

N O B O R D E R

Going beyond it all, to the future of medicine.

Outline of Consolidated Financial Results for the 3rd Quarter Ended December 31, 2018

**February 6, 2019
NIPPON SHINYAKU CO., LTD.**



NIPPON SHINYAKU CO., LTD.

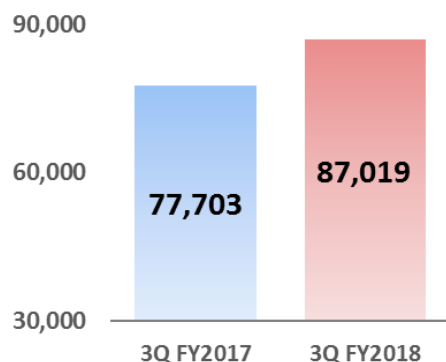
3Q FY2018 Summary



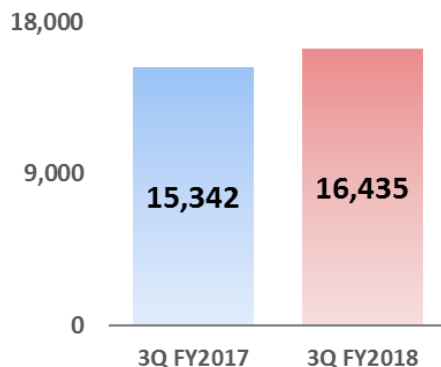
◆ Net sales	:	87,019 million yen	(+12.0%)
◆ Operating profit	:	16,435 million yen	(+7.1%)
◆ Ordinary profit	:	17,244 million yen	(+7.9%)
◆ Profit attributable to owners of parent	:	12,698 million yen	(+8.9%)

(Million yen)

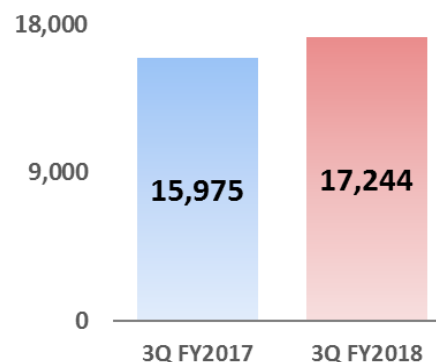
Net Sales



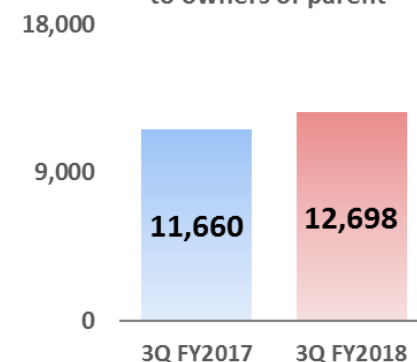
Operating Profit



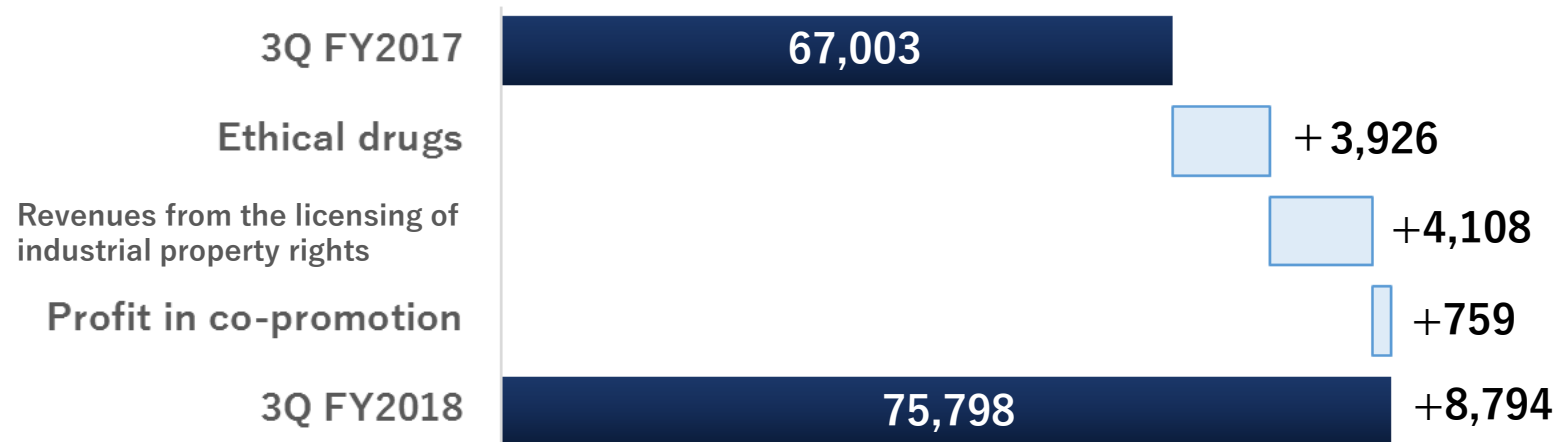
Ordinary Profit



Profit attributable to owners of parent



Segmental Review - Pharmaceuticals -



(Million yen)	3Q FY2017		3Q FY2018		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	56,010	83.6%	59,936	79.1%	+3,926	+7.0%
Revenues from the licensing of industrial property rights	7,854	11.7%	11,963	15.8%	+4,108	+52.3%
Profit in co-promotion	3,138	4.7%	3,898	5.1%	+759	+24.2%
Net sales	67,003	100.0%	75,798	100.0%	+8,794	+13.1%

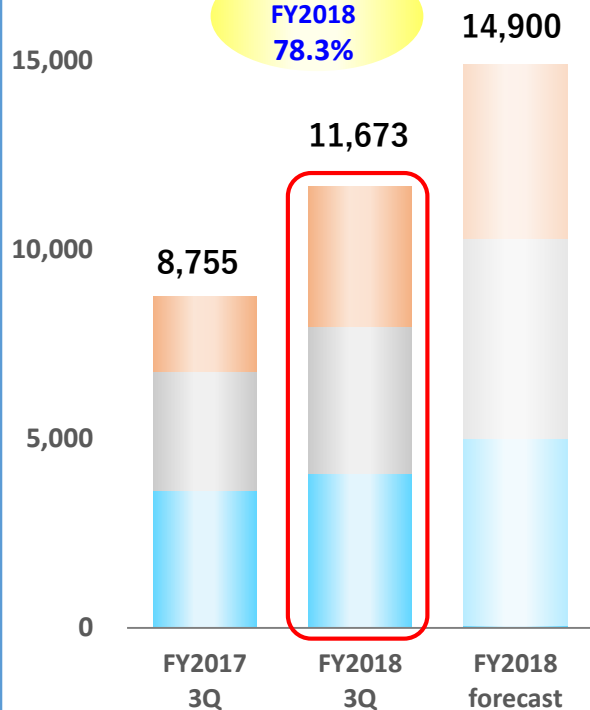
Three Main Fields of Focus



(million yen)

PAH

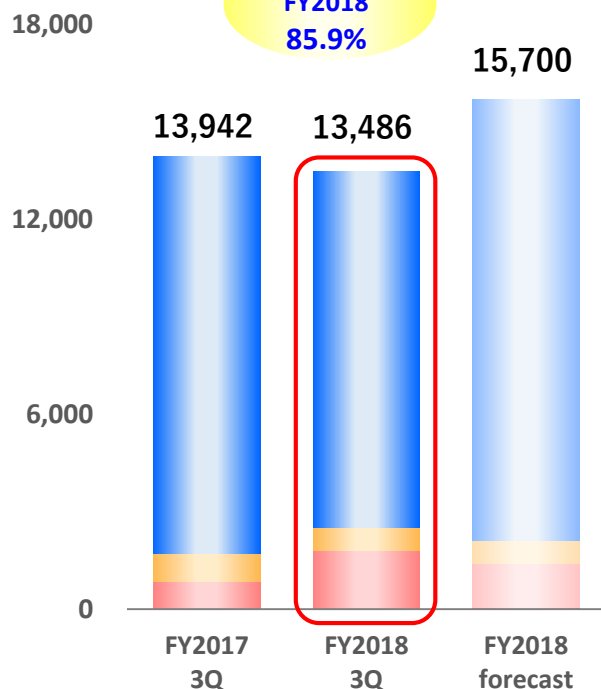
Progress for
FY2018
78.3%



Uptravi
Opsumit (Profit in co-promotion)
Adcirca

Hematology

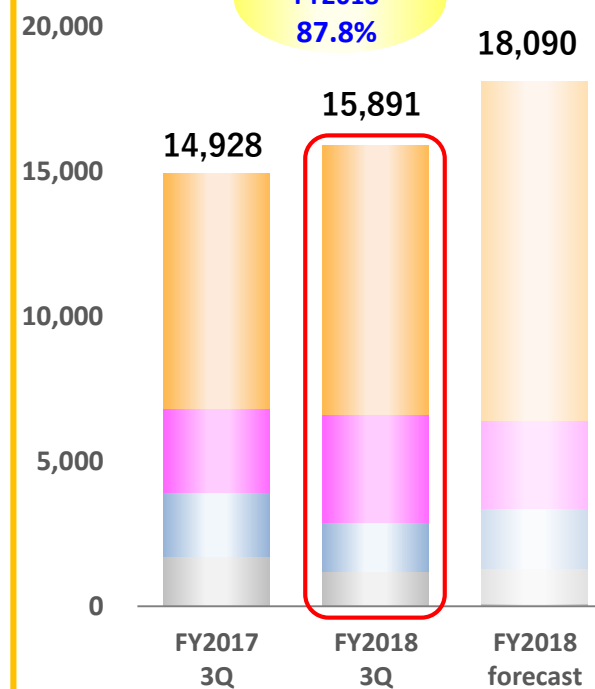
Progress for
FY2018
85.9%



Vidaza
Cycloide
Others

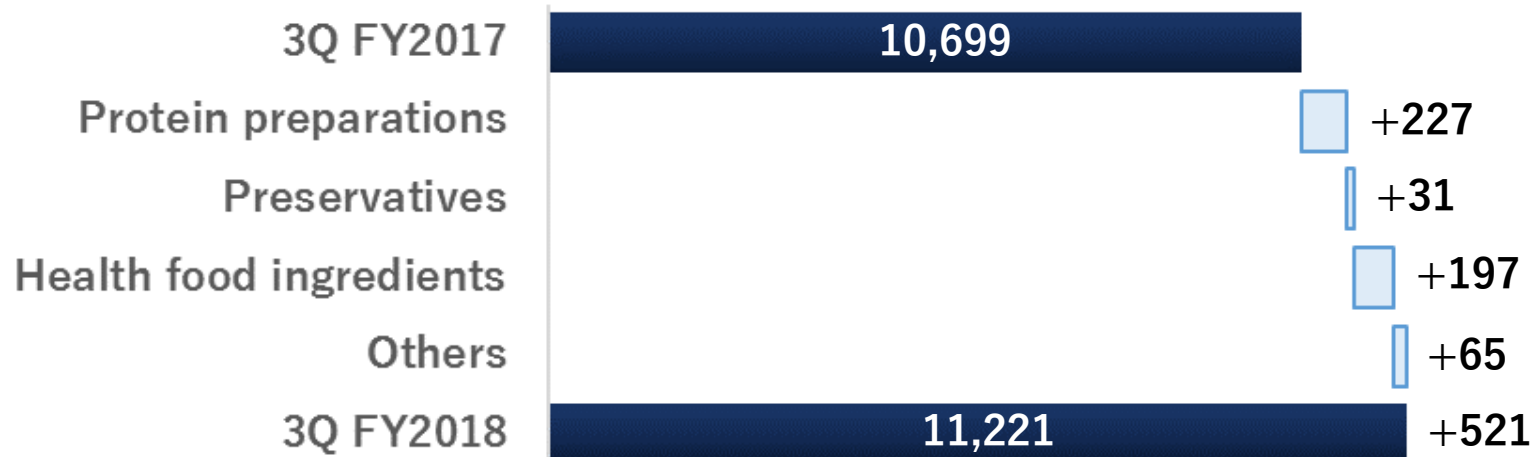
Urology

Progress for
FY2018
87.8%



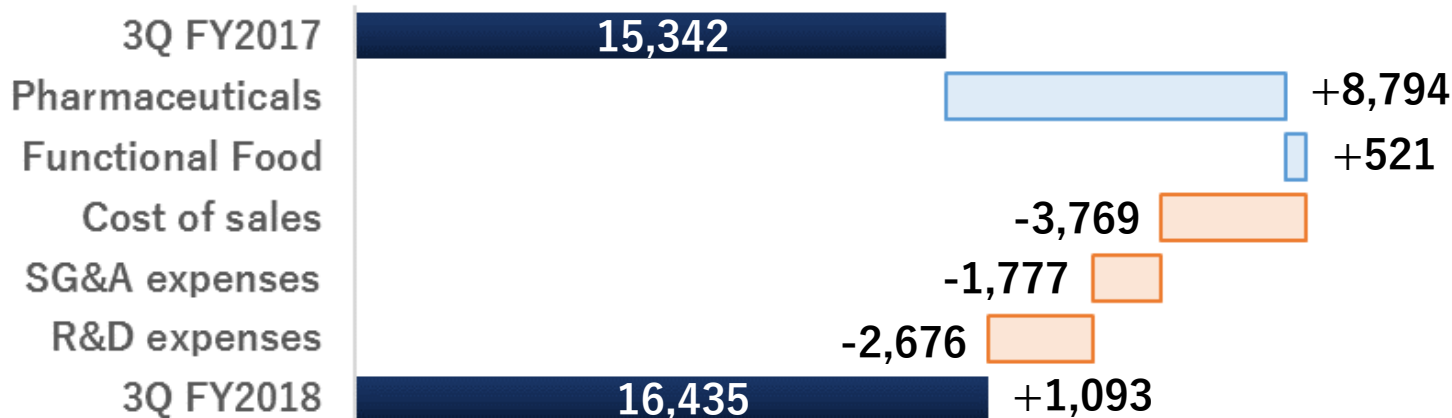
Zalutia
Eviprostat
Cialis
Others

Segmental Review - Functional Food -



(Million yen)	3Q FY2017		3Q FY2018		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	7,212	67.4%	7,439	66.3%	+227	+3.1%
Preservatives	1,782	16.7%	1,814	16.2%	+31	+1.8%
Health food ingredients	657	6.1%	855	7.6%	+197	+30.1%
Others	1,047	9.8%	1,112	9.9%	+65	+6.2%
Net sales	10,699	100.0%	11,221	100.0%	+521	+4.9%

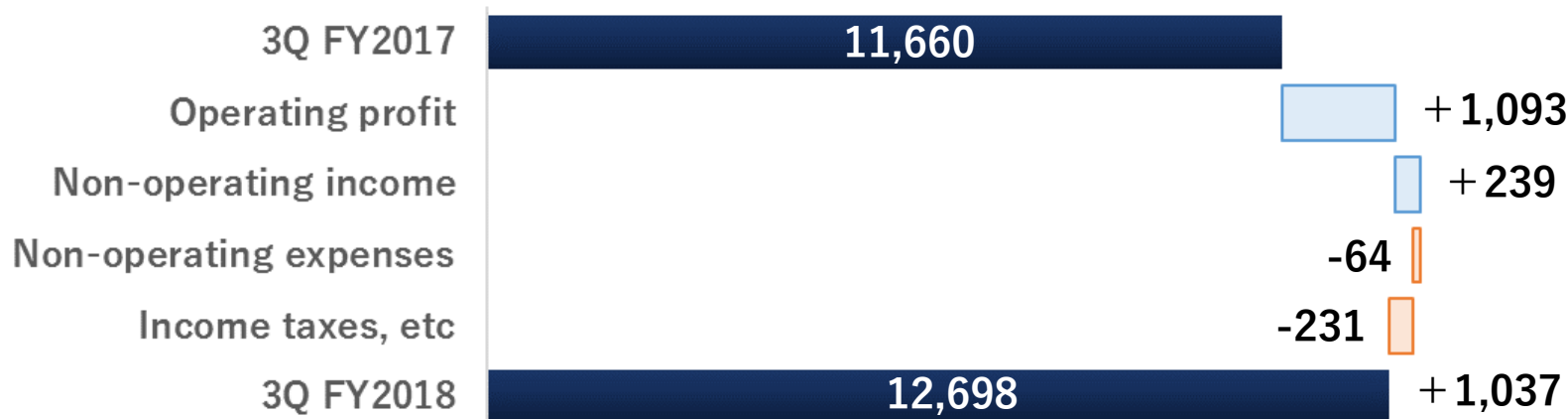
Operating profit



(Million yen)	3Q FY2017		3Q FY2018		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	77,703	100.0%	87,019	100.0%	+9,316	+12.0%
(Pharmaceuticals)	(67,003)	(86.2%)	(75,798)	(87.1%)	(+8,794)	(+13.1%)
(Functional Food)	(10,699)	(13.8%)	(11,221)	(12.9%)	(+521)	(+4.9%)
Operating expenses	62,361	80.3%	70,584	81.1%	+8,223	+13.2%
Cost of sales	35,321	45.5%	39,091	44.9%	+3,769	+10.7%
SG&A expenses	17,987	23.2%	19,765	22.7%	+1,777	+9.9%
R&D expenses	9,051	11.6%	11,727	13.5%	+2,676	+29.6%
Operating profit	15,342	19.7%	16,435	18.9%	+1,093	+7.1%



Profit attributable to owners of parent



(Million yen)	3Q FY2017	3Q FY2018	YoY Change	
	Results	Results	Amt	%
Operating profit	15,342	16,435	+1,093	+7.1%
Non-operating income	969	1,208	+239	+24.7%
Non-operating expenses	335	399	+64	+19.1%
Ordinary profit	15,975	17,244	+1,268	+7.9%
Income taxes, etc	4,314	4,546	+231	+5.4%
Profit attributable to owners of the parent	11,660	12,698	+1,037	+8.9%

Business Forecast for FY2018



(Million yen)	FY2017		FY2018			FY2018 (5th MMP)
	3Q Results	FY Results	3Q Results	Progress for FY	FY Forecast	
Net sales	77,703	101,448	87,019	80.6%	108,000	110,000
(Pharmaceuticals)	(67,003)	(87,416)	(75,798)	(81.0%)	(93,600)	-
(Functional Food)	(10,699)	(14,031)	(11,221)	(77.9%)	(14,400)	-
Operating profit	15,342	17,079	16,435	88.8%	18,500	18,000
Ordinary profit	15,975	17,451	17,244	90.8%	19,000	-
Profit attributable to owners of the parent	11,660	12,953	12,698	90.7%	14,000	12,000

MMP: Medium-Term Management Plan

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	NDA filing
NS-73 (defibrotide) <in-license>	NME	Veno-occlusive disease (treatment)					
	New indication	Veno-occlusive disease (prevention)					
NS-32 <in-license>	NME	Iron deficiency anemia				Preparation for PIII	
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-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy					
NS-917 <in-license>	NME	Relapsed/refractory acute myeloid leukemia					
NS-87 <in-license>	NME	Secondary acute myeloid leukemia					

 : change from the 2nd quarter

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					
NS-018 <in-house>	NME	Myelofibrosis					

Nippon Shinyaku has started a rolling submission
for NS-065/NCNP-01 to the U.S. FDA.

Reference Materials



NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet



(Million yen)	End of FY2017	End of 3Q FY2018	YoY Change Amt		End of FY2017	End of 3Q FY2018	YoY Change Amt
Assets	155,887	159,486	+3,599	Liabilities	30,197	27,273	-2,924
Current assets	95,176	103,217	+8,041	Current liabilities	22,454	20,670	-1,783
Fixed assets	60,710	56,269	-4,441	Long-term liabilities	7,743	6,602	-1,141
				Net assets	125,689	132,213	+6,524
Total assets	155,887	159,486	+3,599	Total liabilities and net assets	155,887	159,486	+3,599

= Assets =

Cash and deposits	+2,451
Notes and accounts receivable	+7,517
Inventories	-1,285
Property, plant and equipment	-469
Investments and other assets	-3,915

= Liabilities and Net assets =

Notes and accounts payable	-1,575
Accrued consumption taxes	+828
Provision for bonuses	-1,424
Net defined benefit liability	-1,144
Retained earnings	+8,993



- Treatment for iron deficiency anemia -

Development Phase	Japan: Preparation for 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"> • 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

NS-065/NCNP-01 (viltolarsen)



- Treatment for Duchenne muscular dystrophy -

Development Phase	<ul style="list-style-type: none">•USA : Rolling submission for NDA (plan to complete NDA in September 2019)•Japan: PI/II completion (under discussion with regulatory authority for early approval)
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">•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



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