in 1Q FY2021, net sales decreased by 17.6%.

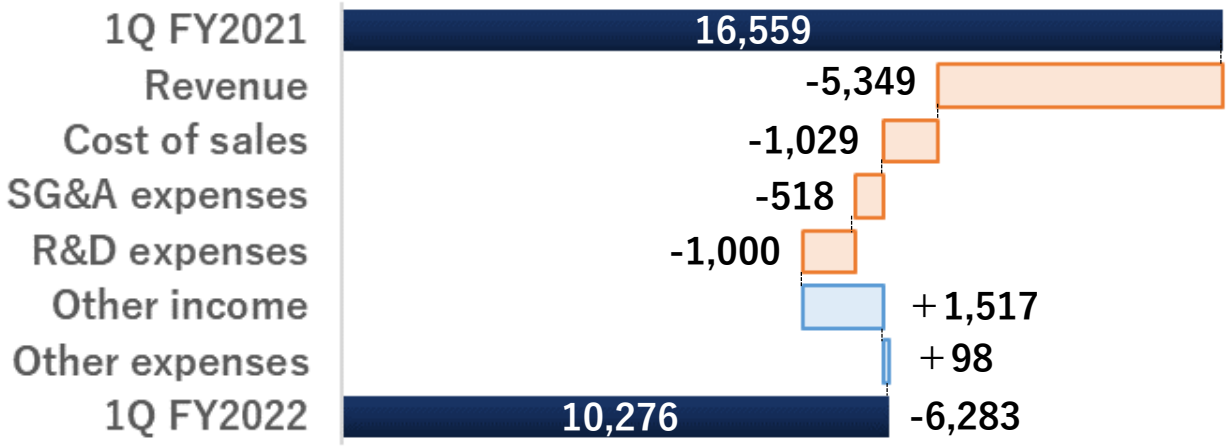
# Segmental Review - Functional Food -




| (Million yen) | 1Q FY2021 | | 1Q FY2022 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Results | Ratio | Amt | % |
| Protein preparations | 2,710 | 66.4% | 3,605 | 69.2% | +894 | +33.0% |
| Preservatives | 645 | 15.8% | 726 | 13.9% | +80 | +12.5% |
| Health food ingredients | 272 | 6.7% | 214 | 4.1% | -57 | -21.2% |
| Others | 450 | 11.1% | 665 | 12.8% | +214 | +47.6% |
| Revenue | 4,079 | 100.0% | 5,211 | 100.0% | +1,132 | +27.8% |

**Net sales increased by 27.8% through sales from Protein preparations including milk proteins and Supplements such as “WINZONE Protein”.**

# Operating profit




| (Million yen) | 1Q FY2021 | | 1Q FY2022 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Results | Ratio | Amt | % |
| **Revenue** | **40,968** | **100.0%** | **35,619** | **100.0%** | **-5,349** | **-13.1%** |
| (Pharmaceuticals) | (36,889) | (90.0%) | (30,407) | (85.4%) | (-6,481) | (-17.6%) |
| (Functional Food) | (4,079) | (10.0%) | (5,211) | (14.6%) | (+1,132) | (+27.8%) |
| **Cost of sales** | **12,898** | **31.5%** | **13,928** | **39.1%** | **+1,029** | **+8.0%** |
| **SG&A expenses** | **7,681** | **18.8%** | **8,200** | **23.0%** | **+518** | **+6.8%** |
| **R&D expenses** | **3,737** | **9.1%** | **4,738** | **13.3%** | **+1,000** | **+26.8%** |
| **Other income** | **135** | **0.3%** | **1,652** | **4.6%** | **+1,517** | **+1,120.9%** |
| **Other expenses** | **226** | **0.5%** | **128** | **0.3%** | **-98** | **-43.4%** |
| **Operating profit** | **16,559** | **40.4%** | **10,276** | **28.9%** | **-6,283** | **-37.9%** |

# Profit attributable to owners of parent


| (Million yen) | 1Q FY2021 Results | 1Q FY2022 Results | YoY Change Amt | YoY Change % |
|---|---|---|---|---|
| Operating profit | 16,559 | 10,276 | -6,283 | -37.9% |
| Finance income | 234 | 266 | +32 | +13.7% |
| Finance costs | 23 | 28 | +5 | +23.4% |
| Profit before tax | 16,770 | 10,514 | -6,256 | -37.3% |
| Income tax expense, etc | 4,181 | 2,265 | -1,916 | -45.8% |
| Profit attributable to owners of parent | 12,589 | 8,249 | -4,339 | -34.5% |

# Business Forecast for FY2022

| (Million yen) | FY2021 | | FY2022 | | | |
|---|---|---|---|---|---|---|
| | 1Q Results | FY Results | 1Q Results | Progress for 1H | 1H Forecasts | FY Forecasts |
| **Revenue** | **40,968** | **137,484** | **35,619** | **53.2%** | **67,000** | **134,000** |
| (Pharmaceuticals) | (36,889) | (120,650) | (30,407) | (53.0%) | (57,400) | (115,000) |
| (Functional Food) | (4,079) | (16,834) | (5,211) | (54.3%) | (9,600) | (19,000) |
| **Operating profit** | **16,559** | **32,948** | **10,276** | **70.9%** | **14,500** | **27,000** |
| **Profit before tax** | **16,770** | **33,301** | **10,514** | **71.5%** | **14,700** | **27,500** |
| **Profit attributable to owners of parent** | **12,589** | **24,986** | **8,249** | **73.0%** | **11,300** | **21,500** |

**Revenue and each profit have progressed toward achievement of 1H, FY forecasts.**

# R&D Pipeline

NIPPON SHINYAKU CO., LTD.

# R&D Pipeline (Domestic) ①

| Code No. (Generic name) <Origin> | Application type | Indications | PI | PI/II | PII | PIII | NDA | Preparation for launch | Launch |
|---|---|---|---|---|---|---|---|---|---|
| NS-065/NCNP-01 (viltolarsen) <in-house> | NME | Duchenne muscular dystrophy | | | | PIII in progress | | | |
| NS-32 (ferric derisomaltose) <in-license> | NME | Iron deficiency anemia | | | | | | | |
| ZX008 (fenfluramine hydrochloride) <in-license> | NME | Dravet syndrome | | | | | | | |
| ZX008 (fenfluramine hydrochloride) <in-license> | NME | Lennox-Gastaut syndrome | | | | | | | |
| GA101 (obinutuzumab) <in-license> | New indication | Lupus nephritis | | | | | | | |

■：changes from the Fiscal Year Ended March 31, 2022

# R&D Pipeline (Domestic) ②

| Code No. (Generic name) <Origin> | Application type | Indications | PI | PI/II | PII | PIII | NDA | Preparation for launch | Launch |
|---|---|---|---|---|---|---|---|---|---|
| NS-304 (selexipag) <in-house> | New indication | Arteriosclerosis obliterans | | | | | | | |
| | New dose | Pediatric pulmonary arterial hypertension | | | | | | | |
| NS-580 <in-house> | NME | Endometriosis | | | | | | | |
| NS-87 (daunorubicin / cytarabine) <in-license> | New combi-nation | Secondary acute myeloid leukemia | | | | | | | |
| NS-401 (tagraxofusp) <in-license> | NME | Blastic plasmacytoid dendritic cell neoplasm | | | | | | | |
| NS-229 <in-house> | NME | Inflammatory diseases | | | | | | | |
| NS-917 (radgocitabine) <in-license> | NME | Relapsed/refractory acute myeloid leukemia | | | | | | | |

■：changes from the Fiscal Year Ended March 31, 2022

# R&D Pipeline (Overseas)

| Code No.<br>(Generic name)<br><Origin> | Application type | Indications | PI | Preparation for P II | PII | PIII | Launch |
|---|---|---|---|---|---|---|---|
| NS-065/NCNP-01<br>(viltolarsen)<br><in-house> | NME | Duchenne muscular dystrophy | | | | PIII<br>in progress | |
| CAP-1002<br><partnership> | NME | Duchenne muscular dystrophy | | | | | |
| NS-018<br>(ilginatinib)<br><in-house> | NME | Myelofibrosis | | | | | |

■：changes from the Fiscal Year Ended March 31, 2022

# Reference Materials

NIPPON SHINYAKU CO., LTD.

# Consolidated Balance Sheet

| (Million yen) | End of FY2021 | End of 1Q FY2022 | Change Amt |
|---|---|---|---|
| Assets | 219,943 | 219,684 | -259 |
| Current assets | 149,724 | 149,284 | -439 |
| Non-current assets | 70,219 | 70,399 | +179 |
| Total assets | 219,943 | 219,684 | -259 |

| | End of FY2021 | End of 1Q FY2022 | Change Amt |
|---|---|---|---|
| Liabilities | 39,057 | 34,456 | -4,600 |
| Current liabilities | 32,029 | 27,616 | -4,412 |
| Non-current liabilities | 7,027 | 6,839 | -188 |
| Equity | 180,886 | 185,227 | +4,341 |
| Total liabilities and equity | 219,943 | 219,684 | -259 |

**＝Assets＝**

| | |
|---|---|
| Cash and cash equivalents | -1,651 |
| Inventories | -1,403 |
| Other financial assets | ＋473 |

**＝Liabilities and equity＝**

| | |
|---|---|
| Trade and other payables | -5,821 |
| Income taxes payable | -1,017 |
| Retained earnings | +4,275 |

# NS-065/NCNP-01 (viltolarsen)
## - Treatment for Duchenne muscular dystrophy -

| | |
|---|---|
| Development Phase | ・Japan : Launch<br>・USA : Launch<br>・Global : PIII in progress |
| Origin | Co-development :<br>National Center of Neurology and Psychiatry |
| Development | Nippon Shinyaku |
| Mechanism of action | Exon 53 Skipping |
| Indication | Duchenne muscular dystrophy |
| Dosage form | Injection |
| Feature | ・Improvement in symptoms and prevention of the disease progression by recovery of dystrophin protein expression<br>・Morpholino based oligonucleotide with possible high safety profile and maximized activity |

# NS-32 (ferric derisomaltose)
## - Treatment for iron deficiency anemia -

| | |
|---|---|
| Development Phase | Japan : Preparation for launch |
| Origin | [Dec. 2016]<br>Licensed-in from : Pharmacosmos A/S |
| Development | Nippon Shinyaku |
| Mechanism of action | Iron |
| Indication | Iron deficiency anemia |
| Dosage form | IV bolus injection or IV drip infusion |
| Feature | ・Can be administered in high doses allowing full iron correction in the majority of patients<br>・Good safety profile with no dose dependent ADRs<br>・Minimal potential toxicity from release of labile iron due to tight iron binding in a matrix structure of interchanging isomaltoside and iron<br>・No profound hypophosphatemia |

# ZX008 (fenfluramine hydrochloride)
## - Treatment for rare intractable epilepsy -

| | |
|---|---|
| Development Phase | Japan : NDA filing　(Dravet syndrome)<br>Japan : PIII　(Lennox-Gastaut syndrome) |
| Origin | [Mar. 2019]<br>Commercial rights from : UCB S.A. (former Zogenix, Inc.) |
| Development | UCB S.A.（former Zogenix, Inc.） |
| Mechanism of action | Serotonin agonist |
| Indication | Dravet syndrome and Lennox-Gastaut syndrome |
| Dosage form | Oral liquid agent |
| Feature | ・Effective for Dravet syndrome and Lennox-Gastaut syndrome patients refractory to existing treatment options<br>・ZX008 can be used in combination with other drugs, as standard of care for intractable epilepsy based on combination therapy |

# CAP-1002
## - Treatment for Duchenne muscular dystrophy -

| | |
|---|---|
| Development Phase | USA : PIII |
| Origin | [Jan. 2022]<br>Partnership for commercialization :<br>Capricor Therapeutics, Inc. |
| Development | Capricor Therapeutics, Inc. |
| Mechanism of action | Exosomes released from cardiosphere-derived cells |
| Indication | Duchenne muscular dystrophy |
| Dosage form | Injection |
| Feature | ・Exosomes released from this drug are expected to reduce oxidative stress, inflammation, fibrosis, and increase cell energy and myocyte generation, resulting in improvement of motor and cardiac functions<br>・Its broad applicability makes it suitable for patients regardless of the type of genetic mutation |

# GA101 (Obinutuzumab)
## - Treatment for lupus nephritis -

| | |
|---|---|
| Development Phase | Japan : PIII |
| Origin | [Nov. 2012]<br>Licensed-in from : Chugai Pharmaceutical Co., Ltd. |
| Development | Co-development : Chugai Pharmaceutical Co., Ltd. |
| Mechanism of action | Anti-CD20 monoclonal antibody |
| Indication | Lupus nephritis |
| Dosage form | Injection |
| Feature | Anti-CD20 monoclonal antibody, increased antibody-dependent cellular cytotoxicity (ADCC) activity and direct cytotoxicity |

# NS-304 (selexipag)

## -Treatment for pulmonary hypertension, arteriosclerosis obliterans-

| | |
|---|---|
| Development Phase | Japan : PIIb（ASO）<br>Japan : PII （Pediatric PAH） |
| Origin | Nippon Shinyaku |
| Development | ・Nippon Shinyaku（ASO）<br>・Co-development :<br>Janssen Pharmaceutical K.K.（Pediatric PAH） |
| Mechanism of action | Selective IP receptor agonist |
| Indication | ・Arteriosclerosis obliterans (ASO)<br>・Pediatric pulmonary arterial hypertension (Pediatric PAH) |
| Dosage form | Tablet |
| Feature | Long-acting oral drug |

# NS-580
## - Treatment for endometriosis -

| | |
|---|---|
| Development Phase | Japan : PIIb |
| Origin | Nippon Shinyaku |
| Development | Nippon Shinyaku |
| Mechanism of action | Inhibition of membrane-associated prostaglandin E synthase-1 |
| Indication | Endometriosis |
| Dosage form | Oral agent |
| Feature | Treatment for endometriosis without hormonal effect and with possible analgesic potency |

# NS-018 (ilginatinib)
## - Treatment for myelofibrosis -

| | |
|---|---|
| Development Phase | Overseas : Preparation for PII |
| Origin | Nippon Shinyaku |
| Development | Nippon Shinyaku |
| Mechanism of action | JAK2 inhibitor |
| Indication | Myelofibrosis |
| Dosage form | Tablet |
| Feature | ・Potent and highly selective JAK2 inhibitor<br>・High efficacy and safety are expected for myelofibrosis (MF) patients with low platelet count |

# NS-87 (daunorubicin / cytarabine)
## - Treatment for secondary acute myeloid leukemia -

| | |
|---|---|
| Development Phase | Japan : PI/II |
| Origin | [Mar. 2017]<br>Licensed-in from: Jazz Pharmaceuticals plc |
| Development | Nippon Shinyaku |
| Mechanism of action | Liposomal combination of daunorubicin and cytarabine |
| Indication | Secondary acute myeloid leukemia (secondary AML) |
| Dosage form | Injection |
| Feature | ・NS-87 is the first therapy for the treatment of secondary AML in Japan<br>・The enhancement of antitumor activity and reducing adverse events are expected by NS-87 accumulated in bone marrow |

# NS-401 (tagraxofusp)

## - Treatment for blastic plasmacytoid dendritic cell neoplasm -

| | |
|---|---|
| Development Phase | Japan : PI/II |
| Origin | [Mar. 2021]<br>Licensed-in from: The Menarini Group |
| Development | Nippon Shinyaku |
| Mechanism of action | Induction apoptosis of cells by inhibiting protein synthesis by specifically targeting cancer cells expressing CD123 |
| Indication | Blastic plasmacytoid dendritic cell neoplasm (BPDCN) |
| Dosage form | Injection |
| Feature | ・Composed of diphtheria toxin (DT) fusion protein and recombinant human IL-3<br>・Novel targeted therapy directed to CD123 on tumor cells<br>・IL-3 binds to CD123-expressing tumor cells and delivers the cytotoxic diphtheria toxin to the cells, resulting in the blockage of protein synthesis in the cell and causing cell death in CD123-expressing cells |

# NS-229
## - Treatment for inflammatory diseases -

| | |
|---|---|
| Development Phase | Japan : PI |
| Origin | Nippon Shinyaku |
| Development | Nippon Shinyaku |
| Mechanism of action | JAK1 inhibitor |
| Indication | Inflammatory diseases (to be determined) |
| Dosage form | Oral agent |
| Feature | ・Potent and highly selective JAK1 inhibitor<br>・High efficacy and good safety profiles are expected in the treatment for inflammatory diseases |

# NS-917 (radgocitabine)

## - Treatment for relapsed or refractory acute myeloid leukemia -

| | |
|---|---|
| Development Phase | Japan : PI |
| Origin | [Mar. 2017]<br>Licensed-in from : Delta-Fly Pharma, Inc. |
| Development | Nippon Shinyaku |
| Mechanism of action | DNA strand-break by incorporating itself into DNA |
| Indication | Relapsed or refractory (r/r) acute myeloid leukemia (AML) |
| Dosage form | Injection |
| Feature | ・Significant anti-leukemic activity with unique mechanism of action from other nucleoside analogs at low dose continuous infusion<br>・Tolerable safety profile available to elderly patients with r/r AML |

# Safe Harbor Statement

- Materials and information provided during this presentation may contain so-called “forward-looking statements.” These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties which could cause actual outcomes and results to differ materially from these statements.
- Risks and uncertainties include general industry and market conditions, and general domestic and international economic conditions such as interest rate and currency exchange fluctuations. Risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, technological advances and patents attained by competitors; challenges inherent in new product development, including completion or failure of clinical trials; claims and concerns about product safety and efficacy; regulatory agency’s examination, obtaining regulatory approvals; domestic and foreign social security reforms; trends toward healthcare cost containment; and governmental laws and regulations affecting domestic and foreign operations.
- Also, for products that are approved, there are manufacturing and marketing risks and uncertainties, which include, but are not limited to, inability to build production capacity to meet demand, unavailability of raw materials, and competition with others.
- The Company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.
- This English presentation was translated from the original Japanese version.
  In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.

NIPPON SHINYAKU CO., LTD.

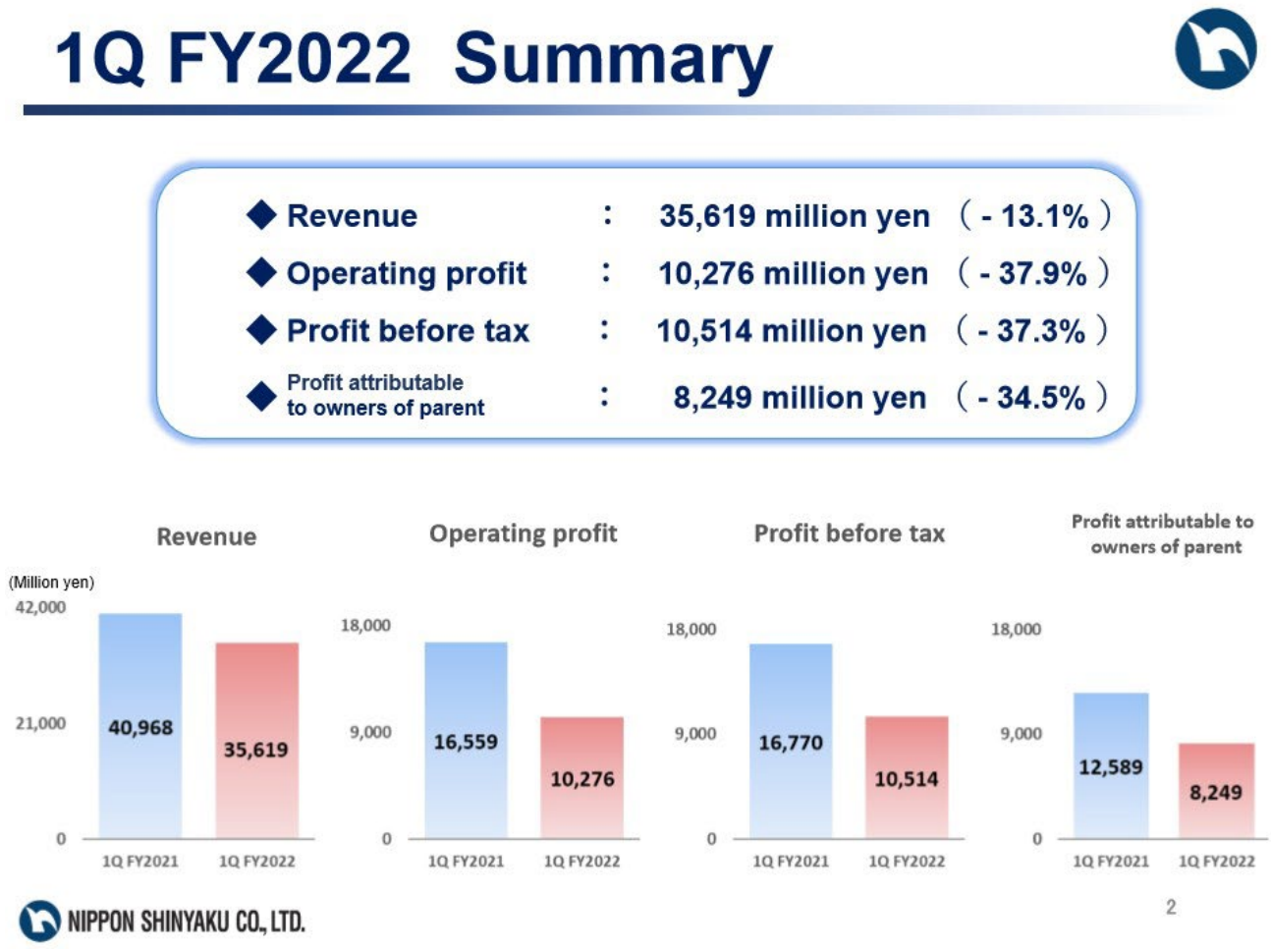
# Nippon Shinyaku Co., Ltd.

Financial Results Briefing for the 1st Quarter Ended June 30, 2022

August 9, 2022

**Edamitsu**: I am Edamitsu in charge of the Business Management & Sustainability Division. Thank you very much for joining our financial results briefing today. I would like to express my greatest gratitude.

I would now like to explain our business results and R&D progress for Q1 of FY2022 in accordance with the presentation materials posted on our website.




Please refer to slide two.

As an overview of our performance in Q1 of FY2022, we reported consolidated revenue of JPY35.619 billion, operating profit of JPY10.276 billion, profit before tax of JPY10.514 billion, and profit attributable to owners of parent of JPY8.249 billion for the quarter.

# Segmental Review - Pharmaceuticals -


| (Million yen) | 1Q FY2021 | | 1Q FY2022 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Results | Ratio | Amt | % |
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| Revenue | 36,889 | 100.0% | 30,407 | 100.0% | -6,481 | -17.6% |

**Sales of Ethical drugs including "Viltepso" and "Uptravi", revenues from the licensing of industrial property rights containing royalty revenue from Uptravi's overseas sales grew. However, due to price revision by MHLW and backlash from the loss of sales revenue from the priority review voucher booked in 1Q FY2021, net sales decreased by 17.6%.**

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Please refer to slide three.

In the pharmaceuticals business, although sales of VILTEPSO, treatment for Duchenne muscular dystrophy, and UPTRAVI, treatment for pulmonary arterial hypertension and chronic thromboembolic pulmonary hypertension, and royalty income from overseas sales of UPTRAVI grew, consolidated revenue of the pharmaceuticals business decreased 17.6% YoY to JPY30.407 billion due to the absence of the one-time income from the sale of priority review voucher that existed in the same period of the previous year.

# Segmental Review - Functional Food -


| (Million yen) | 1Q FY2021 | | 1Q FY2022 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Results | Ratio | Amt | % |
| Protein preparations | 2,710 | 66.4% | 3,605 | 69.2% | +894 | +33.0% |
| Preservatives | 645 | 15.8% | 726 | 13.9% | +80 | +12.5% |
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| Others | 450 | 11.1% | 665 | 12.8% | +214 | +47.6% |
| Revenue | 4,079 | 100.0% | 5,211 | 100.0% | +1,132 | +27.8% |

**Net sales increased by 27.8% through sales from Protein preparations including milk proteins and Supplements such as "WINZONE Protein".**

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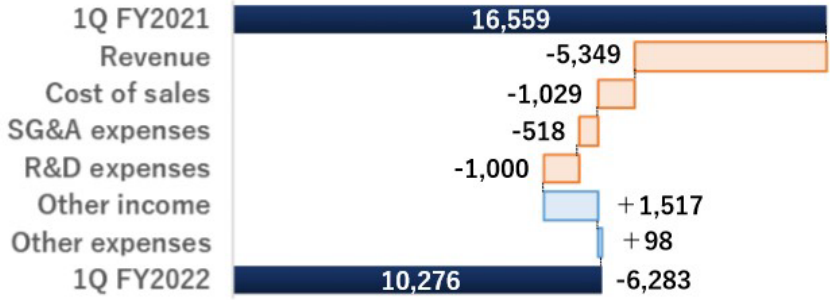
Please refer to slide four.

In the functional food business, sales of protein products such as milk protein and sports supplements centering on WINZONE Protein increased, resulting in consolidated revenue of JPY5.211 billion, up 27.8% YoY.

# Operating profit




| (Million yen) | 1Q FY2021 | | 1Q FY2022 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Results | Ratio | Amt | % |
| Revenue | 40,968 | 100.0% | 35,619 | 100.0% | -5,349 | -13.1% |
| (Pharmaceuticals) | (36,889) | (90.0%) | (30,407) | (85.4%) | (-6,481) | (-17.6%) |
| (Functional Food) | (4,079) | (10.0%) | (5,211) | (14.6%) | (+1,132) | (+27.8%) |
| Cost of sales | 12,898 | 31.5% | 13,928 | 39.1% | +1,029 | +8.0% |
| SG&A expenses | 7,681 | 18.8% | 8,200 | 23.0% | +518 | +6.8% |
| R&D expenses | 3,737 | 9.1% | 4,738 | 13.3% | +1,000 | +26.8% |
| Other income | 135 | 0.3% | 1,652 | 4.6% | +1,517 | +1,120.9% |
| Other expenses | 226 | 0.5% | 128 | 0.3% | -98 | -43.4% |
| Operating profit | 16,559 | 40.4% | 10,276 | 28.9% | -6,283 | -37.9% |

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Please refer to slide five.

The cost of sales ratio worsened by 7.6 percentage points YoY to 39.1% due to factors such as the sales mix, led by decrease in revenues from the licensing of industrial property rights.

SG&A expenses increased 6.8% YoY to JPY8.2 billion, mainly due to sales promotion fees associated with increased domestic sales of UPTRAVI and increased sales expenses in the functional food business.

Research and development expenses increased 26.8% YoY to JPY4.738 billion due to an increase in contract research expenses and nucleic acid investigational new drug manufacturing costs in line with progress in clinical trials.

As a result, operating profit was JPY 10.276 billion, down 37.9% YoY.

# Profit attributable to owners of parent


| (Million yen) | 1Q FY2021 Results | 1Q FY2022 Results | YoY Change Amt | YoY Change % |
|---|---|---|---|---|
| Operating profit | 16,559 | 10,276 | -6,283 | -37.9% |
| Finance income | 234 | 266 | +32 | +13.7% |
| Finance costs | 23 | 28 | +5 | +23.4% |
| Profit before tax | 16,770 | 10,514 | -6,256 | -37.3% |
| Income tax expense, etc | 4,181 | 2,265 | -1,916 | -45.8% |
| Profit attributable to owners of parent | 12,589 | 8,249 | -4,339 | -34.5% |



Please refer to slide six.

Profit before tax was JPY10.514 billion, down 37.3% YoY, and profit attributable to owners of parent was JPY8.249 billion, down 34.5% YoY.

# Business Forecast for FY2022

| (Million yen) | FY2021 | | FY2022 | | | |
|---|---|---|---|---|---|---|
| | 1Q Results | FY Results | 1Q Results | Progress for 1H | 1H Forecasts | FY Forecasts |
| **Revenue** | **40,968** | **137,484** | **35,619** | **53.2%** | **67,000** | **134,000** |
| (Pharmaceuticals) | (36,889) | (120,650) | (30,407) | (53.0%) | (57,400) | (115,000) |
| (Functional Food) | (4,079) | (16,834) | (5,211) | (54.3%) | (9,600) | (19,000) |
| **Operating profit** | **16,559** | **32,948** | **10,276** | **70.9%** | **14,500** | **27,000** |
| **Profit before tax** | **16,770** | **33,301** | **10,514** | **71.5%** | **14,700** | **27,500** |
| **Profit attributable to owners of parent** | **12,589** | **24,986** | **8,249** | **73.0%** | **11,300** | **21,500** |

**Revenue and each profit have progressed toward achievement of 1H, FY forecasts.**

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Please refer to slide seven.

The consolidated earnings forecast for FY2022 remains unchanged from that announced on May 11, 2022, with consolidated revenue of JPY134 billion, operating profit of JPY27 billion, profit before tax of JPY27.5 billion and profit attributable to owners of parent of JPY21.5 billion.

# R&D Pipeline (Domestic) ①

| Code No. (Generic name) <Origin> | Application type | Indications | PI | PI/II | PII | PIII | NDA | Preparation for launch | Launch |
|---|---|---|---|---|---|---|---|---|---|
| NS-065/NCNP-01 (viltolarsen) <in-house> | NME | Duchenne muscular dystrophy | | | | PIII in progress | | | |
| NS-32 (ferric derisomaltose) <in-license> | NME | Iron deficiency anemia | | | | | | | |
| ZX008 (fenfluramine hydrochloride) <in-license> | NME | Dravet syndrome | | | | | | | |
| ZX008 (fenfluramine hydrochloride) <in-license> | NME | Lennox-Gastaut syndrome | | | | | | | |
| GA101 (obinutuzumab) <in-license> | New indication | Lupus nephritis | | | | | | | |

NIPPON SHINYAKU CO., LTD.

■ : changes from the Fiscal Year Ended March 31, 2022

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I will continue with an explanation of the progress of R&D items.

Please refer to slide nine. First, I will explain the development situation in Japan.

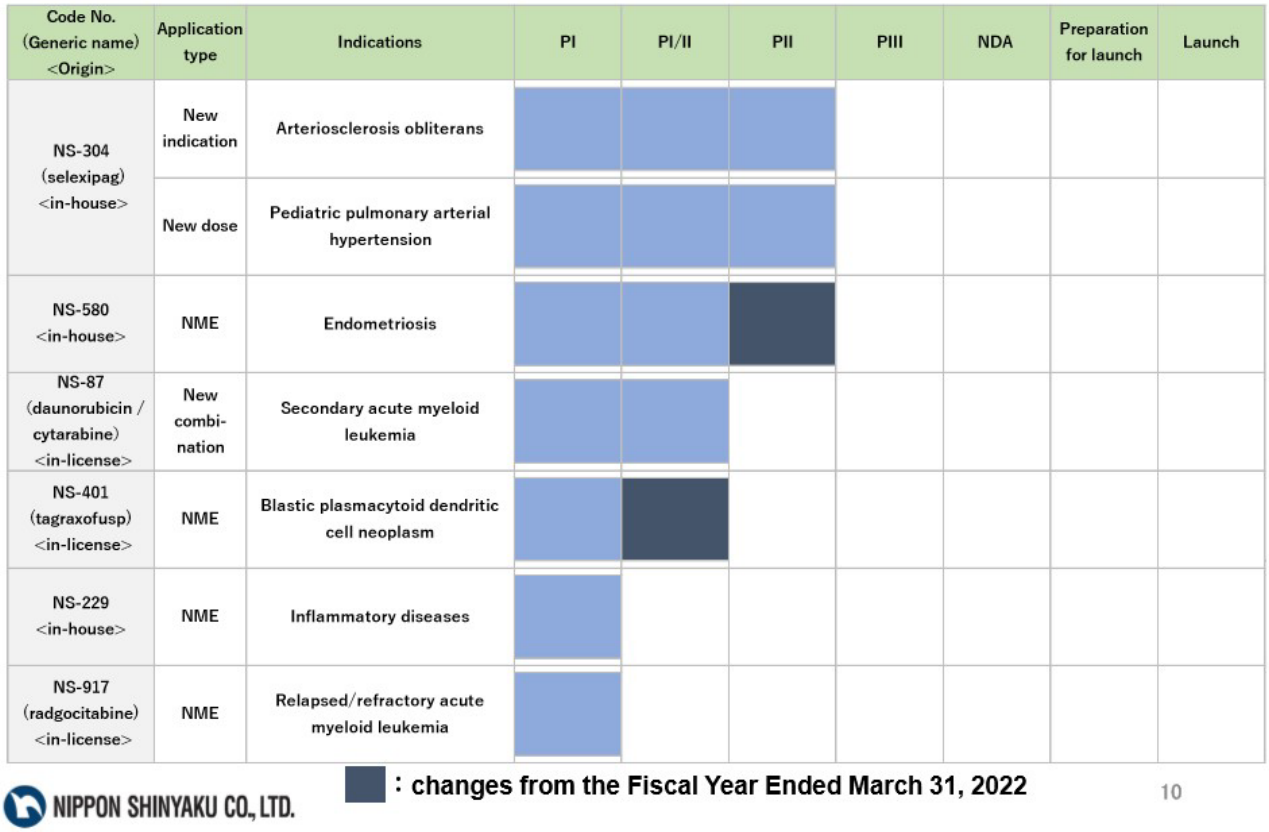
A treatment for Duchenne muscular dystrophy, NS-065/NCNP-01, was approved in March 2020 and launched in May. A global Phase III study is currently underway.

In March this year, we obtained manufacturing and marketing approval for NS-32, a treatment for iron deficiency anemia, and are currently preparing for launch.

As for ZX008, a treatment for intractable epilepsy, UCB Japan Co., Ltd. filed an application for Dravet syndrome in December 2021. In addition, UCB S.A. is conducting a Phase III study for Lennox-Gastaut syndrome.

In June of this year, we initiated a Phase III study of GA101 for lupus nephritis in collaboration with Chugai Pharmaceutical Co.

# R&D Pipeline (Domestic) ②



| Code No. (Generic name) <Origin> | Application type | Indications | PI | PI/II | PII | PIII | NDA | Preparation for launch | Launch |
|---|---|---|---|---|---|---|---|---|---|
| NS-304 (selexipag) <in-house> | New indication | Arteriosclerosis obliterans | | | | | | | |
| | New dose | Pediatric pulmonary arterial hypertension | | | | | | | |
| NS-580 <in-house> | NME | Endometriosis | | | | | | | |
| NS-87 (daunorubicin / cytarabine) <in-license> | New combi-nation | Secondary acute myeloid leukemia | | | | | | | |
| NS-401 (tagraxofusp) <in-license> | NME | Blastic plasmacytoid dendritic cell neoplasm | | | | | | | |
| NS-229 <in-house> | NME | Inflammatory diseases | | | | | | | |
| NS-917 (radgocitabine) <in-license> | NME | Relapsed/refractory acute myeloid leukemia | | | | | | | |



Please refer to slide 10.

Nippon Shinyaku has been conducting Phase IIb study of NS-304 for arteriosclerosis obliterans since February of this year on its own. In addition, Phase II study for pediatric pulmonary arterial hypertension is ongoing in collaboration with Janssen Pharmaceutical K.K.

As for NS-580, a treatment for endometriosis, we completed Phase IIa study and started Phase IIb study in June this year.

As for NS-87, a treatment for secondary acute myeloid leukemia, Phase I/II study is ongoing.

In July of this year, we initiated a Phase I/II study of NS-401, a treatment for blastic plasmacytoid dendritic cell neoplasm.

As for NS-229, JAK1 inhibitor, Phase I study is ongoing for inflammatory diseases.

As for NS-917, a treatment for relapsed/refractory acute myeloid leukemia, we have been conducting Phase I study since February this year.

# R&D Pipeline (Overseas)

| Code No. (Generic name) <Origin> | Application type | Indications | PI | Preparation for P II | PII | PIII | Launch |
|---|---|---|---|---|---|---|---|
| NS-065/NCNP-01 (viltolarsen) <in-house> | NME | Duchenne muscular dystrophy | | | | PIII in progress | |
| CAP-1002 <partnership> | NME | Duchenne muscular dystrophy | | | | | |
| NS-018 (ilginatinib) <in-house> | NME | Myelofibrosis | | | | | |

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Please refer to slide 11. I will continue with an explanation of the overseas R&D situation.

NS-065/NCNP-01, a treatment for Duchenne muscular dystrophy was approved in the US in August 2020 and launched. A global Phase III study is currently underway. It received Orphan Drug Designation in Europe in June 2020.

With regard to CAP-1002, a treatment for Duchenne muscular dystrophy, we concluded a sales collaboration agreement with Capricor Therapeutics Inc. in the US in January 2022. In July of this year, Capricor Therapeutics Inc. initiated Phase III study in the US.

We are currently preparing for the next global clinical trial for NS-018, a treatment for myelofibrosis. We are currently in the process of implementing the trial procedures at medical institutions and have begun recruiting patients.

As for NS-089/NCNP-02 treatment for Duchenne muscular dystrophy, we have been in discussions with the FDA regarding the protocol, and the FDA has requested additional information regarding the interpretation of the IND application data. We are currently preparing to provide information and working to reach an agreement with the FDA by the end of this fiscal year.

As for NS-050/NCNP-03, a treatment for Duchenne muscular dystrophy, we expect to start clinical trials in the first half of the next fiscal year, following a request for additional non-clinical trials in discussions with the FDA.

That is all for overview of our research and development activities.