Outline of Consolidated Financial Results for the Year Ended March 31, 2020

May 18, 2020
NIPPON SHINYAKU CO., LTD.

NIPPON SHINYAKU CO., LTD.

FY2019 Main Topics

2019

4/1	• Start of 6th Five-Year Medium-term Management Plan
5/22	• Launch of Erleada for the treatment of prostate cancer (co-promotion with Janssen Pharmaceutical K.K.)
8/22	• NS-065/NCNP-01 for the treatment of Duchenne muscular dystrophy, granted Orphan Drug Designation
9/4	• Launch of Defitelio for the treatment of sinusoidal obstruction syndrome
10/1	• Nippon Shinyaku 100th anniversary
11/6	• Designation of NS-065/NCNP-01 Subjected to Conditional Early Approval System

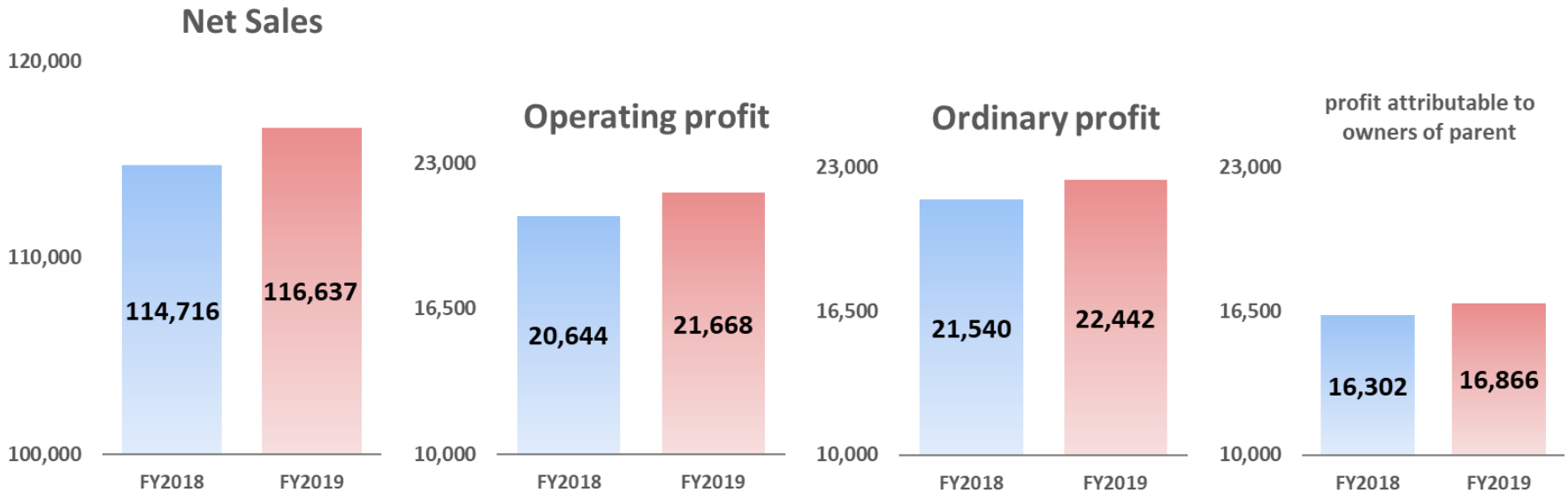
2020

2/7	• NDA Accepted for Filing by the FDA for NS-065/NCNP-01
2/7	• New co-promotion agreement for Zytiga for the treatment of prostate cancer
3/25	• Marketing authorization in Japan for NS-065/NCNP-01

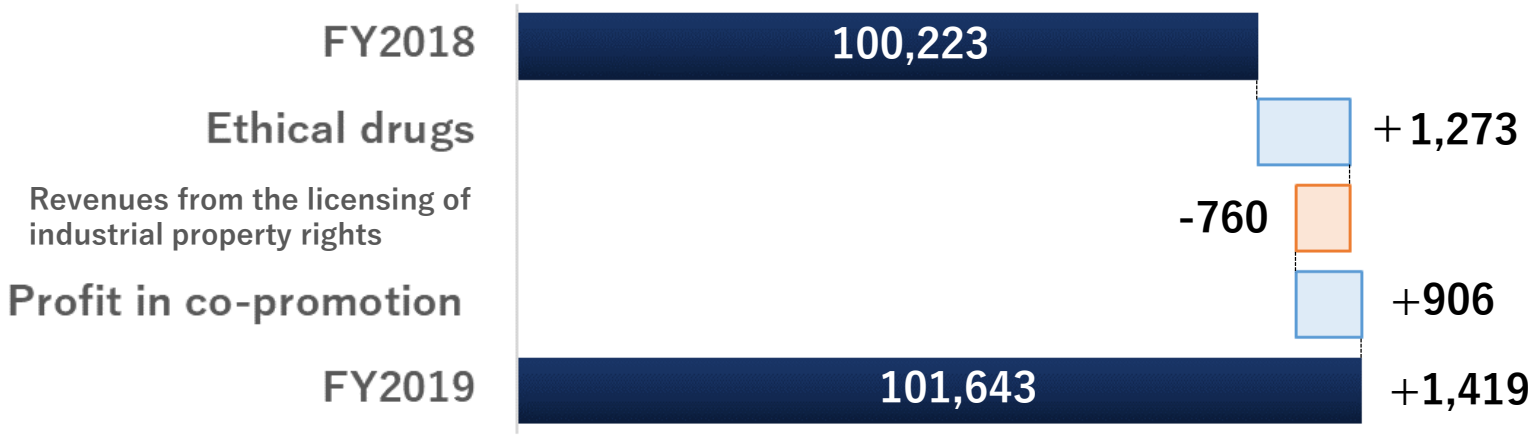
FY2019 Summary

- **Net sales** : 116,637 million yen (+1.7%)
- **Operating profit** : 21,668 million yen (+5.0%)
- **Ordinary profit** : 22,442 million yen (+4.2%)
- **Profit attributable to owners of parent** : 16,866 million yen (+3.5%)

(million yen)



Segmental Review - Pharmaceuticals -



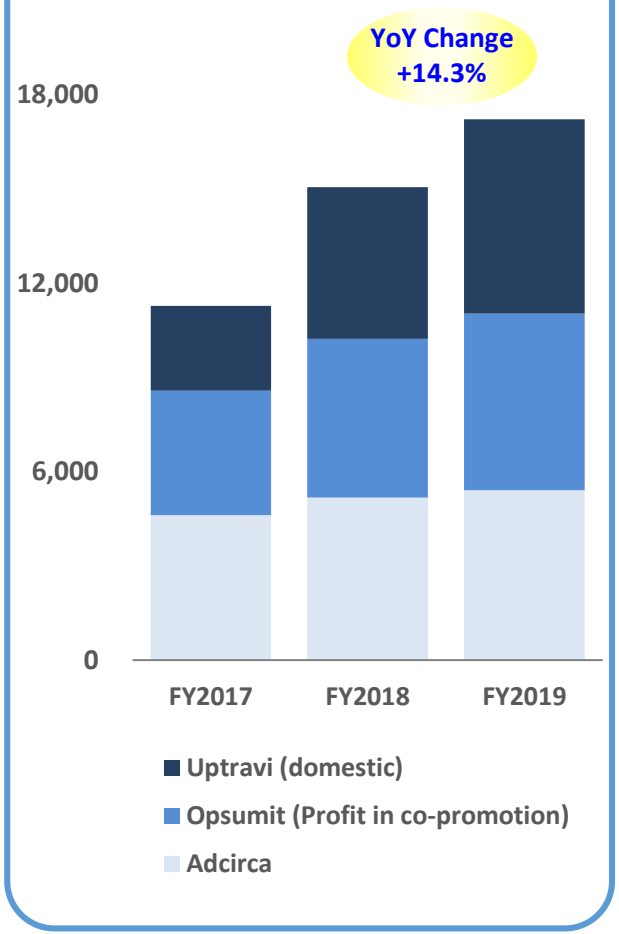
(Million yen)	FY2018		FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	78,544	78.4%	79,818	78.5%	+1,273	+1.6%
Revenues from the licensing of industrial property rights	16,621	16.6%	15,860	15.6%	-760	-4.6%
Profit in co-promotion	5,057	5.0%	5,963	5.9%	+906	+17.9%
Net sales	100,223	100.0%	101,643	100.0%	+1,419	+1.4%

Net sales increased by 1.4% due to growth of new products and profit in co-promotion.

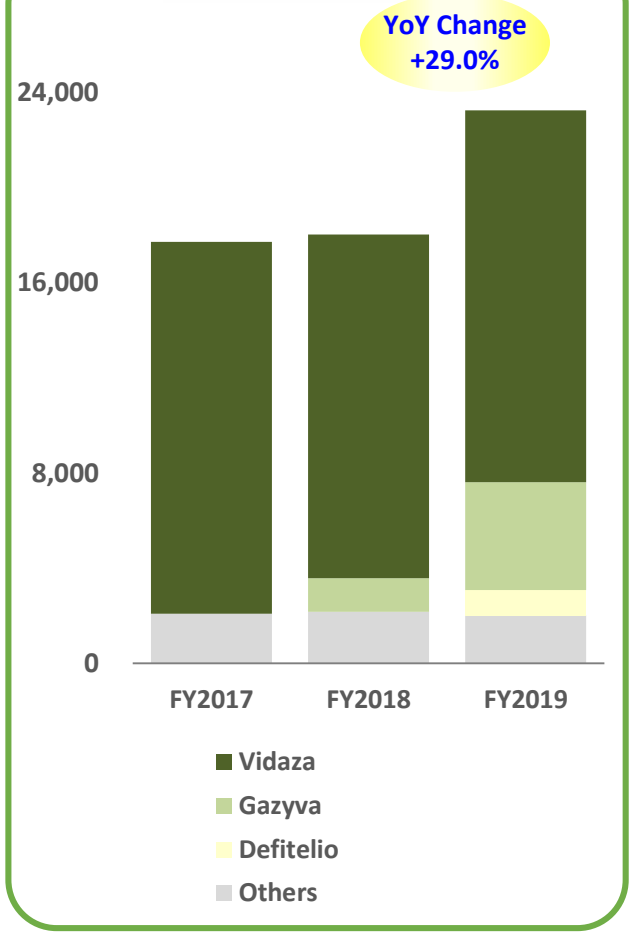
Three Main Fields of Focus

(million yen)

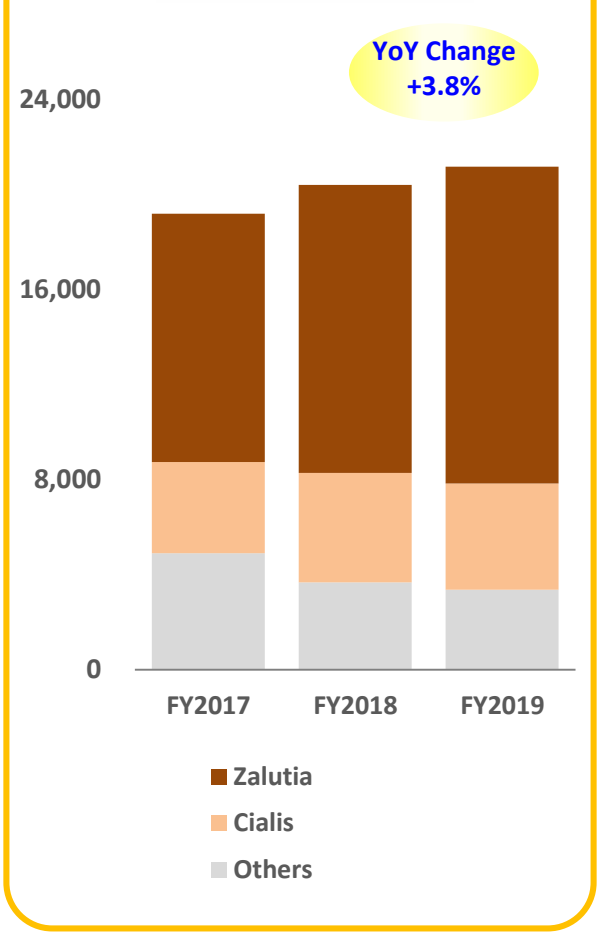
PAH



Hematology

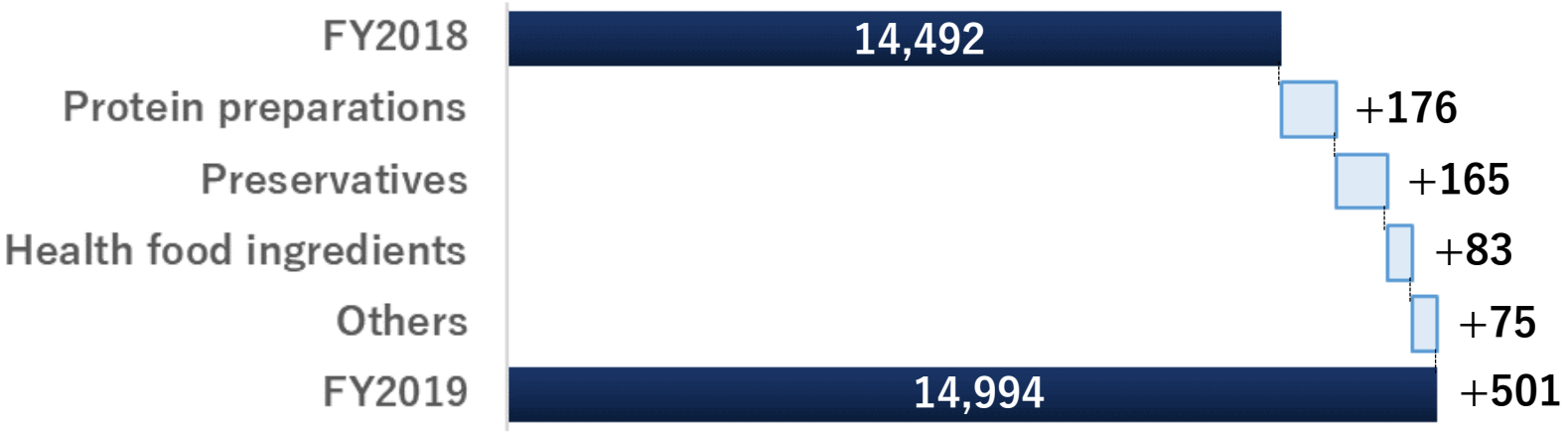


Urology



New products sales from our focus fields increased.

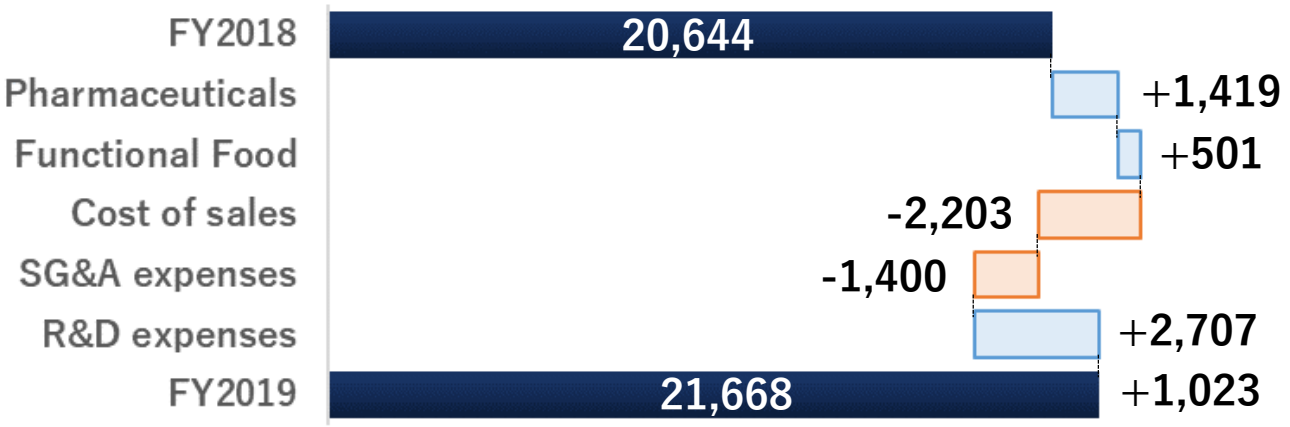
Segmental Review - Functional Food -



(Million yen)	FY2018		FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	9,554	65.9%	9,731	64.9%	+176	+1.9%
Preservatives	2,310	15.9%	2,475	16.5%	+165	+7.1%
Health food ingredients	1,196	8.3%	1,280	8.5%	+83	+7.0%
Others	1,431	9.9%	1,506	10.1%	+75	+5.3%
Net sales	14,492	100.0%	14,994	100.0%	+501	+3.5%

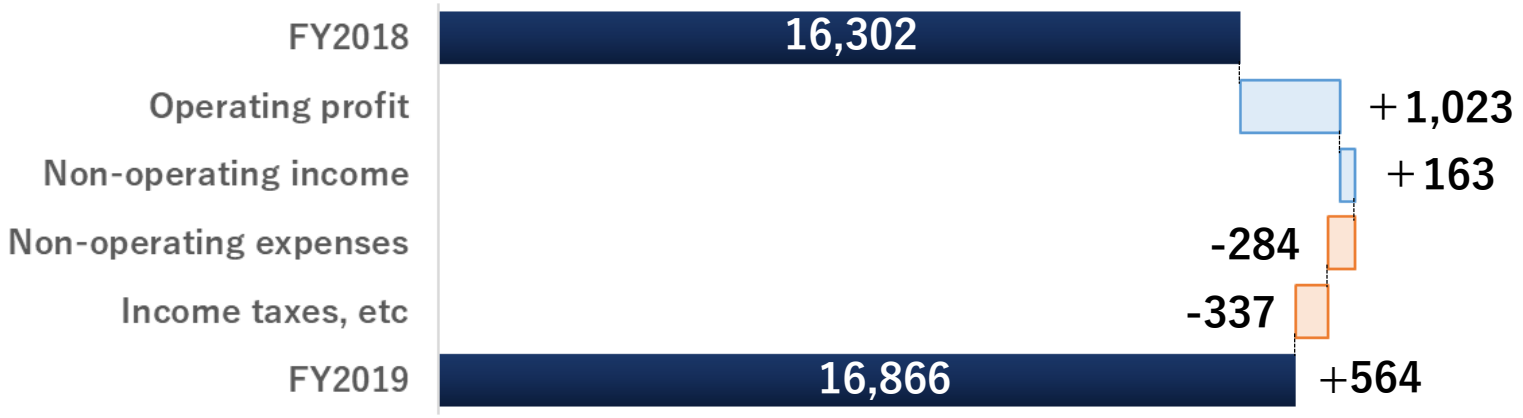
Net sales increased by 3.5% due to growth of protein preparations and preservatives.

Operating profit



(Million yen)	FY2018		FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	**114,716**	**100.0%**	**116,637**	**100.0%**	**+1,921**	**+1.7%**
(Pharmaceuticals)	(100,223)	(87.4%)	(101,643)	(87.1%)	(+1,419)	(+1.4%)
(Functional Food)	(14,492)	(12.6%)	(14,994)	(12.9%)	(+501)	(+3.5%)
Operating expenses	**94,071**	**82.0%**	**94,969**	**81.4%**	**+897**	**+1.0%**
Cost of sales	**50,952**	**44.4%**	**53,155**	**45.6%**	**+2,203**	**+4.3%**
SG&A expenses	**26,418**	**23.0%**	**27,819**	**23.8%**	**+1,400**	**+5.3%**
R&D expenses	**16,701**	**14.6%**	**13,994**	**12.0%**	**-2,707**	**-16.2%**
Operating profit	**20,644**	**18.0%**	**21,668**	**18.6%**	**+1,023**	**+5.0%**

Profit attributable to owners of parent



(Million yen)	FY2018 Results	FY2019 Results	YoY Change Amt	YoY Change %
Operating profit	20,644	21,668	+1,023	+5.0%
Non-operating income	1,435	1,599	+163	+11.4%
Non-operating expenses	539	824	+284	+52.8%
Ordinary profit	21,540	22,442	+901	+4.2%
Income taxes, etc	5,237	5,575	+337	+6.5%
Profit attributable to owners of parent	16,302	16,866	+564	+3.5%

Business Forecast for FY2020

(Million yen)	FY2019 Results	FY2020 Forecast	YoY Change Amt	YoY Change %
Net sales	116,637	126,000	+9,363	+8.0%
Operating profit	21,668	25,000	+3,332	+15.4%
Ordinary profit	22,442	25,500	+3,058	+13.6%
Profit attributable to owners of parent	16,866	19,000	+2,134	+12.6%

We look for net sales, operating profit, ordinary profit and profit attributable to owners of parent to increase year on year.

Segmental Forecast - Pharmaceuticals -

(Million yen)	FY2019		FY2020		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	79,818	78.5%	82,700	74.7%	+2,882	+3.6%
Revenues from the licensing of industrial property rights	15,860	15.6%	19,700	17.8%	+3,840	+24.2%
Profit in co-promotion	5,963	5.9%	8,300	7.5%	+2,337	+39.2%
Net sales	101,643	100.0%	110,700	100.0%	+9,057	+8.9%

Royalty revenue from Uptravi's overseas sales, profit in co-promotion, and launch of Viltepso for the treatment of Duchenne muscular dystrophy will increase our net sales.

Segmental Forecast - Functional Food -

(Million yen)	FY2019		FY2020		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Protein preparations	9,731	64.9%	9,680	63.3%	-51	-0.5%
Preservatives	2,475	16.5%	2,600	17.0%	+125	+5.0%
Health food ingredients	1,280	8.5%	1,300	8.5%	+20	+1.5%
Others	1,506	10.1%	1,720	11.2%	+214	+14.1%
Net sales	14,994	100.0%	15,300	100.0%	+306	+2.0%

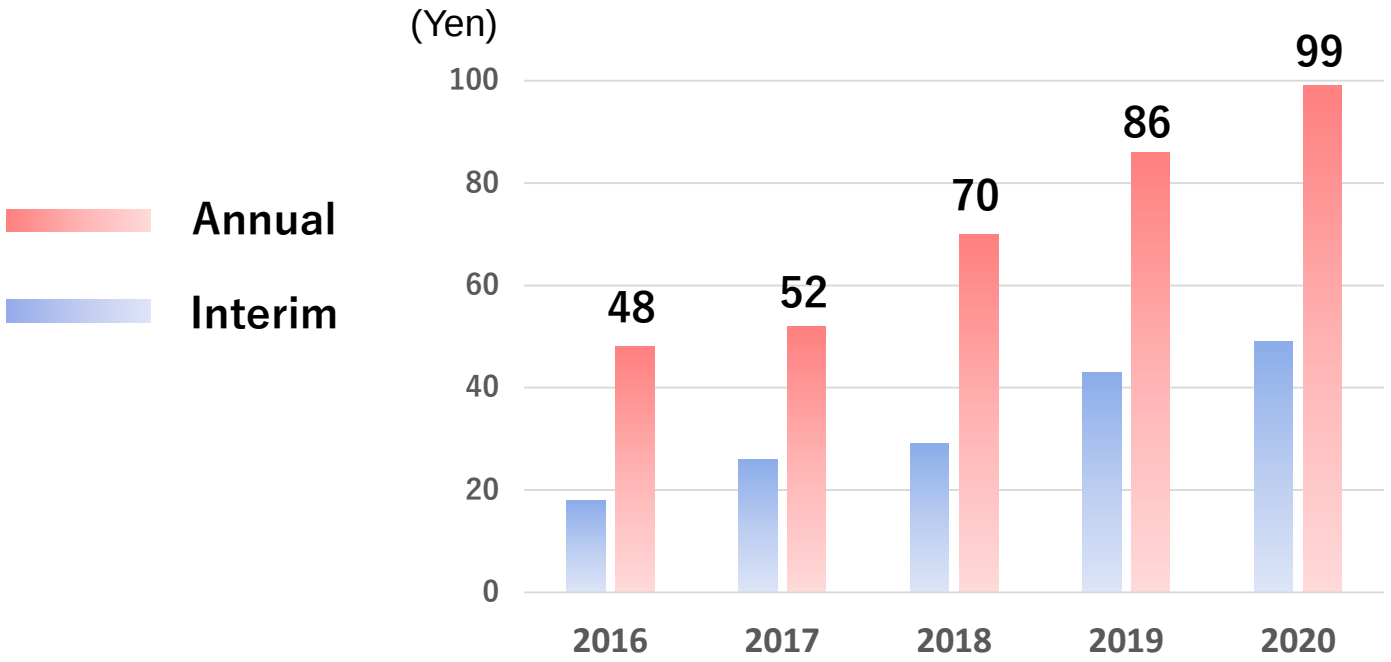
We will enhance our research and development toward new products and continue to launch highly valued products with market needs to increase our net sales.

Consolidated Statements of Income (Forecast)

(Million yen)	FY2019		FY2020		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	116,637	100.0%	126,000	100.0%	+9,363	+8.0%
(Pharmaceuticals)	(101,643)	(87.1%)	(110,700)	(87.9%)	(+9,057)	(+8.9%)
(Functional Food)	(14,994)	(12.9%)	(15,300)	(12.1%)	(+306)	(+2.0%)
Cost of sales	53,155	45.6%	52,600	41.7%	-555	-1.0%
SG&A expenses	27,819	23.9%	30,000	23.8%	+2,181	+7.8%
R&D expenses	13,994	12.0%	18,400	14.6%	+4,406	+31.5%
Operating profit	21,668	18.6%	25,000	19.8%	+3,332	+15.4%
Non-operating income	1,599	1.4%	1,200	1.0%	-399	-25.0%
Non-operating expenses	824	0.7%	700	0.6%	-124	-15.1%
Ordinary profit	22,442	19.2%	25,500	20.2%	+3,058	+13.6%
Income taxes, etc	5,575	4.8%	6,500	5.2%	+925	+16.6%
Profit attributable to owners of parent	16,866	14.5%	19,000	15.1%	+2,134	+12.6%

Dividends Forecast

		FY2019	FY2020
Dividends per share	Interim	¥43	¥49
	Annual	¥86	¥99
E P S		¥250.42	¥282.09
Dividends payout ratio		34.3 %	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	Preparation for launching
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 <in-license>	NME	Dravet syndrome 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-87 <in-license>	New combination	Secondary acute myeloid leukemia					
NS-917 <in-license>	NME	Relapsed/refractory acute myeloid leukemia					

: Changes from 3rd quarter 2019

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-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy				PIII in progress	
NS-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension					
NS-018 (ilginatinib) <in-house>	NME	Myelofibrosis					

NS-018 Development Strategy (1)

[Challenge for current MF treatment]
Because MF patients whose platelet count is going below 50,000/μL during a treatment with JAK inhibitors, can not continue the treatment, it is difficult for them to obtain QOL improvement and their physical condition becomes severe.

[Development strategy for next study]
In next study, a dosage is increased to 300mg BID (600mg/day) from 300mgQD (300mg/day) and a safety and efficacy is assessed in naïve or JAK inhibitor treated MF patients whose platelet count is below 50,000/μL

NS-018 Development Strategy (2)

Summary of study design

Item		Content
Target population		Naïve or JAK inhibitor treated MF patients whose platelet count is below 50,000/μL
Arm	Experimental	NS-018 (300mg BID)
	Comparator	Best Available Therapy (exclude JAK inhibitors)
Estimated enrollment		94 patients in total
Treatment period		24 weeks
Primary Endpoint		A proportion of patients achieving a >35% spleen volume reduction (SVR) at Week
Secondary Endpoint		Improvement of Total Symptom Score (TSS)

Efforts against novel coronavirus infection

NIPPON SHINYAKU CO., LTD.

Efforts against novel coronavirus infection
－Nucleic acid drugs (1)－

The novel coronavirus is a long-chain RNA virus that mutates easily.

The study of nucleic acid drugs will be started with the aim of making them

(1) widely applicable to viral infections of mutant coronavirus as well as the novel coronavirus itself and

(2) long-lived antiviral drugs that can be applied to the past SARS and MERS as well as novel coronavirus infections that will emerge in the future.

Efforts against novel coronavirus infection
－Nucleic acid drugs (2)－

Small-molecule drugs：Potential short-term effects can be expected from drug repositioning. The regions of viral proteins to which small molecules can bind are limited. Even if an effective small-molecule drug is found, the emergence of a virus with a mutated binding region would render the drug ineffective.

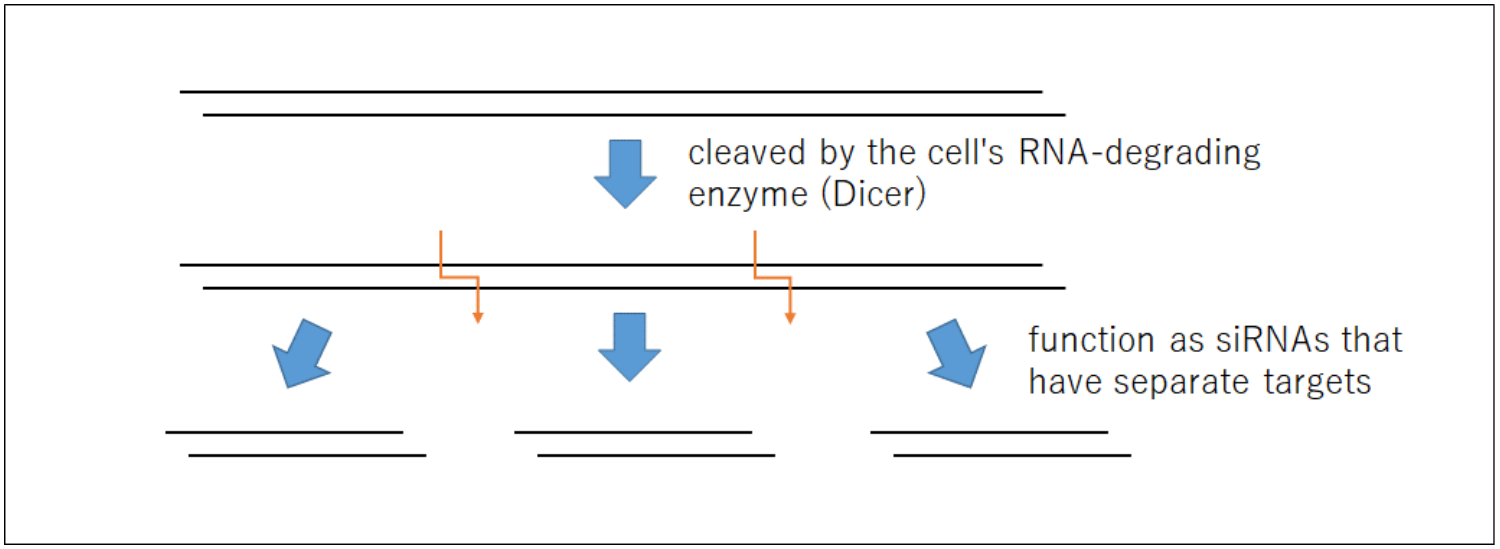
Vaccines target the surface proteins of viruses and have similar limitations to small-molecule drugs. Even if an effective vaccine is found, the emergence of a virus with a mutated binding region would render the vaccine ineffective.

Nucleic acid drugs can target the entire viral genome because they interact directly with the viral genome. They can target invariant regions essential for viral replication.

Efforts against novel coronavirus infection
－Nucleic acid drugs (3)－

The types and structures of nucleic acids, such as long-chain RNA, antisense nucleic acids (morpholino nucleic acids), and DNA enzymes, will be studied to select the nucleic acids that effectively kill the novel coronavirus.

The figure shows an example of the application of state-of-the-art long-chain RNA.



Long-chain RNAs are cleaved within the cell to produce several siRNAs targeting multiple sites on the viral RNA, killing all of the novel coronavirus.

Efforts against novel coronavirus infection －Repositioning (1)－

- In a sudden exacerbation of symptoms caused by the novel coronavirus, the hyperreactivity of the immune system (cytokine storm) is closely involved.
  If this could be controlled, severe respiratory failure could be prevented.

- If intracellular signaling mediated by JAK or IL-6 could be inhibited, the cytokine storm could be suppressed.
  Clinical trials of JAK inhibitors or anti-IL-6 receptor antibodies from other companies have begun.

Efforts against novel coronavirus infection －Repositioning (2)－

- NS-018, which is in clinical trial, and another drug in preparation for clinical trial are JAK inhibitors with excellent subtype selectivity and safety.
  They are under consideration for reprofiling as treatments for severe pneumonia and acute respiratory distress syndrome (ARDS) caused by novel coronavirus infection.

- In addition, repositioning of Uptravi, a treatment for pulmonary arterial hypertension, is under consideration for thrombosis caused by novel coronavirus infection.

Reference Materials

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Impact due to novel coronavirus infection (1)

Business performance

- ✓ In order to stop the pandemic, people are resisting to consult a doctor. However, there is little impact toward our focus fields such as Hematology and PAH which need medical treatment at all times.
- ✓ At this time, there is little impact toward our business performance. However, we can not confirm what will happen when the virus continues to last.

- Any new updates will be announced immediately in the next following quarter.

Research and Development

Domestic

- ✓ There is little impact toward our research and development. Patient enrollment for our main clinical trials has been almost completed.

Overseas

- ✓ Our phase 3 trial for NS-065 has just begun. At this moment, there is no impact.

- Ensuring safety of patients and medical institutions will always be our first priority.

Impact due to novel coronavirus infection (2)

Supply chain

Raw materials

- ✓ We are able to supply our raw materials without any problems. There is no impact toward our manufacturing plan.

Stock status

- ✓ Medical supplies with high medical needs are stably supplied. (corresponding to BCP)
- ✓ Our products have certain levels of supply which has no problem in stable supply.

Employee

Manufacturing base

- ✓ Our manufacturing bases are working as usual.
- ✓ Our workers go through measurement of body temperature and are completely sanitized by alcohol.

Sales activity

- ✓ Most of our medical representatives are working home.
- ✓ Flextime system, and staggered working hours.
- ✓ Communication using cellphones, emails and providing information through the internet.

Headquarter

- ✓ Most of employees are working home.
- ✓ Flextime system, and staggered working hours.
- ✓ Recommending web conferences.

Consolidated Statements of Income

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Consolidated Balance Sheet

(Million yen)	End of FY2018	End of FY2019	YoY Change Amt		End of FY2018	End of FY2019	YoY Change Amt
Assets	168,763	175,017	+6,254	Liabilities	33,572	29,256	-4,316
Current assets	110,720	121,925	+11,204	Current liabilities	25,406	24,965	-441
Fixed assets	58,042	53,091	-4,950	Long-term liabilities	8,165	4,290	-3,875
				Net assets	135,190	145,760	+10,570
Total assets	168,763	175,017	+6,254	Total liabilities and net assets	168,763	175,017	+6,254

＝Assets＝

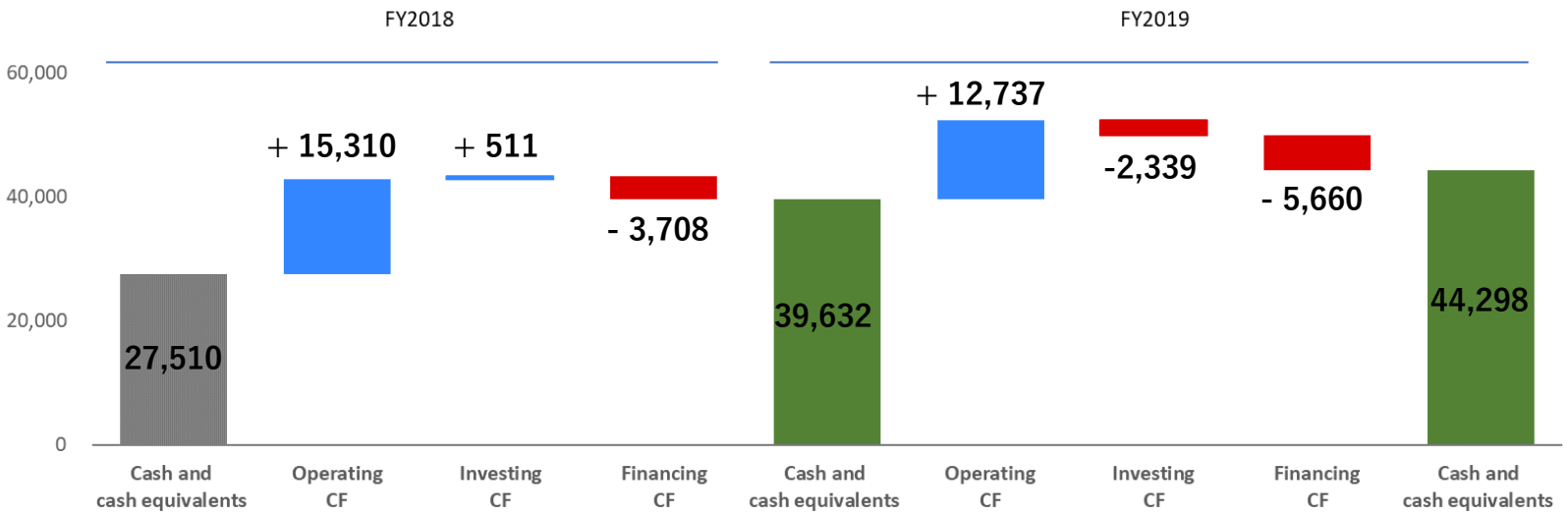
Cash and deposits	+4,485
Notes and accounts receivable	-5,034
Inventories	+10,521
Investment securities	-4,550
Deferred tax asset	-855

＝Liabilities and Net assets＝

Notes and accounts payable	+3,227
Accounts payable	-1,718
Income taxes payable	-1,515
Net defined benefit liability	-3,886
Retained earnings	+11,209

Consolidated Statements of Cash Flows

(Million yen)	FY2018 Results	FY2019 Results	YoY Change Amt
Operating activities	15,310	12,737	-2,572
Investing activities	511	-2,339	-2,851
Financing activities	-3,708	-5,660	-1,951
Cash and cash equivalents at end of year	39,632	44,298	+4,665



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

Development Phase	・Japan: Preparation for launching ・USA　: NDA filing ・global PIII
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 ・Morpholino based oligonucleotide with possible high safety profile and maximized activity

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

Development Phase	Japan: PIII
Origin	[Dec. 2016] 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 ・Good safety profile with no dose dependent ADRs ・Minimal potential toxicity from release of labile iron due to tight iron binding in a matrix structure of interchanging isomaltoside and iron ・No profound hypophosphatemia

ZX008
- Treatment for rare intractable epilepsy -

Development Phase	Japan: PIII
Origin	[March. 2019] Commercial rights from: Zogenix, Inc.
Development	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 ・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 Overseas: PIII <ASO> Japan: PIIb <LSS> Japan: PIIa
Origin	Nippon Shinyaku
Development	・[Apr. 2008] Licensed-out to (outside Japan): Actelion Pharmaceuticals Ltd. (Switzerland) ・Co-development in Japan: Actelion Pharmaceuticals Japan Ltd. (CTEPH) ・Overseas: Johnson & Johnson (CTEPH) ・Nippon Shinyaku (ASO) ・Nippon Shinyaku (LSS)
Mechanism of action	Selective IP receptor agonist
Indication	・Chronic thromboembolic pulmonary hypertension (CTEPH) ・Arteriosclerosis obliterans (ASO) ・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 synthase-1
Indication	Endometriosis
Dosage form	Oral agent
Feature	Treatment for endometriosis without hormonal effect and with possible analgesic potency

NS-17 (azacitidine)
- Treatment for acute myeloid leukemia -

Development Phase	Japan: PII
Origin	[Oct. 2006] 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 ・Improvement for life prognosis

NS-87
- Treatment for secondary acute myeloid leukemia -

Development Phase	Japan: PI/II
Origin	[Mar. 2017] 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 ・The enhancement of antitumor activity and reducing adverse events are expected by NS-87 accumulated in bone marrow.

NS-917

- Treatment for relapsed or refractory acute myeloid leukemia -

Development Phase	Japan: Preparation for Clinical Development
Origin	[Mar. 2017] 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 ・Tolerable safety profile available to elderly patients with r/r AML

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) ・Launch in Italy (Nov. 2004) ・Approval in European countries (Apr. 2005)
・Lee's Pharmaceutical Holdings Ltd. (Hong Kong)	・Launch in Hong Kong (Nov. 2012) ・NDA filing in China
・Algorithm (Lebanon)	・Launch in Lebanon (Jan. 2012)

NS-018 (ilginatinib)
- 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	・Potent and highly selective JAK2 inhibitor ・High efficacy and safety are expected for Myelofiblosis (MF) patients with low platelet count, for whom QOL improvement can’t be obtained because no treatment is available

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