

**Supplementary Materials for
Consolidated Financial Results for
Fiscal Year ended December 31, 2008**



CHUGAI PHARMACEUTICAL CO., LTD.



A member of the Roche group

Financial Highlights

(Millions of Yen)

	FY2005.12	FY2006.12	FY2007.12	FY2008.12		FY2009.12 (Forecasts) ³	FY2007.10-12	FY2008.10-12	
					Change (%)				Change (%)
Revenues ^{*1}	327,155	326,109	344,808	326,937	(5.2)	400,000	94,356	97,257	3.1
Cost of Sales ^{*2}	119,423	133,085	137,293	127,029	(7.5)	176,000	36,333	39,414	8.5
(%)	36.5	40.8	39.8	38.9		44.0	38.5	40.5	
SG&A Expenses	78,504	80,067	86,569	95,120	9.9	100,500	24,944	29,194	17.0
(%)	24.0	24.6	25.1	29.1		25.1	26.4	30.0	
R&D Expenses	50,058	54,609	54,243	53,225	(1.9)	60,500	15,400	16,909	9.8
(%)	15.3	16.7	15.7	16.3		15.1	16.3	17.4	
Operating Income	79,168	58,347	66,702	51,563	(22.7)	63,000	17,677	11,739	(33.6)
(%)	24.2	17.9	19.3	15.8		15.8	18.7	12.1	
Recurring Profit	82,091	60,922	67,687	57,265	(15.4)	63,500	16,728	14,558	(13.0)
(%)	25.1	18.7	19.6	17.5		15.9	17.7	15.0	
Net Income	53,632	38,417	40,060	39,264	(2.0)	40,000	9,840	9,122	(7.3)
(%)	16.4	11.8	11.6	12.0		10.0	10.4	9.4	

- Notes: 1. Revenues include Royalties and other operating income, starting from the fiscal year ended December 31, 2007.
2. Cost of Sales includes the provision for returned goods.
3. The assumed exchange rates for the period ending December 31, 2009, are 1USD=¥90, 1EUR=¥125, 1GBP=¥135, and 1CHF=¥85.

Extraordinary Gains and Losses

Extraordinary Gains

(Millions of Yen)

	Amount	Description
Gain on settlement of co-development costs	6,340	This gain arose from the signing of a new agreement with F. Hoffman-La Roche Ltd. regarding the sharing of co-development costs for Actemra.
Subsidies received	500	Subsidies were received for a new industrial development project accompanying the construction of a solid agent facility at the Fujieda Plant.
Gain on sales of fixed assets	420	Gains from the sale of real estate investments etc.

Extraordinary Losses

(Millions of Yen)

	Amount	Description
Impairment loss	747	Impairment arose from the decision to close down partial establishments at the Company's consolidated subsidiaries and the real estate investments etc.
Loss on office realignment costs	536	Costs arose from the decision to close down partial establishments at the Company's consolidated subsidiaries and the restructuring of manufacturing function etc.
Retirement benefit expenses	107	The amount treated as expenses, accompanying the shift from the simplified method of calculating retirement obligations to the standard method of calculation at one of the Company's consolidated subsidiaries due to an increase in the number of employees.
Loss on revaluation of investment securities	19	Details omitted.
Loss on sales of fixed assets	10	Details omitted.

Statements of Revenues

(Billions of Yen)*1

Product etc.	FY2005.12	FY2006.12	FY2007.12		FY2008.12		FY2009.12 (Forecasts)		FY2007. 10-12	FY2008.10-12	
				Change (%)		Change (%)	First half	Full year			Change (%)
Epogin	71.8	63.4	54.8	(13.6)	44.9	(18.1)	20.6	45.2	14.4	12.1	(16.0)
Neutrogin	32.3	36.1	39.2	8.6	37.9	(3.3)	16.1	31.1	10.6	9.3	(12.3)
Domestic	13.4	12.0	12.6	5.0	12.0	(4.8)	5.7	12.6	3.7	3.5	(5.4)
Herceptin	11.2	14.5	16.1	11.0	23.7	47.2	12.6	27.5	4.4	7.5	70.5
Rituxan	17.8	18.0	18.6	3.3	20.5	10.2	9.4	20.6	5.4	5.9	9.3
Avastin *2	—	—	3.5	—	20.1	474.3	13.0	29.0	2.2	7.3	231.8
Sigmar	19.3	18.0	17.9	(0.6)	17.0	(5.0)	8.0	16.6	5.2	4.5	(13.5)
Domestic	16.1	15.4	15.2	(1.3)	15.0	(1.3)	6.9	14.6	4.4	4.1	(6.8)
Evista	9.2	13.4	16.0	19.4	16.5	3.1	8.4	18.1	4.9	4.8	(2.0)
Alfarol	15.8	14.6	14.4	(1.4)	13.7	(4.9)	6.5	13.4	4.1	3.7	(9.8)
Suvenyl	8.1	9.1	11.0	20.9	12.0	9.1	5.9	13.1	3.2	3.3	3.1
Kytril	12.2	12.9	13.6	5.4	10.9	(19.9)	4.8	10.3	3.9	2.8	(28.2)
Oxarol	7.3	7.6	8.7	14.5	10.0	14.9	4.9	10.6	2.6	2.8	7.7
Pegasys	8.0	5.8	6.3	8.6	9.7	54.0	5.5	13.0	2.2	3.0	36.4
Tamiflu	35.2	38.0	38.7	1.8	8.4	(78.3)	39.0	53.0	6.8	6.7	(1.5)
Actemra *3	0.1	0.4	0.5	25.0	7.2	1,340.0	5.2	15.5	0.1	3.7	3,600.0
Domestic	0.1	0.4	0.5	25.0	3.4	580.0	3.5	9.6	0.1	1.6	1,500.0
Rocephin	5.4	5.5	5.7	3.6	5.9	3.5	3.0	6.2	1.6	1.7	6.3
Renagel	4.6	5.1	5.7	11.8	5.8	1.8	2.6	5.5	1.6	1.6	0.0
Xeloda	2.7	2.5	2.7	8.0	4.8	77.8	2.9	6.5	0.8	1.5	87.5
Tarceva *4	—	—	0.2	—	4.5	2,150.0	2.6	5.5	0.2	1.4	600.0
Copegus *5	—	—	2.0	—	4.2	110.0	2.5	6.2	0.8	1.3	62.5
Cellcept	2.5	3.0	3.5	16.7	4.0	14.3	2.0	4.4	1.0	1.1	10.0
Femara *6	—	0.3	1.0	233.3	1.7	70.0	1.2	2.6	0.4	0.5	25.0
Other products *7	63.7	57.8	52.9	(8.5)	38.5	(27.2)	17.4	36.3	13.6	10.4	(23.5)
Royalties and other operating income *8	—	—	11.9	—	5.1	(57.1)	5.5	9.7	4.3	0.3	(93.0)
Total	327.2	326.1	344.8	5.7	326.9	(5.2)	199.5	400.0	94.4	97.3	3.1
Domestic	303.7	297.7	308.4	3.6	293.1	(5.0)	184.0	369.7	84.3	88.5	5.0
Overseas	23.5	28.4	36.4	28.2	33.8	(7.1)	15.5	30.3	10.0	8.8	(12.0)

Notes: 1. Figures are rounded to the nearest ¥100 million. The percentages are calculated based on the rounded numbers.

2. Launched in June 2007

3. Launched in June 2005

4. Launched in December 2007

5. Launched in March 2007

6. Launched in May 2006

7. 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 "Other products" (11.2 billion yen in FY2007.12; 12.9 billion yen in FY2006.12; 13.9 billion yen in FY2005.12; 2.3 billion yen for FY2007.10-12)

8. Starting from FY2007.12, Royalties and other operating income are included in Revenues.

Balance Sheets

(Millions of Yen)

	As of 2005.12.31	As of 2006.12.31	As of 2007.12.31	As of 2008.12.31
Cash and Deposits	74,380	68,332	73,167	70,768
Trade Notes and Accounts Receivable	118,873	105,897	107,012	108,459
Marketable Securities	68,645	81,894	65,547	54,715
Inventories	47,440	61,531	55,186	78,736
Other Current Assets	19,098	20,004	28,893	31,674
Total Current Assets	328,439	337,661	329,807	344,353
Tangible Fixed Assets	79,459	85,150	92,495	98,345
Intangible Fixed Assets	6,136	5,131	3,724	3,106
Investments and Other Assets	42,407	34,180	32,915	32,711
Total Fixed Assets	128,003	124,462	129,134	134,163
Total Assets	456,442	462,124	458,942	478,517
Notes and Accounts Payable	20,989	28,134	17,325	28,765
Other Current Liabilities	57,478	37,133	52,472	49,757
Total Current Liabilities	78,468	65,268	69,797	78,523
Fixed Liabilities	7,975	5,252	3,346	2,927
Total Liabilities	86,443	70,520	73,144	81,451
Minority Interests *	1,692	—	—	—
Common Stock	72,443	72,893	72,947	72,966
Additional Paid-in Capital	92,296	92,747	92,796	92,815
Retained Earnings	206,834	226,209	248,098	271,008
Treasury Stock, at Cost	(7,611)	(7,590)	(35,108)	(35,168)
Valuation and Translation Adjustments	4,343	5,339	4,701	(6,534)
New Share Warrants	—	—	139	326
Minority Interests *	—	2,006	2,222	1,651
Total Shareholders' Equity	368,306	—	—	—
Total Net Assets	—	391,604	385,797	397,066
Total Liabilities and Net Assets	456,442	462,124	458,942	478,517

Note: The company adopted new accounting standards "Accounting Standard for Presentation of Net Assets in the Balance Sheet" (Accounting Standard Statement No.5, issued on December 9, 2005) and "Guidance on Accounting Standard for Presentation of Net Assets in the Balance Sheet" (Accounting Standards Guidance No.8, issued on December 9, 2005) from the period ended December 31, 2006.

Commitment Line (Loan Framework) Contract

(Millions of Yen)

	Amount
Total Commitments	40,000
Commitments Used	—
Commitments Unused	40,000

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

Performance Indicators

	FY2005.12	FY2006.12	FY2007.12	FY2008.12	FY2009.12 (Forecasts)
Return on Equity (ROE)	15.6%	10.1%	10.4%	10.1%	—
Return on Assets (ROA)	18.9%	13.3%	14.7%	12.2%	—
Net Income per Share [Basic]	¥97.00	¥69.35	¥73.23	¥72.07	¥73.42
Net Income per Share [Fully Diluted]	¥96.33	¥69.26	¥73.16	¥72.04	—
Net assets per Share	¥665.29	¥703.08	¥703.80	¥725.18	—
Equity Ratio	80.7%	84.3%	83.5%	82.6%	—
Payout Ratio	35.1%	43.3%	41.0%	47.2%	46.3%

Capital Expenditures

(Millions of Yen)

	FY2005.12	FY2006.12	FY2007.12	FY2008.12	FY2009.12 (Forecasts)
Capital Expenditures	16,129	16,344	19,609	26,570	16,000
Depreciation	11,957	12,251	13,349	19,429	20,700

Major Capital Investments Plan

(The Company)

(Millions of Yen)

Facilities (Location)	Description of investment	Planned investment		Fund raising method	Start of construction	Slated completion date
		Total amount	Investment to-date			
Ukima area (Kita-ku, Tokyo)	Bio-product technology research building No.2	3,307	3,053	Self-financing	January 2007	January 2009

(Domestic Subsidiaries)

(Millions of Yen)

Company name	Plants (Location)	Description of investment	Planned investment		Fund raising method	Start of construction	Slated completion date
			Total amount	Investment to-date			
Chugai Pharma Manufacturing Co., Ltd.	Fujieda Plant (Fujieda-shi, Shizuoka)	Solid pharmaceutical production lines and related facilities	23,022	20,199	Self-financing	August 2005	September 2009
Chugai Pharma Manufacturing Co., Ltd.	Utsunomiya Plant (Utsunomiya- shi, Tochigi)	Injection products building No.3	14,553	12,384	Self-financing	May 2007	September 2011

Cash Flows

(Millions of Yen)

	FY2005.12	FY2006.12	FY2007. 12	FY2008. 12
Net Cash Provided by (Used in) Operating Activities	64,663	40,538	60,364	39,276
Net Cash Provided by (Used in) Investing Activities	(35,459)	(29,370)	(7,509)	(14,122)
Net Cash Provided by (Used in) Financing Activities	(12,556)	(18,796)	(47,173)	(18,360)
Effect of Exchange Rate Changes on Cash and Cash Equivalents	353	1,580	(291)	(9,864)
Net increase (Decrease) in Cash and Cash Equivalents	16,999	(6,047)	5,390	(3,070)
Cash and Cash Equivalents at Beginning of Year	57,380	74,380	68,332	73,723
Cash and Cash Equivalents at End of Year	74,380	68,332	73,723	70,652

Number of Employees

	As of 2005.12.31	As of 2006.12.31	As of 2007.12.31	As of 2008.12.31	As of 2009.12.31 (Forecasts)
Number of Employees	5,357	5,962	6,282	6,400	6,500

Note: Number of employees includes staff seconded to companies outside the Group.

For reference: Highlights (Non-Consolidated)

(Millions of Yen)

	FY2005.12	FY2006.12	FY2007.12	FY2008.12		FY2007.10-12	FY2008.10-12	
					Change (%)			Change (%)
Revenues ^{*1}	314,524	310,541	329,203	311,510	(5.4)	90,591	93,425	3.1
Cost of Sales ^{*2}	118,605	132,139	139,397	133,090	(4.5)	36,640	41,375	12.9
(%)	37.7	42.6	42.3	42.7		40.4	44.3	
SG&A Expenses	74,008	74,222	80,013	88,246	10.3	23,165	27,501	18.7
(%)	23.5	23.9	24.3	28.3		25.6	29.4	
R&D Expenses	49,885	54,673	53,323	53,088	(0.4)	15,206	16,781	10.4
(%)	15.9	17.6	16.2	17.0		16.8	18.0	
Operating Income	72,024	49,506	56,469	37,085	(34.3)	15,578	7,767	(50.1)
(%)	22.9	15.9	17.2	11.9		17.2	8.3	
Recurring Profit	76,057	53,578	57,355	40,075	(30.1)	13,714	8,131	(40.7)
(%)	24.2	17.3	17.4	12.9		15.1	8.7	
Net Income	51,367	34,907	33,788	29,412	(13.0)	6,684	5,349	(20.0)
(%)	16.3	11.2	10.3	9.4		7.4	5.7	
	FY2005.12	FY2006.12	FY2007.12	FY2008.12				
Return on Equity (ROE)	15.2%	9.5%	9.1%	8.0%				
Return on Assets (ROA)	18.0%	12.2%	13.2%	9.1%				
Net Income per Share [Basic]	¥92.89	¥63.02	¥61.77	¥53.98				
Net Income per Share [Fully Diluted]	¥92.24	¥62.93	¥61.71	¥53.97				
Net Assets per Share	¥649.40	¥678.10	¥667.17	¥688.51				
Dividends per Share	¥34.00 ^{*4}	¥30.00	¥30.00	¥34.00				
Payout Ratio	36.6%	47.6%	48.6%	63.0%				
Equity Ratio	81.1%	86.2%	84.4%	83.1%				
Capital Expenditures	15,925	8,349	8,301	8,710				
Depreciation	11,271	7,945	7,037	9,243				
Number of Employees ^{*3}	4,821	5,156	5,356	5,338				

- Notes: 1. Revenues include Royalties and other operating income, starting from the fiscal year ended December 31, 2007.
2. Cost of Sales includes the provision for returned goods.
3. Number of employees includes staff seconded to subsidiaries and other companies.
4. The annual cash dividend per share for the year ended December 31, 2005, includes a special dividend of ¥10 per share.

For reference: Statement of Revenues (Non-Consolidated)(Billions of Yen)^{*1}

Product etc.	FY2005.12	FY2006.12	FY2007.12		FY2008.12		FY2007 10-12	FY2008.10-12	
				Change (%)		Change (%)			Change (%)
Epogin	71.8	63.4	54.8	(13.6)	44.9	(18.1)	14.4	12.1	(16.0)
Herceptin	11.2	14.5	16.1	11.0	23.7	47.2	4.4	7.5	70.5
Rituxan	17.8	18.0	18.6	3.3	20.5	10.2	5.4	5.9	9.3
Avastin ^{*2}	—	—	3.5	—	20.1	474.3	2.2	7.3	231.8
Evista	9.2	13.4	16.0	19.4	16.5	3.1	4.9	4.8	(2.0)
Sigmart	16.1	15.4	15.2	(1.3)	15.0	(1.3)	4.4	4.1	(6.8)
Alfarol	15.8	14.6	14.3	(2.1)	13.7	(4.2)	4.0	3.7	(7.5)
Suvenyl	8.1	9.1	11.0	20.9	12.0	9.1	3.2	3.3	3.1
Neutrogin	13.4	12.0	12.6	5.0	12.0	(4.8)	3.7	3.5	(5.4)
Kytril	12.2	12.9	13.6	5.4	10.9	(19.9)	3.9	2.8	(28.2)
Oxarol	7.3	7.6	8.7	14.5	10.0	14.9	2.6	2.8	7.7
Pegasys	8.0	5.8	6.3	8.6	9.7	54.0	2.2	3.0	36.4
Tamiflu	35.2	38.0	38.7	1.8	8.4	(78.3)	6.8	6.7	(1.5)
Rocephin	5.4	5.5	5.7	3.6	5.9	3.5	1.6	1.7	6.3
Renagel	4.5	5.0	5.6	12.0	5.7	1.8	1.6	1.6	0.0
Xeloda	2.7	2.5	2.7	8.0	4.8	77.8	0.8	1.5	87.5
Tarceva ^{*3}	—	—	0.2	—	4.5	2,150.0	0.2	1.4	600.0
Copegus ^{*4}	—	—	2.0	—	4.2	110.0	0.8	1.3	62.5
Cellcept	2.5	3.0	3.5	16.7	4.0	14.3	1.0	1.1	10.0
Actemra ^{*5}	0.1	0.4	0.5	25.0	3.4	580.0	0.1	1.6	1,500.0
Femara ^{*6}	—	0.3	1.0	233.3	1.7	70.0	0.4	0.5	25.0
Neutrogin (Export)	6.8	9.2	10.1	9.8	9.8	(3.0)	2.8	1.8	(35.7)
Actemra (Export)	—	—	—	—	3.8	—	—	2.2	—
Sigmart (Export)	2.8	2.2	2.4	9.1	1.8	(25.0)	0.7	0.3	(57.1)
Ulcerimin (Export)	1.2	1.3	1.5	15.4	1.4	(6.7)	0.3	0.2	(33.3)
Other products ^{*7}	62.4	56.3	51.2	(9.1)	37.0	(27.7)	13.2	10.2	(22.7)
Royalties and other operating income ^{*8}	—	—	13.3	—	6.4	(51.9)	4.7	0.6	(87.2)
Total	314.5	310.5	329.2	6.0	311.5	(5.4)	90.6	93.4	3.1

注) 1. Figures are rounded to the nearest ¥100 million. The percentages are calculated based on the rounded numbers.

2. Launched in June 2007

3. Launched in December 2007

4. Launched in March 2007

5. Launched in June 2005

6. Launched in May 2006

7. 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 "Other Products" (11.2 billion yen in FY2007.12; 12.9 billion yen in FY2006.12; 13.9 billion yen in FY2005.12; 2.3 billion yen for FY2007.10-12)

8. Starting from FY2007.12, Royalties and other operating income are included in Revenues.

For reference: Outline of Principal Subsidiary and the State of Its Business Results

Chugai Pharma Marketing Ltd.

Profile

Established	1997
Location	London, United Kingdom
Business	Sale Administration*
Capital	£8,677,808 (December 2008)
Percentage of Ownership	100.0%

Note: Chugai Pharma Marketing Ltd., oversees the sales and marketing operations of the Germany branch, Chugai Pharma France S.A.S., Chugai Pharma U.K. Ltd., and CHUGAI sanofi-aventis S.N.C.

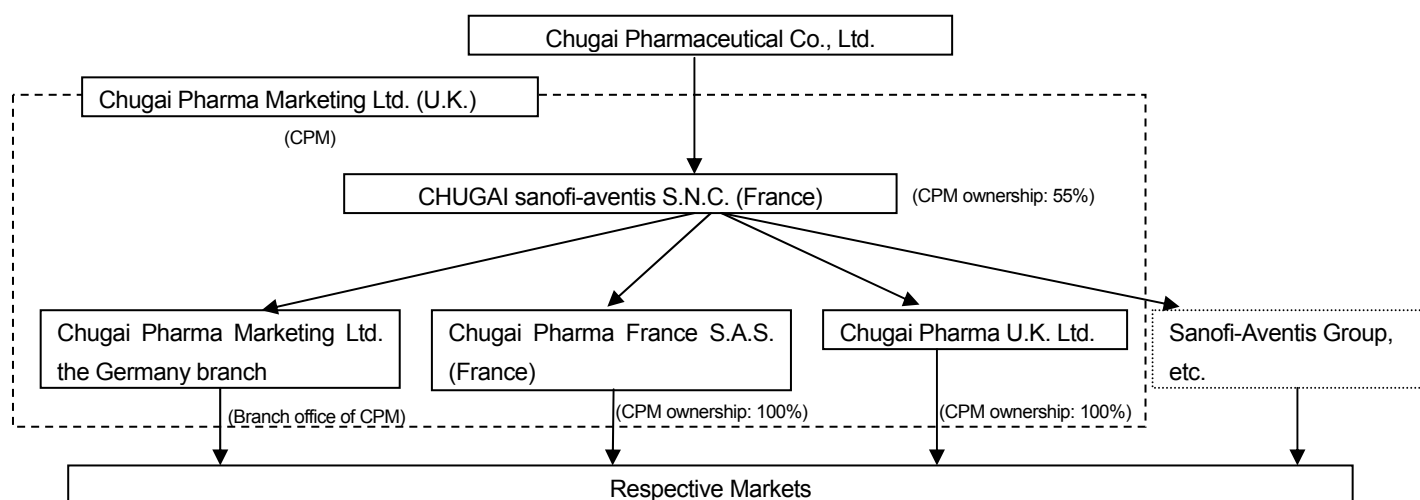
Business Results

(Millions of Yen)

(Consolidated)	FY2007.12	FY2008.12
Revenues	25,423	25,048
Compared with the previous period	(108.3%)	(98.5%)
<i>In local currency (in thousands)</i>	£107,880	£131,939
Net Income	5,308	5,836
Compared with the previous period	(141.4%)	(110.0%)
<i>In local currency (in thousands)</i>	£22,523	£30,742

Note: Translations into yen are based on the average rate during the term. (for the period ended December 2007: £235.66; for the period ended December 2008: £189.85)

For reference: Product distribution structure



Development pipeline (as of February 4, 2009)

Development code	Indication # Additional indication	Stage (date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
<u>Oncology</u>					
R340	Colorectal cancer #	Filed Feb.08	capecitabine Xeloda Oral	Roche Xeloda	Antimetabolite, 5-FU derivative
	Gastric cancer #	Phase III			
R435	Non-small cell lung cancer #	Filed Nov.08	bevacizumab Avastin Injection	Roche /Genentech Avastin	Anti-VEGF(Vascular Endothelial Growth Factor) humanized monoclonal antibody
	Colon cancer (adjuvant) #	Phase III Multinational study			
	Gastric cancer #	Phase III Multinational study			
	Breast cancer (adjuvant) #	Phase III Multinational study			
	Breast cancer #	Phase II			
R597	Gastric cancer #	Phase III Multinational study	trastuzumab Herceptin Injection	Roche /Genentech Herceptin	Anti-HER2 humanized monoclonal antibody
EPOCH	Chemotherapy-induced anemia #	Phase III	epoetin beta Epogin Injection	In-house	Recombinant human erythropoietin
R1415	Pancreatic cancer #	Phase II	erlotinib Tarceva Oral	OSI/Genentech/ Roche Tarceva	EGFR tyrosine kinase inhibitor
R744	Chemotherapy-induced anemia	Phase II		Roche Mircea	Continuous erythropoietin receptor activator
MRA	Multiple myeloma	Phase II Overseas	tocilizumab Actemra Injection	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody
R1273	Breast cancer, etc	Phase I	pertuzumab Injection	Roche /Genentech	HER dimerization inhibitory humanized monoclonal antibody
TP300	Colorectal cancer, etc	Phase I Overseas		In-house	Topoisomerase I inhibitor
CIF (R7167)	Solid tumors	Phase I Overseas		In-house (Roche)	-
GC33	Liver cancer	Phase I Overseas		In-house	Humanized anti-Glypican-3 monoclonal antibody
R7159 (GA101)	Non-Hodgkin's lymphoma	Phase I		Roche/GlycArt	Humanized anti-CD20 monoclonal antibody
CKI27 (R7304)	Solid tumors	Phase I Overseas		In-house (Roche)	-

Development code	Indication # Additional indication	Stage (date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
R1507	Solid tumors	Phase I	Injection	Roche	Human anti-IGF-1R monoclonal antibody
<u>Bone and Joint</u>					
MRA	Rheumatoid arthritis #	Approved Jan.09 Overseas(EU) Filed Nov.07 Overseas(US)	tocilizumab Actemra (US) / RoActemra (EU) Injection	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody
	Systemic onset juvenile idiopathic arthritis (sJIA) #	Phase III Overseas	tocilizumab Actemra Injection	In-house (Roche)	
	Rheumatoid arthritis (new formulation: subcutaneous injection)	Phase I / II	tocilizumab Actemra Injection	In-house (Roche)	
R1594	Rheumatoid arthritis	Phase III Multinational study	ocrelizumab Injection	Roche /Genentech	Humanized anti-CD20 monoclonal antibody
ED-71	Osteoporosis	Phase III	eldecalcitol Oral	In-house (Taisho Pharmaceutical)	Activated Vitamin D ₃ derivative
R484	Osteoporosis	Phase II / III	ibandronate sodium hydrate Injection	Roche Boniva (US) / Bonviva (EU)	Bisphosphonate
		Phase II	ibandronate sodium hydrate Oral	(Taisho Pharmaceutical)	
<u>Renal diseases</u>					
R744	Renal anemia	Phase III	Injection	Roche Mircera	Continuous erythropoietin receptor activator
<u>Transplant, Immunology and Infectious diseases</u>					
R964	Compensated liver cirrhosis caused by hepatitis C virus #	Phase II / III	ribavirin Copegus Oral	Roche Copegus	Anti-viral agent in combination with Pegasys
R442	Chronic hepatitis B #		Phase II / III	peginterferon alfa-2a Pegasys Injection	Roche Pegasys
	MRA	Crohn's disease #	Phase II	tocilizumab Actemra Injection	In-house
	Castleman's disease	Phase I Overseas	tocilizumab Actemra Injection	In-house (Roche)	
	Systemic lupus erythematosus (SLE)	Phase I Overseas			
NA808	Chronic hepatitis C	Phase I Japan	Injection	In-house	-
		Phase I Overseas			

Development code	Indication # Additional indication	Stage (date)	Generic name Product name Dosage form	Origin Overseas name (Collaborator)	Mode of Action
<u>Other diseases</u>					
EPOCH	Predeposit of autologous blood transfusion #	Filed Mar.02	epoetin beta Epogin Injection	In-house	Recombinant human erythropoietin
R1678	Schizophrenia	Phase II Multinational study	Oral	Roche	GLYT1 inhibitor
GM-611	Diabetic gastroparesis	Phase I Completed Japan	mitomcinal Oral	In-house	Motilin agonist Recovery of gastrointestinal motility
		Phase II Overseas			
	Irritable bowel syndrome (IBS)	Phase II Overseas			
R1583 (ITM-077)	Type II diabetes	Phase I	taspoglutide Injection	Roche / Ipsen (Teijin)	GLP-1 analogue
CSG452 (R7201)	Type II diabetes	Phase I	Oral	In-house (Roche)	-
R1579	Type II diabetes	Phase I	Oral	Roche	DPP-IV inhibitor

Changes from the last announcement on October 21, 2008

Oncology

- R435 Phase II → Filed (non-small cell lung cancer)
- CKI27(R7304) Started Phase I (solid tumors / overseas)
- R1507 Started Phase I (solid tumors)

Bone and Joint

- MRA Filed → Approved (rheumatoid arthritis / overseas(EU))
- Started Phase I / II
- (rheumatoid arthritis(new formulation: subcutaneous injection))

R&D Activities (Jan.1, 2008 – Feb. 4, 2009)

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

Oncology

- In February 2008, we obtained the approval and launched for additional indication of adjuvant breast cancer for humanized anti-HER2 monoclonal antibody R597 (product name: Herceptin).
- In February 2008, we filed for combination therapy with antimetabolite 5-FU derivative R340 (product name: Xeloda), and oxaliplatin, plus humanized anti-VEGF monoclonal antibody R435 (product name: Avastin), as well as monotherapy of R340 for the additional indication of colorectal cancer.
- In May 2008, we joined the multinational Phase III clinical trials (expected additional indication: adjuvant breast cancer) conducted by Roche for R435 (product name: Avastin). And in November 2008 we filed an application for the indication of non-small cell lung cancer.
- In June 2008, we started the additional Phase III clinical trials of the additional indication of recombinant human erythropoietin EPOCH (product name: Epogin) for treatment of chemotherapy-induced anemia.
- In September 2008, we obtained the approval for modification of manufacturing process for drug substance (to use porcine derived material) for humanized anti-HER2 monoclonal antibody R597 (product name: Herceptin).
- In October 2008, we started Phase I clinical trials for R7159(GA101) (expected indication: Non-Hodgkin's lymphoma).
- In January 2009, we started Phase I clinical trials for R1507 (expected indication: solid tumors).

Bone and Joint Diseases

- In April 2008, we obtained the approval and launched for additional indication of rheumatoid arthritis, polyarticular-course juvenile idiopathic arthritis and systemic-onset juvenile idiopathic arthritis for humanized anti-human IL-6 receptor monoclonal antibody MRA (product name: Actemra). And in January 2009, we started Phase I /II clinical trials for new formulation subcutaneous injection.
- In May, we entered into an agreement with Taisho Pharmaceutical Co., Ltd, to co-develop and co-market activated vitamin D₃ derivative ED-71 (expected indication: osteoporosis) in Japan. And in December 2008, We announced that the primary endpoint was achieved in Phase III clinical trials.

Renal Diseases

- In March 2008, we filed for modification of manufacturing process for drug substance (serum-free version) for recombinant human erythropoietin EPOCH (product name: Epogin).

Cardio/Cerebro-vascular diseases

- In July 2008, we withdrew the application and suspended the development for hydroxyl radical scavenger AVS (expected indication: subarachnoidal hemorrhage) because the additional Phase III clinical trials under review did not meet the endpoint.

Transplant, Immunology and Infectious Diseases

- In October 2008, we started Phase I clinical trials for NA808 (expected indication: chronic hepatitis C).

Other Diseases

- In May 2008, we joined the multinational Phase II clinical trials (expected indication: schizophrenia) conducted by Roche for GLYT1 inhibitor R1678.
- In June 2008, we started Phase I clinical trials of DPP-IV inhibitor R1579 (expected indication: type II diabetes).

At present, we are awaiting the approval of applications (new molecular entities or additions of indications) filed for 3 development themes, including R340 (expected indication: colorectal cancer).

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

- In April 2008, Roche started Phase I clinical trials for CIF (R7167) (expected indication: solid tumors), a compound licensed-out to Roche.

- In July 2008, we licensed-out the import and marketing rights of the potassium channel opener SG-75 (product name: Sigmart) to Merck Pharmaceutical (HK) Ltd in China. Merck Pharmaceutical Ltd is part of Merck Serono, a division of Merck KGaA, Darmstadt, Germany, and will market the product in mainland China through Merck Serono China.
- In October 2008, we started Phase I clinical trials for GC33 (expected indication: liver cancer).
- In November 2008, Roche started Phase I clinical trials for CKI27(R7304) (expected indication: solid tumors).
- In January 2009, Roche obtained approval for humanized anti-human IL-6 receptor monoclonal antibody MRA (product name: RoActemra) for rheumatoid arthritis in Europe. In September 2008, Roche received a Complete Response letter from the FDA, which requested the submission of further materials.

Major clinical trials in oncology field currently running in Japan

Theme	Expected Indication	Regimen	Stage	Planned Filing Date
R435 (bevacizumab) Avastin	Non-small cell lung	carboplatin + paclitaxel ± R435	Filed (Nov.08)	-
	Breast	paclitaxel + R435	Phase II	2009
	Breast (adjuvant)	standard chemotherapy ± R435	BEATRICE study Phase III Multinational study	2012 2014
R435 (bevacizumab) Avastin R340 (capecitabine) Xeloda	Colon (adjuvant)	FOLFOX4 ± R435 XELOX + R435	AVANT study : Phase III Multinational study	2011
	Gastric	R340(5FU) + CDDP ± R435	AVAGAST study : Phase III Multinational study	2011
	Colorectal	XELOX + R435	Filed (Feb.08)	-
R1415 (erlotinib) Tarceva	Pancreatic	gemcitabine + R1415	Phase II	2009
R597 (trastuzumab) Herceptin	Breast (adjuvant)	R597	Launched (Feb.08)	-
R597 (trastuzumab) Herceptin R340 (capecitabine) Xeloda	Gastric	R340/5FU + CDDP ± R597	ToGA study : Phase III Multinational study	2010