

# **Our vision and three commitments**

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**November 12, 2021  
NIPPON SHINYAKU CO., LTD.**

# Our vision and three commitments

The name of the company, which means “new drugs from Japan,” reflects the founder’s desire to produce high-quality medicines with Japanese expertise, and build a company that would develop its business overseas.

The role and mission of Nippon Shinyaku is to help as many people as possible at the earliest juncture to become a company with a meaningful existence in the global healthcare field.

## Vision

**A company with a meaningful existence  
in the global healthcare field**

## Three commitments to accomplish our vision

①

**Continue to  
launch at least  
one distinctive  
product each year**

②

**Generate  
at least 50% of  
consolidated sales  
from overseas**

③

**Target at least  
100% gains in  
net sales and  
operating profit**



# For further growth



By succeeding to launch at least one distinctive product each year, we have proceeded to accomplish increase in both net sales and operating profit for nine fiscal years in a row.

	FY2006		FY2020	
Net sales	56,320 (million yen)	▶	121,885 (million yen)	▶▶▶
Operating profit	5,220 (million yen)	▶	26,134 (million yen)	
Stock price	994 <sub>yen</sub> (as of 2007/3/30)	▶	8,230 <sub>yen</sub> (as of 2021/3/31)	

# Commitment ①



**Continue to launch at least one distinctive product each year**

**Challenge with a sense of urgency**

**In-house  
drug discovery**

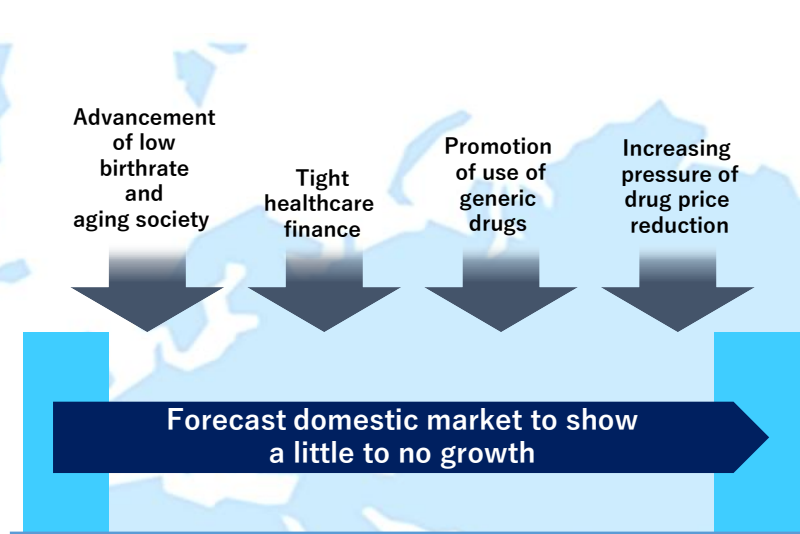
**In-licensing**

**PLCM**

PLCM: Product Life Cycle Management 4



# Overview of pharmaceutical markets



Pharmaceutical market in Japan



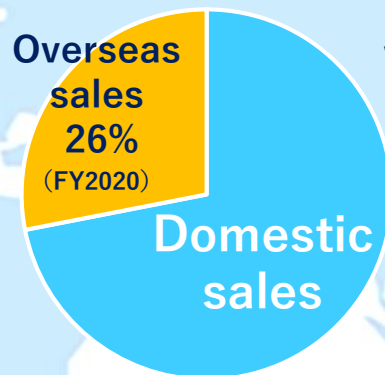
Global pharmaceutical market

It is vital that we develop a stronger presence in overseas markets, such as US, Europe, China and other areas, if we are to forge sustained growth in the future.

# Commitment ②



## Generate at least 50% of consolidated sales from overseas



within 10 years



Our policy must be to develop operations not just in the US, but also in Europe, China and other markets.

We will develop and launch a continual stream of distinctive new products in the Japanese market.

# Commitment ③



## Target at least 100% gains in net sales and operating profit

	FY2020		10 years later
Net sales	121,885 (million yen)	▶	Double or more
Operating profit	26,134 (million yen)	▶	Double or more

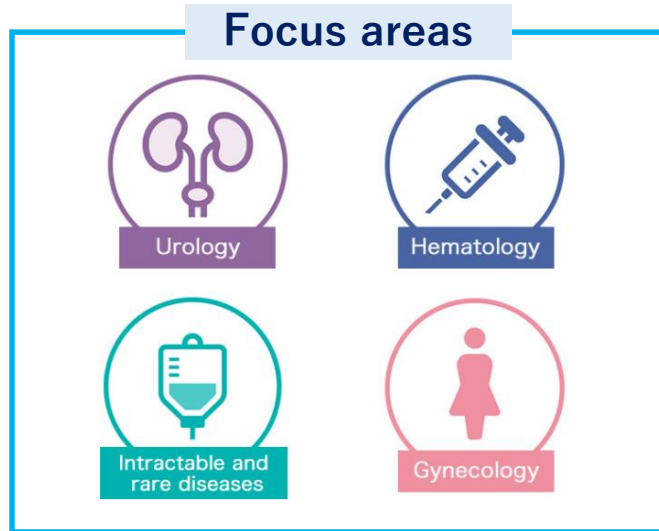
We will build a foundation to expand our net sales in the future to 300 billion yen, and from there to 500 billion yen.



# Specific policies in each business



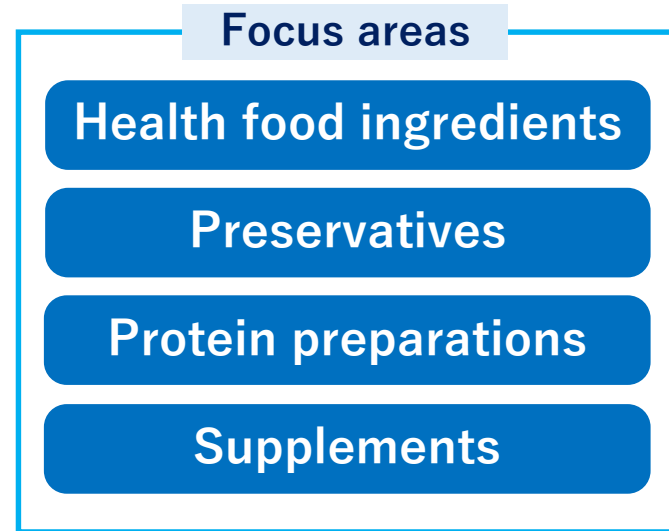
## Pharmaceuticals business



Focusing mainly on our four focus areas, we will seek to develop our R&D pipeline.

In pharmaceuticals business, we will invest aggressively to upgrade our R&D capabilities through advanced drug discovery technologies, and to develop new drug-discovery modalities outside of nucleic acid medicines.

## Functional food business



Focusing mainly on our four focus areas, we will supply high-value-added products.

In our functional food business, we will use our advanced expertise as a manufacturer of medicines to produce products which will address societal needs such as reduction of food waste and efforts to combat aging.





# Initiatives for promoting digital transformation

## Digital Vision

# Digital for Smiles

—Let's Be Digital to Bring Smiles to People around the World—

Nippon Shinyaku aims to fill the world with smiles by utilizing digital technology and data and creating highly original products and services in the healthcare sector.

## Digital strategies



### Strategy 1

#### Digital for Innovation

We will provide people around the world with better products and services more quickly.



### Strategy 2

#### Digital for Operation

We will strengthen our management foundation and shift streamlined operational resources to creative areas.



### Strategy 3

#### Digital for Adaptation

We will promote the development of organizations and human assets suitable for the digital age.

As a milestone to accelerate digital transformation, we are working to obtain the “DX Certification” granted by the Ministry of Economy, Trade and Industry of Japan (METI) and having the company’s stock selected to be on the list of “DX Stocks” within the framework of the METI and Tokyo Stock Exchange.



# Our vision



Every employee will

**pursue originality**

**and challenge with a sense of urgency**

**targeting to create distinctive products of high quality**



**To become a meaningful existence  
in the global healthcare field**

# **Outline of Consolidated Financial Results for the 2<sup>nd</sup> Quarter Ended September 30, 2021**

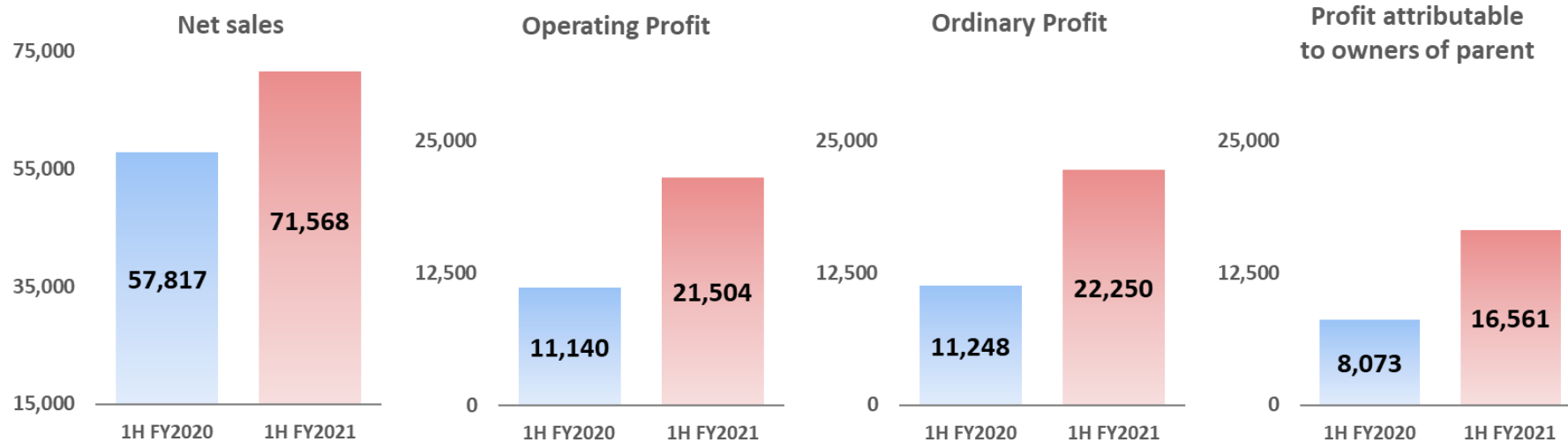
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# 1H FY2021 Summary

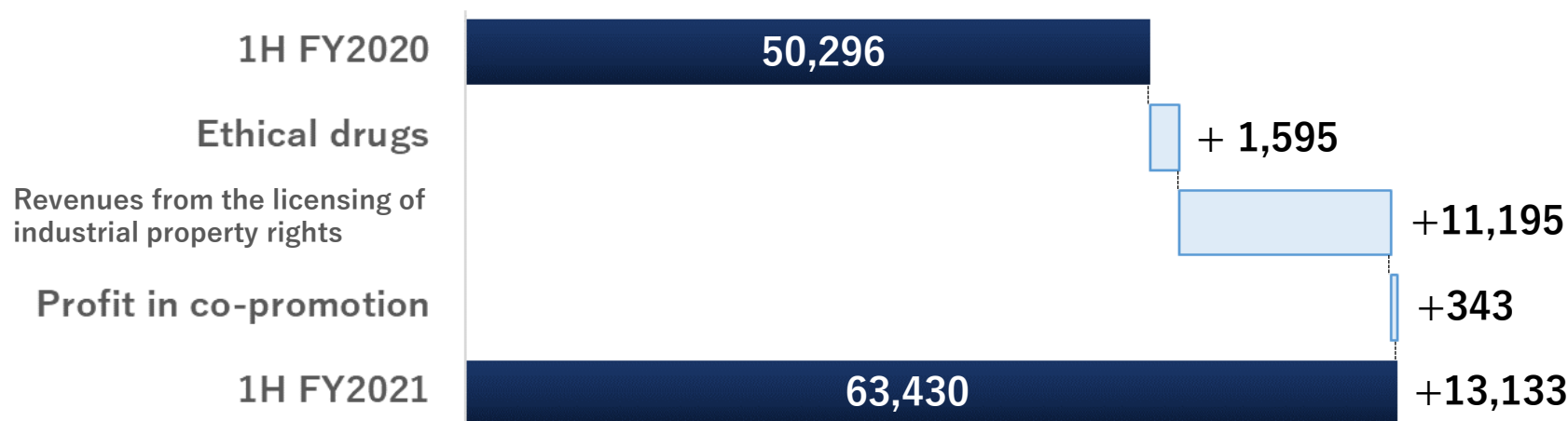


◆ Net sales	:	71,568 million yen	(+23.8%)
◆ Operating profit	:	21,504 million yen	(+93.0%)
◆ Ordinary profit	:	22,250 million yen	(+97.8%)
◆ Profit attributable to owners of parent	:	16,561 million yen	(+105.1%)

(million yen)



# Segmental Review - Pharmaceuticals -



(Million yen)	1H FY2020		1H FY2021		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	36,406	72.4%	38,001	59.9%	+1,595	+4.4%
Revenues from the licensing of industrial property rights	9,769	19.4%	20,964	33.1%	+11,195	+114.6%
Profit in co-promotion	4,121	8.2%	4,464	7.0%	+343	+8.3%
Net sales	50,296	100.0%	63,430	100.0%	+13,133	+26.1%

Net sales increased by 26.1% through growth of ethical drugs such as “Vidaza”, “Viltepso”, “Uptravi”, and revenues from the licensing of industrial property rights which contains of royalty revenue from Uptravi’s overseas sales and gain on sales from the priority review voucher.



# Segmental Review - Functional Food -

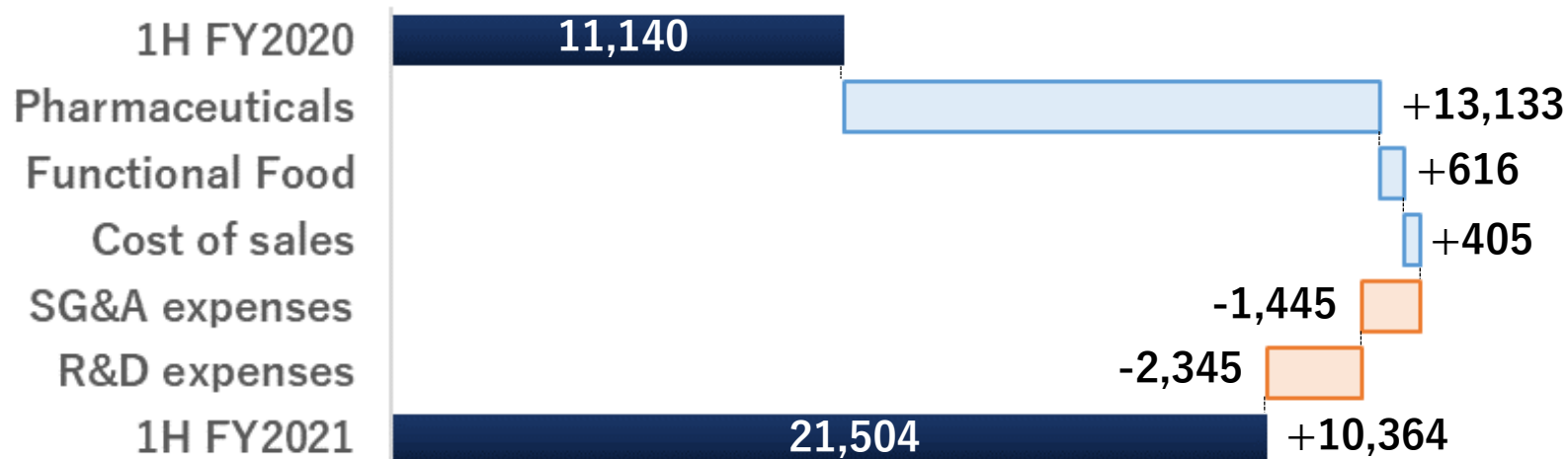


(Million yen)	1H FY2020		1H FY2021		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	5,058	67.3%	5,339	65.6%	+280	+5.5%
Preservatives	1,271	16.9%	1,382	17.0%	+110	+8.7%
Health food ingredients	493	6.6%	523	6.4%	+29	+6.0%
Others	697	9.2%	893	11.0%	+196	+28.1%
Net sales	7,521	100.0%	8,138	100.0%	+616	+8.2%

Net sales increased by 8.2% through sales from protein preparations, preservatives, and health food ingredients.



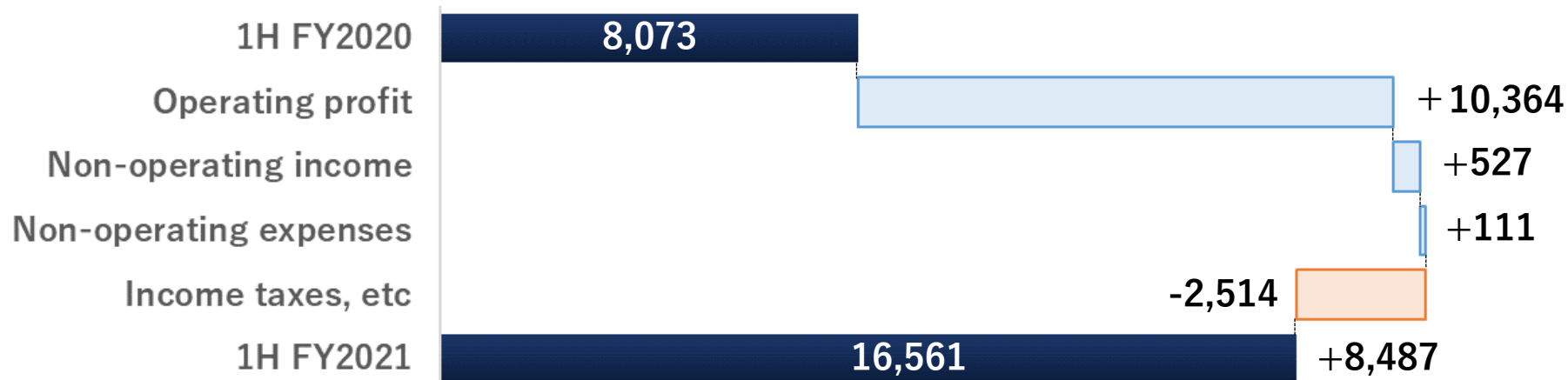
# Operating profit



(Million yen)	1H FY2020		1H FY2021		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
<b>Net sales</b>	<b>57,817</b>	<b>100.0%</b>	<b>71,568</b>	<b>100.0%</b>	<b>+13,750</b>	<b>+23.8%</b>
(Pharmaceuticals)	(50,296)	(87.0%)	(63,430)	(88.6%)	(+13,133)	(+26.1%)
(Functional Food)	(7,521)	(13.0%)	(8,138)	(11.4%)	(+616)	(+8.2%)
<b>Operating expenses</b>	<b>46,677</b>	<b>80.7%</b>	<b>50,063</b>	<b>70.0%</b>	<b>+3,386</b>	<b>+7.3%</b>
<b>Cost of sales</b>	<b>24,994</b>	<b>43.2%</b>	<b>24,589</b>	<b>34.4%</b>	<b>-405</b>	<b>-1.6%</b>
<b>SG&amp;A expenses</b>	<b>14,023</b>	<b>24.3%</b>	<b>15,468</b>	<b>21.6%</b>	<b>+1,445</b>	<b>+10.3%</b>
<b>R&amp;D expenses</b>	<b>7,659</b>	<b>13.2%</b>	<b>10,005</b>	<b>14.0%</b>	<b>+2,345</b>	<b>+30.6%</b>
<b>Operating profit</b>	<b>11,140</b>	<b>19.3%</b>	<b>21,504</b>	<b>30.0%</b>	<b>+10,364</b>	<b>+93.0%</b>



# Profit attributable to owners of parent



(Million yen)	1H FY2019	1H FY2020	YoY Change	
	Results	Results	Amt	%
Operating profit	11,140	21,504	+10,364	+93.0%
Non-operating income	600	1,127	+527	+87.8%
Non-operating expenses	492	380	-111	-22.6%
Ordinary profit	11,248	22,250	+11,002	+97.8%
Income taxes, etc	3,174	5,689	+2,514	+79.2%
Profit attributable to owners of parent	8,073	16,561	+8,487	+105.1%



# Business Forecast for FY2021



(Million yen)	FY2020		FY2021		YoY Change	
	1H	FY	1H	FY	Amt	%
	Results	Results	Results	Forecasts		
Net sales	57,817	121,885	71,568	135,000	+13,115	+10.8%
Operating profit	11,140	26,134	21,504	28,000	+1,866	+7.1%
Ordinary profit	11,248	26,760	22,250	28,500	+1,740	+6.5%
Profit attributable to owners of parent	8,073	20,702	16,561	21,000	+298	+1.4%

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)	FY2020		FY2021		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
<b>Ethical drugs</b>	36,406	73,697	38,001	78,300	+4,603	+6.2%
Revenues from the licensing of industrial property rights	9,769	24,338	20,964	32,000	+7,662	+31.5%
<b>Profit in co-promotion</b>	4,121	8,442	4,464	9,000	+558	+6.6%
<b>Net sales</b>	50,296	106,478	63,430	119,300	+12,822	+12.0%

Due to growth of new products, revenues from the licensing of industrial property rights which contains of royalty revenue from Uptravi's overseas sales, and profit in co-promotion, our net sales will increase.

# Segmental Forecast - Functional Food -



(Million yen)	FY2020		FY2021		YoY Change	
	1H	FY	1H	FY	Amt	%
	Results	Results	Results	Forecasts		
Protein preparations	5,058	10,121	5,339	9,850	-271	-2.7%
Preservatives	1,271	2,597	1,382	2,700	+103	+4.0%
Health food ingredients	493	1,257	523	1,100	-157	-12.5%
Others	697	1,431	893	2,050	+619	+43.2%
Net sales	7,521	15,406	8,138	15,700	+294	+1.9%

We expect an increase in net sales by focusing further on developing new products and introducing high-value-added products that meet market needs.

# Consolidated Statements of Income (Forecast)



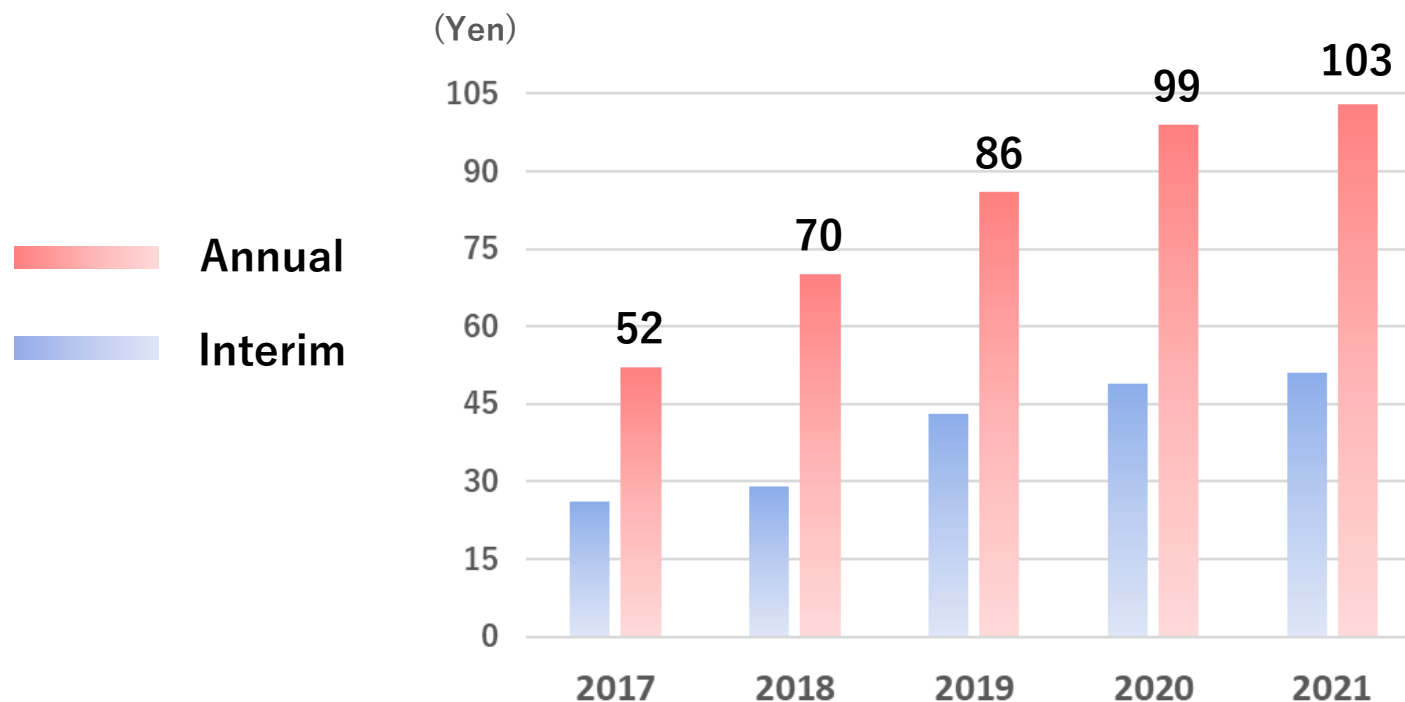
(Million yen)	FY2020		FY2021		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
<b>Net sales</b>	<b>57,817</b>	<b>121,885</b>	<b>71,568</b>	<b>135,000</b>	<b>+13,115</b>	<b>+10.8%</b>
(Pharmaceuticals)	(50,296)	(106,478)	(63,430)	(119,300)	(+12,822)	(+12.0%)
(Functional Food)	(7,521)	(15,406)	(8,138)	(15,700)	(+294)	(+1.9%)
<b>Cost of sales</b>	<b>24,994</b>	<b>49,954</b>	<b>24,589</b>	<b>48,700</b>	<b>-1,254</b>	<b>-2.5%</b>
(Cost of sales ratio)	(43.2%)	(41.0%)	(34.4%)	(36.1%)		
<b>SG&amp;A expenses</b>	<b>14,023</b>	<b>29,691</b>	<b>15,468</b>	<b>31,800</b>	<b>+2,109</b>	<b>+7.1%</b>
<b>R&amp;D expenses</b>	<b>7,659</b>	<b>16,104</b>	<b>10,005</b>	<b>26,500</b>	<b>+10,396</b>	<b>+64.5%</b>
<b>Operating profit</b>	<b>11,140</b>	<b>26,134</b>	<b>21,504</b>	<b>28,000</b>	<b>+1,866</b>	<b>+7.1%</b>
<b>Non-operating income</b>	<b>600</b>	<b>1,326</b>	<b>1,127</b>	<b>1,000</b>	<b>-326</b>	<b>-24.6%</b>
<b>Non-operating expenses</b>	<b>492</b>	<b>701</b>	<b>380</b>	<b>500</b>	<b>-201</b>	<b>-28.7%</b>
<b>Ordinary profit</b>	<b>11,248</b>	<b>26,760</b>	<b>22,250</b>	<b>28,500</b>	<b>+1,740</b>	<b>+6.5%</b>
<b>Income taxes, etc</b>	<b>3,174</b>	<b>8,056</b>	<b>5,689</b>	<b>7,500</b>	<b>-556</b>	<b>-6.9%</b>
<b>Profit attributable to owners of parent</b>	<b>8,073</b>	<b>20,702</b>	<b>16,561</b>	<b>21,000</b>	<b>+298</b>	<b>+1.4%</b>



# Dividends Forecast



		FY2020	FY2021
Dividends per share	Interim	¥49	¥51
	Annual	¥99	¥103
E P S		¥307.37	¥311.79
Dividends payout ratio		32.2 %	33.0 %



# R&D Pipeline

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**NIPPON SHINYAKU CO., LTD.**

# R&D pipeline (Domestic)



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



# R&D pipeline (Overseas)



Code No. (Generic name) <Origin>	Application type	Indications	Preparation for development	PI	Preparation for P II	PII	PIII	Launch
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						



# **Reference Materials**

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**NIPPON SHINYAKU CO., LTD.**

# Consolidated Balance Sheet



(Million yen)	End of FY2020	End of 1H FY2021	YoY Change Amt		End of FY2020	End of 1H FY2021	YoY Change Amt
<b>Assets</b>	197,028	204,052	+7,024	<b>Liabilities</b>	34,485	29,162	-5,322
Current assets	139,090	146,788	+7,697	Current liabilities	31,514	26,155	-5,358
Non-current assets	57,937	57,264	-673	Non-current liabilities	2,970	3,006	+35
				Net assets	162,543	174,890	+12,346
<b>Total assets</b>	197,028	204,052	+7,024	<b>Total liabilities and net assets</b>	197,028	204,052	+7,024

## = Assets =

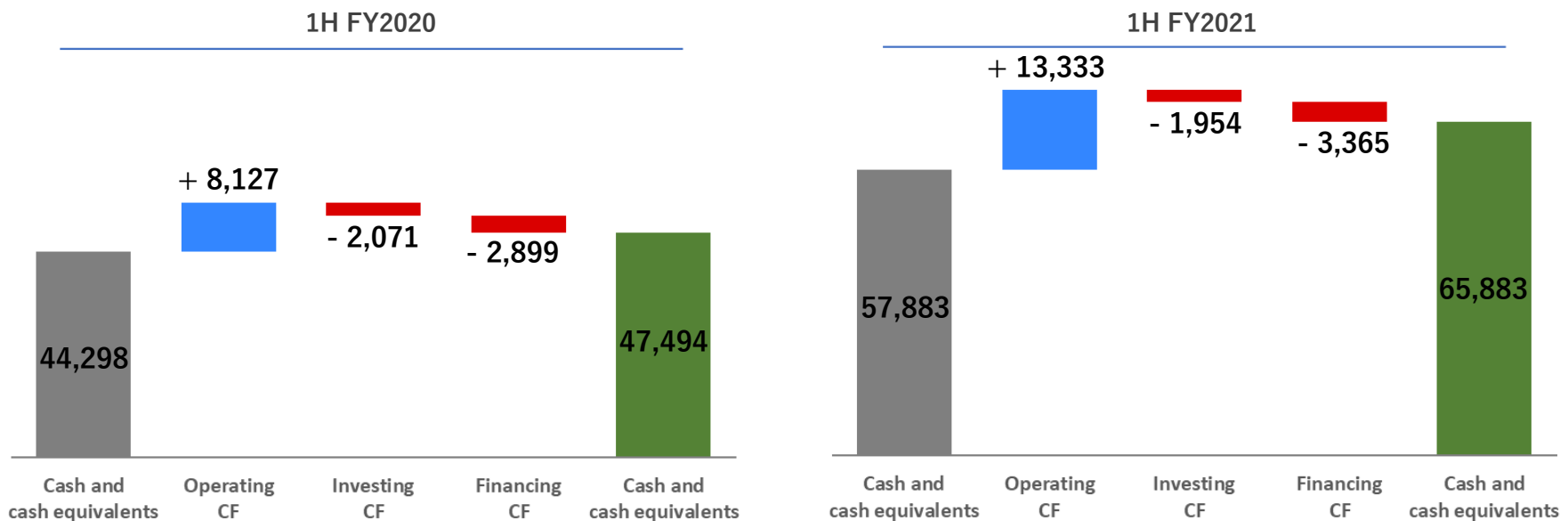
Cash and deposits	+6,529
Securities	+1,070
Investments and other assets	-1,093

## = Liabilities and Net assets =

Notes and accounts payable	-2,369
Accounts payable	-843
Income taxes payable	-637
Retained earnings	+13,193

# Consolidated Statements of Cash Flows

(Million yen)	1H FY2020 Results	1H FY2021 Results	YoY Change Amt
Operating activities	8,127	13,333	+5,206
Investing activities	-2,071	-1,954	+116
Financing activities	-2,899	-3,365	-466
Cash and cash equivalents at end of year	47,494	65,883	+18,388



# NS-065/NCNP-01 (viltolarsen)

## - Treatment for Duchenne muscular dystrophy -



Development Phase	<ul style="list-style-type: none"><li>• Japan : Launch</li><li>• USA : Launch</li><li>• China : NDA filing</li><li>• Global : PIII</li></ul>
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	<ul style="list-style-type: none"><li>• Improvement in symptoms and prevention of the disease progression by recovery of dystrophin protein expression</li><li>• Morpholino based oligonucleotide with possible high safety profile and maximized activity</li></ul>

# NS-32 (ferric derisomaltose)

## - Treatment for iron deficiency anemia -



Development Phase	Japan: NDA filing
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	<ul style="list-style-type: none"><li>• Can be administered in high doses allowing full iron correction in the majority of patients</li><li>• Good safety profile with no dose dependent ADRs</li><li>• Minimal potential toxicity from release of labile iron due to tight iron binding in a matrix structure of interchanging isomaltoside and iron</li><li>• No profound hypophosphatemia</li></ul>



# ZX008 (fenfluramine hydrochloride)

## - 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	<ul style="list-style-type: none"><li>• Effective for Dravet syndrome and Lennox-Gastaut syndrome patients refractory to existing treatment options</li><li>• ZX008 can be used in combination with other drugs, as standard of care for intractable epilepsy based on combination therapy</li></ul>



# NS-304 (selexipag)



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

Development Phase	<CTEPH> Japan: Launch Overseas: PIII <ASO> Japan: PIIb <LSS> Japan: PIIa <Pediatric PAH> Japan: PII
Origin	Nippon Shinyaku
Development	<ul style="list-style-type: none"><li>• Co-development in Japan: Janssen Pharmaceutical K.K. (CTEPH / Pediatric PAH)</li><li>• Overseas: Johnson &amp; Johnson (CTEPH / Pediatric PAH)</li><li>• Nippon Shinyaku (ASO)</li><li>• Nippon Shinyaku (LSS)</li></ul>
Mechanism of action	Selective IP receptor agonist
Indication	<ul style="list-style-type: none"><li>• Chronic Thromboembolic Pulmonary Hypertension (CTEPH)</li><li>• Arteriosclerosis obliterans (ASO)</li><li>• Lumbar spinal stenosis (LSS)</li><li>• Pediatric pulmonary arterial hypertension (Pediatric PAH)</li></ul>
Dosage form	Tablet
Feature	Long-acting oral drug





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



# NS-018 (ilginatinib)

## - Treatment for myelofibrosis -



Development Phase	Overseas (USA): Preparation for PII
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Mechanism of action	JAK2 inhibitor
Indication	Myelofibrosis
Dosage form	Tablet
Feature	<ul style="list-style-type: none"><li>• Potent and highly selective JAK2 inhibitor</li><li>• High efficacy and safety are expected for myelofibrosis (MF) patients with low platelet count, for whom QOL improvement can't be obtained because no treatment is available</li></ul>

# NS-87 (daunorubicin / cytarabine)

## - Treatment for secondary acute myeloid leukemia



Development Phase	Japan: PI/II
Origin	[Mar. 2017] Licensed-in from: Jazz Pharmaceuticals plc
Development	Nippon Shinyaku
Mechanism of action	Liposomal combination of cytarabine and daunorubicin
Indication	Secondary acute myeloid leukemia (secondary AML)
Dosage form	Injection
Feature	<ul style="list-style-type: none"><li>• NS-87 is the first therapy for the treatment of secondary AML in Japan</li><li>• The enhancement of antitumor activity and reducing adverse events are expected by NS-87 accumulated in bone marrow</li></ul>



## - 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	<ul style="list-style-type: none"><li>• Potent and highly selective JAK1 inhibitor</li><li>• High efficacy and good safety profiles are expected in the treatment for inflammatory diseases</li></ul>

# NS-917 (radgocitabine)



- Treatment for relapsed or refractory acute myeloid leukemia -

Development Phase	Japan: Preparation for PI
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	<ul style="list-style-type: none"><li>• Significant anti-leukemic activity with unique mechanism of action from other nucleoside analogs at low dose continuous infusion</li><li>• Tolerable safety profile available to elderly patients with r/r AML</li></ul>



# NS-401 (tagraxofusp)



## - Treatment for blastic plasmacytoid dendritic cell neoplasm -

Development Phase	Japan: Preparation for Clinical Development
Origin	[Mar. 2021] 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	<ul style="list-style-type: none"><li>• Composed of diphtheria toxin (DT) fusion protein and recombinant human IL-3</li><li>• Novel targeted therapy directed to CD123 on tumor cells</li><li>• 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</li></ul>



# 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.
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In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.