Supplementary Materials for Consolidated Financial Results for Fiscal Year 2010. 12



- Notes: 1. Portions of this report that refer to performance forecasts or any other future events are believed to be reasonable under information available at the time of the forecasts. Actual results may materially differ from these forecasts due to potential risks and uncertainties.
  - 2. Amounts shown in Financial Highlights, Extraordinary Gains and Losses, Statements of Revenues, Balance Sheets, Cash Flows and Capital Expenditures etc. of this report are rounded to the nearest 0.1 billion yen. Variance and % are calculated based on the amounts shown.
  - 3. Exchange rates used for each period are as follows.

											(Yen)
											Forecast
	FY2007	FY2008		FY2	009			FY2	010		FY2011
	1-12	1-12	1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12	1-12
	(Full-year)	(Full-year)	(YTD)	(Full-year)							
Fx rates	average	average	average	average	average	average	average	average	average	average	forecast
CHF	98.13	95.54	81.55	84.52	85.68	86.20	85.80	84.42	84.00	84.17	85.00
EUR	161.17	151.38	122.06	127.19	129.32	130.10	125.58	121.21	117.66	116.32	110.00
USD	117.80	103.44	93.51	95.46	94.87	93.60	90.69	91.41	89.56	87.81	85.00
GBP	235.66	189.85	134.34	142.14	145.77	145.99	141.62	139.45	137.32	135.65	131.00

(Yen)

## Financial Highlights (YTD)

(Billions of Yen)

(Billions of Yen)

														(Billions of	Yen)
													Forec		
	FY2007	FY2008		FY2	009				FY	2010			FY2		
	1-12	1-12	1-3	1-6	1-9	1-12		Change	1-6 Change	1-9 Change	1-12 Change		Change		Change
	Full-year	Full-year	YTD	YTD	YTD	YTD	YTD	(%)	YTD <sup>(%)</sup>	YTD <sup>(%)</sup>	YTD <sup>(%)</sup>	Half-year		Full-year	(%)
Revenues	344.8	326.9	94.7	191.7	309.7	428.9	87.1	-8.0	182.4 -4.		379.5 -11.5	190.0	+4.2	403.0	+6.2
Sales	332.9	321.8	92.9	185.9	303.4	419.1	86.2	-7.2	180.6 -2.		375.6 -10.4	182.5	+1.1	391.7	+4.3
excl. Tamiflu	294.3	313.4	72.5	160.6	247.6	342.9	75.4	+4.0	168.6 +5.		357.4 +4.2	176.8	+4.9	379.5	+6.2
Tamiflu	38.7	8.4	20.4	25.4	55.8	76.2		-47.1	12.0 -52.		18.2 -76.1	•	-52.5	12.2	-33.0
Ordinary sales	10.2	7.1	6.0	11.0	18.5	36.2		-76.7	1.4 -87.		1.6 -95.6	5.3 +2	278.6		+387.5
Govt. stockpile etc.	28.5	1.3	14.4	14.4	37.3	40.0		-34.0	10.6 -26.4		16.6 -58.5		-96.2	4.4	-73.5
Other operating revenues	11.9	5.1	1.8	5.7	6.3	9.8	0.9	-50.0	1.7 -70.		3.9 -60.2	7.5 +3	341.2		+189.7
Cost of sales	137.3	127.0	43.7	83.9	143.3	192.9	41.1	-5.9	80.5 -4.		162.4 -15.8	-	-	167.8	+3.3
(% of Sales)	41.2	39.5	47.0	45.1	47.2	46.0	47.7	-	44.6	- 43.8 -	43.2 -	_	-	42.8	-
Gross profit	207.5	199.9	51.0	107.8	166.4	236.1	46.0	-9.8	101.8 -5.		217.1 -8.0	_	-	235.2	+8.3
(% of Revenues)	60.2	61.2	53.9	56.2	53.7	55.0	52.8	-	55.8	- 56.7 -	57.2 -	_	-	58.4	-
SG&A (excl. R&D) expenses	86.6	95.1	21.6	46.1	69.8	98.2	22.8	+5.6	47.7 +3.	5 71.4 +2.3	96.2 -2.0	-	-	101.0	+5.0
(% of Revenues)	25.1	29.1	22.8	24.0	22.5	22.9	26.2	-	26.2	- 25.9 -	25.3 -	_	-	25.1	-
R&D expenses	54.2	53.2	11.8	24.5	37.8	55.3	12.2	+3.4	26.6 +8.		54.7 -1.1	-	-	59.2	+8.2
(% of Revenues)	15.7	16.3	12.5	12.8	12.2	12.9	14.0	-	14.6	- 14.5 -	14.4 -	_	-	14.7	-
Operating income	66.7	51.6	17.5	37.2	58.8	82.6	11.1	-36.6	27.6 -25.		66.2 -19.9		+23.2	75.0	+13.3
(% of Revenues)	19.3	15.8	18.5	19.4	19.0	19.3	12.7	-	15.1	- 16.3 -	17.4 -	17.9	-	18.6	-
Non-operating income	4.3	9.9	5.4	6.9	7.8	9.4	11.	-75.9	3.0 -56.		2.4 -74.5	_	-	-	-
Non-operating expenses	3.3	4.2	0.2	0.6	0.5	1.6	0.3	+50.0	4.4 +633.	3.0 +500.0	3.5 +118.8	-	-	-	-
Recurring profit	67.7	57.3	22.8	43.5	66.0	90.4	12.1	-46.9	26.2 -39.	44.3 -32.9	65.1 -28.0	34.5	+31.7	75.5	+16.0
(% of Revenues)	19.6	17.5	24.1	22.7	21.3	21.1	13.9	-	14.4	- 16.0 -	17.2 -	18.2	-	18.7	-
Extraordinary gain	0.3	7.3	0.3	0.3	0.3	0.3		-66.7	0.1 -66.	•	0.6 +100.0	-	-	-	-
Extraordinary loss	1.6	1.4	0.0	0.1	0.1	1.3	0.0	-	0.1 +0.	0.1 +0.0	0.0 -100.0	_	-	-	-
Income before income taxes etc.	66.4	63.1	23.1	43.7	66.3	89.4		-47.6	26.1 -40.	3 44.3 -33.2	65.7 -26.5	_	-	-	-
(% of Revenues)	19.3	19.3	24.4	22.8	21.4	20.8	13.9	-	14.3	- 16.0 -	17.3 -	-	-	-	-
Net income	40.1	39.3	13.8	26.3	40.9	56.6	7.9	-42.8	16.4 -37.		41.4 -26.9	17.0	+3.7	42.5	+2.7
(% of Revenues)	11.6	12.0	14.6	13.7	13.2	13.2	9.1	-	9.0	- 10.2 -	10.9 -	8.9	-	10.5	-

#### Extraordinary Gains and Losses

Extraordinary Gains

	Amount	Description
Restructuring and liquidation gains		This is mainly arising from the expenses that the Company expected to incur in connection with closing down Kamakura Plant for the restructuring of manufacturing function were lower than originally expected.

## Financial Highlights (QTR)

(Billions of Yen)

																	(Billions of	: Yen)
																Forec	asts	
	FY2007	FY2008		FY20	009					FY2010	0					FY2	D11	
	1-12	1-12	1-3	4-6	7–9	10-12	1-3	Change		nange		Change	10-12	Change	1-6	Change	7-12	Change
	Full-year	Full-year	QTR	QTR	QTR	QTR	QTR	(%)	QTR	(%)	QTR	(%)	QTR	(%)	1st Half	(%)	2nd Half	(%)
Rev <u>enues</u>	344.8	326.9	94.7	97.0	118.0	119.2	87.1	-8.0		-1.8		-20.6	103.4	-13.3	190.0	+4.2	213.0	+8.1
Sales	332.9	321.8	92.9	93.0	117.5	115.7	86.2	-7.2		+1.6		-21.2	102.3	-11.6	182.5	+1.1	209.2	+7.3
excl. Tamiflu	294.3	313.4	72.5	88.1	87.0	95.3	75.4	+4.0		+5.9	88.8	+2.1	100.0	+4.9	176.8	+4.9	202.7	+7.4
Tamiflu	38.7	8.4	20.4	5.0	30.4	20.4	10.8	-47.1		76.0		-87.5	2.3	-88.7	5.7	-52.5	6.5	+6.6
Ordinary sales	10.2	7.1	6.0	5.0	7.6	17.7	1.4	-76.7	0.0 -1	00.0		-100.0	0.2	-98.9	5.3	+278.6	2.5	+1,150.0
Govt. stockpile etc.	28.5	1.3	14.4	-	22.9	2.7	9.5	-34.0	1.2	-	3.8	-83.4	2.1	-22.2	0.4	-96.2	4.0	-32.2
Other operating revenues	11.9	5.1	1.8	4.0	0.5	3.6	0.9	-50.0		80.0		+120.0	1.1	-69.4	7.5	+341.2	3.8	+72.7
Cost of sales	137.3	127.0	43.7	40.1	59.4	49.5	41.1	-5.9		-1.5		-34.2	42.8	-13.5	-	-	-	
(% of Sales)	41.2	39.5	47.0	43.1	50.6	42.8	47.7	-	41.8	-	42.2	-	41.8	-	-	-	-	-
Gross profit	207.5	199.9	51.0	56.9	58.6	69.7	46.0	-9.8	55.8	-1.9	54.6	-6.8	60.6	-13.1	-	-	-	-
(% of Revenues)	60.2	61.2	53.9	58.7	49.7	58.5	52.8	-	58.6	-	58.3	-	58.6	-	-	-	-	i –
SG&A (excl. R&D) expenses	86.6	95.1	21.6	24.5	23.7	28.3	22.8	+5.6	24.9	+1.6	23.7	+0.0	24.7	-12.7	-	-	-	
(% of Revenues)	25.1	29.1	22.8	25.3	20.1	23.7	26.2	-	26.1	-	25.3	-	23.9	-	-	-	-	
R&D expenses	54.2	53.2	11.8	12.7	13.3	17.5	12.2	+3.4	14.4 +	13.4	13.3	+0.0	14.8	-15.4	-	-	-	ı –
(% of Revenues)	15.7	16.3	12.5	13.1	11.3	14.7	14.0	-	15.1	-	14.2	-	14.3	-	-	-	-	-
Operating income	66.7	51.6	17.5	19.6	21.6	23.8	11.1	-36.6	16.5 -	15.8	17.6	-18.5	21.1	-11.3	34.0	+23.2	41.0	+5.9
(% of Revenues)	19.3	15.8	18.5	20.2	18.3	20.0	12.7	-	17.3	-	18.8	-	20.4	-	17.9	-	19.2	-
Non-operating income	4.3	9.9	5.4	1.5	1.2	1.7	1.3	-75.9	1.7 +	13.3	1.6	+33.3	0.5	-70.6	-	-	-	
Non-operating expenses	3.3	4.2	0.2	0.5	0.2	1.1	0.3	+50.0		20.0		+450.0	0.7	-36.4	-	-	-	
Recurring profit	67.7	57.3	22.8	20.7	22.6	24.4	12.1	-46.9	14.1 -	31.9	18.1	-19.9	20.8	-14.8	34.5	+31.7	41.0	+5.4
(% of Revenues)	19.6	17.5	24.1	21.3	19.2	20.5	13.9	-	14.8	-	19.3	-	20.1	-	18.2	-	19.2	-
Extraordinary gain	0.3	7.3	0.3	-	0.0	-	0.1	-66.7	-	-	0.1	-	0.6	-	-	-	-	
Extraordinary loss	1.6	1.4	0.0	0.0	0.0	1.2	0.0	-	0.0	-	0.0	-	0.0	-100.0	-	-	-	
Income before income taxes etc.	66.4	63.1	23.1	20.6	22.6	23.2	12.1	-47.6	14.1 -	31.6	18.2	-19.5	21.4	-7.8	-	-	-	-
(% of Revenues)	19.3	19.3	24.4	21.2	19.2	19.5	13.9	-	14.8	-	19.4	-	20.7	-	-	-	-	
Net income	40.1	39.3	13.8	12.5	14.6	15.7	7.9	-42.8	8.5 –	32.0	11.7	-19.9	13.4	-14.6	17.0	+3.7	25.5	+1.6
(% of Revenues)	11.6	12.0	14.6	12.9	12.4	13.2	9.1	-	8.9	-	12.5	-	13.0	-	8.9	-	12.0	-

#### Statements of Revenues (YTD)

(Billions of Yen)

																		(Billions o	of Y
																	Fore		
		FY2007	FY2008		FY2						FY2						FY2		
		1-12	1-12	1-3	1-6	1-9	1-12	1-3	Change	1-6	Change	1-9	Change	1-12	Change	1-6	Change	1-12	Ch
		Full-year	Full-year	YTD	YTD	YTD	YTD	YTD	(%)	YTD	(%)	YTD	(%)	YTD	(%)	Half-year	(%)	Full-year	-
es		332.9	321.8	92.9	185.9	303.4	419.1	86.2	-7.2	180.6	-2.9	273.3	-9.9	375.6	-10.4	182.5	+1.1	391.7	
Excl. T		294.3	313.4	72.5	160.6	247.6	342.9	75.4	+4.0	168.6	+5.0	257.4	+4.0	357.4	+4.2	176.8	+4.9	379.5	
Dor	nestic	263.1	279.9	66.2	146.3	223.9	309.3	68.0	+2.7	150.6	+2.9	231.3	+3.3	324.4	+4.9	157.5	+4.6	340.8	
	Oncology field	74.0	102.3	25.7	57.8	88.9	123.7	28.8	+12.1	64.6	+11.8	100.1	+12.6	141.2	+14.1	69.4	+7.4	153.5	_
	Avastin *1	3.5	20.1	6.7	15.4	24.3	34.9	10.3	+53.7	23.3	+51.3	36.8	+51.4	52.6	+50.7	28.8	+23.6	64.8	
	Herceptin	16.1	23.7	6.6	14.7	22.0	29.7	5.7	-13.6	12.1	-17.7	18.3	-16.8	25.3	-14.8	11.8	-2.5	24.6	
	Rituxan	18.6	20.5	4.3	9.7	15.1	21.1	4.5	+4.7	10.3	+6.2	16.1	+6.6	23.0	+9.0	10.5	+1.9	23.5	_
	Xeloda	2.7	4.8	1.3	2.8	4.4	6.6	2.3	+76.9	5.1	+82.1	7.8	+77.3	10.7	+62.1	5.0	-2.0	11.7	
	Neutrogin	12.6	12.0	2.2	5.2	8.2	11.3	2.0	-9.1	4.6	-11.5	7.2	-12.2	10.4	-8.0	4.6	+0.0	10.4	_
	Tarceva *1	0.2	4.5	1.2	2.7	4.1	5.8	1.4	+16.7	3.5	+29.6	5.5	+34.1	7.9	+36.2	4.0	+14.3	8.8	
	Kytril	13.6	10.9	2.1	4.5	6.6	8.6	1.5	-28.6	3.0	-33.3	4.3	-34.8	5.5	-36.0	1.8	-40.0	3.9	_
	Femara	1.0	1.7	0.5	1.1	1.7	2.4	0.6	+20.0	1.4	+27.3	2.2	+29.4	3.2	+33.3	1.7	+21.4	3.8	
	Other products	5.6	4.1	0.8	1.7	2.5	3.3	0.6	-25.0	1.3	-23.5	1.9	-24.0	2.5	-24.2	1.0	-23.1	2.0	_
	Bone and joint diseases field	46.6	50.0	12.2	26.9	41.2	57.6	13.0	+6.6	28.6	+6.3	44.1	+7.0	62.6	+8.7	31.8	+11.2	68.8	
	Evista	16.0	16.5	3.8	8.4	12.8	17.9	3.8	+0.0	8.6	+2.4	13.1	+2.3	18.7	+4.5	8.3	-3.5	17.5	
	Actemra	0.5	3.4	1.5	3.5	5.7	8.4	2.6	+73.3	5.8	+65.7	9.4	+64.9	14.1	+67.9	9.6	+65.5	21.8	
	Suvenyl	11.0	12.0	2.8	6.5	10.0	13.7	2.9	+3.6	6.4	-1.5	9.7	-3.0	13.6	-0.7	6.7	+4.7	14.4	
	Alfarol	14.3	13.7	3.0	6.5	9.9	13.6	2.7	-10.0	5.9	-9.2	8.8	-11.1	12.3	-9.6	5.2	-11.9	11.1	Τ
	Other products	4.8	4.5	1.1	2.1	2.8	3.9	1.0	-9.1	1.9	-9.5	3.1	+10.7	4.0	+2.6	1.9	+0.0	4.0	
	Renal diseases field	69.6	61.3	13.0	28.8	44.4	61.0	12.5	-3.8	27.2	-5.6	41.7	-6.1	57.4	-5.9	26.6	-2.2	56.7	
	Epogin	54.8	44.9	9.4	20.8	32.3	44.4	8.7	-7.4	19.0	-8.7	29.2	-9.6	40.0	-9.9	18.5	-2.6	39.2	
	Oxarol	8.7	10.0	2.2	4.9	7.7	10.6	2.5	+13.6	5.6	+14.3	8.6	+11.7	12.0	+13.2	5.7	+1.8	12.4	
	Renagel	5.6	5.7	1.3	2.7	4.0	5.3	1.1	-15.4	2.3	-14.8	3.5	-12.5	4.9	-7.5	2.2	-4.3	4.6	
	Other products	0.5	0.7	0.2	0.4	0.5	0.7	0.2	+0.0	0.3	-25.0	0.4	-20.0	0.5	-28.6	0.2	-33.3	0.5	
	Transplant, Immunology & Infectious diseases field	17.7	24.0	5.9	12.8	19.3	26.2	5.3	-10.2	11.9	-7.0	18.3	-5.2	25.8	-1.5	11.6	-2.5	25.2	T
	Pegasys	6.3	9.7	2.5	5.5	8.2	11.1	2.2	-12.0	4.8	-12.7	7.4	-9.8	10.5	-5.4	4.9	+2.1	10.7	
	Copegus *1	2.0	4.2	1.1	2.4	3.6	4.9	0.9	-18.2	2.0	-16.7	3.1	-13.9	4.5	-8.2	2.2	+10.0	4.7	
	Rocephin	5.7	5.9	1.3	2.7	4.1	5.5	1.1	-15.4	2.6	-3.7	3.9	-4.9	5.4	-1.8	1.8	-30.8	3.7	Τ
	CellCept	3.5	4.0	0.9	2.1	3.2	4.4	1.0	+11.1	2.3	+9.5	3.6	+12.5	5.2	+18.2	2.7	+17.4	5.8	
	Other products	0.3	0.3	0.1	0.1	0.2	0.3	0.1	+0.0	0.1	+0.0	0.2	+0.0	0.3	+0.0	0.1	+0.0	0.3	
	Others field	55.1	42.3	9.4	20.0	30.1	40.9	8.3	-11.7	18.3	-8.5	27.1	-10.0	37.4	-8.6	18.0	-1.6	36.6	
	Sigmart	15.2	15.0	3.3	7.1	10.6	14.7	2.9	-12.1	6.3	-11.3	9.4	-11.3	13.0	-11.6	6.2	-1.6	12.6	T
	SA products *2	11.2	-	_	-	-	-	-	-	_	-	-	-	-	-	-	-	_	Τ
	Other products	28.8	27.3	6.2	13.0	19.4	26.3	5.4	-12.9	12.0	-7.7	17.7	-8.8	24.4	-7.2	11.9	-0.8	24.0	Τ
Ove	erseas	31.2	33.5	6.3	14.2	23.7	33.6	7.4	+17.5	18.1	+27.5	26.1	+10.1	33.0	-1.8	19.3	+6.6	38.7	
	Neutrogin	26.6	25.9	4.8	10.2	15.8	21.3	4.4	-8.3	8.8	-13.7	13.0	-17.7	17.0	-20.2	6.9	-21.6	13.6	T
	Actemra	1	3.8	0.4	1.8	5.1	8.9	2.0	+400.0	7.4	+311.1	10.5	+105.9	12.7	+42.7	10.5	+41.9	21.7	T
	Sigmart	2.8	2.0	0.6	1.3	1.5	1.9	0.8	+33.3	1.3	+0.0	1.8	+20.0	2.2	+15.8	1.3	+0.0	2.2	T
	Other products	1.9	1.7	0.5	1.0	1.2	1.5	0.2	-60.0	0.5	-50.0	0.8	-33.3	1.2	-20.0	0.7	+40.0	1.1	
Tamiflu		38.7	8.4	20.4	25.4	55.8	76.2	10.8	-47.1	12.0	-52.8	15.8	-71.7	18.2	-76.1	5.7	-52.5	12.2	
	Ordinary sales	10.2	7.1	6.0	11.0	18.5	36.2	1.4	-76.7	1.4	-87.3	1.4	-92.4	1.6	-95.6	5.3	+278.6	7.8	_
	Govt. stockpile etc.	28.5	1.3	14.4	14.4	37.3	40.0	9.5	-34.0	10.6	-26.4	14.4	-61.4	16.6	-58.5	0.4	-96.2	4.4	
er oper	rating revenues	11.9	5.1	1.8	5.7	6.3	9.8	0.9	-50.0	1.7	-70.2	2.8	-55.6	3.9	-60.2	7.5	+341.2	11.3	_
enues		344.8	326.9	94.7	191.7	309.7	428.9	87.1	-8.0	182.4	-4.9	276.1	-10.8	379.5	-11.5	190.0	+4.2	403.0	_
	mestic	308.4	293.1	86.7	175.5	283.7	392.6	78.9	-9.0	162.8	-7.2	247.5	-12.8	342.9	-12.7	166.6	+2.3	356.6	_
	erseas	36.4	33.8	8.0	16.2	26.1	392.0	8.2	+2.5	102.8	+21.0	247.5	+9.6	342.9	+0.5	23.4	+19.4	46.5	

Notes: 1. The products marketed in 2007 and subsequent years are as follows: Avastin (launched in June 2007), Tarceva (December 2007), Copegus (March 2007)

2. Sales of the products for which the marketing collaboration in Japan with sanofi-aventis K.K. ended on December 31, 2007, are included in the "Others field (SA products)."

#### Statements of Revenues (QTR)

(Billions of Yen)

	T																(Billions o	of Y
																	casts	
	FY2007	FY2008		FY2	009					FY20	010					FY2	.011	
	1-12	1-12	1-3	4-6	7-9	10-12	1-3	Change	4-6	Change	7-9	Change	10-12	Change	1-6	Change	7-12	Cha
	Full-year	Full-year	QTR	QTR	QTR	QTR	QTR	(%)	QTR	(%)	QTR	(%)	QTR	(%)	1st Half	(%)	2nd Half	
es	332.9	321.8	92.9	93.0	117.5	115.7	86.2	-7.2	94.5	+1.6	92.6	-21.2	102.3	-11.6	182.5	+1.1	209.2	
Excl. Tamiflu	294.3	313.4	72.5	88.1	87.0	95.3	75.4	+4.0	93.3	+5.9	88.8	+2.1	100.0	+4.9	176.8	+4.9	202.7	
Domestic	263.1	279.9	66.2	80.1	77.6	85.4	68.0	+2.7	82.6	+3.1	80.8	+4.1	93.0	+8.9	157.5	+4.6	183.4	
On <u>cology</u> field	74.0	102.3	25.7	32.1	31.1	34.8	28.8	+12.1	35.7	+11.2	35.5	+14.1	41.1	+18.1	69.4	+7.4	84.2	
Avastin	3.5	20.1	6.7	8.6	8.9	10.6	10.3	+53.7	13.0	+51.2	13.5	+51.7	15.8	+49.1	28.8	+23.6	36.0	
Herceptin	16.1	23.7	6.6	8.1	7.3	7.7	5.7	-13.6	6.4	-21.0	6.2	-15.1	6.9	-10.4	11.8	-2.5	12.8	
Rituxan	18.6	20.5	4.3	5.5	5.4	5.9	4.5	+4.7	5.8	+5.5	5.8	+7.4	6.9	+16.9	10.5	+1.9	13.0	
Xeloda	2.7	4.8	1.3	1.5	1.6	2.2	2.3	+76.9	2.8	+86.7	2.7	+68.8	2.9	+31.8	5.0	-2.0	6.7	
Neutrogin	12.6	12.0	2.2	3.0	3.0	3.1	2.0	-9.1	2.6	-13.3	2.6	-13.3	3.3	+6.5	4.6	+0.0	5.8	
Tarceva	0.2	4.5	1.2	1.5	1.4	1.7	1.4	+16.7	2.0	+33.3	2.0	+42.9	2.4	+41.2	4.0	+14.3	4.8	
Kytril	13.6	10.9	2.1	2.4	2.1	2.1	1.5	-28.6	1.5	-37.5	1.3	-38.1	1.2	-42.9	1.8	-40.0	2.0	-
Femara	1.0	1.7	0.5	0.6	0.6	0.7	0.6	+20.0	0.8	+33.3	0.8	+33.3	1.0	+42.9	1.7	+21.4	2.0	
Other products	5.6	4.1	0.8	0.9	0.8	0.8	0.6	-25.0	0.7	-22.2	0.6	-25.0	0.7	-12.5	1.0	-23.1	1.0	
Bone and joint diseases field	46.6	50.0	12.2	14.8	14.3	16.4	13.0	+6.6	15.7	+6.1	15.4	+7.7	18.5	+12.8	31.8	+11.2	37.0	
Evista	16.0	16.5	3.8	4.6	4.4	5.1	3.8	+0.0	4.8	+4.3	4.5	+2.3	5.6	+9.8	8.3	-3.5	9.2	Т
Actemra	0.5	3.4	1.5	2.0	2.2	2.7	2.6	+73.3	3.3	+65.0	3.6	+63.6	4.7	+74.1	9.6	+65.5	12.2	
Suvenyl	11.0	12.0	2.8	3.7	3.5	3.7	2.9	+3.6	3.5	-5.4	3.3	-5.7	3.9	+5.4	6.7	+4.7	7.6	t
Alfarol	14.3	13.7	3.0	3.5	3.3	3.7	2.7	-10.0	3.2	-8.6	2.9	-12.1	3.5	-5.4	5.2	-11.9	5.9	
Other products	4.8	4.5	1.1	1.0	0.8	1.1	1.0	-9.1	0.9	-10.0	1.1	+37.5	0.9	-18.2	1.9	+0.0		
Renal diseases field	69.6	61.3	13.0	15.8	15.6	16.5	12.5	-3.8	14.7	-7.0	14.6	-6.4	15.6	-5.5	26.6	-2.2		t
Epogin	54.8	44.9	9.4	11.5	11.4	12.1	8.7	-7.4	10.3	-10.4	10.2	-10.5	10.8	-10.7	18.5	-2.6		t
Oxarol	8.7	10.0	2.2	2.8	2.7	2.9	2.5	+13.6	3.1	+10.7	3.0	+11.1	3.4	+17.2	5.7	+1.8		t
Renagel	5.6	5.7	1.3	1.4	1.3	1.3	1.1	-15.4	1.2	-14.3	1.2	-7.7	1.3	+0.0	2.2	-4.3		+
Other products	0.5	0.7	0.2	0.1	0.2	0.1	0.2	+0.0	0.1	+0.0	0.1	-50.0	0.1	+0.0	0.2	-33.3		t
Transplant, Immunology & Infectious diseases field	17.7	24.0	5.9	6.9	6.5	6.8	5.3	-10.2	6.6	-4.3	6.4	-1.5	7.4	+8.8	11.6	-2.5		t
Pegasys	6.3	9.7	2.5	2.9	2.8	2.9	2.2	-12.0	2.6	-10.3	2.6	-7.1	3.0	+3.4	4.9	+2.1	5.9	Ŧ
Copegus	2.0	4.2	1.1	1.3	1.2	1.2	0.9	-18.2	1.1	-15.4	1.1	-8.3	1.3	+8.3	2.2	+10.0	2.5	
Rocephin	5.7	5.9	1.1	1.5	1.4	1.4	1.1	-15.4	1.1	+0.0	1.1	+0.0	1.5	+7.1	1.8	-30.8	1.9	
CellCept	3.5	4.0	0.9	1.1	1.1	1.4	1.0	+11.1	1.3	+18.2	1.4	+18.2	1.5	+25.0	2.7	+17.4	3.1	+
Other products	0.3	0.3	0.3	0.1	0.1	0.1	0.1	+0.0	0.1	+0.0	0.1	+0.0	0.1	+0.0	0.1	+0.0		+
Others field	55.1	42.3	9.4	10.6	10.0	10.9	8.3	-11.7	9.9	-6.6	8.8	-12.0	10.3	-5.5	18.0	-1.6	•	+
Sigmart	15.2	15.0	3.3	3.8	3.6	4.0	2.9	-12.1	3.4	-10.5	3.0	-16.7	3.7	-7.5	6.2	-1.6		Ŧ
SA products	11.2	-	-	-	-	-	-		- 0.4		- 0.0		-	7.0	-	1.0	-	+
Other products	28.8	27.3	6.2	6.8	6.5	6.8	5.4	-12.9	6.5	-4.4	5.8	-10.8	6.7	-1.5	11.9	-0.8	12.2	+
Overseas	31.2	33.5	6.3	7.9	9.5	9.9	7.4	+17.5	10.7	+35.4	8.0	-15.8	6.9	-30.3	19.3	+6.6		t
Neutrogin	26.6	25.9	4.8	5.4	5.6	5.5	4.4	-8.3	4.4	-18.5	4.2	-25.0	4.0	-27.3	6.9	-21.6		+
Actemra	- 20.0	3.8	0.4	1.4	3.3	3.8	2.0	+400.0	5.4	+285.7	3.1	-6.1	2.2	-42.1	10.5	+41.9	11.2	+
Sigmart	2.8	2.0	0.4	0.6	0.3	0.4	0.8	+33.3	0.6	+0.0	0.4	+33.3	0.4	+0.0	1.3	+0.0		-
Other products	1.9	1.7	0.0	0.0	0.3	0.4	0.0	-60.0	0.0	-40.0	0.4	+50.0	0.4	+50.0	0.7	+40.0		
Tamiflu	38.7	8.4	20.4	5.0	30.4	20.4	10.8	-47.1	1.2	-76.0	3.8	-87.5	2.3	-88.7	5.7	-52.5		
Ordinary sales	10.2	<u>8.4</u> 7.1	6.0	5.0	<u> </u>	20.4	1.4	-47.1	0.0		0.0	-87.5	0.2	-98.9	5.3	-52.5 +278.6		
	28.5	1.3	0.0 14.4	5.0	22.9	2.7	9.5	-76.7	1.2	-100.0	3.8	-100.0	2.1	-98.9	0.4	-96.2	4.0	_
Govt. stockpile etc.																		ł
er operating revenues	11.9	5.1	1.8	4.0	0.5	3.6	0.9	-50.0	0.8	-80.0	1.1	+120.0	1.1	-69.4	7.5	+341.2	3.8	
enues (total)	344.8	326.9	94.7	97.0	118.0	119.2	87.1	-8.0	95.3	-1.8	93.7	-20.6	103.4	-13.3	190.0	+4.2		_
Domestic	308.4	293.1	86.7	88.8	108.1	108.9	78.9	-9.0	83.9	-5.5	84.7	-21.6	95.5	-12.3	166.6	+2.3	190.0	_
Overseas	36.4	33.8	8.0	8.2	9.9	10.3	8.2	+2.5	11.4	+39.0	9.0	-9.1	8.0	-22.3	23.4	+19.4	23.0	1

# **Balance Sheets**

(Billions of Yen)

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					000						
	FY2007	FY2008		FY2					FY2010		
	As of	vs. Dec.									
	Dec. 31	Dec. 31	Mar. 31	Jun. 30	Sep. 30	Dec. 31	Mar. 31	Jun. 30	Sep. 30	Dec. 31	31, 2009
Cash and deposits	73.2	70.8	77.6	90.8	77.6	107.0	101.1	81.3	70.2	76.2	-30.8
Trade notes and accounts receivable	107.0	108.5	111.3	102.7	121.8	121.6	85.4	99.2	99.3	113.4	-8.2
Marketable securities	65.5	54.7	46.0	54.5	55.6	52.2	55.7	61.7	58.7	59.7	7.5
Inventries	55.2	78.7	78.7	94.0	90.4	92.6	100.0	111.7	115.9	104.9	12.3
Other current assets	28.9	31.7	34.3	30.9	32.3	37.9	41.7	29.5	35.0	32.3	-5.6
Total Current assets	329.8	344.4	347.9	372.9	377.7	411.3	383.9	383.4	379.1	386.5	-24.8
Property, plant and equipment	92.5	98.3	97.1	96.2	93.7	93.7	91.4	89.8	88.4	88.0	-5.7
Intangible assets	3.7	3.1	3.2	3.0	2.7	3.2	3.0	2.6	2.6	2.4	-0.8
Investments and other assets	32.9	32.7	30.6	29.6	31.2	32.3	32.9	31.4	31.1	31.2	-1.1
thereof Investment securities	16.8	14.4	11.8	10.6	9.8	9.7	9.5	8.0	7.3	7.6	-2.1
Total Noncurrent Assets	129.1	134.2	130.9	128.8	127.6	129.2	127.2	123.8	122.1	121.5	-7.7
Total Assets	458.9	478.5	478.7	501.7	505.3	540.5	511.1	507.2	501.2	508.0	-32.5
Trade notes and accounts payable	17.3	28.8	34.0	37.8	34.3	34.3	35.4	32.2	26.2	19.5	-14.8
Short-term loans and bonds	0.3	-	_	_	_	-	-	_	_	-	-
Other current liabilities	52.1	49.8	41.4	44.7	49.0	66.2	42.2	36.3	33.2	35.1	-31.1
Total current liabilities	69.8	78.5	75.4	82.5	83.3	100.5	77.6	68.5	59.4	54.6	-45.9
Long-term debt and bonds	-	1	-	-	-	Ι	-	_	_	_	-
Other noncurrent liabilities	3.3	2.9	3.0	3.3	3.6	5.4	5.2	4.8	5.0	4.0	-1.4
Total noncurrent liabilities	3.3	2.9	3.0	3.3	3.6	5.4	5.2	4.8	5.0	4.0	-1.4
Total liabilities	73.1	81.5	78.4	85.8	86.9	105.9	82.8	73.3	64.4	58.6	-47.3
Common stock	72.9	73.0	73.0	73.0	73.0	73.0	73.0	73.0	73.0	73.0	-
Additional paid-in capital	92.8	92.8	92.8	92.8	92.8	92.8	92.8	92.8	92.8	92.8	-
Retained earnings	248.1	271.0	274.4	286.9	292.3	308.0	303.3	311.8	314.3	327.6	19.6
Treasury stock, at cost	-35.1	-35.2	-35.2	-35.2	-36.3	-36.3	-36.3	-36.3	-36.3	-36.3	0.0
Net unrealized gain on securities	2.8	1.4	0.9	2.0	1.7	1.6	1.8	1.5	1.2	1.3	-0.3
Foreign currency translation adjustments	1.9	-7.9	-7.3	-5.8	-6.9	-6.8	-8.2	-11.1	-10.1	-11.3	-4.5
New share warrants	0.1	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.7	0.8	0.3
Minority interests	2.2	1.7	1.3	1.8	1.4	1.8	1.3	1.4	1.2	1.4	-0.4
Total net assets	385.8	397.1	400.4	416.0	418.4	434.7	428.4	433.9	436.7	449.4	14.7
Total liabilities and net assets	458.9	478.5	478.7	501.7	505.3	540.5	511.1	507.2	501.2	508.0	-32.5

#### **Cash Flows**

									(Billio	ons of Yen)
	FY2007	FY2008		FY2	009			FY20	010	
	1-12	1-12	1-3	1-6	1-9	1-12	1-3	1-6	1–9	1-12
	Full-year	Full-year	YTD	YTD	YTD	Full-year	YTD	YTD	YTD	Full-year
Net cash provided by (used in) operating activities	60.4	39.3	13.0	33.7	36.9	66.5	16.4	6.8	4.4	15.6
Net cash provided by (used in) investing activities	-7.5	-14.1	-3.9	-13.3	-21.6	-20.3	1.2	-16.6	-16.2	-20.2
Net cash provided by (used in) financing activities	-47.2	-18.4	-11.0	-11.0	-22.3	-22.3	-13.2	-13.2	-23.1	-23.1
Effect of exchange rate changes on cash and cash equivalents	-0.3	-9.9	-0.6	0.6	1.0	-0.1	-0.6	-1.5	-1.2	-1.7
Net increase (decrease) in cash and cash equivalents	5.4	-3.1	-2.5	9.9	-6.1	23.8	3.8	-24.5	-36.1	-29.3
Cash and cash equivalents at beginning of period	68.3	73.7	70.7	70.7	70.7	70.7	94.5	94.5	94.5	94.5
Cash and cash equivalents at end of period	73.7	70.7	68.1	80.6	64.6	94.5	98.2	69.9	58.4	65.1

## **Performance Indicators**

											Forecast
	FY2007	FY2008		FY2	2009			FY2	010		FY2011
	1-12	1-12	1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12	1-12
	As of Dec. 31	As of Dec. 31	As of Mar. 31	As of Jun. 30	As of Sep. 30	As of Dec. 31	As of Mar. 31	As of Jun. 30	As of Sep. 30	As of Dec. 31	As of Dec. 31
Net income per share (Basic)	73.23yen	72.07yen	25.27yen	48.29yen	75.07yen	104.00yen	14.43yen	30.09yen	51.55yen	76.14yen	78.10yen
Net income per share (Fully diluted)	73.16yen	72.04yen	25.27yen	48.28yen	75.06yen	103.98yen	14.43yen	30.09yen	51.54yen	76.12yen	-
Return on equity (ROE)*	10.4%	10.1%	3.5%	6.5%	10.1%	13.7%	1.8%	3.8%	6.5%	9.4%	-
Return on assets (ROA)*	14.7%	12.2%	4.8%	8.9%	13.4%	17.7%	2.3%	5.0%	8.5%	12.4%	-
Net assets per share	703.80yen	725.18yen	731.74yen	759.41yen	765.47yen	794.51yen	783.67yen	793.50yen	799.11yen	821.87yen	-
Equity ratio	83.5%	82.6%	83.3%	82.5%	82.4%	80.0%	83.4%	85.1%	86.8%	88.0%	-
Dividends per share (Annual)	30yen	34yen				40yen				40yen	40yen
Dividends per share (Interim)	15yen	15yen				17yen				17yen	20yen
Payout ratio	41.0%	47.2%				38.5%				52.5%	51.2%

Note: Quarterly (year-to-date) ROE and ROA are not annualized.

#### Number of Employees

											Forecast
	FY2007	FY2008		FY2	2009			FY2	2010		FY2011
	As of Dec. 31	As of Dec. 31	As of Mar. 31	As of Jun. 30	As of Sep. 30	As of Dec. 31	As of Mar. 31	As of Jun. 30	As of Sep. 30	As of Dec. 31	As of Dec. 31
Number of employees	6,257	6,383	6,347	6,474	6,481	6,485	6,472	6,707	6,723	6,709	6,830

Note: Number of employees doesn't includes staff seconded to companies outside the Group.

## **Capital Expenditures**

										(Billio	ons of Yen)
											Forecast
	FY2007	FY2008		FY2	2009			FY2	010		FY2011
	1-12	1-12	1-3	1-6	1-9	1-12	1-3	1-6	1-9	1-12	1-12
	Full-year	Full-year	YTD	YTD	YTD	Full-year	YTD	YTD	YTD	Full-year	Full-year
Capital expenditures	19.6	26.6	2.8	6.6	9.1	14.6	1.8	4.6	7.9	12.7	14.0
Depreciation	13.3	19.4	4.2	8.9	14.1	19.5	4.1	8.4	13.0	18.0	17.0

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#### Major Capital Investments Plan

(The Company) None

(Domestic Subsidiaries) None

## Commitment Line (Loan Framework) Contract

	(Billions of Yen)
	Amount
Total Commitments	40.0
Commitments used	-
Commitments unused	40.0

Note: The Company maintains commitment line contracts with ten financial institutions.

# Development pipeline (as of February 2, 2011)

Development code	Indication # Additional indication	Stage (date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action	
<u>Oncology</u>						
RG435	Breast cancer #	Filed Oct. 09	bevacizumab Avastin Injection	Roche Avastin	Humanized anti-VEGF(Vascular Endothelial Growth Factor) monoclonal antibody	
	Gastric cancer #	Phase III Multinational study				
	Breast cancer (adjuvant) #	Phase III Multinational study				
	Glioblastoma #	Phase III Multinational study				
	Glioblastoma (relapsed) #	Phase II	1			
	Colon cancer (adjuvant) #	Development suspended				
EPOCH	Chemotherapy-induced anemia #	Filed Nov. 09	epoetin beta Epogin Injection	In-house	Recombinant human erythropoietin	
RG340	Gastric cancer #	Filed Sep. 10	capecitabine Xeloda Oral	Roche Xeloda	Antimetabolite, 5-FU derivative	
RG597	Gastric cancer #	Filed Mar. 10	trastuzumab Herceptin Injection	Roche Herceptin	Humanized anti-HER2 monoclonal antibody	
RG1415	Pancreatic cancer #	Filed Sep. 09	erlotinib Tarceva	Roche/OSI Tarceva	EGFR tyrosine kinase inhibitor	
	Non-small cell lung cancer (1st line) #	Phase II	Oral			
RG1273	Breast cancer	Phase III Multinational study	pertuzumab Injection	Roche	Humanized HER dimerization inhibitory monoclonal antibody	
RG3502	Breast cancer	Phase II		Roche	HER2 antibody-drug conjugate (T-DM1)	
			Injection			

Development code	Indication # Additional indication	Stage (date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
TP300	Gastric cancer, etc	Phase II		In-house	Topoisomerase I inhibitor
		Overseas			
			Injection		
MRA	Pancreatic cancer	Phase I / II	tocilizumab	In-house	Humanized anti-human IL-6 receptor monoclonal antibody
	#		Actemra		
AF802	Non-small cell lung cancer	Phase I / II	Injection	(Roche) In-house	ALK inhibitor
AF0UZ	Non-small cell lung cancer	Phase 17 II		In-house	ALKINIDIO
			Oral		
WT4869	Myelodysplastic syndromes	Phase I / II		In-house / Dainippon Sumitomo Pharma	WT1 peptide cancer vaccine
			Injection		
CIF (RG7167)	Solid tumors	Phase I		In-house	MEK inhibitor
		Phase I	Oral	(Roche)	
		Overseas			
CKI27 (RG7304)	Solid tumors	Phase I		In-house	Raf and MEK dual inhibitor
		Phase I	Oral	(Roche)	
		Overseas			
GC33	Liver cancer	Phase I		In-house	Humanized anti-Glypican-3 monoclonal antibody
		Phase I	Injection	(Roche)	
		Overseas			
PA799	Solid tumors	Phase I		In-house	-
		Overseas			
			Oral		
GA101 (RG7159)	Non-Hodgkin's lymphoma	Phase I		Roche	Humanized anti-CD20 monoclonal antibody
			Injection		
Bone and Joi	nt diseases				
ED-71	Osteoporosis	Approved	eldecalcitol	In-house	Active Vitamin D <sub>3</sub> derivative
		Jan. 11	Edirol	(Taisho Pharmaceutical)	
			Oral		

Development code	Indication # Additional indication	Stage (date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
MRA	Systemic onset juvenile idiopathic arthritis (sJIA) #	Filed Oct. 10 Overseas	tocilizumab Actemra / RoActemra(EU) Injection	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody
	Rheumatoid arthritis	Phase III			
	(new formulation: subcutaneous injection)	Phase III Overseas			
RG484	Osteoporosis	Phase II / III	ibandronate sodium hydrate Injection	Roche Boniva (US) / Bonviva (EU)	Bisphosphonate
		Phase II	ibandronate sodium hydrate Oral	(Taisho Pharmaceutical)	
SA237	Rheumatoid arthritis	Phase I		In-house	Humanized anti-human IL-6 receptor monoclonal antibody
<b></b>			Injection		
Renal disease		1		1	
RG744	Renal anemia	Filed Jul. 09	Epoetin beta pegol Mircera Injection	Roche Mircera	Continuous erythropoietin receptor activator
Transplant, Im	munology and Infectious disease	s			
RG964	Compensated liver cirrhosis caused by hepatitis C virus	Filed Oct. 10	ribavirin Copegus Oral	Roche Copegus	Anti-viral agent, in combination with Pegasys
RG442	# Chronic hepatitis B #	Filed Jan. 11	peginterferon alfa-2a Pegasys Injection	Roche Pegasys	Peginterferon alfa-2a agent (recombinant)
NA808	Chronic hepatitis C	Development suspended	Injection	In-house	Serine palmitoyltransferase inhibitor
Other disease	і S	1	1	1	1
CSG452 (RG7201)	Type II diabetes	Phase III	tofogliflozin	In-house	SGLT2 inhibitor
			Oral	(Roche)	

Development code	Indication # Additional indication	Stage (date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
RG1678	Schizophrenia	Phase III Multinational study		Roche	GLYT1 inhibitor
			Oral		
RG1583 (ITM-077)	Type II diabetes	Phase II	taspoglutide	Roche/lpsen (Teijin)	GLP-1 analogue
			Injection		
RG1450	Alzheimer's disease	Phase I	gantenerumab	Roche/Morphosys	Human anti-amyloid-beta monoclonal antibody
			Injection		

Changes from the last announcement on October 22, 2010

<u>Oncology</u>	
-RG435	Phase III $\rightarrow$ Development suspended (Colon cancer (adjuvant))
-WT4869	Phase I/II (Myelodysplastic syndromes)
-GC33	Phase I (Liver cancer: Japan)

## Bone and Joint diseases -ED-71

-ED-71Filed  $\rightarrow$  Approved (Osteoporosis)-SA237Phase I (Rheumatoid arthritis)

# Transplant, Immunology and Infectious diseases

-RG964/RG442	Phase II/III $\rightarrow$ Filed (Compensated liver cirrhosis caused by hepatitis C virus)
-RG442	Phase II/III $\rightarrow$ Filed (Chronic hepatitis B)
-NA808	Phase I $\rightarrow$ Development suspended (Chronic hepatitis C)

## Other diseases

-CSG452	Phase II multinational study $\rightarrow$ Phase III (Type II diabete	es)
-RG1678	Phase II multinational study $\rightarrow$ Phase III multinational st	udy (Schizophrenia)

R&D Activities (Jan. 1, 2010 – Feb. 2, 2011)

As for clinical development activities in Japan, the Company saw progress as described below:

## <u>Oncology</u>

- We decided to suspend our development of a humanized anti-VEGF monoclonal antibody, RG435 (product name: Avastin, expected indication: colon cancer (adjuvant)), following the fact that results from a Phase III multinational study conducted by Roche did not meet primary endpoint.
- In March 2010, we filed an application for an additional indication of combination therapy with a 5-FU derivative, RG340 (product name: Xeloda), and a humanized anti-HER2 monoclonal antibody, RG597 (product name: Herceptin), for gastric cancer. In September 2010, we filed an "NDA based on evidence in the public domain" for RG340 (product name: Xeloda), for gastric cancer in a result that the "Review Committee on Unapproved Drugs and Indications with High Medical Needs" concluded this process is applicable.
- In April 2010, we started a Phase II trial (expected indication: non-small cell lung cancer [1st line]) for an EGFR tyrosine kinase inhibitor, RG1415 (product name: Tarceva).
- In October 2010, we started a Phase II trial (expected indication: breast cancer) for a HER2 antibody-drug conjugate, RG3502.
- In September 2010, we started a Phase I/II trial (expected indication: non-small cell lung cancer) for an ALK inhibitor, AF802.
- In February 2011, we will start a Phase I/II trial (expected indication: myelodysplastic syndromes) for a WT1 peptide cancer vaccine, WT4869.
- In January 2010, we started a Phase I trial (expected indication: solid tumors) for a Raf and MEK dual inhibitor, CKI27 (RG7304).
- In October 2010, we started a Phase I trial (expected indication: liver cancer) for a humanized anti-Glypican-3 monoclonal antibody, GC33.

## Bone and Joint diseases

- In January 2011, we obtained an approval for an active Vitamin D3 derivative, ED-71 (product name: Edirol), for osteoporosis.
- In May 2010, we started a Phase III trial (new formulation: subcutaneous injection) for a humanized anti-human IL-6 receptor monoclonal antibody, MRA (product name: Actemra).
- Äfter re-evaluating risk/benefit balance, we have decided to suspend our development of a humanized anti-CD20 monoclonal antibody, RG1594 for rheumatoid arthritis.
- In December 2010, we started a Phase I trial (expected indication: Rheumatoid arthritis) for a humanized anti-human IL-6 receptor monoclonal antibody, SA237.

## Transplant, Immunology and Infectious Diseases

- In October 2010, we filed an application for an additional indication of an anti-viral agent, RG964 (product name: Copegus), in combination with a peginterferon alfa-2a agent (recombinant), RG442 (product name: Pegasys), for compensated liver cirrhosis caused by hepatitis C virus.
- In January 2011, we filed an application for an additional indication of a peginterferon alfa-2a agent (recombinant), RG442 (product name: Pegasys), for chronic hepatitis B.
- We decided to suspend our development for a serine palmitoyltransferase inhibitor, NA808 (expected indication: Chronic hepatitis C), following the fact that the results did not meet the efficacy criteria to proceed, though the results shows decrease of HCV viral load in a PI trial with chronic hepatitis C patients.
- After re-evaluating the allocation of resources to ongoing development programs, we have decided to discontinue our development of nitazoxanide for chronic hepatitis C. Romark Laboratories will continue development of nitazoxanide for chronic hepatitis C in Japan as part of its worldwide development program.

#### Other Diseases

- In June 2010, we obtained an approval for an additional indication of a recombinant human erythropoietin, EPOCH (product name: Epogin), for predeposit of autologous blood transfusion.
- In November 2010, we started a Phase III trial (expected indication: Type II diabetes) for a SGLT2 inhibitor, CSG452 (RG7201).
- In January 2011, we started a Phase III multinational study (expected indication: Schizophrenia) for a GLYT1 inhibitor, RG1678.

At present, we are awaiting the approvals of applications (new molecular entities or additions of indications) filed for 9 development themes, including RG435 (expected indication: breast cancer).

Also, as for development activities overseas, the Company saw progress as described below.

- In August 2010, we started a Phase I trial (expected indication: solid tumor) for PA799.
- In January 2010, Roche obtained an approval for a humanized anti-human IL-6 receptor monoclonal antibody, MRA (product name: Actemra), for rheumatoid arthritis from the U.S. Food & Drug Administration (FDA).

In September, Roche started a Phase III trial (new formulation: subcutaneous injection) for MRA for rheumatoid arthritis. In October, Roche filed an application for MRA for systemic onset juvenile idiopathic arthritis (sJIA).

# Major clinical trials in oncology field currently running in Japan

Theme	Expected Indication	Regimen	Stage	Planned Filing Date	
	Breast	paclitaxel + RG435	Filed (Oct. 09)	-	
	Breast (adjuvant)	standard chemotherapy ± RG435	BEATRICE study: Phase III Multinational study	2014   2016	
RG435 (bevacizumab) Avastin	Glioblastoma	temozolomide ± RG435	Phase III Multinational study	2014   2016	
	Glioblastoma [relapsed]	RG435	Phase II	2014   2016	
RG1415 (erlotinib) Tarceva	Pancreatic	gemcitabine + RG1415	Filed (Sep. 09)	-	
RG597 (trastuzumab) Herceptin	Herceptin		Filed (Mar. 10)		
RG340 (capecitabine) Xeloda	Gastric	± RG597	Filed (Sep. 10)	-	
RG1273 (pertuzumab)	Breast	RG597 + docetaxel ± RG1273	CLEOPATRA study: Phase III Multinational study	2012	
RG3502 (T-DM1)	Breast	RG3502	Phase II	2013	