

# **Outline of Consolidated Financial Results for the 2<sup>nd</sup> Quarter Ended September 30, 2020**

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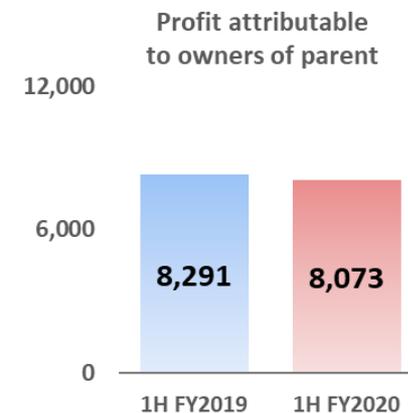
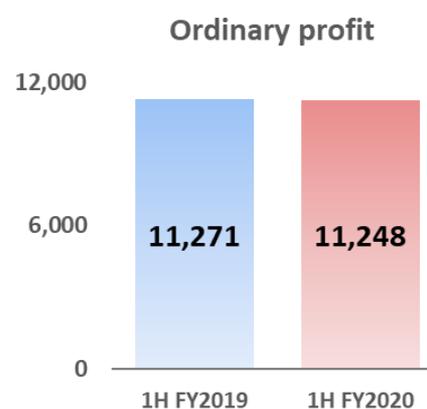
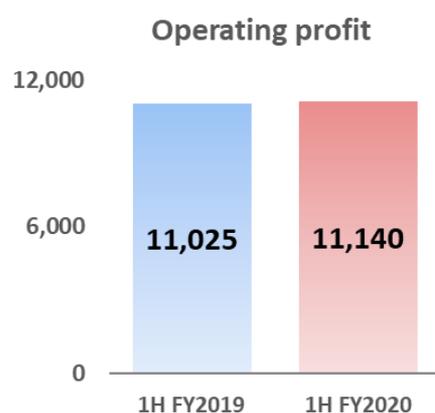
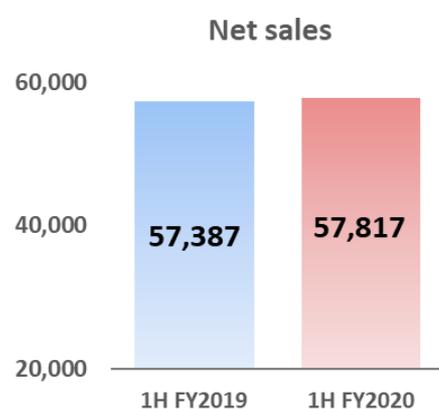
**November 9, 2020  
NIPPON SHINYAKU CO., LTD.**

# 1H FY2020 Summary



◆ Net sales	:	57,817 million yen	(+0.8%)
◆ Operating profit	:	11,140 million yen	(+1.0%)
◆ Ordinary profit	:	11,248 million yen	(-0.2%)
◆ Profit attributable to owners of parent	:	8,073 million yen	(-2.6%)

(million yen)



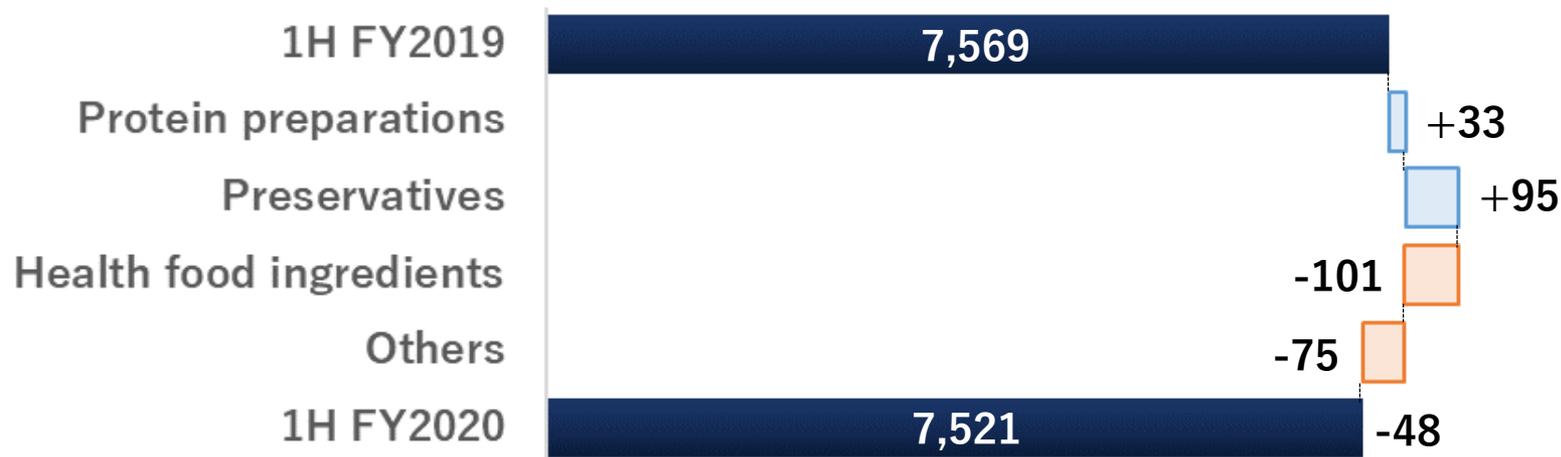
# Segmental Review - Pharmaceuticals -



(Million yen)	1H FY2019		1H FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	39,491	79.3%	36,406	72.4%	-3,085	-7.8%
Revenues from the licensing of industrial property rights	7,424	14.9%	9,769	19.4%	+2,345	+31.6%
Profit in co-promotion	2,901	5.8%	4,121	8.2%	+1,219	+42.0%
Net sales	49,817	100.0%	50,296	100.0%	+479	+1.0%

Net sales increased by 1.0% through revenues from the licensing of industrial property rights and profit in co-promotion.

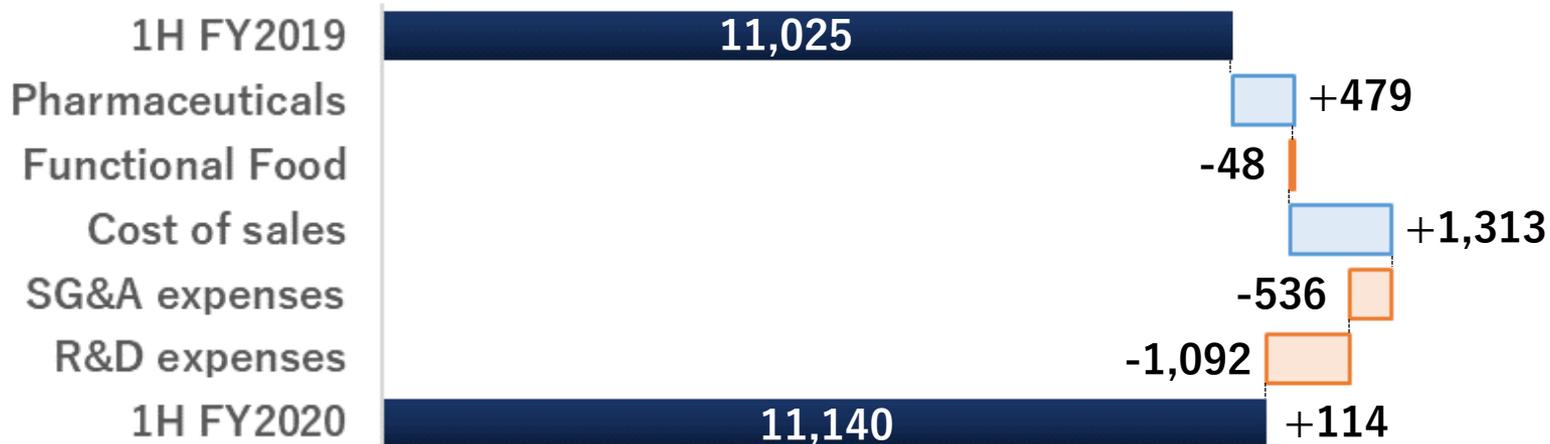
# Segmental Review - Functional Food -



(Million yen)	1H FY2019		1H FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	5,025	66.4%	5,058	67.3%	+33	+0.7%
Preservatives	1,176	15.5%	1,271	16.9%	+95	+8.1%
Health food ingredients	595	7.9%	493	6.6%	-101	-17.1%
Others	772	10.3%	697	9.3%	-75	-9.8%
Net sales	7,569	100.0%	7,521	100.0%	-48	-0.6%

Sales from protein preparations and preservatives increased however due to the decrease in health food ingredients and other products, net sales decreased by 0.6%.

# Operating profit



(Million yen)	1H FY2019		1H FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
<b>Net sales</b>	<b>57,387</b>	<b>100.0%</b>	<b>57,817</b>	<b>100.0%</b>	<b>+430</b>	<b>+0.8%</b>
(Pharmaceuticals)	(49,817)	(86.8%)	(50,296)	(87.0%)	(+479)	(+1.0%)
(Functional Food)	(7,569)	(13.2%)	(7,521)	(13.0%)	(-48)	(-0.6%)
<b>Operating expenses</b>	<b>46,361</b>	<b>80.8%</b>	<b>46,677</b>	<b>80.7%</b>	<b>+315</b>	<b>+0.7%</b>
<b>Cost of sales</b>	<b>26,307</b>	<b>45.8%</b>	<b>24,994</b>	<b>43.2%</b>	<b>-1,313</b>	<b>-5.0%</b>
<b>SG&amp;A expenses</b>	<b>13,486</b>	<b>23.6%</b>	<b>14,023</b>	<b>24.3%</b>	<b>+536</b>	<b>+4.0%</b>
<b>R&amp;D expenses</b>	<b>6,567</b>	<b>11.4%</b>	<b>7,659</b>	<b>13.2%</b>	<b>+1,092</b>	<b>+16.6%</b>
<b>Operating profit</b>	<b>11,025</b>	<b>19.2%</b>	<b>11,140</b>	<b>19.3%</b>	<b>+114</b>	<b>+1.0%</b>

# Profit attributable to owners of parent



(Million yen)	1H FY2019	1H FY2020	YoY Change	
	Results	Results	Amt	%
Operating profit	11,025	11,140	+114	+1.0%
Non-operating income	767	600	-167	-21.8%
Non-operating expenses	521	492	-29	-5.6%
Ordinary profit	11,271	11,248	-23	-0.2%
Income taxes, etc	2,980	3,174	+194	+6.5%
Profit attributable to owners of parent	8,291	8,073	-218	-2.6%

# Business Forecast for FY2020



(Million yen)	FY2019		FY2020		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Net sales	57,387	116,637	57,817	123,000	+6,363	+5.5%
Operating profit	11,025	21,668	11,140	25,000	+3,332	+15.4%
Ordinary profit	11,271	22,442	11,248	25,500	+3,058	+13.6%
Profit attributable to owners of parent	8,291	16,866	8,073	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	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
<b>Ethical drugs</b>	39,491	79,818	36,406	76,800	-3,018	-3.8%
Revenues from the licensing of industrial property rights	7,424	15,860	9,769	22,500	+6,640	+41.9%
<b>Profit in co-promotion</b>	2,901	5,963	4,121	8,400	+2,437	+40.9%
<b>Net sales</b>	49,817	101,643	50,296	107,700	+6,057	+6.0%

Revenues from the licensing of industrial property rights from Uptravi's overseas sales and profit in co-promotion will increase our net sales.

# Segmental Forecast - Functional Food -



(Million yen)	FY2019		FY2020		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
Protein preparations	5,025	9,731	5,058	9,680	-51	-0.5%
Preservatives	1,176	2,475	1,271	2,600	+125	+5.0%
Health food ingredients	595	1,280	493	1,300	+20	+1.5%
Others	772	1,506	697	1,720	+214	+14.1%
Net sales	7,569	14,994	7,521	15,300	+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)

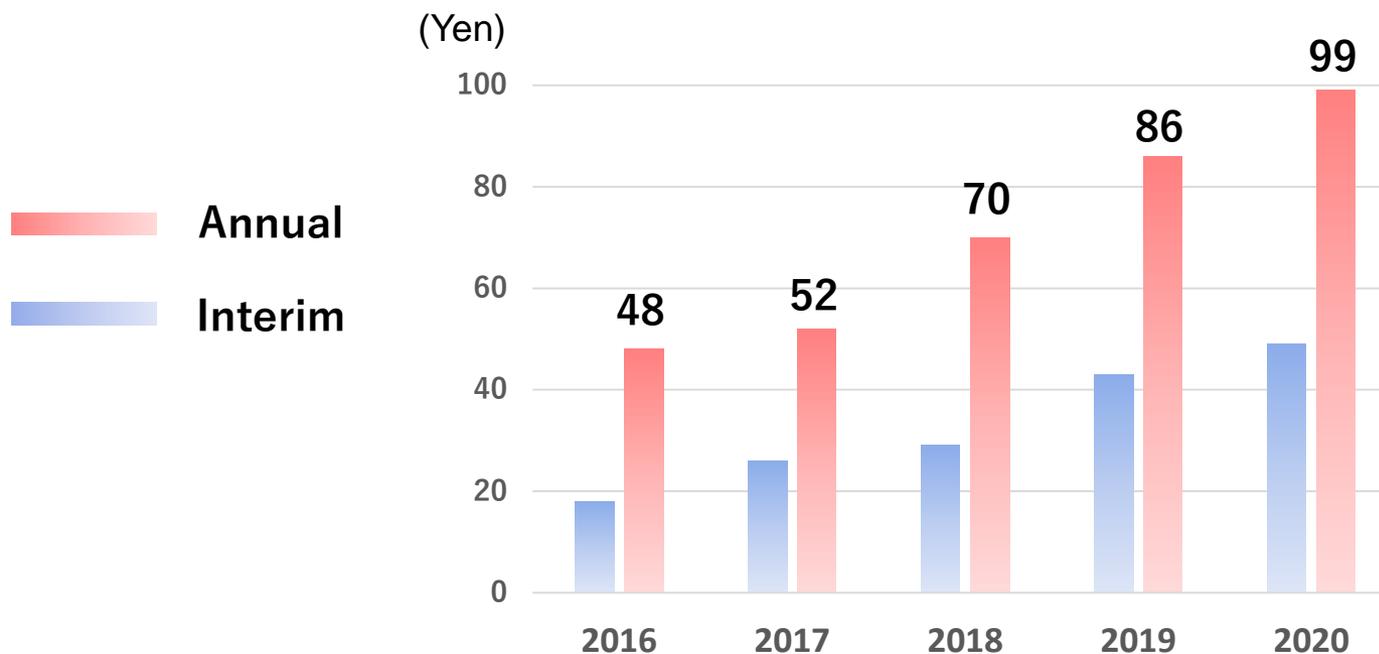


(Million yen)	FY2019		FY2020		YoY Change	
	1H Results	FY Results	1H Results	FY Forecasts	Amt	%
<b>Net sales</b>	<b>57,387</b>	<b>116,637</b>	<b>57,817</b>	<b>123,000</b>	<b>+6,363</b>	<b>+5.5%</b>
(Pharmaceuticals)	(49,817)	(101,643)	(50,296)	(107,700)	(+6,057)	(+6.0%)
(Functional Food)	(7,569)	(14,994)	(7,521)	(15,300)	(+306)	(+2.0%)
<b>Cost of sales</b>	<b>26,307</b>	<b>53,155</b>	<b>24,994</b>	<b>50,700</b>	<b>-2,455</b>	<b>-4.6%</b>
(Cost of sales ratio)	(45.8%)	(45.6%)	(43.2%)	(41.2%)		
<b>SG&amp;A expenses</b>	<b>13,486</b>	<b>27,819</b>	<b>14,023</b>	<b>29,800</b>	<b>+1,981</b>	<b>+7.1%</b>
<b>R&amp;D expenses</b>	<b>6,567</b>	<b>13,994</b>	<b>7,659</b>	<b>17,500</b>	<b>+3,506</b>	<b>+25.0%</b>
<b>Operating income</b>	<b>11,025</b>	<b>21,668</b>	<b>11,140</b>	<b>25,000</b>	<b>+3,332</b>	<b>+15.4%</b>
<b>Non-operating income</b>	<b>767</b>	<b>1,599</b>	<b>600</b>	<b>1,200</b>	<b>-399</b>	<b>-25.0%</b>
<b>Non-operating expenses</b>	<b>521</b>	<b>824</b>	<b>492</b>	<b>700</b>	<b>-124</b>	<b>-15.1%</b>
<b>Ordinary income</b>	<b>11,271</b>	<b>22,442</b>	<b>11,248</b>	<b>25,500</b>	<b>+3,058</b>	<b>+13.6%</b>
<b>Income taxes, etc</b>	<b>2,980</b>	<b>5,575</b>	<b>3,174</b>	<b>6,500</b>	<b>+925</b>	<b>+16.6%</b>
<b>Profit attributable to owners of parent</b>	<b>8,291</b>	<b>16,866</b>	<b>8,073</b>	<b>19,000</b>	<b>+2,134</b>	<b>+12.6%</b>

# 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

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# R&D Compounds (Domestic)



Code No. (Generic name) <Origin>	Application type	Indications	Preparation for development	PI	PII	PIII	Preparation for NDA	NDA	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy	[Blue bar]			PIII in progress	[Blue bar]		
NS-17 (azacitidine) <in-license>	New indication	Acute myeloid leukemia	[Blue bar]			PIII not conduct	[Dark blue bar]		
NS-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension	[Blue bar]				[Dark blue bar]		
		Arteriosclerosis obliterans	[Blue bar]						
		Lumbar spinal stenosis	[Blue bar]						
NS-32 (ferric derisomaltose) <in-license>	NME	Iron deficiency anemia	[Blue bar]						
ZX008 <in-license>	NME	Dravet syndrome Lennox-Gastaut syndrome	[Blue bar]						
NS-580 <in-house>	NME	Endometriosis	[Blue bar]						
NS-87 <in-license>	New combination	Secondary acute myeloid leukemia	[Blue bar]						
NS-229 <in-house>	NME	Inflammatory Diseases	[Dark blue bar]						
NS-917 <in-license>	NME	Relapsed/refractory acute myeloid leukemia	[Blue bar]						

 : Changes from 1<sup>st</sup> quarter 2020

# R&D Compounds (Overseas)



Code No. (Generic name) <Origin>	Application type	Indications	Preparation for development	PI	PII	PIII	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy	[Blue bar]			PIII in progress	[Dark blue bar]
NS-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension	[Blue bar]				
NS-018 (ilginatinib) <in-house>	NME	Myelofibrosis	[Blue bar]				

 : Changes from 1<sup>st</sup> quarter 2020

# Reference Materials

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# Consolidated Balance Sheet



(Million yen)	End of	End of 1H	YoY Change		End of	End of 1H	YoY Change
	FY2019	FY2020	Amt		FY2019	FY2020	Amt
<b>Assets</b>	175,017	180,453	+5,436	<b>Liabilities</b>	29,256	27,831	-1,424
Current assets	121,925	125,376	+3,450	Current liabilities	24,965	24,333	-632
Non-current assets	53,091	55,077	+1,985	Non-current liabilities	4,290	3,498	-792
				<b>Net assets</b>	145,760	152,621	+6,860
<b>Total Asset</b>	175,017	180,453	+5,436	<b>Total liabilities and net assets</b>	175,017	180,453	+5,436

## = Assets =

Cash and deposits	+3,246
Notes and accounts receivable	-3,938
Inventories	+4,286
Investment securities	+2,530

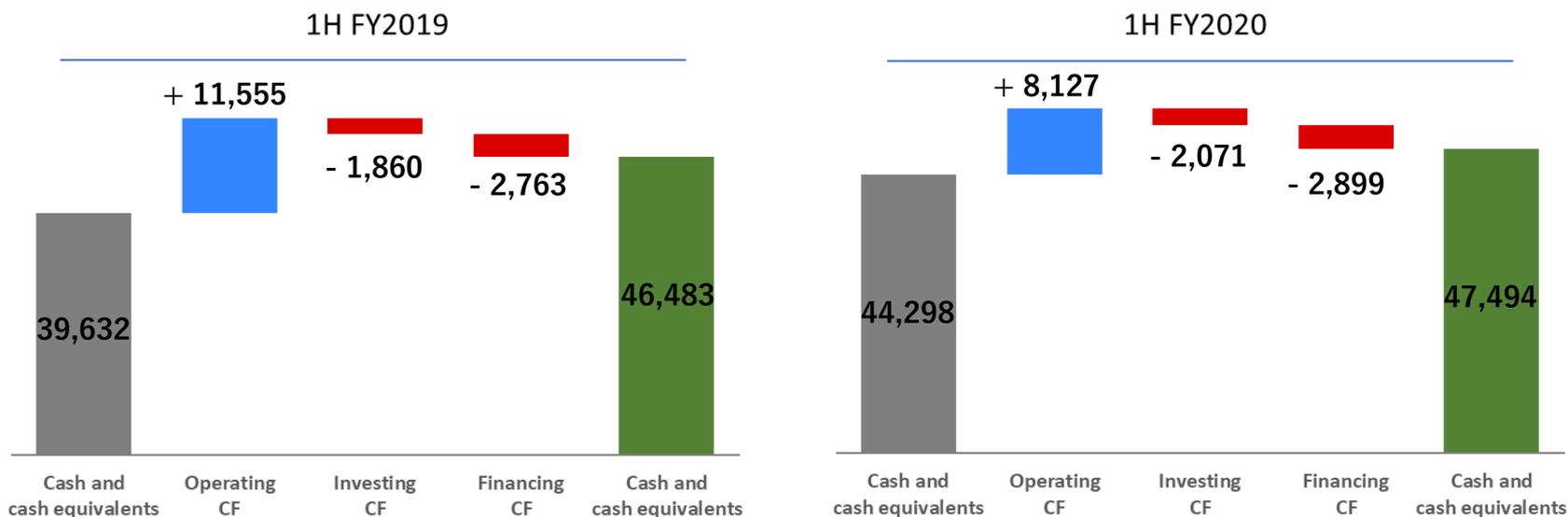
## = Liabilities and Net assets =

Notes and accounts payable	-988
Accrued tax payable	+1,242
Net defined benefit liability	-782
Retained earnings	+5,177

# Consolidated Statements of Cash Flows



(Million yen)	1H FY2019 Results	1H FY2020 Results	YoY Change Amt
Operating activities	11,555	8,127	-3,428
Investing activities	-1,860	-2,071	-211
Financing activities	-2,763	-2,899	-136
Cash and cash equivalents at end of year	46,483	47,494	+1,011



# 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>▪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-17 (azacitidine)

## - Treatment for acute myeloid leukemia -



Development Phase	Japan: NDA filing
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	<ul style="list-style-type: none"><li>▪ Standard Treatment for acute myeloid leukemia that ineligible for intensive chemotherapy</li><li>▪ Improvement for life prognosis</li></ul>

# NS-304 (selexipag)



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

Development Phase	<CTEPH> Japan: Preparation for NDA filing Overseas: PIII <ASO> Japan: PIIb <LSS> Japan: PIIa
Origin	Nippon Shinyaku
Development	<ul style="list-style-type: none"><li>• Co-development in Japan: Janssen Pharmaceutical K.K. (CTEPH)</li><li>• Overseas: Johnson &amp; Johnson (CTEPH)</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></ul>
Dosage form	Tablet
Feature	Long-acting oral drug

# 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	<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>



## - 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 is based on combination therapy.</li></ul>



## - 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



## - 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 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
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

## - 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	<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-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	<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>

# 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.
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