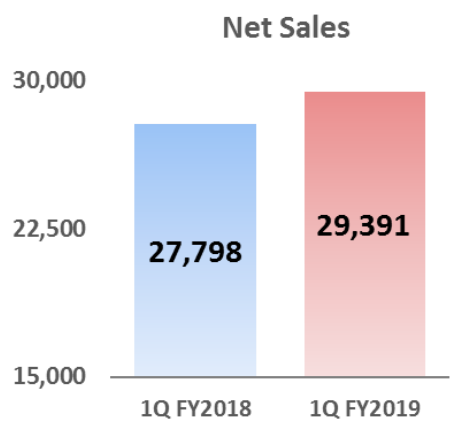
Outline of Consolidated Financial Results for the 1st Quarter Ended June 30, 2019

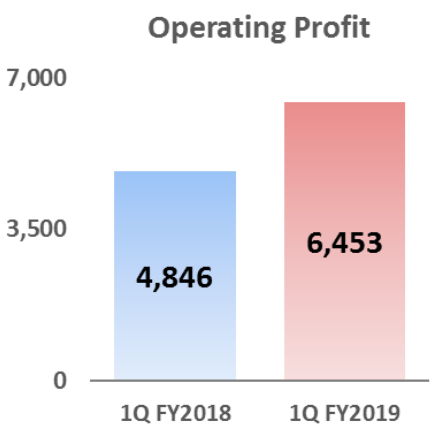
August 7, 2019
NIPPON SHINYAKU CO., LTD.

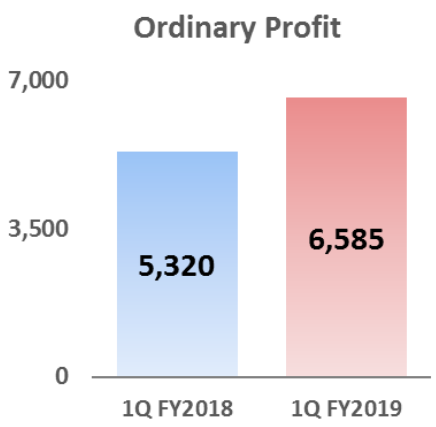
1Q FY2019 Summary

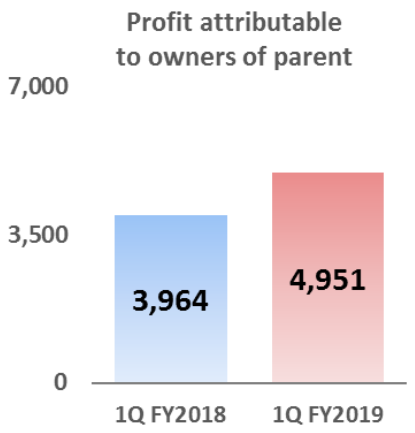
- **Net sales** : 29,391 million yen (+5.7%)
- **Operating profit** : 6,453 million yen (+33.1%)
- **Ordinary profit** : 6,585 million yen (+23.8%)
- **Profit attributable to owners of parent** : 4,951 million yen (+24.9%)

(Million yen)

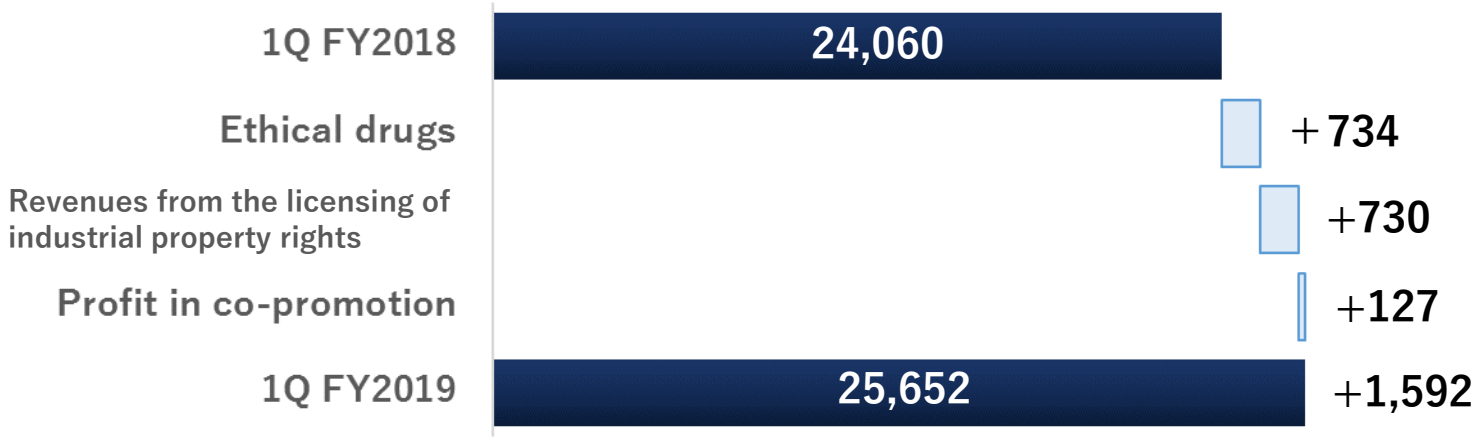








Segmental Review - Pharmaceuticals -

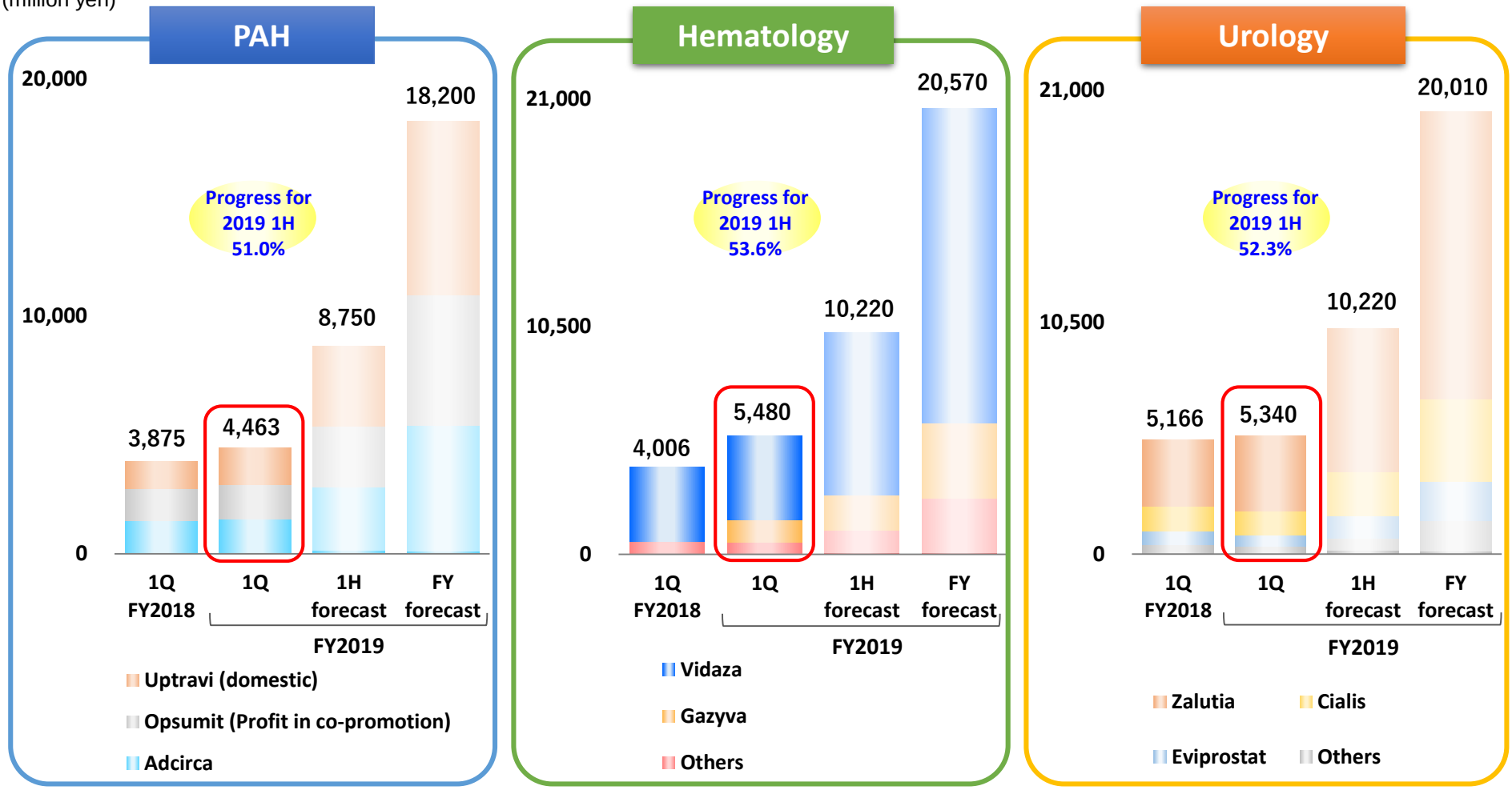


(Million yen)	1Q FY2018		1Q FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Ethical drugs	19,630	81.5%	20,365	79.4%	+734	+3.7%
Revenues from the licensing of industrial property rights	3,092	12.9%	3,822	14.9%	+730	+23.6%
Profit in co-promotion	1,337	5.6%	1,464	5.7%	+127	+9.6%
Net sales	24,060	100.0%	25,652	100.0%	+1,592	+6.6%

Net sales increased by 6.6% through growth of new products, revenues from the licensing of industrial property rights and profit in co-promotion.

Three Main Fields of Focus

(million yen)

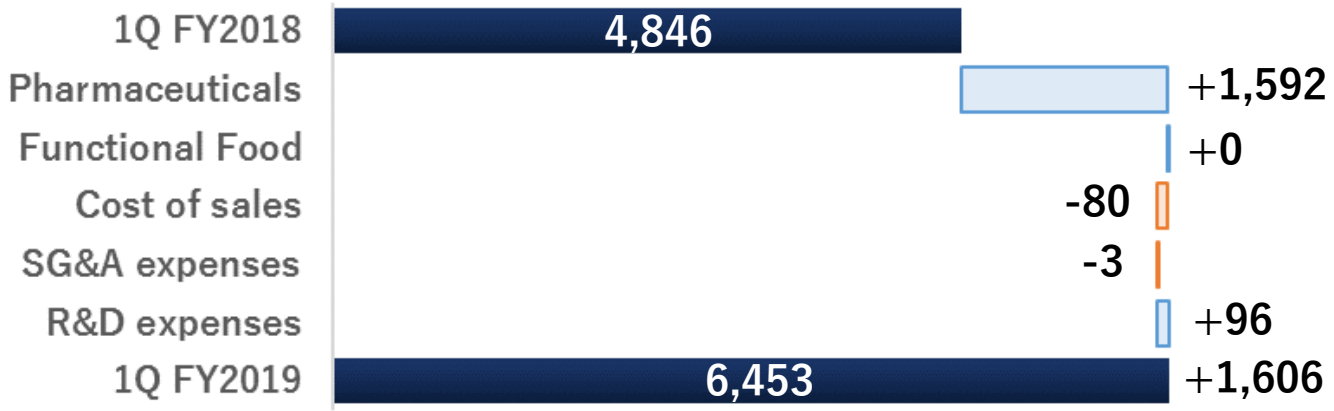


Sales in the focus fields have smoothly progressed toward 1H forecasts.

Segmental Review - Functional Food -

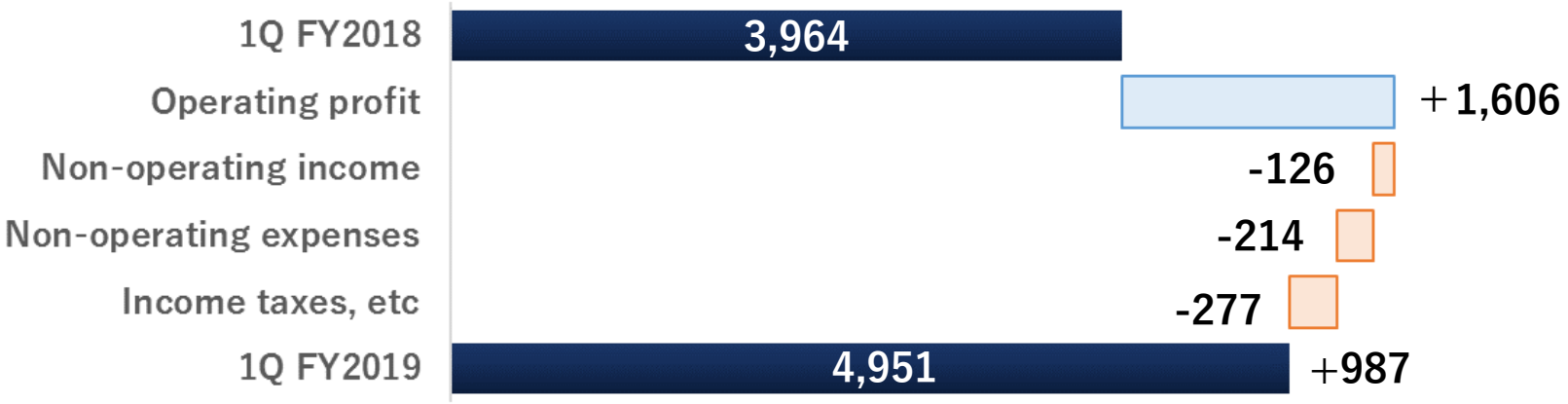
(Million yen)	1Q FY2018		1Q FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Protein preparations	2,519	67.4%	2,491	66.6%	-27	-1.1%
Preservatives	563	15.1%	570	15.3%	+6	+1.2%
Health food ingredients	281	7.5%	277	7.4%	-4	-1.6%
Others	373	10.0%	400	10.7%	+26	+7.1%
Net sales	3,738	100.0%	3,739	100.0%	+0	+0.0%

Operating profit



(Million yen)	1Q FY2018		1Q FY2019		YoY Change	
	Results	Ratio	Results	Ratio	Amt	%
Net sales	**27,798**	**100.0%**	**29,391**	**100.0%**	**+1,593**	**+5.7%**
(Pharmaceuticals)	(24,060)	(86.6%)	(25,652)	(87.3%)	(+1,592)	(+6.6%)
(Functional Food)	(3,738)	(13.4%)	(3,739)	(12.7%)	(+0)	(+0.0%)
Operating expenses	**22,951**	**82.6%**	**22,938**	**78.0%**	**-12**	**-0.1%**
Cost of sales	**13,220**	**47.6%**	**13,300**	**45.3%**	**+80**	**+0.6%**
SG&A expenses	**6,665**	**24.0%**	**6,668**	**22.6%**	**+3**	**+0.1%**
R&D expenses	**3,065**	**11.0%**	**2,969**	**10.1%**	**-96**	**-3.2%**
Operating profit	**4,846**	**17.4%**	**6,453**	**22.0%**	**+1,606**	**+33.1%**

Profit attributable to owners of parent



(Million yen)	1Q FY2018 Results	1Q FY2019 Results	YoY Change Amt	YoY Change %
Operating profit	4,846	6,453	+1,606	+33.1%
Non-operating income	582	455	-126	-21.8%
Non-operating expenses	108	323	+214	+197.9%
Ordinary profit	5,320	6,585	+1,264	+23.8%
Income taxes, etc	1,356	1,634	+277	+20.5%
Profit attributable to owners of parent	3,964	4,951	+987	+24.9%

Business Forecast for FY2019

(Million yen)	FY2018		FY2019			
	1Q Results	FY Results	1Q Results	Progress for 1H	1H Forecasts	FY Forecasts
Net sales	**27,798**	**114,716**	**29,391**	**51.6%**	**57,000**	**116,000**
(Pharmaceuticals)	(24,060)	(100,223)	(25,652)	(51.7%)	(49,600)	(101,100)
(Functional Food)	(3,738)	(14,492)	(3,739)	(50.5%)	(7,400)	(14,900)
Operating profit	**4,846**	**20,644**	**6,453**	**64.5%**	**10,000**	**21,000**
Ordinary profit	**5,320**	**21,540**	**6,585**	**61.5%**	**10,700**	**22,000**
Profit attributable to owners of parent	**3,964**	**16,302**	**4,951**	**60.4%**	**8,200**	**16,500**

Sales of pharmaceuticals and functional food, and each profit have progressed toward achievement of 1H, FY forecasts.

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	Preparation for launching
NS-73 (defibrotide) <in-license>	NME	Sinusoidal obstruction syndrome/ Veno-occlusive disease (treatment)					2019.6 Approval
	New indication	Sinusoidal obstruction syndrome/ Veno-occlusive disease (prevention)					
NS-32 <in-license>	NME	Iron deficiency anemia					
ZX-008 <in-license>	NME	Dravet syndrome Lennox-Gastaut syndrome					
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-87 <in-license>	NME	Secondary acute myeloid leukemia			Preparation for PI/II		
NS-917 <in-license>	NME	Relapsed/refractory acute myeloid leukemia					

: changes from the Fiscal Year Ended March 31, 2019

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-304 (selexipag) <in-house>	New indication	Chronic thromboembolic pulmonary hypertension					
NS-065/NCNP-01 (viltolarsen) <in-house>	NME	Duchenne muscular dystrophy					
NS-018 <in-house>	NME	Myelofibrosis					

NS-065/NCNP-01: in the process of a rolling submission to the U.S. FDA.

Reference Materials

NIPPON SHINYAKU CO., LTD.

Consolidated Balance Sheet

(Million yen)	End of FY2018	End of 1Q FY2019	YoY Change Amt		End of FY2018	End of 1Q FY2019	YoY Change Amt
Assets	168,763	168,934	+170	Liabilities	33,572	32,626	-945
Current assets	110,720	110,657	-63	Current liabilities	25,406	24,846	-560
Fixed assets	58,042	58,276	+233	Long-term liabilities	8,165	7,780	-385
				Net assets	135,190	136,307	+1,116
Total Asset	168,763	168,934	+170	Total liabilities and net assets	168,763	168,934	+170

＝Assets＝

Cash and deposits	+332
Notes and accounts receivable	-481
Securities	-490
Inventories	-168
Investment securities	-1,664
Long-term prepaid expenses	+959

＝Liabilities and Net assets＝

Notes and accounts payable	+549
Accounts payable	-883
Income taxes payable	-1,698
Provision for bonuses	+1,451
Retained earnings	+2,189

NS-73 (defibrotide)
- Treatment of hepatic sinusoidal obstruction syndrome -

Development Phase	Japan : Preparation for launching (treatment) Japan : PIII (prevention)
Origin	[Mar. 2017] Licensed-in from : Jazz Pharmaceuticals
Development	Nippon Shinyaku in Japan (treatment) Co-development in Japan : Jazz Pharmaceuticals (prevention)
Mechanism of action	Protective action on vascular endothelium, normalization of the coagulation/fibrinolysis balance
Indication	Sinusoidal obstruction syndrome (SOS)/ Veno-occlusive disease (VOD)
Dosage form	Injection
Feature	・SOS/VOD is a life-threatening complication which develops in patients following HSCT, and in severe cases, leading to death at high rates. ・NS-73 is the only drug for the treatment of SOS/VOD (EU/US guideline). It has been launched in various countries. ・NS-73 is the only drug for the prevention of SOS/VOD.

NS-87
- Treatment of secondary acute myeloid leukemia -

Development Phase	Japan: Preparation for 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.

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