Outline of Consolidated Financial Results for the 3rd Quarter Ended December 31, 2020

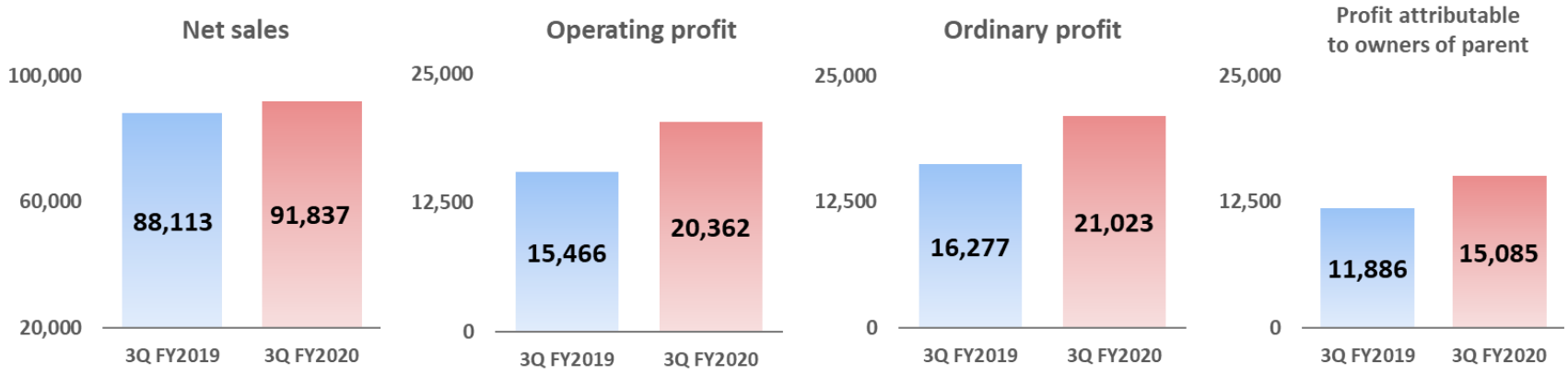
February 8, 2021
NIPPON SHINYAKU CO., LTD.

NIPPON SHINYAKU CO., LTD.

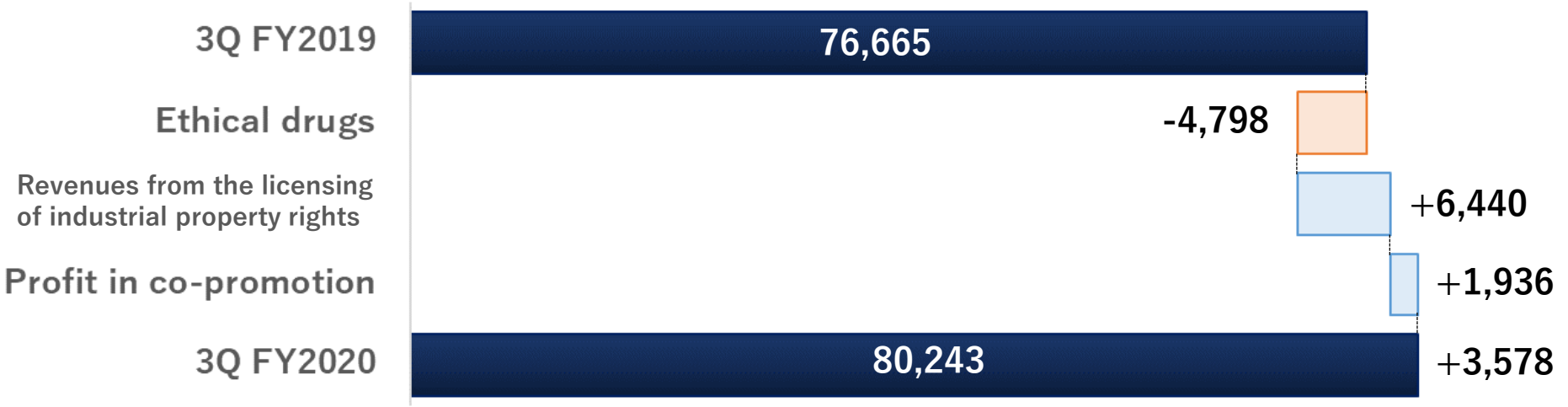
3Q FY2020 Summary

- **Net sales** : 91,837 million yen (+4.2%)
- **Operating profit** : 20,362 million yen (+31.7%)
- **Ordinary profit** : 21,023 million yen (+29.2%)
- **Profit attributable to owners of parent** : 15,085 million yen (+26.9%)

(Million yen)



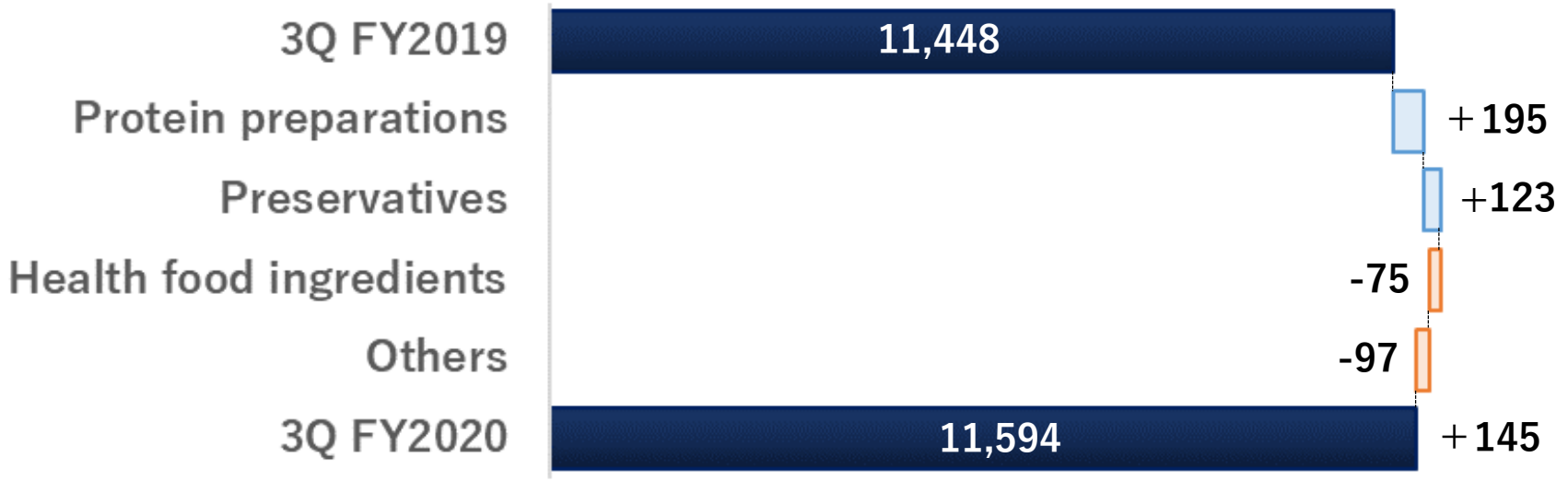
Segmental Review - Pharmaceuticals -



(Million yen)	3Q FY2019		3Q FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	61,029	79.6%	56,230	70.1%	-4,798	-7.9%
Revenues from the licensing of industrial property rights	11,197	14.6%	17,637	22.0%	+6,440	+57.5%
Profit in co-promotion	4,438	5.8%	6,375	7.9%	+1,936	+43.6%
Net sales	76,665	100.0%	80,243	100.0%	+3,578	+4.7%

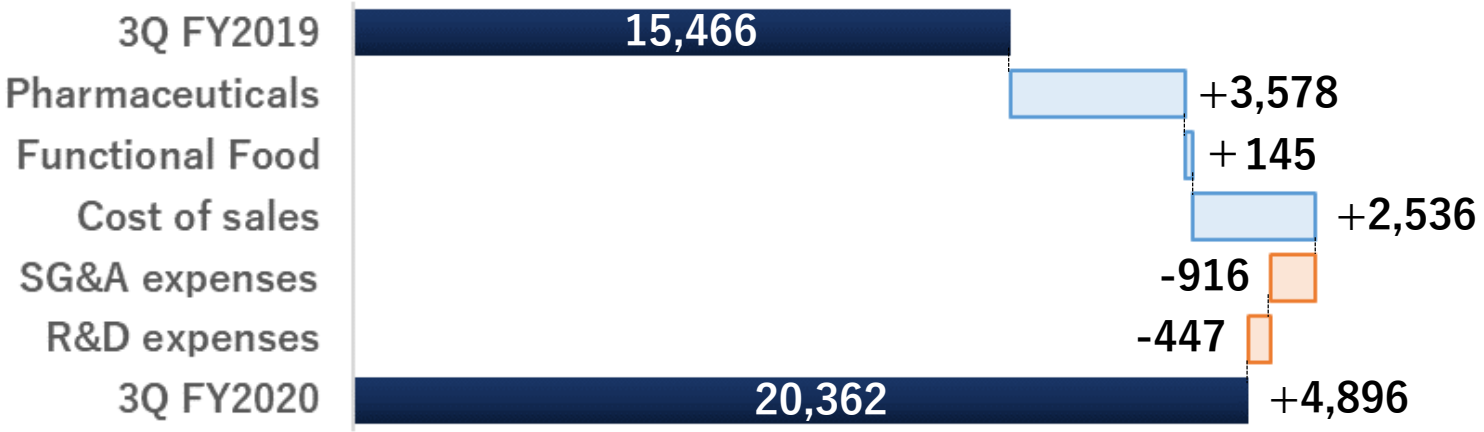
Net sales increased by 4.7% through revenues from the licensing of industrial property rights and profit in co-promotion.

Segmental Review - Functional Food -



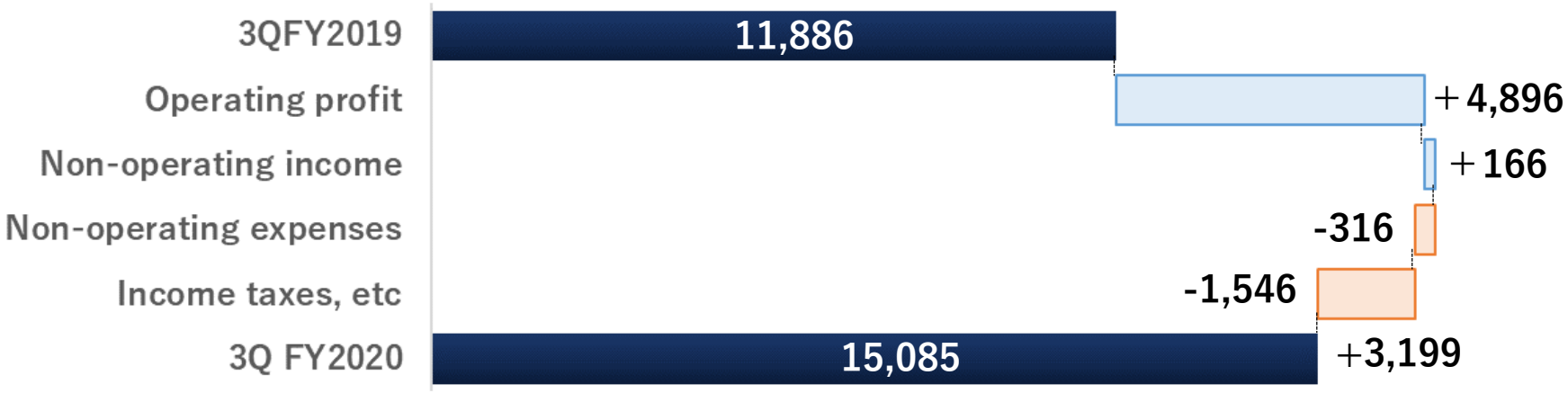
(Million yen)	3Q FY2019		3Q FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	7,550	65.9%	7,745	66.8%	+195	+2.6%
Preservatives	1,884	16.5%	2,008	17.3%	+123	+6.6%
Health food ingredients	850	7.4%	774	6.7%	-75	-8.9%
Others	1,164	10.2%	1,066	9.2%	-97	-8.4%
Net sales	11,448	100.0%	11,594	100.0%	+145	+1.3%

Operating profit



(Million yen)	3Q FY2019		3Q FY2020		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	**88,113**	**100.0%**	**91,837**	**100.0%**	**+3,724**	**+4.2%**
(Pharmaceuticals)	(76,665)	(87.0%)	(80,243)	(87.4%)	(+3,578)	(+4.7%)
(Functional Food)	(11,448)	(13.0%)	(11,594)	(12.6%)	(+145)	(+1.3%)
Operating expenses	**72,647**	**82.4%**	**71,475**	**77.8%**	**-1,172**	**-1.6%**
Cost of sales	**40,683**	**46.2%**	**38,146**	**41.5%**	**-2,536**	**-6.2%**
SG&A expenses	**20,952**	**23.7%**	**21,869**	**23.8%**	**+916**	**+4.4%**
R&D expenses	**11,011**	**12.5%**	**11,459**	**12.5%**	**+447**	**+4.1%**
Operating profit	**15,466**	**17.6%**	**20,362**	**22.2%**	**+4,896**	**+31.7%**

Profit attributable to owners of parent



(Million yen)	3Q FY2019 Results	3Q FY2020 Results	YoY Change Amt	YoY Change %
Operating profit	15,466	20,362	+4,896	+31.7%
Non-operating income	1,433	1,599	+166	+11.6%
Non-operating expenses	621	938	+316	+50.9%
Ordinary profit	16,277	21,023	+4,746	+29.2%
Income taxes, etc	4,391	5,938	+1,546	+35.2%
Profit attributable to owners of parent	11,886	15,085	+3,199	+26.9%

Business Forecast for FY2020

(Million yen)	FY2019		FY2020		
	3Q Results	FY Results	3Q Results	Progress for FY	FY Forecasts
Net sales	**88,113**	**116,637**	**91,837**	**74.7%**	**123,000**
(Pharmaceuticals)	(76,665)	(101,643)	(80,243)	(74.5%)	(107,700)
(Functional Food)	(11,448)	(14,994)	(11,594)	(75.8%)	(15,300)
Operating profit	**15,466**	**21,668**	**20,362**	**81.4%**	**25,000**
Ordinary profit	**16,277**	**22,442**	**21,023**	**82.4%**	**25,500**
Profit attributable to owners of parent	**11,886**	**16,866**	**15,085**	**79.4%**	**19,000**

Sales of pharmaceuticals and functional food, and each profit have progressed toward achievement of FY forecasts.

Status of Product Pipeline

NIPPON SHINYAKU CO., LTD.

R&D Compounds (Domestic)

Code No. (Generic name) <Origin>	Application type	Indications	Preparation for PI	PI	PII	PIII	NDA	Launch
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy				PIII in progress		
NS-17 (azacitidine) <in-license>	New indication	Acute myeloid leukemia						
NS-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension					■	
		Arteriosclerosis obliterans						
		Lumbar spinal stenosis						
	New dose	Pediatric pulmonary arterial hypertension	■					
NS-32 (ferric derisomaltose) <in-license>	NME	Iron deficiency anemia						
ZX008 <in-license>	NME	Dravet syndrome Lennox-Gastaut syndrome						
NS-580 <in-house>	NME	Endometriosis						
NS-87 <in-license>	New combination	Secondary acute myeloid leukemia						
NS-229 <in-house>	NME	Inflammatory diseases						
NS-917 <in-license>	NME	Relapsed/refractory acute myeloid leukemia	■					

■ : Changes from 2nd 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				PIII in progress	
NS-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension					
NS-018 (ilginatinib) <in-house>	NME	Myelofibrosis					

Reference Materials

NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet

(Million yen)	End of FY2019	End of 3Q FY2020	YoY Change Amt		End of FY2019	End of 3Q FY2020	YoY Change Amt
Assets	175,017	181,840	+6,823	Liabilities	29,256	25,584	-3,672
Current assets	121,925	127,719	+5,793	Current liabilities	24,965	22,391	-2,573
Non-current assets	53,091	54,120	+1,029	Non-current liabilities	4,290	3,192	-1,098
				Net assets	145,760	156,256	+10,495
Total Asset	175,017	181,840	+6,823	Total liabilities and net assets	175,017	181,840	+6,823

＝Assets＝

Cash and deposits	-6,051
Notes and accounts receivable	＋7,098
Inventories	＋3,794
Investment securities	＋2,448

＝Liabilities and Net assets＝

Notes and accounts payable	-3,519
Income taxes payable	＋1,287
Provision for bonuses	-1,458
Retained earnings	+8,888

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

Development Phase	・Japan: Launch ・USA　: Launch ・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-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	・Standard Treatment for acute myeloid leukemia that is ineligible for intensive chemotherapy ・Improvement for life prognosis

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 <Pediatric PAH> Japan: PII
Origin	Nippon Shinyaku
Development	・Co-development in Japan: Janssen Pharmaceutical K.K. (CTEPH / Pediatric PAH) ・Overseas: Johnson & Johnson (CTEPH / Pediatric PAH) ・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) ・Pediatric pulmonary arterial hypertension (Pediatric PAH)
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	・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 based on combination therapy.

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-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 cytarabine 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-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	Tablet
Feature	・Potent and highly selective JAK1 inhibitor ・High efficacy and good safety profiles are expected in the treatment for inflammatory diseases

NS-917

- 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	・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

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 myelofibrosis (MF) patients with low platelet count, for whom QOL improvement can't be obtained because no treatment is available.

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