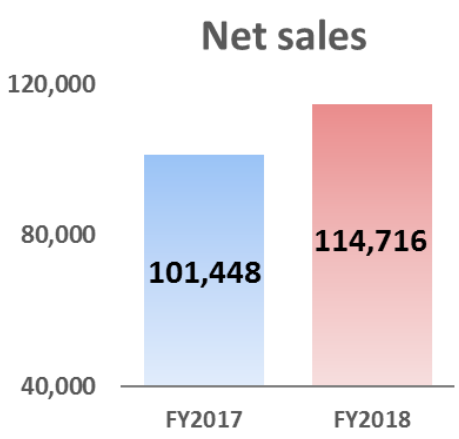
# Outline of Consolidated Financial Results for the Year Ended March 31, 2019

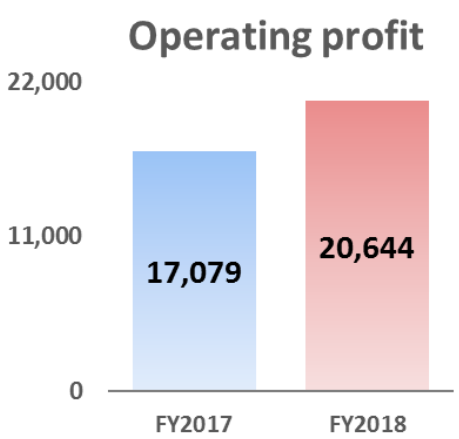
May 15, 2019
NIPPON SHINYAKU CO., LTD.

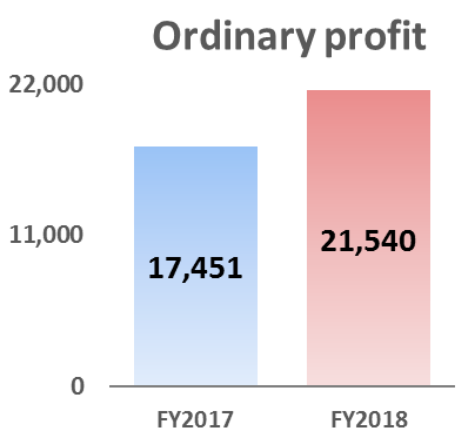
# FY2018 Summary

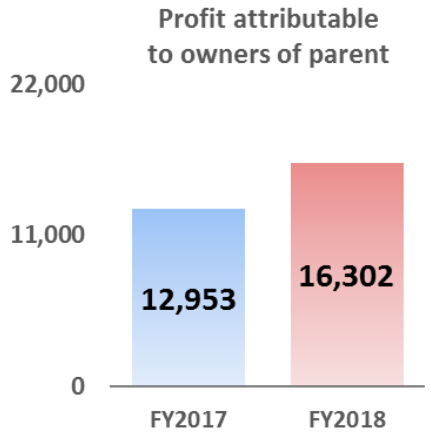
- **Net sales** : 114,716 million yen (+13.1%)
- **Operating profit** : 20,644 million yen (+20.9%)
- **Ordinary profit** : 21,540 million yen (+23.4%)
- **Profit attributable to owners of parent** : 16,302 million yen (+25.9%)

(Million yen)

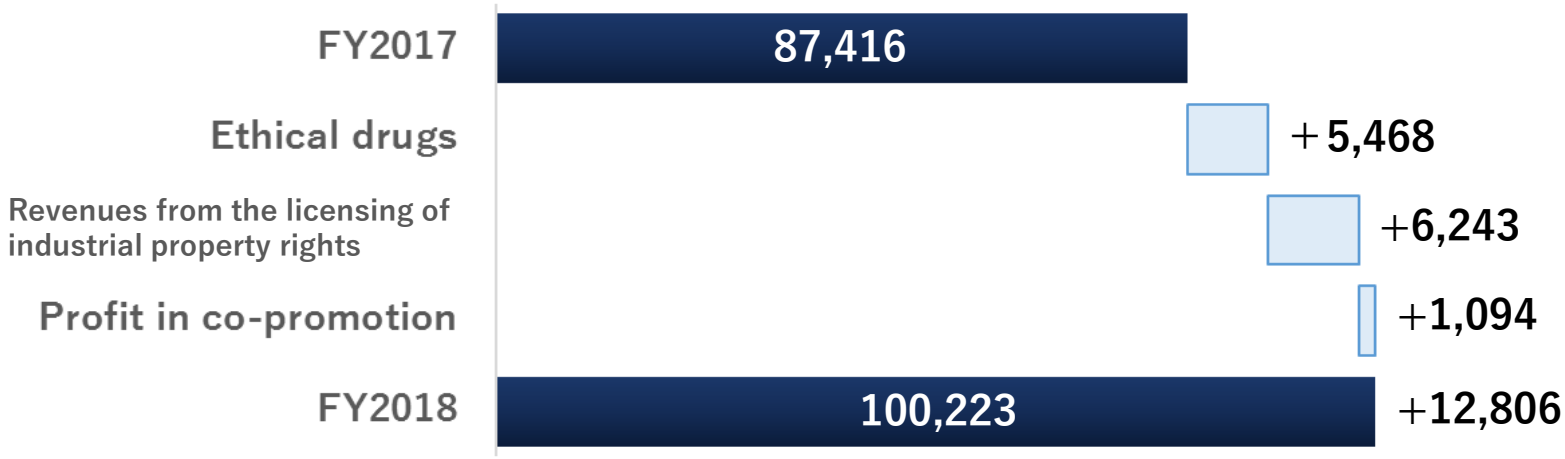


# Segmental Review - Pharmaceuticals -

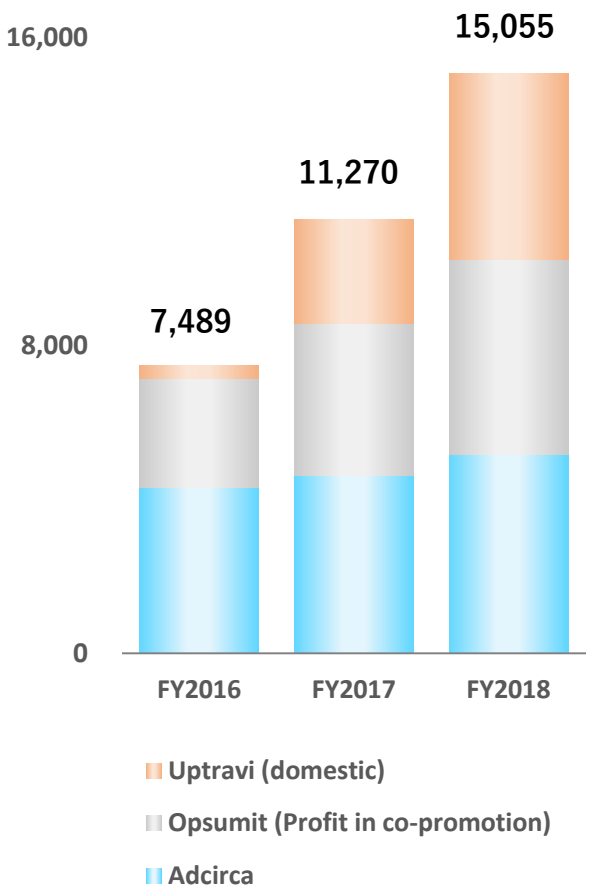



| (Million yen) | FY2017 | | FY2018 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Results | Ratio | Amt | % |
| Ethical drugs | 73,076 | 83.6% | 78,544 | 78.4% | +5,468 | +7.5% |
| Revenues from the licensing of industrial property rights | 10,378 | 11.9% | 16,621 | 16.6% | +6,243 | +60.2% |
| Profit in co-promotion | 3,962 | 4.5% | 5,057 | 5.0% | +1,094 | +27.6% |
| Net sales | 87,416 | 100.0% | 100,223 | 100.0% | +12,806 | +14.6% |

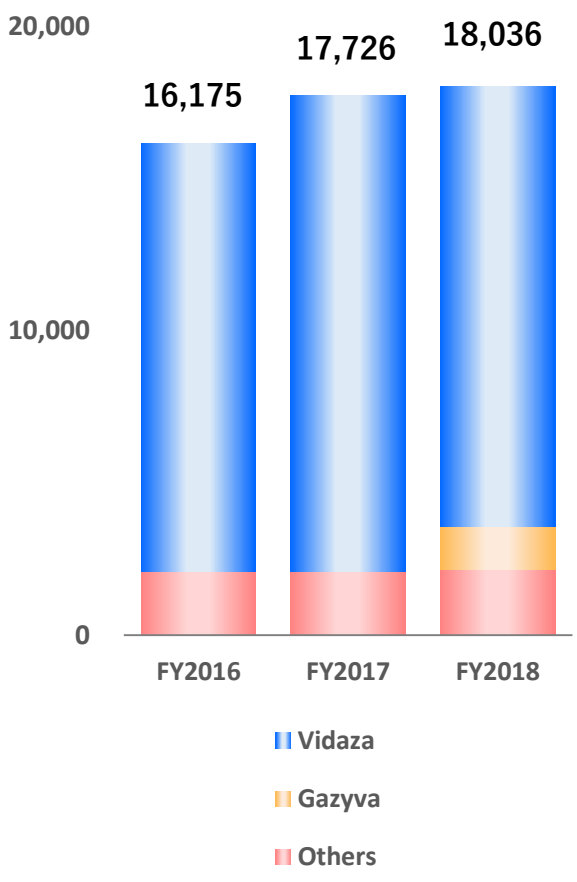
# Three Main Fields of Focus

(million yen)

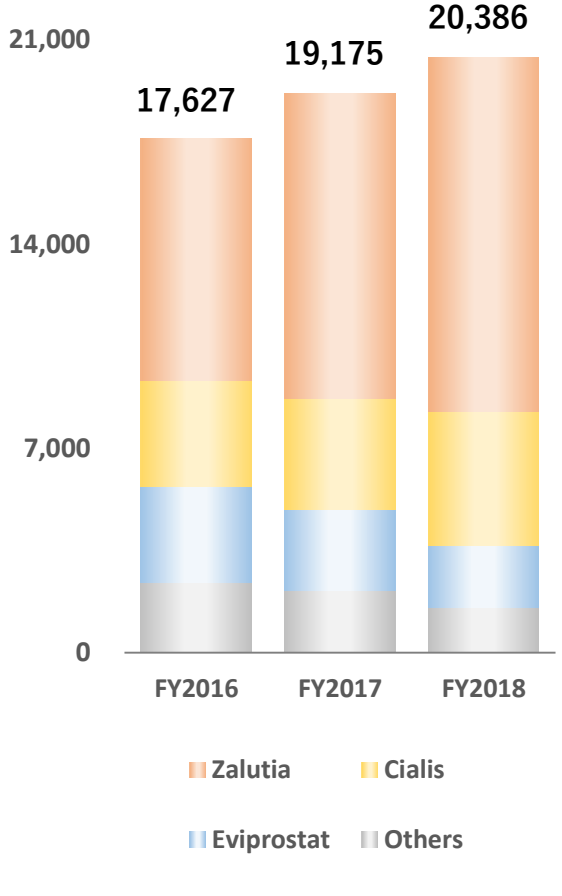
## PAH



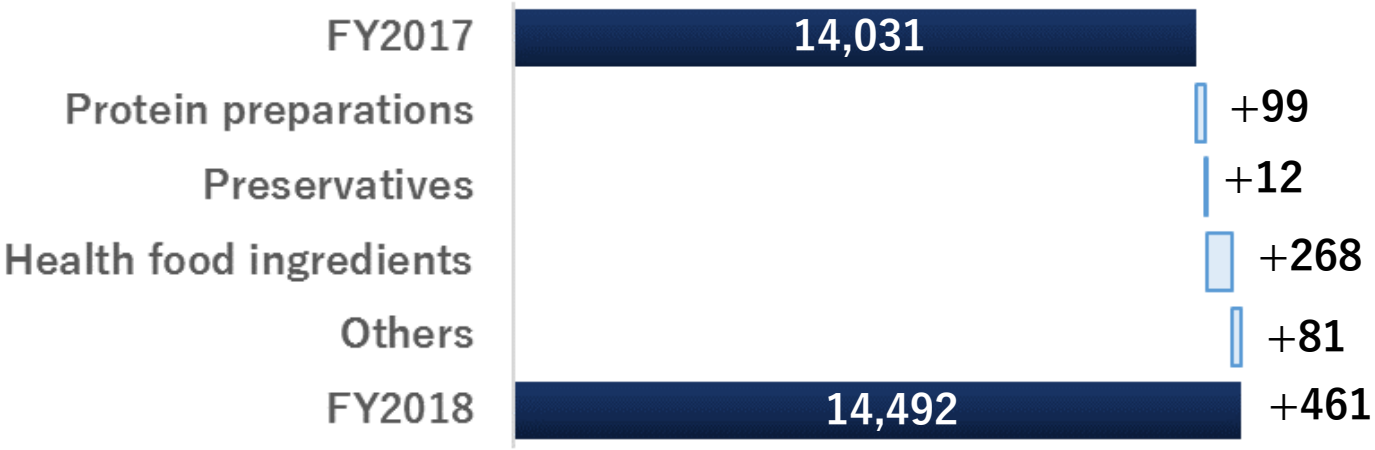

## Hematology




## Urology

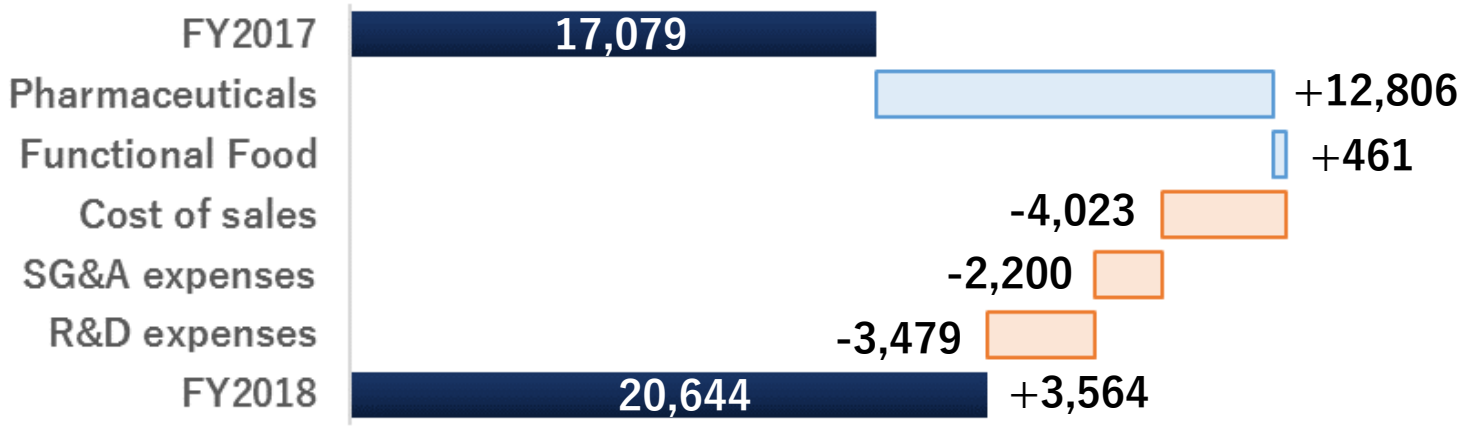


# Segmental Review - Functional Food -



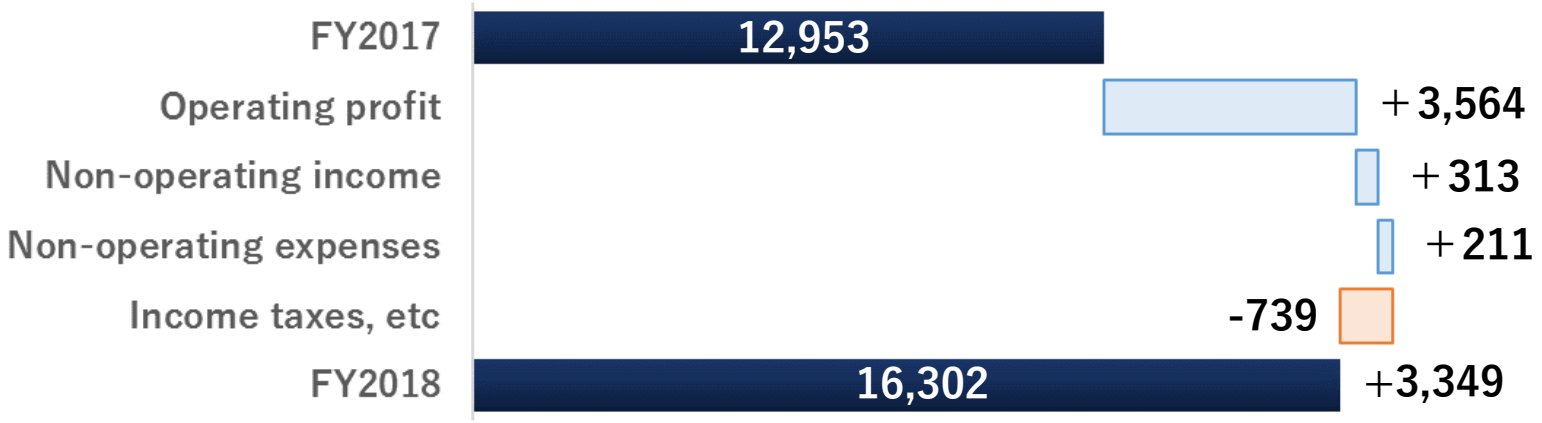

| (Million yen) | FY2017 | | FY2018 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Results | Ratio | Amt | % |
| Protein preparations | 9,454 | 67.4% | 9,554 | 65.9% | +99 | +1.1% |
| Preservatives | 2,298 | 16.4% | 2,310 | 15.9% | +12 | +0.6% |
| Health food ingredients | 927 | 6.6% | 1,196 | 8.3% | +268 | +28.9% |
| Others | 1,350 | 9.6% | 1,431 | 9.9% | +81 | +6.0% |
| Net sales | 14,031 | 100.0% | 14,492 | 100.0% | +461 | +3.3% |

# Operating profit




| (Million yen) | FY2017 | | FY2018 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Results | Ratio | Amt | % |
| **Net sales** | **101,448** | **100.0%** | **114,716** | **100.0%** | **+13,268** | **+13.1%** |
| (Pharmaceuticals) | (87,416) | (86.2%) | (100,223) | (87.4%) | (+12,806) | (+14.6%) |
| (Functional Food) | (14,031) | (13.8%) | (14,492) | (12.6%) | (+461) | (+3.3%) |
| **Operating expenses** | **84,368** | **83.2%** | **94,071** | **82.0%** | **+9,703** | **+11.5%** |
| **Cost of sales** | **46,929** | **46.3%** | **50,952** | **44.4%** | **+4,023** | **+8.6%** |
| **SG&A expenses** | **24,217** | **23.9%** | **26,418** | **23.0%** | **+2,200** | **+9.1%** |
| **R&D expenses** | **13,221** | **13.0%** | **16,701** | **14.6%** | **+3,479** | **+26.3%** |
| **Operating profit** | **17,079** | **16.8%** | **20,644** | **18.0%** | **+3,564** | **+20.9%** |

# Profit attributable to owners of parent




| (Million yen) | FY2017 Results | FY2018 Results | YoY Change Amt | YoY Change % |
|---|---|---|---|---|
| Operating profit | 17,079 | 20,644 | +3,564 | +20.9% |
| Non-operating income | 1,122 | 1,435 | +313 | +27.9% |
| Non-operating expenses | 751 | 539 | -211 | -28.1% |
| Ordinary profit | 17,451 | 21,540 | +4,089 | +23.4% |
| Income taxes, etc | 4,497 | 5,237 | +739 | +16.4% |
| Profit attributable to owners of parent | 12,953 | 16,302 | +3,349 | +25.9% |

# Business Forecast for FY2019

| (Million yen) | FY2018 Results | FY2019 Forecast | YoY Change Amt | YoY Change % |
|---|---|---|---|---|
| Net sales | 114,716 | 116,000 | +1,284 | +1.1% |
| Operating profit | 20,644 | 21,000 | +356 | +1.7% |
| Ordinary profit | 21,540 | 22,000 | +460 | +2.1% |
| Profit attributable to owners of parent | 16,302 | 16,500 | +198 | +1.2% |

# Segmental Forecast - Pharmaceuticals -

| (Million yen) | FY2018 | | FY2019 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Forecast | Ratio | Amt | % |
| Ethical drugs | 78,544 | 78.4% | 78,500 | 77.7% | -44 | -0.1% |
| Revenues from the licensing of industrial property rights | 16,621 | 16.6% | 16,800 | 16.6% | +179 | +1.1% |
| Profit in co-promotion | 5,057 | 5.0% | 5,800 | 5.7% | +743 | +14.7% |
| Net sales | 100,223 | 100.0% | 101,100 | 100.0% | +877 | +0.9% |

# Segmental Forecast - Functional Food -

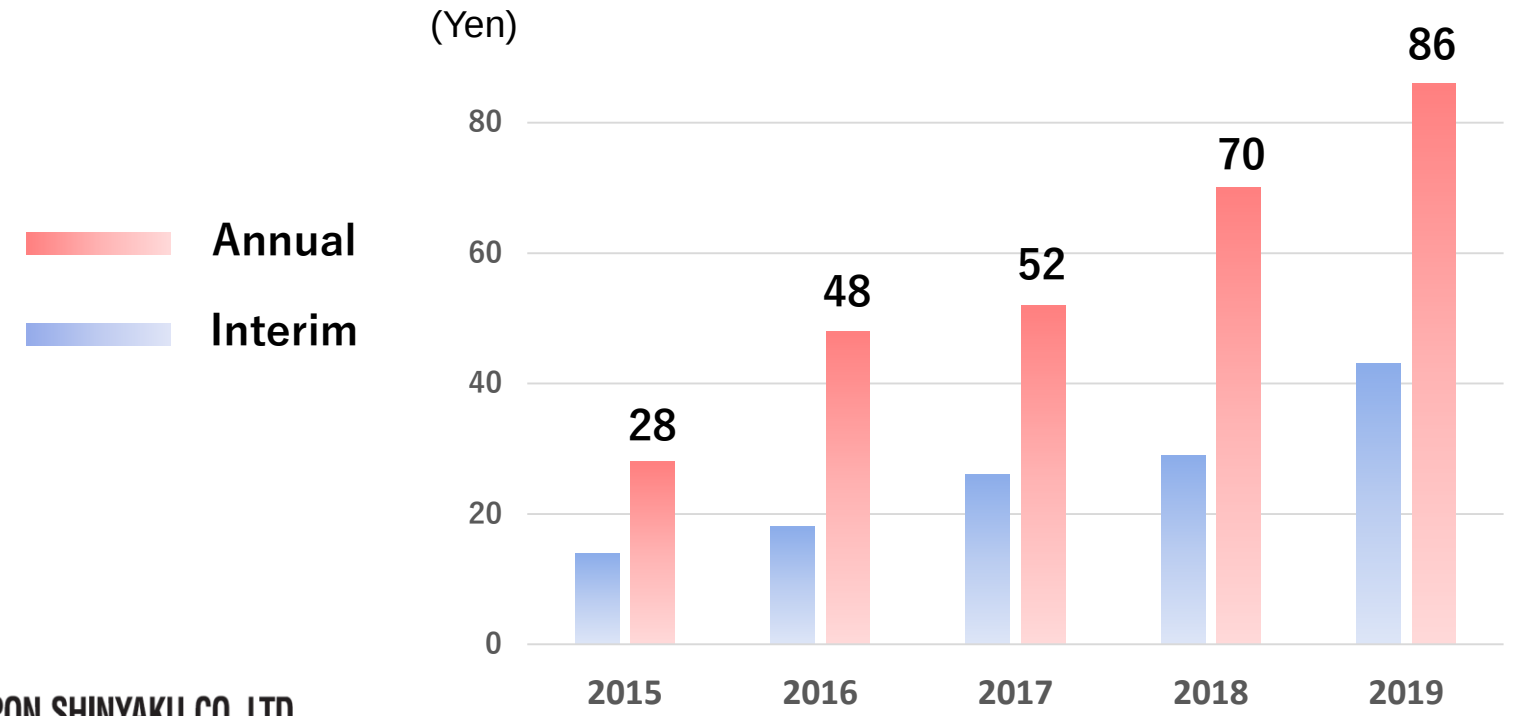
| (Million yen) | FY2018 | | FY2019 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Forecast | Ratio | Amt | % |
| Protein preparations | 9,554 | 65.9% | 9,660 | 64.8% | +106 | +1.1% |
| Preservatives | 2,310 | 15.9% | 2,470 | 16.6% | +160 | +6.9% |
| Health food ingredients | 1,196 | 8.3% | 1,250 | 8.4% | +54 | +2.7% |
| Others | 1,431 | 9.9% | 1,520 | 10.2% | +89 | +6.2% |
| Net sales | 14,492 | 100.0% | 14,900 | 100.0% | +408 | +2.8% |

# Consolidated Statements of Income (Forecast)

| (Million yen) | FY2018 | | FY2019 | | YoY Change | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Forecast | Ratio | Amt | % |
| Net sales | 114,716 | 100.0% | 116,000 | 100.0% | +1,284 | +1.1% |
| (Pharmaceuticals) | (100,223) | (87.4%) | (101,100) | (87.2%) | (+877) | (+0.9%) |
| (Functional Food) | (14,492) | (12.6%) | (14,900) | (12.8%) | (+408) | (+2.8%) |
| Cost of sales | 50,952 | 44.4% | 51,600 | 44.5% | +648 | +1.3% |
| SG&A expenses | 26,418 | 23.0% | 28,300 | 24.4% | +1,882 | +7.1% |
| R&D expenses | 16,701 | 14.6% | 15,100 | 13.0% | -1,601 | -9.6% |
| Operating profit | 20,644 | 18.0% | 21,000 | 18.1% | +356 | +1.7% |
| Non-operating income | 1,435 | 1.3% | 1,500 | 1.3% | +65 | +4.5% |
| Non-operating expenses | 539 | 0.5% | 500 | 0.4% | -39 | -7.4% |
| Ordinary profit | 21,540 | 18.8% | 22,000 | 19.0% | +460 | +2.1% |
| Income taxes, etc | 5,237 | 4.6% | 5,500 | 4.7% | +263 | +5.0% |
| Profit attributable to owners of parent | 16,302 | 14.2% | 16,500 | 14.2% | +198 | +1.2% |

# Dividends Forecast

| | | FY2018 | FY2019 |
|---|---|---|---|
| Dividends per share | Interim | ¥29 | ¥43 |
| | Annual | ¥70 | ¥86 |
| E P S | | ¥242.04 | ¥244.97 |
| Dividends payout ratio | | 28.9 % | 35.1 % |



# Status of Product Pipeline

NIPPON SHINYAKU CO., LTD.

# R&D Compounds (Domestic)

| Code No. (Generic name) <Origin> | Application type | Indications | Preparation for development | PI | PII | PIII | NDA filing |
|---|---|---|---|---|---|---|---|
| NS-73 (defibrotide) <in-license> | NME | Veno-occlusive disease (treatment) | | | | | |
| | New indication | Veno-occlusive disease (prevention) | | | | | |
| NS-32 <in-license> | NME | Iron deficiency anemia | | | | | |
| ZX-008 <in-license> | NME | Dravet syndrome<br>Lennox-Gastaut syndrome | | | | | |
| NS-304 (selexipag) <in-house> | New indication | Chronic thromboembolic pulmonary hypertension | | | | | |
| | | Arteriosclerosis obliterans | | | | | |
| | | Lumbar spinal stenosis | | | | | |
| NS-580 <in-house> | NME | Endometriosis | | | | | |
| NS-17 (azacitidine) <in-license> | New indication | Acute myeloid leukemia | | | | | |
| NS-065/NCNP-01 (viltolarsen) <in-house> | NME | Duchenne muscular dystrophy | | | | | |
| NS-917 <in-license> | NME | Relapsed/refractory acute myeloid leukemia | | | | | |
| NS-87 <in-license> | NME | Secondary acute myeloid leukemia | | | | | |

: changes from the third quarter

# R&D Compounds (Overseas)

| Code No. (Generic name) <Origin> | Application type | Indications | Preparation for development | PI | PII | PIII | NDA filing |
|---|---|---|---|---|---|---|---|
| prulifloxacin <in-house> | NME | Bacterial infections | | | | | |
| NS-304 (selexipag) <in-house> | New indication | Chronic thromboembolic pulmonary hypertension | | | | | |
| NS-065/NCNP-01 (viltolarsen) <in-house> | NME | Duchenne muscular dystrophy | | | | | |
| NS-018 <in-house> | NME | Myelofibrosis | | | | | |

: changes from the third quarter

**NS-065/NCNP-01: in the process of a rolling submission to the U.S. FDA.**

# Reference Materials

NIPPON SHINYAKU CO., LTD.

# Consolidated Statements of Income

| (Million yen) | FY2017 | | FY2018 | | YoY chenge | |
|---|---|---|---|---|---|---|
| | Results | Ratio | Results | Ratio | Amt | % |
| **Net sales** | **101,448** | **100.0%** | **114,716** | **100.0%** | **+13,268** | **+13.1%** |
| (Pharmaceuticals) | (87,416) | (86.2%) | (100,223) | (87.4%) | (+12,806) | (+14.6%) |
| (Functional Food) | (14,031) | (13.8%) | (14,492) | (12.6%) | (+461) | (+3.3%) |
| **Cost of sales** | **46,929** | **46.3%** | **50,952** | **44.4%** | **+4,023** | **+8.6%** |
| **SG&A expenses** | **24,217** | **23.8%** | **26,418** | **23.0%** | **+2,200** | **+9.1%** |
| **R&D expenses** | **13,221** | **13.0%** | **16,701** | **14.6%** | **+3,479** | **+26.3%** |
| **Operating profit** | **17,079** | **16.8%** | **20,644** | **18.0%** | **+3,564** | **+20.9%** |
| **Non-operating income** | **1,122** | **1.1%** | **1,435** | **1.3%** | **+313** | **+27.9%** |
| **Non-operating expenses** | **751** | **0.8%** | **539** | **0.5%** | **-211** | **-28.1%** |
| **Ordinary profit** | **17,451** | **17.2%** | **21,540** | **18.8%** | **+4,089** | **+23.4%** |
| **Income taxes, etc** | **4,497** | **4.4%** | **5,237** | **4.6%** | **+739** | **+16.4%** |
| **Profit attributable to owners of parent** | **12,953** | **12.8%** | **16,302** | **14.2%** | **+3,349** | **+25.9%** |

# Consolidated Balance Sheet

| (Million yen) | End of FY2017 | End of FY2018 | YoY Change Amt | | End of FY2017 | End of FY2018 | YoY Change Amt |
|---|---|---|---|---|---|---|---|
| Assets | 155,887 | 168,763 | +12,876 | Liabilities | 30,197 | 33,572 | +3,375 |
| Current assets | 95,176 | 110,720 | +15,544 | Current liabilities | 22,454 | 25,406 | +2,952 |
| Fixed assets | 60,710 | 58,042 | -2,668 | Long-term liabilities | 7,743 | 8,165 | +422 |
| | | | | Net assets | 125,689 | 135,190 | +9,501 |
| Total assets | 155,887 | 168,763 | +12,876 | Total liabilities and net assets | 155,887 | 168,763 | +12,876 |

## ＝Assets＝

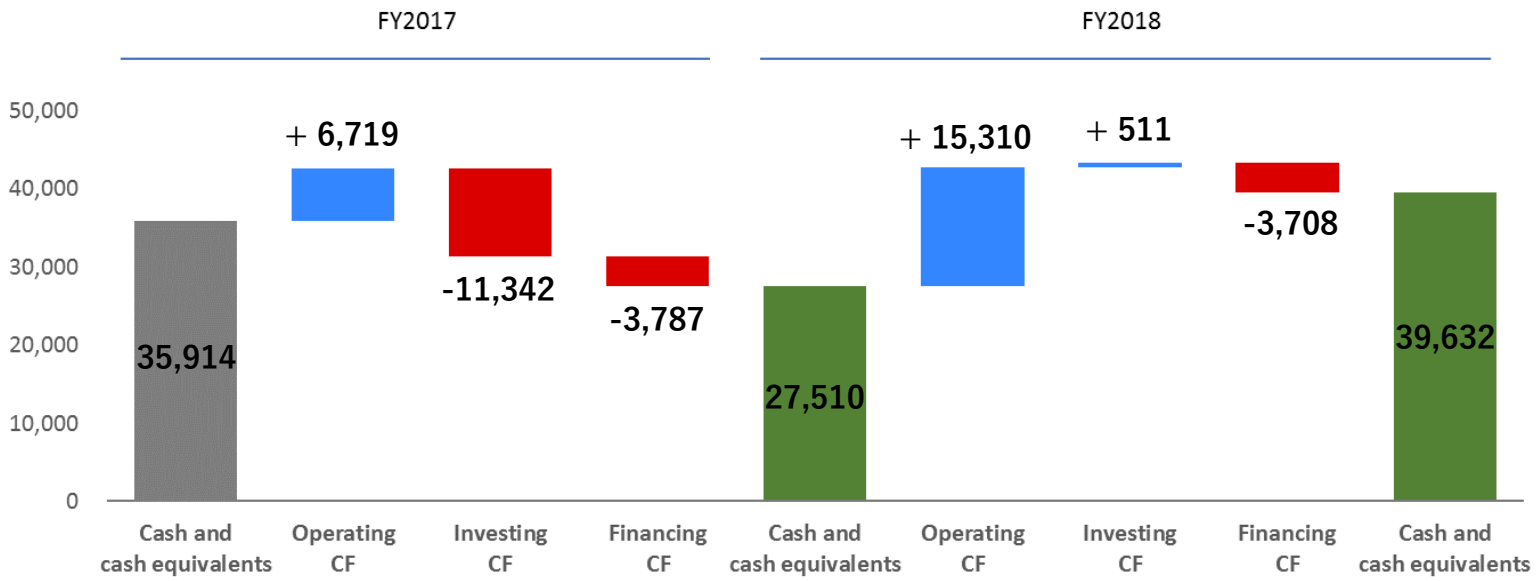
| | |
|---|---|
| Cash and deposits | +10,452 |
| Notes and accounts receivable | +6,388 |
| Securities | -1,200 |
| Inventories | -972 |
| Investment securities | -2,848 |
| Long-term prepaid expenses | -855 |

## ＝Liabilities and Net assets＝

| | |
|---|---|
| Notes and accounts payable | -653 |
| Income taxes payable | +1,481 |
| Accrued consumption taxes | +1,055 |
| Net defined benefit liability | +420 |
| Retained earnings | +12,598 |

# Consolidated Statements of Cash Flows

| (Million yen) | FY2017 Results | FY2018 Results | YoY Change Amt |
|---|---|---|---|
| Operating activities | 6,719 | 15,310 | +8,590 |
| Investing activities | -11,342 | 511 | +11,854 |
| Financing activities | -3,787 | -3,708 | +78 |
| Cash and cash equivalents at end of year | 27,510 | 39,632 | +12,122 |



# NS-73 (defibrotide)
## - Treatment of hepatic veno-occlusive disease -

| | |
|---|---|
| Development Phase | Japan : NDA filing (treatment)<br>Japan : PIII (prevention) |
| Origin | [Mar. 2017]<br>Licensed-in from : Jazz Pharmaceuticals |
| Development | Nippon Shinyaku in Japan (treatment)<br>Co-development in Japan :<br>Jazz Pharmaceuticals (prevention) |
| Mechanism of action | Protective action on vascular endothelium, normalization of the coagulation/fibrinolysis balance |
| Indication | Hepatic veno-occlusive disease (VOD) |
| Dosage form | Injection |
| Feature | ・VOD is a life-threatening complication which develops in patients following HSCT, and in severe cases, leading to death at high rates.<br>・NS-73 is the only drug for the treatment of VOD (EU/US guideline). It has been launched in 35 countries.<br>・NS-73 is the only drug for the prevention of VOD. |

# NS-32
## - Treatment for iron deficiency anemia -

| | |
|---|---|
| Development Phase | Japan: PIII |
| 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
## - Treatment for rare intractable epilepsy-

| | |
|---|---|
| Development Phase | Japan: PIII |
| Origin | [March. 2019]<br>Commercial rights from: Zogenix, inc |
| Development | Zogenix, inc |
| Mechanism of action | Serotonin agonist |
| Indication | Dravet Syndrome and Lennox-Gastaut syndrome |
| Dosage form | Oral 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 is based on combination therapy. |

# NS-304 (selexipag)

**- Treatment for pulmonary hypertension, arteriosclerosis obliterans, lumbar spinal stenosis -**

| | |
|---|---|
| Development Phase | <CTEPH> Japan: PIII<br>Overseas: PIII<br><ASO> Japan: PIIb<br><LSS> Japan: PIIa |
| Origin | Nippon Shinyaku |
| Development | ・[Apr. 2008] Licensed-out to (outside Japan):<br>Actelion Pharmaceuticals Ltd. (Switzerland)<br>・Co-development in Japan:<br>Actelion Pharmaceuticals Japan Ltd. (CTEPH)<br>・Overseas: Johnson-Johnson (CTEPH)<br>・Nippon Shinyaku (ASO)<br>・Nippon Shinyaku (LSS) |
| Mechanism of action | Selective IP receptor agonist |
| Indication | ・Chronic thromboembolic pulmonary hypertension (CTEPH)<br>・Arteriosclerosis obliterans (ASO)<br>・Lumbar spinal stenosis (LSS) |
| Dosage form | Tablet |
| Feature | Long-acting oral drug |

# NS-580
## - Treatment for endometriosis -

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

# NS-17
## - Treatment for acute myeloid leukemia -

| | |
|---|---|
| Development Phase | Japan: PII |
| Origin | [Oct. 2006]<br>Licensed-in from :Celgene Corporation |
| Development | Nippon Shinyaku |
| Mechanism of action | Inhibition of DNA methylation, Cytotoxic effects |
| Indication | Acute myeloid leukemia |
| Dosage form | Injection |
| Feature | ・Standard Treatment for acute myeloid leukemia that ineligible for intensive chemotherapy<br>・Improvement for life prognosis |

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

| | |
|---|---|
| Development Phase | ・USA　: Rolling submission for NDA<br>(plan to complete NDA in September 2019)<br>・Japan: PI/II completion<br>(under discussion with regulatory authority for early approval) |
| Origin | Co-development: 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-917

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

| | |
|---|---|
| Development Phase | Japan: Preparation for Clinical Development |
| Origin | [Mar. 2017]<br>Licensed-in from: Delta-Fly Pharma |
| 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 |

# NS-87
## - Treatment of secondary acute myeloid leukemia -

| | |
|---|---|
| Development Phase | Japan: Preparation for Clinical Development |
| Origin | [Mar. 2017]<br>Licensed-in from : Jazz Pharmaceuticals |
| Development | Nippon Shinyaku |
| Mechanism of action | Liposomal combination of cytrabine and daunorubicin |
| 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. |

# Prulifloxacin
## - Quinolone antibacterial -

Japan

| Licensee | Development phase |
|---|---|
| ・Meiji Seika Pharma Co., Ltd. | ・Launch (Dec. 2002) / Sword® Tablets |

Overseas

| Licensee | Development phase |
|---|---|
| ・Angelini (Italy) | ・Approval (Sep. 2004)<br>・Launch in Italy (Nov. 2004)<br>・Approval in European countries (Apr. 2005) |
| ・Lee's Pharmaceutical Holdings Ltd. (Hong Kong) | ・NDA filing in China |
| ・Algorithm (Lebanon) | ・Launch in Lebanon (Jan. 2012)<br>・Preparation for launch in 1 country and NDA filing in 5 countries |

# NS-018
## - Treatment for myelofibrosis -

| | |
|---|---|
| Development Phase | Overseas (USA): PI/II |
| Origin | Nippon Shinyaku |
| Development | Nippon Shinyaku |
| Mechanism of action | JAK2 inhibitor |
| Indication | Myelofibrosis |
| Dosage form | Tablet |
| Feature | ・Highly selective for active form of JAK2<br>・Possibly best-in-class treatment for myelofibrosis |

# 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.
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