Outline of Consolidated Financial Results for the 2nd Quarter Ended September 30, 2015

NIPPON SHINYAKU CO., LTD.





## FY2015 2Q Summary

(Million yen)

	2QFY2014		2QFY	2QFY2015		hange
	Results	Ratio	Results	Ratio	Amt	%
Net sales	36,470	100.0%	39,413	100.0%	2,942	8.1%
Operating income	2,033	5.6%	2,110	5.4%	76	3.7%
Ordinary income	2,272	6.2%	2,335	5.9%	63	2.8%
Net income attributable to owners of the parent	1,440	4.0%	1,523	3.9%	82	5.7%

### **Topics**

- ◆ Launch NS-24(Onetram tablet 100mg) · · · (Jun.)
- **◆** Launch ACT-064992(Opsumit tablet 10mg)··· (Jun.)
- ◆ Selexipag:Listed of 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension · · · (Aug.)
- **♦NS-065:Selected by the Japanese MHLW as one of the projects** for Sakigake designation · · · (Oct.)



# Segmental Review - Pharmaceuticals —

(Million yen)

	2QFY2014		2QFY2015		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	29,011	98.5%	31,392	97.4%	2,380	8.2%
Revenues from the licensing of industrial property rights	64	0.2%	115	0.4%	50	78.0%
Others	378	1.3%	736	2.2%	358	94.7%
Net sales	29,454	100.0%	32,244	100.0%	2,789	9.5%

Others: API, Contract manufacturing business and Promotion fee

#### Increase in sales:

- Zalutia (+1,567million yen ,+208.0%)
   ( urinary disorder caused by benign prostatic hyperplasia)
- Vidaza (+1,017 million yen, +20.2%)
   ( myelodysplastic syndromes )
- Tramal, Onetram (+942million yen, +81.5%)
   ( cancer pain, chronic pain)
- Lunabell(+493million yen, +16.5%)
   (Remedy for dysmenorrhea)

#### Decrease in sales:

- Eviprostat (-622 million yen, -22.2%)
  ( Remedy for benign prostatic hyperplasia )
- GaslonN (-380 million yen, -19.5%) (gastric ulcer, gastritis)

etc

etc



# New Products Review — Pharmaceuticals —

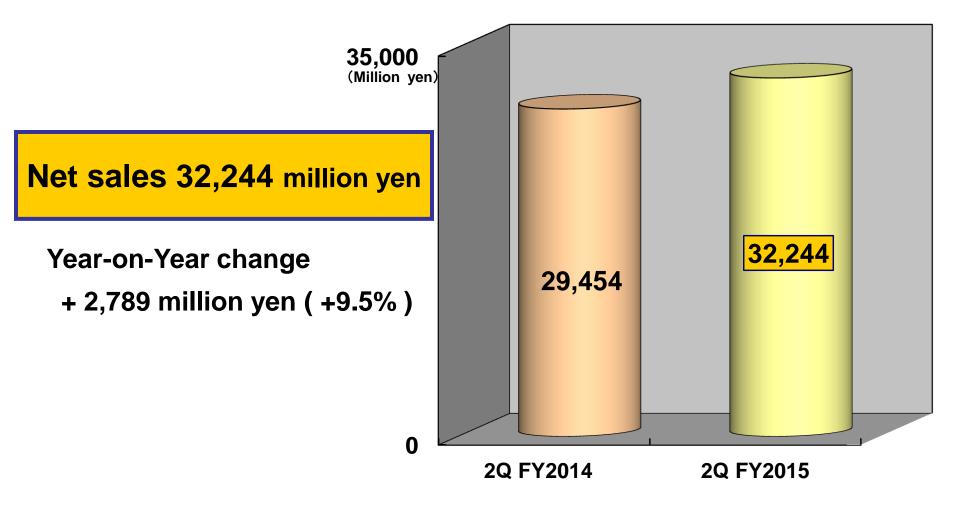
### Sales Growth of New Products Group

New Products	FY2014 2Q	FY2015 2Q	Y on Y Change
Vidaza	5,048	6,066	+20.2%
Lunabell	2,999	3,493	+16.5%
Zalutia	753	2,320	+208.0%
Tramal• Onetram	1,156	2,098	+81.5%
Adcirca	1,440	1,765	+22.5%
Cialis	1,737	1,687	-2.9%
Erizas	399	463	+16.1%
Regtect	345	435	+26.2%
Total	13,881	18,330	+32.1%





# Segmental Review - Pharmaceuticals -



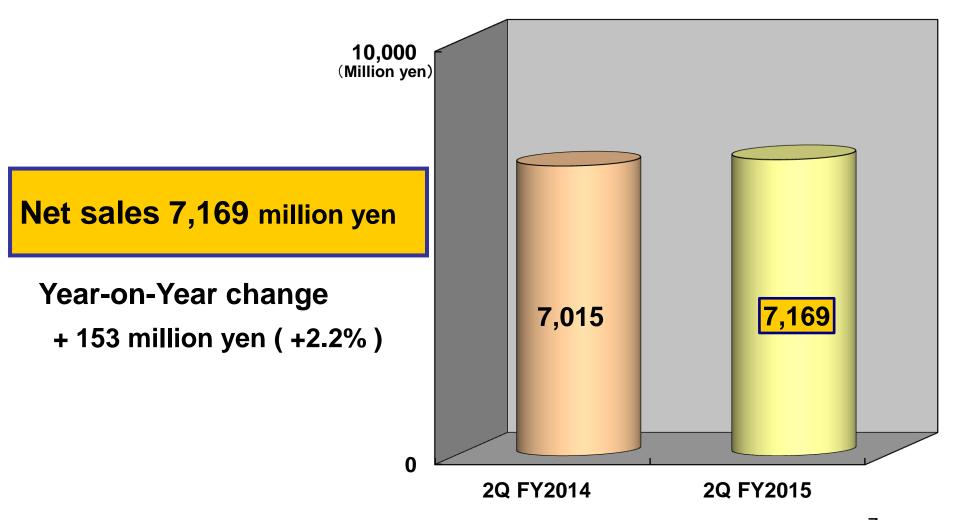


# Segmental Review Functional Food —

	2QFY2014		2QFY	2015	YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Health food ingredients	352	5.0%	419	5.9%	66	18.9%
Preservatives	916	13.1%	923	12.9%	7	0.8%
Protein preparations	3,836	54.7%	3,873	54.0%	37	1.0%
Nutritional ingredients	1,155	16.5%	1,222	17.0%	66	5.8%
Others	754	10.7%	730	10.2%	-24	-3.2%
Net sales	7,015	100.0%	7,169	100.0%	153	2.2%



# Segmental Review Functional Food —





## **Net Sales**

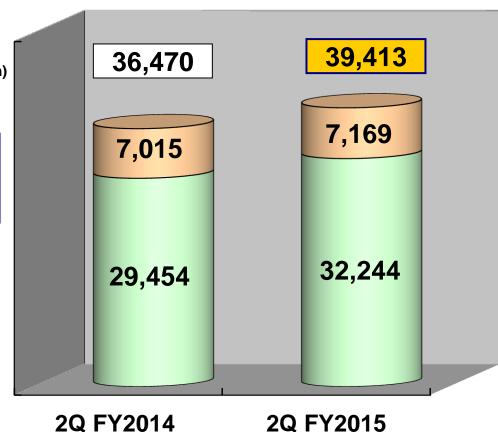


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Net sales 39,413 million yen

Year-on-Year change

+ 2,942 million yen ( +8.1% )



2Q FY2014

■ Functional Food

□ Pharmaceuticals



## **Consolidated Statements of Income** ①

	2QFY2014		2QFY	2QFY2015		hange
	Results	Ratio	Results	Ratio	Amt	%
Revenue						
Net sales	36,470	100.0%	39,413	100.0%	2,942	8.1%
Pharmaceuticals	29,454	80.8%	32,244	81.8%	2,789	9.5%
Functional Food	7,015	19.2%	7,169	18.2%	153	2.2%
Operating expenses	34,436	94.4%	37,303	94.6%	2,866	8.3%
Cost of sales	19,529	53.5%	21,569	54.7%	2,039	
SG&A expenses	10,663	29.3%	11,008	27.9%	345	
R&D expenses	4,243	11.6%	4,725	12.0%	481	
Operating income	2,033	5.6%	2,110	5.4%	76	3.7%



## **Consolidated Statements of Income 2**

	2QFY2014		2QFY	2015	YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Operating income	2,033	5.6%	2,110	5.4%	76	3.7%
Non-operating income	442	1.2%	483	1.2%	41	9.4%
Non-operating expenses	203	0.6%	258	0.7%	54	26.7%
Ordinary income	2,272	6.2%	2,335	5.9%	63	2.8%
Income taxes, etc	831	2.3%	812	2.1%	-19	-2.3%
Net income attributable to owners of the parent	1,440	4.0%	1,523	3.9%	82	5.7%



## **Consolidated Balance Sheet**

							<u>-</u>
	FY2014	FY2015	Change		FY2014	FY2015	Change
	4Q Results	2Q Results	Amt		4Q Results	2Q Results	Amt
Assets	129,757	127,652	-2,104	Liabilities	28,550	25,889	-2,660
(Current assets)	80,422	78,026	-2,395	(Current liabilities)	17,770	15,797	-1,973
(Fixed assets)	49,334	49,625	291	(Long-term liabilities)	10,779	10,092	-687
				Net assets	101,207	101,763	555
Total Assets	129,757	127,652	-2,104	Total liabilities and net assets	129,757	127,652	-2,104



### **Consolidated Statements of Cash Flows**

#### (Million yen)

	2QFY2014	2QFY2015	YoY Change
	Results	Results	Amt
Operating activities	1,690	-271	-1,961
Investing activities	-2,367	-1,554	813
Financing activities	-893	-916	-22
Cash and cash equivalents at end of quarter	19,647	19,192	-454

Cash and cash equivalents at end of quarter : -2,721 Million yen (YonY FY2014)



## Capital Investment

#### **Capital Investment and Depreciation**

(Million yen)

	2QResults					
	FY2014 FY2015 Amt Chg					
Capital investment	808	1,157	349			
Depreciation	1,294	1,184	-110			

#### **Breakdown of Capital Investment**

	2QResults				
	FY2014	FY2015	Amt Chg		
<nippon co.,ltd.="" shinyaku=""></nippon>	762	1,102	340		
Production	381	345	-36		
R&D	316	677	360		
(Manufacturing facility for investigational drugs)	(0)	(585)	(585)		
Others	64	80	15		
<sioe co.,ltd.="" pharmaceutical=""></sioe>	8	25	17		
<tajima co.,ltd.="" kogyo="" shokuhin=""></tajima>	37	29	-7		
Total capital investment	808	1,157	349		



## **Business Forecast for FY2015**

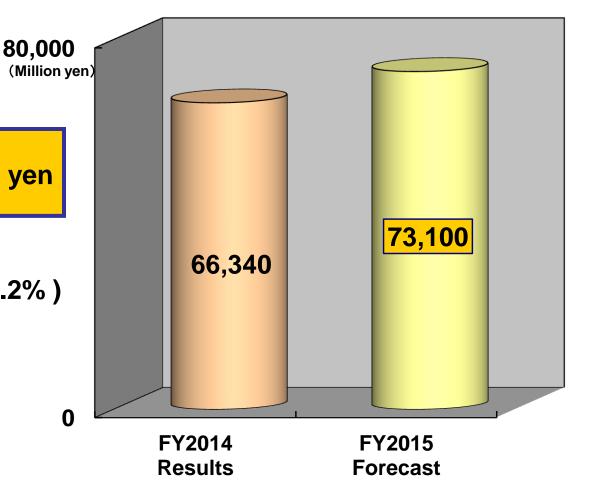
	FY20	14	FY20	FY2015		hange
	Results	Ratio	Forecast	Ratio	Amt	%
Net sales	79,991	100.0%	87,000	100.0%	7,009	8.8%
Operating income	8,562	10.7%	9,300	10.7%	738	8.6%
Ordinary income	8,928	11.2%	9,500	10.9%	572	6.4%
Net income attributable to owners of the parent	5,882	7.4%	6,700	7.7%	818	13.9%



## Segmental Forecast - Pharmaceuticals -

Net sales 73,100 million yen

Year-on-Year change +6,760 million yen ( +10.2% )





# Segmental Forecast - Pharmaceuticals -

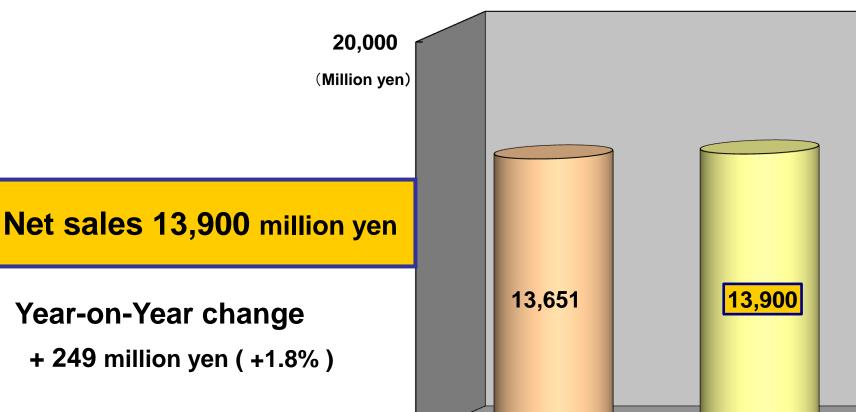
(Million yen)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Ethical drugs	62,898	94.8%	66,300	90.7%	3,402	5.4%
Revenues from the licensing of industrial property rights	2,510	3.8%	5,000	6.8%	2,490	99.1%
Others	930	1.4%	1,800	2.5%	870	93.5%
Net sales	66,340	100.0%	73,100	100.0%	6,760	10.2%

Others: API, Contract manufacturing business and Promotion fee



# Segmental Forecast - Functional Food —



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FY2014 Results FY2015 Forecast



# **Segmental Forecast**Functional Food

	FY2014		FY2015		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Health food ingredients	747	5.5%	830	6.0%	83	11.0%
Preservatives	1,886	13.8%	1,900	13.7%	14	0.7%
Protein preparations	7,290	53.4%	7,450	53.6%	160	2.2%
Nutritional ingredients	2,295	16.8%	2,320	16.7%	25	1.1%
Others	1,431	10.5%	1,400	10.0%	-31	-2.2%
Net sales	13,651	100.0%	13,900	100.0%	249	1.8%



## Consolidated Statements of Income (Forecast) (1)

	FY2014		FY2015		YoY Change	
	Results	Ratio	Forecast	Forecast Ratio		%
Revenue						
Net sales	79,991	100.0%	87,000	100.0%	7,009	8.8%
Pharmaceuticals	66,340	82.9%	73,100	84.0%	6,760	10.2%
Functional Food	13,651	17.1%	13,900	16.0%	249	1.8%
Operating expenses	71,429	89.3%	77,700	89.3%	6,271	8.8%
Cost of sales	41,226	51.5%	44,700	51.4%	3,474	
SG&A expenses	21,233	26.6%	22,600	26.0%	1,367	
R&D expenses	8,968	11.2%	10,400	11.9%	1,432	
Operating income	8,562	10.7%	9,300	10.7%	738	8.6%



## Consolidated Statements of Income (Forecast) (2)

	FY20	14	FY2015		YoY Change	
	Results	Ratio	Forecast	Ratio	Amt	%
Operating income	8,562	10.7%	9,300	10.7%	738	8.6%
Non-operating income	939	1.2%	900	1.0%	-39	- 4.2%
Non-operating expenses	573	0.7%	700	0.8%	127	22.0%
Ordinary income	8,928	11.2%	9,500	10.9%	572	6.4%
Income taxes, etc	3,046	3.8%	2,800	3.2%	-246	- 8.1%
Net income attributable to owners of the parent	5,882	7.4%	6,700	7.7%	818	13.9%



## **Dividends Forecast**

	FY2014	FY2015	
	Interim	¥12	¥14
Dividends per share	Year-end	¥13	¥14
	Annual	¥25	¥28
EPS	¥87.26	¥99.45	
Dividends payout ratio	28.7 %	28.2 %	



## Capital Investment Plan

#### **Capital Investment and Depreciation**

(Million yen)

	FY2014 Results	FY2015 Forecast	Amt Chg
Capital investment	1,239	4,000	2,761
Depreciation	2,665	2,500	-165

#### **Breakdown of Capital investment**

	FY2014 Results	FY2015 Forecast	Amt Chg
<nippon co.,ltd.="" shinyaku=""> Production</nippon>	1,160 510	3,850 700	2,690 190
(Manufacturing facility for highly active medicines)	(0)	(100)	(100)
R&D	508	2,600	2,092
(Manufacturing facility for investigational drugs)	(19)	(1,850)	(1,831)
Others	140	550	410
<sioe co.,ltd.="" pharmaceutical=""></sioe>	14	50	36
<tajima co.,ltd.="" kogyo="" shokuhin=""></tajima>	64	100	36
Total capital investment	1,239	4,000	2,761

## Status of Development Pipeline



## **R&D Pipeline(Domestic)**

Code No. (Generic name) <origin></origin>	Application type	Indications	Stage	FY2013	FY2014	FY2015	FY2016
GA101 (obinutuzumab) <in-license></in-license>	NME	indolent non-Hodgkin's lymphoma aggressive non-Hodgkin's	РШ	РШ			
		lymphoma  pulmonary arterial hypertension	Preparation For NDA	PII		NDA	
NS-304 (selexipag)	NME	chronic thromboembolic pulmonary hypertension	РШ			Filing	<b></b>
<in-house></in-house>		arteriosclerosis obliterans	PΙ	PI			
NS-141 <in-house></in-house>	NME	pruritus associated with cutaneous disease	PΙ	PΙΙ			-
NS-986 <in-license></in-license>	NME	nocturia	PΙΙ	PI .		PII	
NS-065/ NCNP-01 <in-house></in-house>	NME	duchenne muscular dystropy	Preparation For P II			РІ	
NS-580 <in-house></in-house>	NME	endometriosis	PΙ		PI 📥		



## **R&D Pipeline (Overseas)**

Code No. (Generic name) <origin></origin>	Application type	Indications	Stage	FY2013	FY2014	FY2015	FY2016
NS-304 (selexipag)	1/11//11	pulmonary arterial	US/EU	Actelion	NDA		
<in-house></in-house>	14141	hypertension	NDA Filing	РШ	Filing		
prulifloxacin	NME	bacterial infections	China Preparation	Lee's Pharn	na		NDA
<in-house></in-house>	INIVIE	bacteriai iriiections	For NDA	PⅢ			Filing
NS-018			US				
<in-house></in-house>	NIME IMVEIOTIDIOSIS			PI/I			



## GA101 (Obinutuzumab)

- Treatment for non-Hodgkin's lymphoma -

Develoment Phase	<ul><li>Overseas: PIII (Multinational studies, Roche)</li><li>Japan: PIII (Multinational studies)</li></ul>			
Origin	[Nov. 2012] Licensed-in from: Chugai Pharmaceutical Co., Ltd.			
Development	Co-development in Japan: Chugai Pharmaceutical Co., Ltd.			
Indication	<ul><li>Indolent non-Hodgkin's lymphoma</li><li>Aggressive non-Hodgkin's lymphoma</li></ul>			
Mechanism of action	Anti-CD20 monoclonal antibody			
Dosage form	Injection			
Feature	Anti-CD20 monoclonal antibody, increased antibody-dependent cellular cytotoxicity (ADCC) activity and direct cytotoxicity			



## NS-304 (Selexipag)

- Treatment for pulmonary hypertension -

Development phase	<ul><li>Overseas: NDA filing</li><li>Japan : Preparation for NDA</li></ul>
Origin	Nippon Shinyaku
Development	<ul> <li>[Apr. 2008]</li> <li>Licensed-out to (outside Japan):     Actelion Pharmaceuticals Ltd.(Switzerland)</li> <li>Co-development in Japan:     Actelion Pharmaceuticals Japan Ltd.</li> </ul>
Indication	<ul><li>Pulmonary arterial hypertension</li><li>Chronic thromboembolic pulmonary hypertension</li><li>Arteriosclerosis obliterans</li></ul>
Dosage form	Tablet
Mechanism of action	Selective PGI <sub>2</sub> receptor agonist
Feature	Long-acting oral drug Orphan drug designation by EMA [Aug.2005], FDA [Apr.2010] and MHLW [Sep.2014] Listed of 2015 ESC/ERS Guidelines for the diagnosis and treatment of pulmonary hypertension [Aug.2015]



## **NS-141**

### - Anti-pruritic drug -

Development phase	Additional PII (exploratory study)
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Indication	Pruritus associated with cutaneous disease
Dosage form	Ointment
Feature	<ul> <li>New mechanism of action (not antihistaminic)</li> <li>Effective against intractable pruritus which cannot be treated by existing treatments</li> </ul>



## NS-986

### - Treatment for nocturia -

Development phase	PII (exploratory study) completed
Origin	[Mar.2013] Licensed-in from: Dainippon Sumitomo Pharma Co., Ltd.
Development	Nippon Shinyaku
Indication	Nocturia
Dosage form/ Dosing regimen	Tablet
Mechanism of action	<ul><li>Muscarinic receptor antagonist</li><li>Na+ channel blocker</li></ul>
Feature	<ul> <li>Rapid onset of effect</li> <li>Improvement in nocturia refractory to existing antimuscarinic drugs</li> </ul>



## NS-065/NCNP-01

### Treatment for Duchenne Muscular Dystrophy -

Development Phase	An investigator-initiated clinical trial completed Preparation for PII
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Indication	Duchenne Muscular Dystrophy
Dosage form	Infusion
Mechanism of action	Exon Skipping
Feature	<ul> <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> <li>Selected by the Japanese MHLW as one of the projects for Sakigake designation[Oct.2015]</li> </ul>



## NS-580

### - Treatment for endometriosis -

Development Phase	PI
Origin	Nippon Shinyaku
Development	Nippon Shinyaku
Indication	Endometriosis
Dosage form	Oral agent
Mechanism of action	Inhibition of membrane-associated prostaglandin E syntase-1
Feature	Treatment for endometriosis without hormonal effect and with possible analgesic potency and improvement effect on endometriotic lesions.



## Prulifloxacin

### - Quinolone antibacterial -

#### Japan

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

#### **Overseas**

Licensee	Development phase
-Angelini (Italy)	<ul><li>Approval (Sep. 2004)</li><li>Launch in Italy (Nov. 2004)</li><li>Approval in European countries (Apr. 2005)</li></ul>
·Lee's Pharmaceutical Holdings Ltd. (Hong Kong)	China Preparation For NDA
-Algorithm (Lebanon)	<ul> <li>Launch in Lebanon (Jan. 2012)</li> <li>NDA filing in 7 countries and preparation for NDA in 2 countries of the Middle East and North Africa</li> </ul>



## **NS-018**

### - Treatment for myelofibrosis -

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



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- 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 causeactual outcomes and results to differ materially from these statements.
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  regulatory approvals; domestic and foreign social security reforms; trends toward healthcare cost
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